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Maintaining product integrity in the Australian seed and grain supply chain – the role of sampling and testing for GM events

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Foreword

Sampling and testing in the Australian seed and grain supply chain is necessary to maintain the integrity of marketed products and to ensure that they meet defined industry quality standards. Industry routinely segregates and supplies to the market differentiated products such as feed and malting barley and many different grades of wheat.

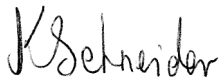
This report provides advice on the current sampling and testing capabilities and the future sampling and testing needs for managing the adventitious presence (AP) of approved genetically modified organisms (GMOs) in non-GM seed and grain in the Australian seed and grain supply chain. The report focuses on four commodities: canola, cottonseed, soybean and maize.

Drivers for assessing sampling and testing needs and capabilities for GM events include domestic demands for differentiated products and export market access. Current thresholds for AP of genetically modified (GM) events in non-GM seed and grain in Australia's primary export markets for canola and cottonseed are identified and discussed in this report as well as the requirements in export market countries for marketing approval, imports and labelling. Coexistence strategies and sampling and testing regimes in these markets are also described.

Potential sampling and testing screening packages for AP of GM events at several points along the Australian seed and grain supply chain have been developed. If testing to maintain product integrity is required, packages such as these could be used to screen for approved GM canola and cotton varieties in domestically produced non-GM seed and grain and for unapproved GMOs in imported non-GM commodities. The development of these packages is timely given the emerging importance and use of these commodities as food ingredients and their trade on world markets.

The sampling and testing screening packages presented in this report could be used as a model approach to assist continued product integrity in the Australian seed and grain supply chain. They also highlight the potential complexity of sampling and testing for specific purposes.

Introducing GM canola varieties into the Australian seed and grain supply chain will not represent significant difficulties for industry but may involve expansion of existing sampling and testing regimes. However, in regard to coexisting GM and non-GM varieties of a crop in a farming system, the sampling and testing needs of the Australian seed and grain industry for AP of GM events in non-GM seed and grain will ultimately depend on the market demand for differentiated products.



Karen Schneider
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Executive Summary

Sampling and testing in the seed and grain supply chain is necessary to confirm that product integrity has been maintained.

Industry will segregate and supply products to meet customer demands and will carry out sampling and testing to verify that their systems are working effectively and to provide customers with the assurance that the product delivered meets their specifications.

If the market requires, sampling and testing for the adventitious presence (AP) of genetically modified (GM) events in non-GM seed and grain in the Australian seed and grain supply chain can confirm the efficacy of coexistence strategies and validate that product integrity has been maintained by the seed and grain industries.

Coexistence strategies for GM and non-GM seed and grain exist for economic and marketing reasons. In the context of this report, coexistence relates to strategies that facilitate farmers' freedom to cultivate the agricultural crops they choose and allow customers to determine the market demands by making a selection between GM and non-GM products.

This report examines the needs and capabilities for sampling and testing for GM events in non-GM seed and grain in Australia's seed and grain supply chain.

In June 2006, the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) hosted a GM canola sampling and testing workshop with the aim of identifying specific studies or activities that could be undertaken to develop or underpin sampling and testing regimes for GM canola. Acting on the recommendations arising from this workshop, DAFF commissioned the Bureau of Rural Sciences (BRS) to undertake this current study.

The aim of this report is to provide scientific advice to decision-makers about the current sampling and testing capabilities and the future sampling and testing needs for managing potential AP of GM events in non-GM seed and grain in the Australian seed and grain supply chain. The scope of the report is confined primarily to cotton and canola as these are the only two GM crops currently grown commercially in Australia; there is also some reference to soybean and maize. GM varieties of these four crops currently comprise almost all the GM crops grown commercially worldwide.

Adventitious presence refers to low levels of an unintended material in products and can arise in the seed and grain supply chain in different ways.

AP refers to low levels of unintended material in seed, grain, or food and feed products. AP of various materials in the food and feed supply chain (e.g. weed seeds) has always existed, and whilst it can be minimised, it cannot be eliminated entirely and is not a challenge that is unique to the coexistence of GM and non-GM crops.

AP of GM material can arise from gene flow (the movement of genes between individual plants during reproduction), GM plant volunteers (that is, plants that have resulted from natural propagation, as opposed to having been deliberately planted by humans), and physical admixture (unintended mixing of GM and non-GM seed or grain at different points along the supply chain).

Thresholds for approved GMOs in non-GM canola seed and grain have been set in Australia.

In 2005 the intergovernmental Primary Industries Ministerial Council (PIMC) specified AP thresholds for Gene Technology Regulator-approved GM canola of 0.9 per cent in non-GM canola grain and 0.5 per cent in non-GM canola seed-for-sowing. These thresholds are also agreed nationally by the Australian seed and grain industries.

These AP thresholds for canola seed and grain were adopted in 2005 by all Australian states and territories except Queensland and the Northern Territory (which did not have moratoria in place on the commercial cultivation of GMOs) and Tasmania, which differed from the mainland states in that it adopted a GM-free stance on GM canola, an option available under the PIMC agreement.

Analytical testing to a strictly zero-presence level is not possible as detection will always be limited by the sensitivity of the test methods used, by the number of samples taken and the number of seeds analysed per sample.

Activities involving GMOs in Australia fall under a national regulatory scheme agreed to by state and federal governments in 2001.

Dealings with GM organisms (GMOs) in Australia are stringently regulated by the federal Gene Technology Regulator (the 'Regulator') supported by the Office of the Gene Technology Regulator (OGTR) under the *Gene Technology Act 2000* (Cwlth). The role of the Regulator is to protect human health and safety and the environment by identifying and managing potential risks posed by the use of this technology. Dealings with GMOs are illegal in Australia unless authorised under the *Gene Technology Act*.

The Regulator operates alongside and liaises with other federal regulatory agencies which are part of a national framework involved in regulating gene technology and GM products. Other agencies include Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Therapeutic Goods Administration (TGA).

Foods derived from GMOs are also regulated in a national scheme.

Most of the GM foods currently available in Australia come from GM crops which have been grown and processed overseas. GM foods cannot be sold in Australia unless they have been approved by FSANZ. Labelling of approved GM food is required to indicate that it is GM or contains GM ingredients. The purpose of labelling approved GM food is to allow consumer choice, not for food safety reasons.

There are some instances when labelling of approved GM foods or ingredients is not required—for example in highly refined foods where the effect of the refining process is to remove novel deoxyribonucleic acid (DNA) and/or novel protein, or where an approved GM food is unintentionally present in the food, ingredient or processing aid at a concentration of no more than 10g/kg (1 per cent) per ingredient.

All Australian governments are part of the national regulatory framework for GMOs and GM food.

As part of setting up the national regulatory framework for GMOs, each Australian state and territory agreed to enact corresponding legislation to the *Gene Technology Act 2000* (Cwlth). All jurisdictions in Australia are also parties to the national system for joint Food Standards and the associated Food Standards Code for food safety. These frameworks enable national consistency in applying the GM Food Standard and in assessing and, if necessary, managing any human health and environmental risks associated with the use of GMOs.

Most states also have separate legislation allowing them to designate areas as non-GM or GM for marketing purposes.

The Regulator issued licences for the commercial release of two types of GM herbicide-tolerant canola in 2003. However, the enactment of state and territory 'moratorium' legislation in all major canola-growing states prevented commercial plantings of GM canola varieties. The 'moratorium' legislation was introduced because of perceived marketing risks, not for health and safety (including food safety) or environmental reasons.

The lapsing of the ban on GM canola in Victoria in February 2008, the approval for commercial production granted for GM canola in New South Wales in March 2008, and the expectation that there will continue to be markets for non-GM canola domestically and internationally, all highlight the need for sampling and testing in facilitating the coexistence of non-GM and approved GM canola varieties and the export of non-GM and GM seed and grain.

Australian import and export regulations for GMOs are based on declarations of the GM status of the product.

GM seeds and grain imported into Australia must be declared to the Australian Quarantine and Inspection Service (AQIS). The *Quarantine Act 1908* (Cwlth) requires prior approval (via an import permit) to import declared GM seed and grain. In granting permits AQIS must consider risk assessments prepared by the Regulator and, for food, advice from FSANZ.

In the case of Australian exports, if an importing country requires certification of the GM status of a product or commodity, where appropriate AQIS will attach to the export documentation a statement from the Regulator regarding the GM crop approval status in relation to the commodity.

There are several international agreements, organisations and standards that are relevant to the trade and transboundary movement of GMOs...

Global trade in GMOs continues to increase and, against this background, Australia continues to work in international fora and with trading partners to maintain and improve market access for food and agricultural products.

There are a number of intergovernmental international organisations, agreements and standards that are relevant to the trade and transboundary movement of GMOs. The most notable organisations and agreements are: the World Trade Organization (WTO) and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (the TBT Agreement); the United Nations Food and Agriculture Organization (FAO) and the International Plant Protection Convention (IPPC); the United Nations Environment Programme and its Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety (CPB); and the FAO/World Health Organization Codex Alimentarius Commission.

...and which variously specify international rules, guidance and standards for measures countries can take during trade and other transboundary movement of GMOs.

These trade and environment agreements variously specify international rules and/or provide guidance (and in some cases standards) for the measures (including technical measures) that countries can take to protect animal and plant health, human health and the environment during trade and other transboundary movement. Measures can relate to GM commodities, grains and food, where there is legitimate need, and may involve or relate to sampling and testing for GM events, depending on the commodity and event, the country and its national measures, and national policies on specific issues, particularly GM food labelling. Sampling and testing for the AP of GM events in seed and grain may be necessary to ensure that Australian exports meet a country's requirements imposed under these various agreements.

The International Seed Testing Association (ISTA) and the International Organization for Standardization (ISO) aim to achieve uniform application of procedures for evaluation of seed and grain moving in international trade. These agencies are non-government standard-setting bodies that have developed guidance documents, rules and/or standards on sampling for seeds and grains (ISO and ISTA), testing for foodstuffs (ISO), and testing for seeds (ISTA). Test methods for specific GM events are not provided in these standards; the focus is on defining principles, describing general methods, and specifying definitions and performance requirements. ISTA also accredits testing laboratories, provides a certification system, and conducts GM seed testing workshops and training.

The industry-approved thresholds set in Australia for AP of approved GMOs in non-GM canola seed and grain are equal to or lower than those set by our international trading partners.

Australia's major export markets for canola in the five years to 2007 were Japan, Pakistan, Bangladesh, China, Nepal and the EU.

Japan has approved for food and feed all GM canola varieties approved by the Australian Gene Technology Regulator for commercial release in Australia. Japan has set a threshold level of 5 per cent for GM ingredients in products that are labelled 'Non-Biotech' provided that the events have been approved in Japan.

The GM canola lines approved by the Regulator for commercial release have also been approved for food and feed in the EU. The AP level for EU-approved GMOs in non-GM seed and grain for use in food and feed is set at 0.9 per cent. Above this level, all products must be labelled as GM.

China has placed its listed agricultural GMOs (soybean, corn (maize) canola, cotton and tomato) under a mandatory labelling system. China has not approved for commercial production any of the GM canola lines approved for commercial release in Australia; however, GM canola can still be imported and used for oil and meal provided it is labelled appropriately as GM material.

Pakistan and Bangladesh have not set a tolerance for AP of GM events in non-GM commodities. These countries import GM canola from Canada.

The major customers for Australia's exported cottonseed (which is traded as a separate commodity distinct from cotton fibre), measured as a share of total exports in the five years to 2007, were Japan and the Republic of Korea.

All GM cotton approved in Australia for human food (e.g. used for cotton oil and linters) and commercial cultivation is approved in Japan and the Republic of Korea for food and feed. Korea has in place a 3 per cent AP allowance for approved GM event(s) in a non-GM consignment.

All thresholds set for AP of GMOs in seed and grain in Australia's canola export markets are equal to or higher than the thresholds set in Australia for AP in non-GM canola. So provided the Australian canola industry meets its own thresholds for the AP of GM canola in non-GM canola, exported commodities should meet all export requirements.

Coexistence strategies overseas generally focus on managing gene flow through separation distances between GM and non-GM varieties of a crop.

Some countries have adopted a more statute-based approach to coexistence (for example EU-27 countries, where guidelines tend to be embedded in legislation), whereas other countries have adopted a market-based approach (for example Canada and the USA, where coexistence measures are described in industry Best Practice Guidelines or equivalent).

Of the overseas coexistence strategies reviewed in this report, most were found to be focussed at the farm level, and generally provide rules or guidance for farmers to manage gene flow through separation distances between GM and non-GM varieties of the crop and other measures. Sampling and testing is generally a small component of coexistence strategies overseas, if mentioned at all.

Understanding Australia's seed and grain supply chain is important to determine the best points for sampling and testing of GM events.

This report focuses on the sampling and testing requirements and responsibilities from the breeding to the marketing and exporting stages of the supply chain. The relevant stages of the supply chain include: breeding, where new varieties with desired traits are developed and seed may be imported for breeding purposes; on-farm production, where certified seed is grown to produce grain; accumulation and storage, where the grain is received at a storage facility and the bulk handler consolidates grain; grain out-turn, where grain is out-loaded from the storage facility and transported to the domestic market or an export terminal; and marketing and exporting, where sale and delivery of grain takes place.

Sampling and testing methods and protocols assist industry to demonstrate that AP thresholds in Australia and those set by its trading partners have been met.

As noted above, the major countries to which Australia exports canola have thresholds equal to or above that of Australian thresholds for the AP of GM canola events in non-GM canola seed and grain. In the case where both non-GM and GM crops are grown and segregation is needed, sampling and testing screening protocols could well have a role in demonstrating that Australian AP thresholds and any international requirements have been met.

Additionally, some GMOs/GM foods have been approved in overseas countries but not in Australia. For example, GM maize and soybean varieties that are commercially cultivated in the USA are not approved for commercial release in Australia. Dealings with GMOs

are illegal in Australia unless authorised under the *Gene Technology Act 2000* (Cwlth).

International rules exist for sampling seed and grain lots.

ISTA has developed and published rules for the sampling and testing of seeds, with the aim of achieving uniform application of procedures for evaluation of seeds moving in international trade.

ISO has published a number of standards on sampling grain and testing foodstuffs for the presence of GMOs or GMO-derived products.

There is a step-by-step process involved in sampling and testing for GM events.

The sampling process involves taking a number of primary samples from the original seed lot. The number of primary samples required will depend on the size of the seed lot and how well it is mixed. To accurately represent adventitious GM material that may be unevenly distributed throughout the lot requires a large number of primary samples to be taken.

The appropriate test method can be protein- or DNA-based, and is selected depending on the limit of detection and the level of specificity for GM events that are required. A method can screen for a range of GM events, or it can be specific to one particular event.

Harmonisation and standardisation are necessary for results to be reliable and comparable across international boundaries.

Seed and grain is tested using different methods and different instruments all over the world. The choice of method can add variability to analytical results. Appropriate reference materials are required in order to verify that testing methodologies used in different laboratories are able to produce accurate and comparable results.

For example, in an ideal harmonised system, the testing carried out by an Australian bulk handling company at its grain receival points should be comparable with the testing carried out on the grain at port by an importing country. Key measures for achieving harmonised sampling and testing are: the use of certified reference materials for testing; the development of standard methods for testing and sampling; validation in laboratories (this involves global inter-laboratory collaboration); and, the accreditation of laboratories by internationally-recognised national accreditation bodies to demonstrate their compliance with international standards. Continued accreditation of a laboratory depends on ongoing successful participation in a relevant proficiency testing program where 'blind' samples are sent to the laboratory for analysis.

Laboratory testing capabilities in Australia, North America and the European Union were surveyed to give an indication of testing capabilities.

Three laboratories in each of Australia, North America (USA/Canada) and the European Union (nine in total) were surveyed to give an indication of the GM testing capabilities in these countries. Australian laboratories surveyed do not appear to cover testing for the AP of all GM events approved in other countries, but, capabilities exist overseas and Australian laboratories not surveyed for this study may also have such a capability.

For canola, there is a qualitative and quantitative event-specific test available in the Australian laboratories surveyed for the GM canola varieties intended for commercial release in Australia and approved by the Regulator. A number of other GM canola varieties are of interest as they may have been approved for release overseas, but not in Australia; however, some of these varieties were never grown on a

commercial scale overseas (although they may have undergone extensive field trials) and others have not been grown commercially for a number of years.

For cotton, there are event-specific testing methods available in the Australian laboratories surveyed to test for all the GM cotton varieties approved by the Regulator for commercial release in Australia.

For imported soybean and maize, there are only limited testing methods available in the Australian laboratories surveyed. More extensive testing methods for these two commodities are available overseas. Although a number of GM soybean varieties have been reviewed for planting in the USA, only two have been grown on a commercial scale. An event-specific test is available in Australia for one of these.

Screening packages have been developed which could be of use to the Australian bulk handling industry to perform sampling and testing for the AP of GM events in domestically produced or imported grains.

Prior to the commercial release of GM canola in 2008, sampling and testing in Australia for the AP of GM events in canola, cottonseed, soybean and maize has primarily taken place at the plant breeder/seed increase stage of the supply chain, as this had been identified by industry as the point of highest risk.

This report describes sampling and testing screening packages that could be applied, if required, to detect GM events in domestically grown non-GM canola and cottonseed along the supply chain, and to detect GM events in imported canola, maize and soybean seeds.

Reference to such 'screening packages' in the Single Vision Grains Australia *Principles for process management of grain within the Australian supply chain* document could provide a layer of detail and transparency which may benefit the grains industry and its customers. For example, in addition to ensuring the identity of certified seed through appropriate sampling and testing at the breeding stage, the grain receival point could be a second point for sampling and testing grain for markets which require segregated product. Adoption (where needed) by the bulk handling industry of transparent sampling and testing screening packages for canola grain at grain receival or grain out-turn points could provide confidence that the integrity of products supplied to customers is being maintained.

For all grain commodities, the industry already samples and tests for other quality attributes at the grain receival point. Existing grain sampling protocols are adequate to collect samples for GMO testing. Grain could be held in a silo for sufficient time to allow test results to be obtained and appropriate action taken. For example, the canola in a designated non-GM canola silo in which AP of GM canola had been detected could be redesignated, if over the 0.9 per cent threshold.

There has not been a need for widespread adoption of sampling and testing protocols for AP of GM events in canola prior to the commercial release of GM canola. Now that GM canola is grown commercially, the supply chain will introduce sampling and testing as required to provide the confidence that it can meet customer demands.

The need for sampling and testing will depend on the market demand for differentiated seed and grain products.

The sampling and testing screening packages presented in this report could be used as a model approach to ensure continued product integrity in the Australian seed and grain supply chain. They also highlight the potential complexity of sampling and testing for specific purposes.

Ultimately, the sampling and testing needs of the Australian seed and grain industry for AP of GM events in non-GM seed and grain will depend on the market demand for differentiated products.

Contents

Abbreviations

A2LA	American Association for Laboratory Accreditation
AACC	American Association of Cereal Chemists
ABARE	Australian Bureau of Agricultural and Resource Economics
ACLASS	Assured Calibration and Laboratory Accreditation Select Service
AIA	Advanced informed agreement
AMS	Agricultural Marketing Service
AOCS	American Oil Chemists' Society
AOF	Australian Oilseeds Federation
AOSA	Association of Official Seed Analysts
AP	Adventitious presence
APLAC	Asia Pacific Laboratory Accreditation Cooperation
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ASF	Australian Seed Federation
BRS	Bureau of Rural Sciences
CBD	Conventional on Biological Diversity
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CFIA	Canadian Food Inspection Agency
CIPRS	Canadian Identity Preserved Recognition System
Codex	Codex Alimentarius Commission
CPB	Cartagena Protocol on Biosafety
CRL – GMFF	The Community Reference Laboratory for GM Food and Feed (EU)
CRL GMO	The Community Reference Laboratory for GMOs (EU)
Cwlth	Commonwealth
DAFF	Department of Agriculture, Fisheries and Forestry
DAP	Deutches Akkreditierungssystem Prufwesen
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DIR	Dealing involving intentional release
DNA	Deoxyribonucleic acid
DNIR	Dealing not involving intentional release
EC	European Commission
ELISA	Enzyme-Linked Immunosorbent Assay
ENGL	The European Network of GMO Laboratories
ERMA	Environmental Risk Management Authority (New Zealand)

EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FSANZ	Food Standards Australia New Zealand
GIPSA	The Grain Inspection, Packers and Stockyards Administration (USA)
GM	Genetically modified
GMO	Genetically modified organism
GTGC	Gene Technology Grains Committee
GTMC	Gene Technology Ministerial Council
HOLL	High oleic low linolenic
IAS	US International Accreditation Service
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ISPM	International Standards for Phytosanitary Measures
ISTA	International Seed Testing Authority
JRC	Joint Research Centre
L-A-B	US Laboratory Accreditation Bureau
LMO	Living modified organism
LOD	Limit of detection
LSA	Licensing and Stewardship Agreement
MAF	Ministry for Agriculture and Forestry (New Zealand)
MAFF	Ministry for Agriculture, Fisheries and Forestry (Japan)
NACMA	National Agricultural Commodities Marketing Association
NATA	National Association of Testing Authorities
NBS	National Biotechnology Strategy
NMI	National Measurement Institute
NRS	National Residue Survey
NVLAP	US National Voluntary Laboratory Accreditation Program
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
OIE	Office Internationale des Epizooties
PCR	Polymerase Chain Reaction
PIMC	Primary Industries Ministerial Council
PRAMOG	Paddock Risk Assessment and Management Option Guide
QA	Quality assurance
RNA	Ribonucleic acid

SCC	Standards Council of Canada
SCIMAC	Supply Chain Initiative on Modified Agricultural Crops
SVGA	Single Vision Grains Australia
TGA	Therapeutic Goods Administration
TSP	Technology Service Provider
TUA	Technology User Agreement
UK	United Kingdom
UKAS	United Kingdom Accreditation Service
USA	United States of America
WHO	World Health Organization
WTO	World Trade Organization

Abbreviations for genetic elements

Note: By convention, a gene is denoted in lower case italics whilst the protein product with the same name is in roman type.

3'	terminator
5'	promoter
bar	phosphinothricin N-acetyltransferase (from *Streptomyces hygroscopicus*)
bxn	nitrilase (from *Klebsiella pneumoniae* subspecies ozanae)
CaMV35s	35S (from Cauliflower mosaic virus)
CMoVb35s	35S (from Caulimovirus figwort mosaic virus)
cp4 epsps	5-enolpyruvylshikimate-3-phosphate synthase (from *Agrobacterium tumefaciens* strain CP4)
cry1Ab	cry1Ab (from *Bacillus thuringiensis* subspecies kurstaki)
cry9C	cry9c (from *B. thuringiensis* subspecies tolworthi)
nos	nopaline synthase (from *A. tumefaciens*)
nptII	neomycin phosphotransferase II (from *Eschericia coli* Tn5 transposon)
pat	phosphinothricin N-acetyltransferase (modified) (from *Streptomyces viridochromogenes*)

Section 1: Introduction

Chapter 1: Background to the study

In June 2006, the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) hosted a genetically modified (GM) canola sampling and testing workshop in Melbourne. The aim of the workshop was to identify specific studies or activities that could be funded by DAFF under the Australian Government's National Biotechnology Strategy (NBS), as a contribution to developing and/or underpinning sampling and testing regimes for GM canola.

Acting on the recommendations arising from this workshop, DAFF commissioned the Bureau of Rural Sciences (BRS) to undertake this current study. Its aim is to provide scientific advice to decision-makers about the current sampling and testing capabilities and the future sampling and testing needs for managing the potential for adventitious (unintended) presence (AP) of GM events in non-GM seed and grain in the Australian seed and grain supply chain.

Research for this report was based on a combination of a desktop literature review and consultations with industry and state governments. The research and writing was carried out collaboratively by BRS and the Australian Government National Measurement Institute (NMI), which identified and reviewed domestic and international scientific and technical developments in sampling and testing methods and protocols for GM events and crops.

Definitions of the term 'GM' vary, but in this report the term refers to plants that have acquired new genes by laboratory 'gene technology' methods, as defined in the *Gene Technology Act 2000* (Cwlth). Chapter 2 contains further background on GM crops and gene technology.

Why sampling and testing?

Sampling and testing can be used to validate coexistence strategies and confirm industry has maintained the integrity of the products they supply to the market. Industry will segregate and supply products to meet customer preferences and will carry out sampling and testing both to verify that their systems are working properly and to provide customers with the assurance that products meet their specifications. For example, industry is already segregating canola from high oleic low linolenic (HOLL) canola, feed barley from malting barley, and many different grades of wheat. This report demonstrates that introducing GM canola varieties into the Australian seed and grain supply chain will not represent significant difficulties for industry, but may involve expansion of existing sampling and testing regimes.

It is important to note that GM and non-GM coexistence strategies exist purely for economic and marketing reasons—in Australia risks to human health and safety or the environment posed by the release of GM organisms must first be identified and assessed through the gene technology regulatory system overseen by the Gene Technology Regulator (the 'Regulator') (see Chapter 5) prior to their commercial release. Coexistence in the context of this report relates to the potential economic consequences of AP of material from one crop in another and to the principle that farmers should have the freedom to cultivate the agricultural crops they choose, whether it be GM, conventional or organic crops (European Commission 2003). In this instance, coexistence allows consumers to determine the market demands by making a selection between GM and non-GM products (Co-Extra 2006).

The value of assessing sampling and testing needs and capabilities for GM events rests not only in Australia's potential market demands for differentiated products, but also in enabling access to overseas markets.

Australia's major export markets for canola include Japan, Pakistan, Bangladesh, China, Nepal and the EU. Current thresholds for AP of GM events in canola in these export countries are identified and discussed in the report, as well as the requirements for marketing approval, imports and labelling. The same information is reported for our major export markets for cottonseed. Coexistence strategies and sampling and testing regimes in these markets are also reviewed where they could be identified.

The lapsing of the GM moratorium in Victoria, the exemption from the moratorium granted to GM canola in NSW, and the expectation that there will continue to be markets for non-GM and other special grades of canola (for example HOLL canola), highlights the need for sampling and testing in facilitating coexistence and maintaining product integrity of non-GM and approved GM canola crops and export of non-GM and GM seed and grain. Additionally, the rapid global uptake of, and trade in GM crops requires a robust approach to sampling and testing for GM material imported in seed for breeding and planting and grain for food and feed.

In this report BRS presents an independent review and analysis of Australia's current sampling and testing capabilities in the supply chain and considers future needs. The study is confined to canola, cottonseed, soybean and maize. The report focuses on the requirements and responsibilities from the breeding to the marketing and exporting stages of the supply chain (see Figure 6.1). It presents sampling and testing protocols which have been developed for the detection and quantification of various GM traits. The report also presents 'best practice screening packages' for sampling and testing for AP of GM events in the Australian seed and grain supply chain that could be adopted or used as a model by industry (see Chapter 11) if required. Whilst this report outlines the cost of various testing options (for example the difference in the cost of testing between Australia, North America and the European Union), it does not attempt to evaluate the cost-effectiveness of sampling and testing needs or their commercial consequences for supply chain participants. The report also does not comment on who should bear the cost of testing, as this will ultimately be decided by the market.

The robustness of tests is often highly context-dependent so transparent and coordinated approaches are needed which take account of the type of test and the event(s) being tested as well as the crop, genomic background and tissue being tested. Sampling protocols need to be robust and appropriate for the testing methods and objectives and are similarly context-dependent. The tests and methods available are continually being developed and improved, including the emergence of economical, high-throughput systems.

Despite recent technical advances, there are a number of outstanding issues, including the lack of universal validation for existing methods and lack of harmonisation of, for example, sampling and quantitative measurement approaches. Use and development of appropriate reference materials is another significant issue. There is currently no single generic test or testing system or protocol for GM events in general (the development of one may not be possible), and differentiation between approved and unapproved GMOs can be complex. Further challenges are that Australian jurisdictions have different state/territory-based GM organism regulatory systems and/or policies, and overseas trading partners have diverse AP thresholds and utilise different sampling and testing methodologies.

Chapter 2: A background to genetically modified crops

What are GM crops?

In agriculture, new plant varieties are created using the technology of selective breeding which, over many generations and sometimes hundreds of years, has produced varieties that are modified to such an extent that they may bear little resemblance to the wild form from which they originated. To match plant varieties to local growing conditions, or produce a desired product, plant breeders rely on naturally occurring genetic variation within species.

Cross-breeding methods (such as hybridisation) were developed over time and have allowed plant breeders to combine the desired characteristics of closely related species. For example triticale, a grain crop used for stockfeed, was produced by crossing wheat and rye.

From the early 1900s, plant breeders have been able to use technologies such as gamma radiation and chemical mutagenesis to artificially increase the genetic variation by means of introducing multiple random mutations into a plants germplasm, a small fraction of which may result in commercial applications.

The discovery of the double helix structure of deoxyribonucleic acid (DNA) in 1953 resulted in a new understanding of the expression of characteristics through genetic material. The use of modern gene technology techniques as a tool to develop new varieties of plants with desirable characteristics has appealed to plant breeders as it offers greater precision than random mutagenesis approaches. Most importantly, gene technology allows for the transfer of genes from unrelated species to the crop plant, which would not be possible using conventional breeding and hybridisation methods.

Genetically modified organisms (GMOs) are living organisms whose genomes have been modified using gene technology—to introduce, remove or alter a specific characteristic or trait. Gene technology complements conventional breeding. It can speed up conventional breeding, for example through marker-assisted selection, particularly for novel traits. As well as allowing for greater precision in the selection of desired genes and traits, its greatest capacity is in the potential to introduce novel genes and traits into crop species.

What are genes and how does gene technology work?

The basic building blocks of all living organisms are cells, and all cells in a multicellular organism normally contain an identical copy of the entire genome. The genome is made up of DNA, which is composed of four different chemical units known as nucleotide bases (commonly abbreviated to A, G, C and T) (Figure 2.1 (a)). The nucleotide bases form two complementary chains bound together and wound around each other to form the DNA double helix (Figure 2.1 (b)). The genome of the well-researched model organism for flowering plants, *Arabidopsis thaliana*, is approximately 142 000 000 nucleotide pairs long.

Within the enormous expanse of a DNA molecule, particular functional regions of nucleotide sequence are defined as genes (Figure 2.1 (c)). The *Arabidopsis* genome contains at least 26 000 genes. Each gene is composed of a promoter, a coding region and a terminator. The promoter can be considered as the control switch, part of the cellular machinery that determines where and when a gene is active or inactive. The terminator represents the endpoint of a gene or the DNA equivalent to a full-stop. The sequence of DNA within the coding region, between the promoter and the terminator, is the template for ('encodes') the synthesis of proteins—the molecules that provide the functionality of an organism. The coding region (in multi-cellular organisms) is split into multiple 'exons' (open reading frames or 'coding-DNA') and 'introns' ('non-coding DNA') which are removed during messenger ribonucleic acid (mRNA) processing.

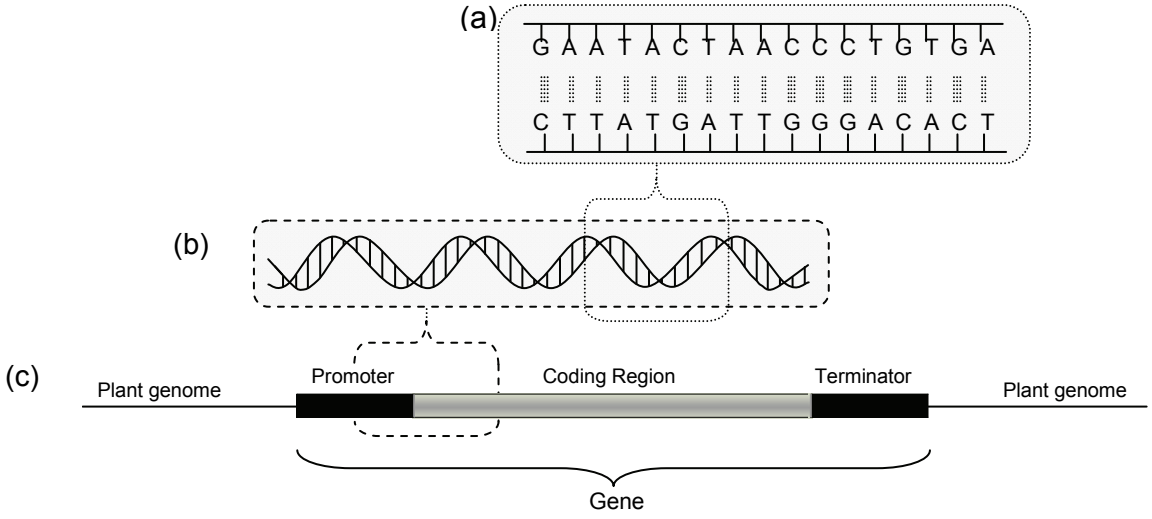

Figure 2.1: The entire genome, including all of the genes, is made up of DNA. Two complementary strands of nucleotide bases (a) wind around each other to form a DNA double helix (b). Regions of DNA within the genome are designated as genes (c) and are made up of a coding region bracketed by a promoter and a terminator.

Cellular mechanisms make an mRNA copy of the DNA within the coding region. The mRNA is transported to another part of the cell where it serves as a template for synthesis of protein based on the specific sequence of the mRNA copy. This whole process is referred to as 'expression' of the gene. Different genes encode for the synthesis of different proteins in the cell, and there are controls built into the DNA that regulate which genes are expressed to make proteins, how much protein is synthesised, in what kind of cell, and when. Every organism has within its genome a specific set of genes.

As in conventional breeding, in GM plants the gene to be inserted may be from a related species, or be a modified gene of the crop or a close relative. While this could be achieved through conventional breeding, it would be slower and more difficult. Unlike cross-breeding techniques, gene technology allows breeders to select and insert a gene from an unrelated species into the genome of an organism. For instance, the gene that confers tolerance to the herbicide glyphosate is derived from a common soil bacterium (*Agrobacterium tumefaciens* strain CP4). Insertion of a gene using gene technology is known as a 'transformation event'. A transformed plant is known as a GM plant.

When a gene is inserted into a genome using gene technology, the three parts of a gene must be included—a promoter, the open reading frame of the gene (its DNA sequence) and a terminator. This inserted DNA is called a construct (Figure 2.2). The three parts of a construct are referred to separately because they are usually individually selected from different sources for any given construct. The unique junctions between the host plants genomic DNA and the inserted construct characterise a transformation event.

When there are multiple events within the one GM plant, this is referred to in the singular as a 'stacked event'. Stacked events can be generated by inserting multiple constructs into the one genome, or by cross-breeding two plants that already have at least one event each.

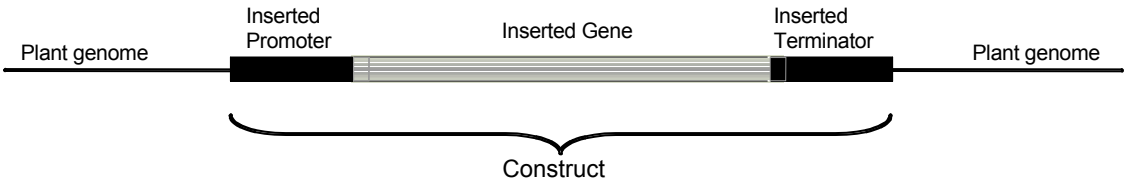

Figure 2.2: A construct inserted into a plant's genome by gene technology. When a foreign gene is inserted into a genome, it must contain a promoter and a terminator to perform the regulatory functions that lead to the production of a protein. The DNA sequence between the promoter and terminator determines the type of protein that is produced. The entire DNA segment inserted into a genome is called a construct.

Chapter 3: How can Adventitious Presence of GM events arise in the supply chain?

Introduction – What is 'AP'?

Adventitious presence (AP) refers to 'low levels of unintended material in seed, grain, or feed and food products' (AC21 2005). AP is not a challenge that is unique to GM crops and GM material. AP of materials in the food and feed supply chain has always existed, and whilst it can be minimised, it cannot be eliminated entirely. To manage for AP, allowances (or thresholds) for unintended materials are presently incorporated into national grain and oilseed standards in Australia, administered by the National Agricultural Commodities Marketing Association (NACMA)[1] and the Australian Oilseeds Federation (AOF)[2]. For example, the current standard for canola (CSO1) includes allowances for some weed seeds, snails/stones and field insects. For coexistence of GM and non-GM commodities to be cost-effective, realistic thresholds have to be established for AP of approved GMOs (Chapter 5). Current Australian and international thresholds for the AP of approved GM events in non-GM seed and grain lots are discussed in later chapters.

In the case of canola, there are three main potential causes for AP of GM events in non-GM canola (McDonald and Hudson 2006):

- Firstly, because canola can be both self- and cross-fertilised there is potential for adventitious GM events to be introduced through outcrossing. Outcrossing could occur during commercial seed development in breeding nurseries or open field production; or on-farm if the appropriate crop management practices are not observed. Outcrossing may occur through either insect or wind-borne transfer of pollen.
- Secondly, because canola seed is able to remain dormant in the soil from one growing season to the next, regrowth of volunteer plants may occur in a subsequent crop.
- Thirdly, mechanical or physical admixture of canola seed may occur during any one of the various stages of the seed production and grain supply chain, particularly during seed harvest, transport, processing, storage and marketing.

Similar sources of AP can arise in seed and grain supply chains of other crops. It is important to reiterate that the AP of low levels of unintended material in seed and grain is not a new concept to the grains industry, is recognised in customer contracts, and is accepted as a feature of normal production systems. Most commercial contracts for the sale of grain in Australia nominate tolerances and testing standards for impurities based on the standards administered by NACMA and the AOF (see above).

How can AP of GM events arise in the canola supply chain?

Gene Flow and Outcrossing

Gene flow is the natural process of movement of genes between individual organisms (Glover 2002). In plants, gene flow mainly occurs through a process known as outcrossing, whereby the pollen from one plant successfully cross pollinates a flower from another plant, resulting in the production of viable seed (Glover 2002). Salisbury (2000) argues that in addition to outcrossing, gene flow can also occur through seed movement over time and space. The germination of volunteer seed remaining in a field from a previous year's crop is an example of gene flow over time; and gene flow over space occurs when seed is moved around the farm

[1] http://www.nacma.com.au/grain_specifications accessed 29 May 2008

[2] http://www.australianoilseeds.com/aof_trading_standards accessed 29 May 2008

by farm equipment and beyond the farm during transport to bulk handling facilities (Salisbury 2000).

Because of the outcrossing nature of canola, some gene flow from GM to non-GM canola and *vice versa* will occur. Previous studies have reviewed this issue in detail (Glover 2002; Salisbury 2002b). Outcrossing has implications for the coexistence of GM and non-GM canola or related crops. For canola, the two main pollination vectors are wind and insect pollination. Glover (2002) comments that the relative importance of these vectors is unclear, and varies both regionally and seasonally. Studies conducted in 1998 and 2000 showed that most canola pollen travels less than 10 m from the source (Salisbury 2000) and 50 per cent of pollen falls within three metres of a plant (Lavigne et al. 1998).

Rieger et al (2002) performed a large-scale study that examined outcrossing from non-GM herbicide-tolerant canola into neighbouring canola crops in the Australian environment. Whilst gene flow was variable, the highest frequency of outcrossing detected was just 0.07 per cent. Some long-distance pollen travel occurs at very low levels, with levels of outcrossing beyond 400 metres irregular, and maximum distances less than three kilometres in the Australian studies (Rieger et al. 2002). A later study based on conditions in the UK concluded that like in Australia, pollination from one canola field to the next is likely to be less than 0.1 per cent when averaged over the whole field (Ramsay et al. 2004). Not only are these levels below the agreed AP threshold for GM events in non-GM canola seed and grain in Australia (0.9 per cent, see Chapter 5), but gene flow from GM canola to non-GM canola is intended to be to be managed further through industry Stewardship Principles and Crop Management Plans (Chapter 6). These include recommendations such as GM/non-GM crop separation distances and harvesting of adjacent non-GM canola borders for inclusion in the GM canola harvest.

For a less than 1 per cent threshold of seed impurity, canola crops are recommended to be separated by at least 1.5 to 30 m; for a less than 0.5 per cent threshold of seed impurity by 10 to 120 m; and for a less than 0.1 per cent threshold of seed impurity by 100 to 400 m (Glover 2002 based on Salisbury 2002b). One of the Australian seed companies consulted for this report uses separation distances of 600 m for certified canola seed production in its open pollinated varieties and up to 3 km for its hybrid varieties.

Seed production paddocks for hybrid canola varieties involve larger isolation distances as opposed to open-pollinated varieties because creating hybrids in self-pollinating species such as canola is complicated since the female parent line cannot be allowed to produce pollen (which would result in self fertilisation events). The larger separation distances are required to avoid the risk of pollen from the wrong source pollinating the female parent line. The first step in developing hybrid canola varieties is to create female parental lines that do not produce pollen (i.e. they are male-sterile) and male plants that do. The next step is to restore fertility in the seed produced from the cross so that when farmers plant the F1 hybrid seed[3], the crop can flower and self-pollinate. Breeders have accomplished this by introducing a fertility restorer gene into the male line to be used in crossing. The restorer gene is completely dominant so that all of the F1 hybrid seed resulting from the cross is able to grow, flower and produce seed the same as an open-pollinated canola crop. In a standard hybrid seed production paddock, approximately two-thirds of the production area is planted to male-sterile female lines. Following flowering, the male lines are slashed to ensure that F1 hybrid planting seed is harvested only from the female lines. The major benefit of planting hybrid canola varieties as opposed to open-pollinated varieties is the ability to take advantage of early hybrid vigour and hybrid heterosis that increases yield and oil content.

In the Risk Assessment and Risk Management Plans for field trials of GM canola, the Regulator imposes specific licence conditions related to managing gene flow from GM canola

[3] F1 seed is seed from the first generation following the parental cross.

(for example DIR 011/2001—Field trials of Roundup Ready® canola (*Brassica napus*) in Australia in 2002; and DIR 10/2001—Small and large scale trialling of InVigor® canola (*Brassica napus*) for the Australian cropping system and seed production). These licences required the establishment of Isolation Zones of at least 400 m if the flowering heads are bagged, the GMO is in an insect proof tent or the location is surrounded by a pollen trap. If none of these methods is adopted, an Isolation Zone of least one kilometre was required. These conditions are intended to minimise the likelihood of gene flow from the GM canola to other *Brassicaceae* plants by either physical separation and/or removal of related species outside or within the release site.

The Regulator did not specify isolation distances for GM and non-GM canola in the Risk Assessment and Risk Management Plans for the commercial releases of GM canola (DIR 021/2002—Commercial release of Invigor® hybrid canola (*Brassica napus*) for use in the Australian cropping system; and DIR 020/2002—General release of Roundup Ready® canola (*Brassica napus*) in Australia). The Regulator concluded that these GM canola lines pose no greater risk to human health and the environment than conventional canola. As part of the commercial release of GM canola varieties in Australia, the technology providers specify separation distances between GM and non-GM canola crops as part of their Crop Management Plans.

Volunteers

Volunteer plants are domesticated plants that have resulted from natural propagation, as opposed to having been deliberately planted by humans (Glover 2002). In cropping systems, seed from previous crop harvests can result in volunteer plants appearing in subsequent crop rotations. These volunteer plants can act as sources of seed and of pollen for gene flow.

Volunteers from previous crop rotations can be due to either seed dormancy which results in delayed germination or seed losses during harvesting. In the case of canola, seed losses during harvesting have been found to result in significant numbers of volunteers. Canola has no primary dormancy, with most volunteers germinating within two years. However an environmentally induced secondary dormancy, caused by deep burial in dry soils, can result in canola seeds surviving in the soil for some time, with European studies reporting dormancies of up to 10 years (Lutman et al. 2005).

Salisbury (2002a) conducted a review of the potential for and management of GM herbicide-tolerant canola volunteers. It was reported that the number of volunteers in subsequent crops is comparable for both GM canola and conventional canola. In GM canola trials in Australia during 1996–2001, the number of volunteers varied widely, and was influenced by the trial size, sowing time, harvest conditions and environmental conditions. General trends revealed that for winter-sown crops, the vast majority of GM volunteers germinated in the first year following harvest, with few the second year. No volunteers were seen in the third year in 82.5 per cent of the trials. For late spring/summer sown GM trials, volunteer germination patterns were more variable, with delayed germination more common. For 54 per cent of the trial sites, the majority of volunteer germination occurred in second and third years following harvesting. In some trials, germination was also reported in the fourth year (Salisbury 2002a).

In terms of management, Salisbury (2002a) reported that volunteer GM canola populations were generally adequately controlled by broadacre cultivation and herbicide application. Management practices to minimise seed loss during harvesting, such as ensuring combines are properly adjusted and used at lower speeds, as well as delaying cultivation to discourage the burial of seed after harvest (and thus prevent secondary dormancy) were also recommended to reduce volunteers (Salisbury 2002a).

Stanton (2004) conducted a five year crop rotation in which Roundup Ready® canola was trialled and compared with conventional canola. It was reported that volunteers after Roundup Ready® were managed without difficulty, with the herbicide Spray Seed® (a paraquat/diquat

mix) used as a knockdown in the first two years following the canola crop. This achieved total control of canola volunteers.

Volunteer plants can also occur in disturbed habitats such as roadsides, railways lines, field margins and wastelands. This is due to seed loss during harvesting, cleaning equipment and leakage during transport of the grain. These populations could potentially act as a source of gene flow to neighbouring fields. Salisbury (2002a) identifies canola as a plant which can colonise disturbed lands. It is however a poor competitor and unless the habitat is regularly disturbed, or replenished with seed, canola will be displaced by other plants. GM herbicide-tolerant canola, in the absence of selection by its companion herbicide, is unlikely to possess an increased ability to colonise disturbed areas. Studies in Canada have indicated that the frequency of GM canola volunteers in unmanaged areas adjacent to fields and along transportation corridors were equal to conventional canola volunteers (Rasche and Gadsby 1997; MacDonald and Kuntz 2000 as cited in Salisbury 2002a).

Canola volunteers along fence lines, around sheds and silos and along roadsides should be controlled through mowing or herbicides. To reduce the chance of volunteers occurring outside of the harvested paddock, equipment should be cleaned prior to moving. Also, well sealed trucks and trains will prevent seed loss during transportation of the grain and reduce volunteers on roadsides and along railway tracks (Salisbury 2002a).

Physical admixture

AP of GM material in non-GM seed and grain can occur through unintended mixing at all points along the supply chain. In order to minimise the risk of this, adequate maintenance and hygiene is required for all machinery, transport containers and storage facilities. For example if a farmer chooses to cultivate both GM and non-GM canola, it would be necessary to thoroughly clean out the planter and the combine between GMO and non-GMO planting and harvesting runs (Bullock and Desquilbet 2002).

ACIL Tasman (2007) have identified that for growers, modern seeding equipment is designed to be relatively easy to clean. Bullock and Desquilbet (2002) cite two studies which concluded that it would take approximately 40 (for an 8-row planter) to 55 minutes (for a 12-row planter) to clean down typical planting equipment used in the Midwestern United States of America (USA) to effectively segregate GM and non-GM soybean. ACIL Tasman (2007) note that while Australian planting equipment may vary to that used in the USA, this data provides an indication that planter cleanliness can be achieved.

Maintaining the cleanliness of harvesting machinery is also important in order to minimise the opportunities for adventitious presence. Foster (2006) presents data from the Australian Grain Harvesters Association which estimates that a 20–30 minute clean-down is necessary for a harvester moving from a GM crop to a non-GM crop, in order to meet an AP level of 0.1 per cent. However, Foster notes that researchers in the USA suggest that cleaning times of one hour may be more appropriate. As part of existing Good Agricultural Practice, harvesters and seeders are currently cleaned-down using compressed air blowers as they move between crops or between farms. Therefore, the cleaning down of machinery when moving between a GM and non-GM crop is part of existing practice and should not represent any extra or new work.

Segregation practices to reduce the risk of AP through physical admixture are detailed further in Chapter 6.

Traceability in the canola supply chain

Traceability in this context refers to the ability to trace seed and grain along the entire supply chain, from technology development to consumer (see Figure 6.1, Chapter 6).

In Australia, the technology providers and seed, grain and marketing industries have tracking systems in place so a given load of seed or grain may in some cases be able to be traced back to the original parental cross. For GM seed, it may even be possible to trace back to the original insertion of the GM event in the parent seed line. In terms of grain, where comingling has occurred it may be traced back to a silo and even to individual farmers if samples have been maintained.

Using Roundup Ready® canola as an example, seed breeding companies licensing the Roundup Ready® technology are required to keep 'a full set of records… for each pedigree of seed maintained by the seed companies for at least 3 years after the last commercial sale of the variety'. Additionally, it is considered Good Agricultural Practice for farmers sowing Roundup Ready® seed to record which seed bag lot numbers were sown in each paddock (Monsanto Australia Ltd. 2008).

Chapter 4: An Introduction to Sampling and Testing

Overview of the process from sampling to detection

This chapter provides a brief overview of the process from sampling to detection. Further details of sampling and detection are then discussed in subsequent chapters. The International Seed Testing Association (ISTA) and the International Organization for Standardization (ISO) have developed standards for sampling lots of seed and grain, respectively. ISO terminology refers to primary samples as increments, the composite sample as the bulk sample and the submitted sample as the laboratory sample (Figure 4.1). In this report, sampling terminology and sampling protocols are based on ISTA standards for discussion on seed-for-sowing and on ISO standards for discussion on grain.

Based on ISTA terminology, the sampling process (Figure 4.1) involves taking a number of primary samples from the original seed lot. The number of primary samples required depends on the size of the seed lot and how well it is mixed (International Organization for Standardization 1990; 1999; 2002; Kruse 2004). If adventitious GM material is unevenly distributed throughout the lot then more primary samples are required to accurately represent what is in the lot. The primary samples are combined and mixed to form a composite sample which is representative of the whole seed lot (Kruse 2004).

As the concentration of GM material in the lot decreases, larger composite samples are required to ensure that the composition of the lot is accurately reflected. If the composite sample is too large to be sent to the laboratory, it is reduced in size (with very thorough mixing) into a submitted sample. In the laboratory, the submitted sample is mixed and further sub-divided into one or more working samples which are then analysed using the chosen test method.

Where GM and non-GM crops are being developed and grown in the same country, AP could theoretically be introduced at any point in the supply chain, from initial pre-breeding, through breeding, seed-increase, on-farm production, transport and storage through to use (delivered for export, food or feed processing). For example, AP would occur at storage sites if GM grain was inadvertently mislabelled or mixed with non-GM grain. Monitoring for such inadvertent errors could be undertaken using an on-site test with a relatively low sensitivity since such mislabelled or misdirected truckloads are likely to contain a very high level of GM grain. Commercially available tests would need to be assessed to ensure that they have adequate sensitivity. To minimise errors with sampling and possible heterogeneity at storage sites, grain arising from entirely different sources would preferably not be combined prior to sampling and testing. The appropriate test method can be protein- or DNA-based, and would be selected depending on the limit of detection and the level of specificity for GM events that are required. A method can screen for a range of GM events, or it can be specific to one particular event.

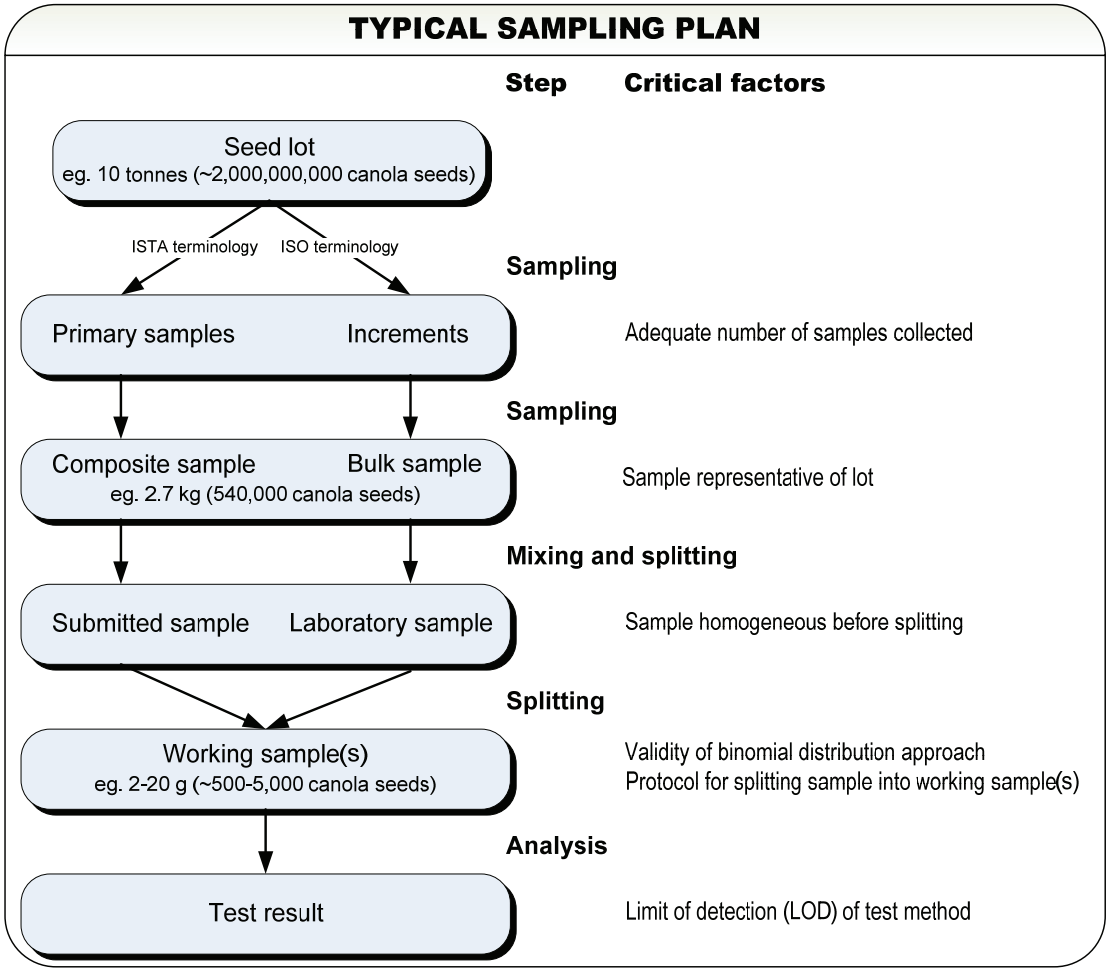

Figure 4.1: Steps involved in a typical sampling plan for detection of GM seed in a seed lot. An accurate test method has limited value if the working sample does not accurately represent the seed lot from which it originated.

Sampling — when, how and what size?

When should sampling be done?

Australia imports seed and also grain for food and feed from countries that commercially produce GM varieties. Using the example of imported labelled non-GM canola seed for breeding purposes; it could be tested for the presence of both GMOs that are approved in Australia for commercial release, and those GMOs that may be unapproved in Australia but are approved in the countries exporting canola seed to Australia (see Section 4). Testing for unapproved GMOs in imported seed for breeding in Australia helps ensure sown seed is compliant with the Australian regulatory system; dealings with GMOs are illegal in Australia unless authorised under the *Gene Technology Act 2000* (Cwlth). If imported seed meets regulatory requirements, and there is sureness that unapproved GM canola was not being bred and sown, then AP testing further along the supply chain could focus on testing for only Regulator-approved GMOs in marketed non-GM grain to enable market requirements to be met.

In the case of GM canola approved for sowing in Australia, labelling thresholds for AP of GM events in non-GM canola grain are lower than or equal to equivalent thresholds in the

countries to which Australian canola is exported. Hence, if the non-GM canola meets Australian thresholds, then it may not require re-testing to ensure it meets the receiving country's standards.

For cotton, as the majority of cotton grown in Australia is GM, testing for the AP of GM events in cottonseed is required only in the case of certified non-GM cottonseed that is being exported to niche markets. For soybean and maize, no GM events have been approved by the Regulator for commercial release.

How should sampling be done?

The strategies and techniques used in taking, mixing and reducing the samples are designed to ensure that the composition of the working sample analysed in the laboratory corresponds as closely as possible to the composition of the original lot (Figure 4.1) (Kay and Paoletti 2002). In reality this process does not work perfectly, and the errors associated with each of the sampling steps need to be considered when estimating the total uncertainty of the sampling process.

Two linked factors are involved in developing strategies for sampling and testing. The first is the level of confidence required. This is a measure of how confident one can be that a calculated result is correct. A confidence level of 100 per cent means that 100 out of 100 times, the result given is correct. A confidence level of 95 per cent means that 95 out of 100 times, the result is correct. Also to be taken into account is the relative uncertainty of the measurement (often expressed as the error). Uncertainty is given as a projection of how far away the actual value could be from the calculated result due to the cumulative errors of the processes leading to that result. It is expressed as a range around a value (i.e. 1 per cent GM ± 0.05, or 1 per cent GM with 5 per cent relative uncertainty).

The application of confidence levels and uncertainty to AP testing plays a very large role in deciding the sample size required for testing. Statistics can identify the minimum bulk sample size required to provide a specified level of confidence that the GM content of the sample lies within a specified error range of the actual composition of the lot (Figure 4.2) (Smith and James 1981; Minnet et al. 2007). As shown in Figure 4.2 for an 'ideal' homogenous seed lot, larger numbers of seeds are required as the proportion of GM content in the lot decreases. In the case of a perfectly homogenous lot, only a single increment of the requisite size would be needed. However, as it cannot be assumed that real lots are homogenous, most sampling protocols specify the collection of multiple increments from different parts of the lot with the aim of obtaining a bulk sample representative of the average composition of the lot (see Figure 4.3).

At a specified threshold level (per cent GM), to decrease the relative uncertainty, the size of the sample collected should be increased. In addition, the sample size also needs to increase as the threshold level decreases. This is because the lower the relevant concentration (i.e. the allowable threshold) of GM material in a seed lot, the more seeds are required in the collected sample to accurately detect and measure it.

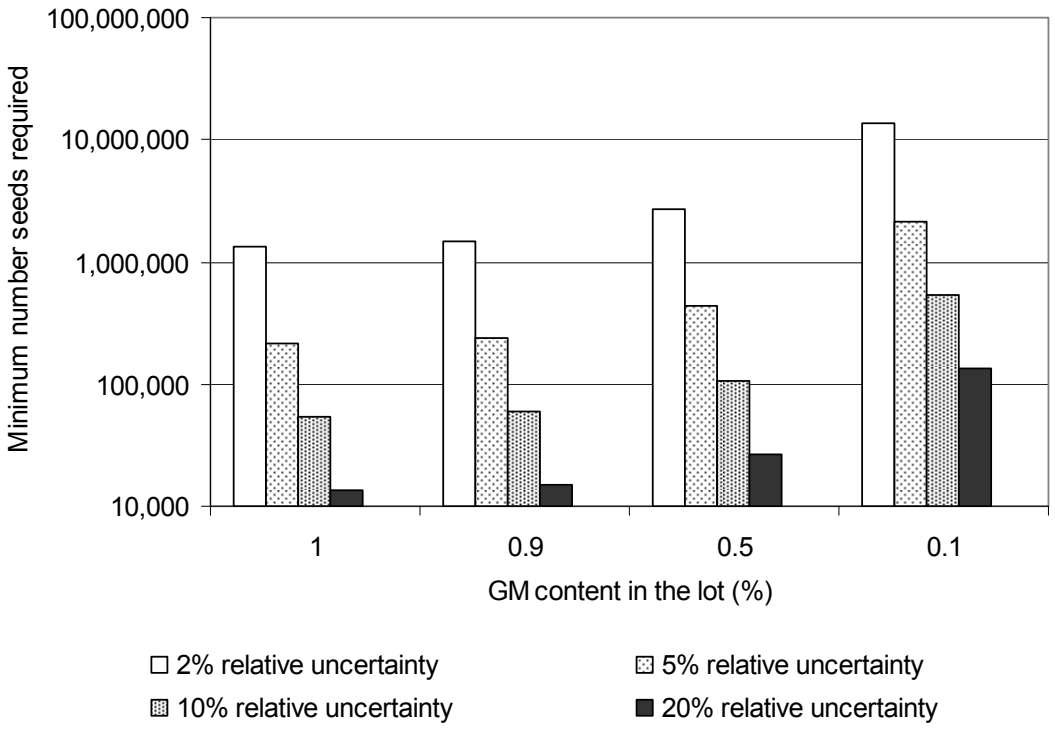

Figure 4.2: The number of seeds required in a composite sample to be 98 per cent certain that the sample is representative of the composition of the original lot (to within 2, 5, 10, or 20 per cent of the true value, assuming that all of the seeds have an identical size and are completely mixed).

Where there is AP of a GM event, it would be very difficult to know how well dispersed any GM presence may be within any given seed lot. Therefore, most grain and seed sampling and testing protocols require that a large number of primary samples are taken (see Figure 4.3 for an example of sampling GM grain), and that the maximum lot size to be tested is limited, to minimise the uncertainty inherent in the sampling.

ISTA has developed rules for sampling seed lots that are designed to provide confidence that the submitted or laboratory sample is representative of the lot in most cases. The maximum seed lot size for maize should be 40 tonnes (± 5 per cent), and for canola 10 tonnes (± 5 per cent) (Kruse 2004). There should be documentary evidence that the lot being tested is all from the same source and batch. ISTA rules define the minimum number of primary samples to be collected, in containers ranging from less than 15 kg up to the maximum permitted (and also for a seed stream), and state that the primary samples should be approximately the same size as each other. In the case of a 10 tonne seed lot for any seed, the ISTA rules specify the collection of twenty 500 g primary samples (Kruse 2004). The maximum lot size recommended for grain is much larger. For instance, ISO guidelines specify a maximum lot size of 500 tonne when sampling grain.

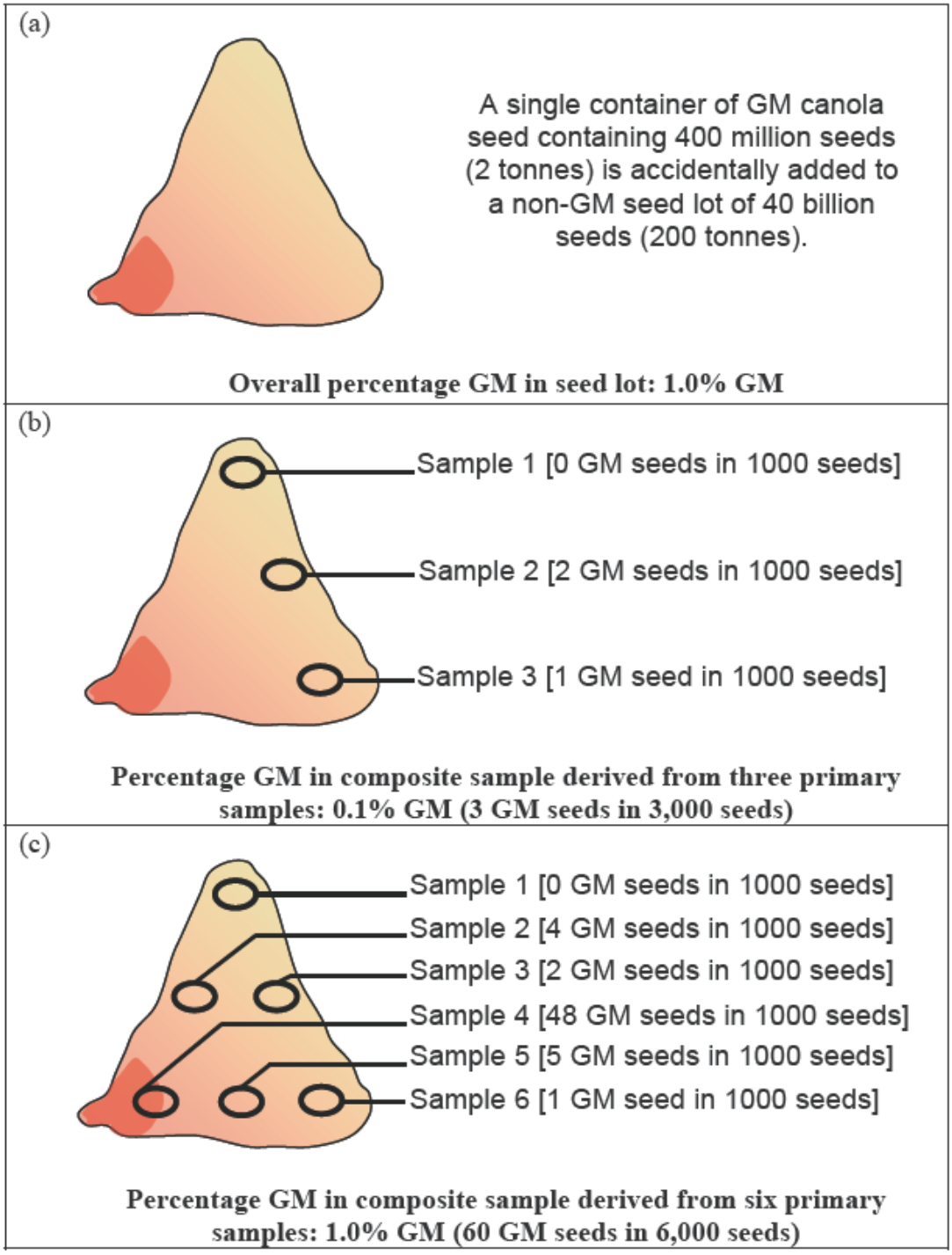

Figure 4.3: Taking more primary samples from a bulk lot of grain decreases sampling uncertainty. When a non-GM lot contains a relatively small amount of GM grain (as shown in (a)), unless the GM seed is evenly distributed, a small number of primary samples (such as the three samples shown in (b)) may not accurately represent the composition of the entire lot. Taking more primary samples (as shown in (c)) increases the confidence level that the composite (or bulk) sample accurately represents the original lot.

The minimum number of seeds that needs to be collected from the bulk sample for analysis depends on the relevant threshold level for AP of GM seed and the level of confidence required in the result. Based on these two factors, a statistical approach can be used to determine the minimum number of seeds required in a sample to ensure, with a defined level of confidence, that at least one GM seed is present (GIPSA 2000; Emslie et al. 2007). This approach is based on two assumptions: the bulk sample is homogenous, and the number of GM seeds present in any working sample taken from such a bulk sample which contains GM seed follows a binomial distribution (Remund et al. 2001; Whitaker et al. 2001). These are fair assumptions provided that appropriate protocols (ISTA) are followed for mixing and dividing the bulk and laboratory samples.

For instance, if a homogeneous bulk sample contains 0.9 per cent GM seed, a sample of 332 seeds collected from the bulk sample will contain at least one GM seed 95 per cent of the time (Table 4.1). In other words, if a buyer wants to be 95 per cent confident that seed lots with adventitious GM presence at the level of 0.9 per cent or more in the bulk sample will be detected, then the working sample needs to contain a minimum of 332 seeds. To increase the buyer's confidence to 99 per cent, the number of seeds analysed would need to increase to 510.

These estimates for the minimum number of seeds to be analysed are valid for use with a *qualitative* analytical method only if the method has no false positives or false negatives. Under these circumstances, a positive result from a qualitative test would indicate, with the defined level of confidence, that presence of GM material in the bulk sample exceeded the threshold level (in this example presence of GM material greater than or equal to 0.9 per cent).

Table 4.1: Number of seeds required in a working sample to ensure with a defined degree of confidence that at least one GM seed will be present (Emslie et al. 2007).

% GM seed in bulk sample	Confidence level	
	95%	99%
0.1	2995	4603
0.5	598	919
0.9	332	510
1.0	299	459
3.0	99	152
5.0	59	90

The measurement uncertainty associated with DNA-based *quantitative* assays is relatively large due to the intrinsic nature of the amplification process of the polymerase chain reaction assay that is used to detect the DNA. Sampling error is not likely to be a significant contributor to the total uncertainty provided that good sampling practice is used—small sample sizes should not be chosen and the sampling error should be below 20–30 per cent (Huebner et al. 2001). The total measurement uncertainty of a quantitative result should be taken into account if such an assay is to be used to screen for the presence of GM material in grain and seed.

In practice the level of confidence for results from a *qualitative* assay is also affected by the uncertainty introduced by the sampling process. If a sampling protocol introduces a 10 per cent relative uncertainty, this can be allowed for by targeting the testing at the lower limit of the uncertainty range (Table 4.1) (i.e. test for 0.9 per cent GM instead of 1.0 per cent GM by taking a sample of 510 seeds instead of 459 seeds). The sampled seeds are combined to form a working sample before testing—they are not tested individually.

Table 4.2: Suggested number of working samples required to meet target confidence levels when operating at an assay limit of detection of one GM seed in 1000 seeds and taking into consideration a relative uncertainty in sampling of 10%.

Acceptable threshold level (% GM Seed)	Lower limit of sampling uncertainty (% GM seed)	Number of working samples	
		95% confidence level	99% confidence level
0.1	0.09	4	6
0.5	0.45	2	2
0.9	0.81	1	2

Notes: Assumes the assay is operating at the limit of detection with a 5 per cent false negative rate whilst still maintaining a zero false positive rate. SeedCalc v7.0 software was used to calculate the number of working samples required (Remund et al. 2005).

As outlined above, statistics can be used to determine the minimum number of seeds to be analysed to ensure with a defined degree of confidence that at least one GM seed will be present in the sample if the bulk sample contains GM seed above a defined threshold (Table 4.2). Assay methods used to test for the AP of GM events in non-GM grain should be validated under the conditions of use to verify their limit of detection (Emslie et al. 2007). If the analytical method is capable of detecting a single seed in this minimum number of seeds, it can be used directly on a representative working sample of the appropriate size. However, in some cases the chosen analytical assay may not be sensitive enough to detect a single GM seed in the sample. If this is the case, then the sample should be split evenly into several working samples and the number of seeds in the working samples should be selected to ensure that the analysis is conducted within the detection limit of the assay. Each of these working samples should be analysed using the same method.

Zero presence levels

Analytical testing to a zero presence level is not possible. It is possible to test only as low as the limit of detection of the analytical method will allow. For example if a test is capable of detecting down to a concentration of only 0.1 per cent GM (that is one GM seed in 1 000 non-GM seeds), then a negative result (no GM material detected) does not mean that there is no GM material present. There could still be GM material present at a concentration lower than 0.1 per cent. Therefore, detection will always be limited by the sensitivity of the analytical test method and the number of seeds analysed in the working sample(s).

Detecting GMOs — what options are available?

All GMOs contain at least one transgenic construct inserted into their genome (Figure 4.4). The two main approaches for detecting constructs in GM seed are DNA-based assays to detect novel DNA sequences and protein-based assays to detect novel proteins (Griffiths et al. 2002). For identification of specific GM events, DNA tests are required.

The most cost-effective approach for a monitoring program that covers a large number of GM events is to test the sample initially using one or more screening methods that can detect several GMOs. Screening methods may be either DNA- or protein-based. If required, subsequent analysis can then be undertaken to identify and, if needed, quantify the specific GM event(s) detected in a sample.

The detection limit of the assay will play a significant factor in choosing which method to use. In particular, some protein-based methods are not sensitive enough for practical purposes when analysing GM seed at the thresholds for AP. Even DNA-based methods should be carefully validated to ensure that they are sensitive enough to meet the requirements of the working sample size.

Protein-based detection methods

Several immunoassays have been developed to detect the novel proteins that are expressed by different GM plants. The sensitivity of these immunoassays depends on the level of expression of the novel protein in the plant tissue being analysed. For example, some GMOs have been specifically designed so that the novel protein is expressed in leaf tissue with relatively weak expression in seeds. Use of a protein assay on seeds under these circumstances may not be feasible due to lack of assay sensitivity. Since the same novel protein may be expressed by plants containing different GM events, protein assays are not event-specific but may be useful for screening and for qualitative analysis.

The most sensitive protein-based detection technique is the enzyme-linked immunosorbent assay (ELISA). ELISA works by detecting the presence of either antibody or antigen in a sample. The tag indicating the antibody-antigen affinity can either be an enzyme or a fluorescent dye (Pita et al. 2008). For the basic ELISA, molecules of an antibody specific to the target protein are bound to the walls in each well of a microtitre plate and used to bind to the target protein, if present in the sample. A second antibody, that is also specific to the target protein, is then added. This antibody is labelled with an enzyme that catalyses a colour reaction. After removing unbound labelled antibody from the wells through washing steps, the amount of colour is proportional to the amount of target protein present. A number of ELISA assays are on the market for detection of different herbicide-tolerant or insect-resistant traits. In general, these assays require some level of sample preparation and laboratory instrumentation for analysis. One disadvantage with ELISA relates to the large number of incubation and wash steps that are required when using enzymatic activity as the detection system as it makes the procedure difficult to automate when screening large numbers of samples, and prolongs the time taken to obtain results (Velappan et al. 2008). Using fluorescent dyes as opposed to enzymatic activity for detection can help overcome some of these difficulties. Velappan et al (2008) comment that by avoiding the extensive washing steps required when using enzyme tags, the use of fluorescent dyes can significantly reduce the time required to carry out assays. A concurrent reduction in the number of incubation steps will also facilitate automation of the technology.

The most rapid detection method that requires minimal sample preparation and equipment is the lateral flow strip device. This is a test strip containing immobilised antibodies in specific zones on the strip. Sample preparation simply involves crushing the sample and mixing it with the protein extraction solution provided in the kit. The lateral flow test strip is dipped into the prepared sample extract which migrates up the strip by capillary action. As it moves up the strip, the sample passes through a zone of reagent that contains antibodies, usually labelled with colloidal gold. This labelled antibody binds to the GM protein, if present in the sample. The antibody-protein complex then continues to move up the strip until it reaches a second zone of antibodies, which in this case are immobilised onto the test strip. The complex concentrates into this immobilised antibody zone where the gold becomes visible as a red band. The test strip also contains an immobilised control zone that binds a control complex that is present in the extraction solution and also produces a visible line. If there is no target GM protein present only a single line will form at the control zone. A result is called positive when both the control line and the line indicating presence of target GM protein change colour. Theoretically, lateral flow strips are suitable for analysis in the field. However, their robustness under field conditions may require further research (Emslie et al. 2007).

It is most likely that expression levels of the novel protein being tested will vary between seeds. Consequently, if the assay system is protein-based, the detection limit when testing working samples containing a single GM seed in the working sample will not be as good as the detection limit when testing working samples derived from a larger, uniform, homogenised sample containing the equivalent percentage of GM seeds since the level of expressed protein in a large, homogenised sample will reflect the average expression level over a number of GM

seeds. On the other hand, a working sample that contains an individual GM seed with an expression level of the novel protein that is less than the average expression level for the GM seeds may not be detected by the assay.

DNA-based detection methods

DNA-based detection methods include end-point and real-time polymerase chain reactions (PCR), microarrays, and DNA fingerprinting techniques. DNA-based detection methods are designed to be specific for a short sequence of DNA, generally much smaller than a gene. To detect GM events, these techniques target the transgenic DNA of a construct (Figure 4.4).

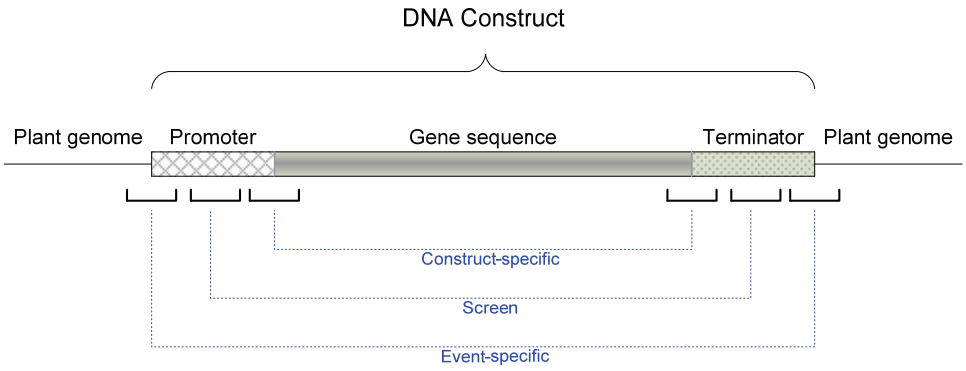

Figure 4.4: Simplified diagram of a DNA construct and the range of DNA tests available.

End-point PCR

PCR works by making multiple copies of the targeted DNA sequence through a process known as DNA amplification. PCR detection can provide both *qualitative* results (whether or not the target sequence was present) and *quantitative* results (the amount of DNA that is amplified in the reaction can be used to calculate the percentage of transgenic DNA that was in the original sample). PCR assays can be designed to detect a specific region of the transgenic DNA. The region used will determine how selective the test is. For instance, a method that detects a promoter or a terminator sequence (Figure 4.4) is useful as a screen since these regulatory sequences are common to a number of GM constructs. These sequences are most commonly derived from viruses or bacteria so their detection in a sample does not absolutely confirm the presence of a GM event. An additional, more selective test would need to be conducted to be more certain that the sample contained GM material. A false positive result could be obtained if the virus or bacterium from which the promoter or terminator were derived, is itself present. For a number of reasons, PCR assays can also produce false negative results; this is another reason why the laboratory testing methods used need to be both verified and standardised.

PCR assays which are event- rather than construct-specific (Figure 4.4) are designed to detect the DNA at the junction between the plant genomic DNA and the inserted construct. This junction region is unique for each GM event. Construct-specific assays target regions of the transgenic DNA within the construct. These are specific for the trait, but not for the event; as the developer may have created more than one event for a given trait. Construct-specific methods may be capable of detecting multiple GM events, so are less specific than event-specific methods.

End-point PCR refers to assays where the PCR product is detected at the end of a defined number of amplification cycles and is a *qualitative* detection method. Generally, each PCR product is amplified in a separate tube. Hence, if one sample is to be screened for the presence of several different genetic elements, a series of individual PCR assays is needed.

Real-time PCR

Real-time PCR refers to assays where the PCR product is detected during the amplification process by monitoring an increase in fluorescence throughout the PCR and can be used as a *quantitative* detection method. The fluorescence detection system is either based on a fluorescent dye or probes. In each case, the intensity of the fluorescence is directly related to the amount of amplified product. Whether assays are *qualitative* or *quantitative*, controls are still required to verify that the assay is working correctly and to convert results to a 'per cent threshold' level.

Microarray techniques

Microarray technologies allow simultaneous detection of a number of DNA sequences and, theoretically, are highly suited for use as a screening tool for GMO analysis. In late 2007, the first commercially available microarray system for GMO screening was validated in the EU through a collaborative study which was coordinated by the Joint Research Centre of the European Commission (Hamels et al. 2007). The performance of the DualChip® GMO assay (DualChip is a registered trademark of Eppendorf Array Technologies) was assessed as a qualitative method for screening for authorised GMOs in the European Union. In the collaborative study, different genetic elements were detected at a concentration of 0.1 per cent GM with an accuracy rate of 95 per cent using blind DNA reference samples.

DNA fingerprinting techniques

The Canadian Food Inspection Agency (CFIA) has developed a DNA fingerprinting technique for qualitative detection of approved and unapproved GM crops. The technique targets common genetic elements such as promoters and terminators, and provides a characteristic 'fingerprint' pattern based on the gene sequence adjacent to the promoter or terminator (the coding region of the introduced gene). The CFIA have obtained specific and reproducible DNA fingerprint patterns to identify GM presence down to a LOD of 0.5 per cent GM seed or grain in a non-GM lot. This technique is not a quantitative method, it cannot be used to verify AP above or below threshold levels, but it does have the potential to be used as a screening method to simultaneously monitor for the presence of a large number of GMOs. NMI, in Australia, currently has a collaborative agreement with CFIA to validate the methods within a second laboratory and develop additional fingerprint patterns relevant to Australia.

Section 2: The Domestic Environment

Chapter 5: The Domestic Regulatory Environment for Genetically Modified Organisms

Introduction

Gene technology is regulated in Australia under a national scheme, agreed to by the state and federal governments in 2001. An overview of Australia's national regulatory framework for GMOs and GM products is given in Appendix A.

Dealings with GMOs are regulated by the Gene Technology Regulator (the Regulator) supported by the Office of the Gene Technology Regulator (OGTR) under the *Gene Technology Act 2000* (Cwlth). The Act is supported by the Gene Technology Regulations 2001; an inter-governmental agreement between the Australian Government and each State and Territory Government; and corresponding legislation that is enacted in each state and territory. The role of the Regulator is to protect human health and safety and the environment by identifying and managing potential risks posed by the use of this technology. The Regulator does not evaluate economic and social considerations, such as risks to trade and marketing. The OGTR has developed a Risk Analysis Framework describing the Regulator's approach to risk assessment and risk management for genetically modified organisms. More information on the regulatory scheme is available at http://www.ogtr.gov.au.

A Gene Technology Ministerial Council (GTMC) with representatives from the Commonwealth and each State and Territory provides broad oversight of the implementation of the regulatory system.

The Regulator liaises with other regulatory agencies, including Food Standards Australia New Zealand (FSANZ), the Australian Pesticide and Veterinary Medicines Authority (APVMA) and the Therapeutic Goods Administration (TGA) to enhance coordinated decision-making with respect to GMOs for intentional release into the environment and related GM products.

The Regulator has approved GM lines of canola, cotton (Chapter 9) and carnations for commercial release in Australia.

FSANZ has approved thirty-five GM foods/food ingredients from seven crops: soy, canola, corn (maize), potato, sugar beet, lucerne and cotton as of July 2008 (FSANZ 2008). Most of the GM foods currently available in Australia come from GM crops which have been grown and processed overseas. Genetically modified food and ingredients, as defined in Australia's Food Standard 1.5.2—Food Produced Using Gene Technology—see Appendix A), are required to be labelled where they contain novel DNA and/or novel protein in the final food or have altered characteristics. The purpose of labelling is for consumer choice, and not for food safety reasons. The following are not required to be labelled:

- Highly refined foods where the effect of the refining process is to remove novel DNA and novel protein;
- Processing aids or food additives where novel DNA and novel protein is not present in the final food;
- Flavours which are present in the food in a concentration of no more than 1g/kg (0.1 per cent);
- Foods, ingredients or processing aids in which the genetically modified food is unintentionally present in a quantity of no more than 10g/kg (1 per cent) per ingredient. This tolerance level only applies where the manufacturer has sought to source non-genetically modified foods or ingredients;

- Food intended for immediate consumption that is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers or self-catering institutions. In these situations, consumers have the right to ask the proprietor what is in the food being purchased and whether it is from a GM source.

Thresholds in Australia for approved GMOs in conventional canola

In July 2005, testing of a consignment of conventional canola in Victoria revealed trace levels (at a level close to 0.01 per cent) of a GMO approved for commercial release. The Regulator was asked by the Victorian government to provide technical assistance to an investigation into how this could have happened. The Regulator's report concluded that whilst there was insufficient evidence to definitively identify a pathway, the most likely cause was human error, being the accidental mixing of two types of seed (OGTR 2005). The report also noted that at the time the co-mingling is most likely to have occurred there was no gene technology regulatory system in place and that the introduction of the current regulatory system in 2001 has resulted in the establishment of an extremely robust regulatory regime to manage dealings with GMOs (OGTR 2005).

This incident was considered at the Primary Industries Ministerial Council (PIMC) meeting on 26 October 2005 and as a result the Council agreed to a nationally consistent definition of threshold levels in canola grain and seed for traces of GMOs approved for commercial release by the Regulator (PIMC 2005). The Council agreed to two thresholds:

- an AP threshold of 0.9 per cent Regulator-approved GM canola in non-GM canola grain—supported by the Australian Oilseeds Federation
- an AP threshold of 0.5 per cent Regulator-approved GM canola in non-GM canola seed-for-sowing for 2006 and 2007—supported by the Australian Seed Federation.

Setting a 0.5 per cent tolerance level in canola seed-for-sowing has the support of the Australian seed industry as it:

- achieves end user requirements
- is economically achievable
- practical for industry to implement.

Following this decision, the four mainland Australian states that had imposed a moratorium on the commercial cultivation of GM canola approved for commercial release by the Regulator (see below)—Victoria, New South Wales, South Australia and Western Australia—adopted the PIMC thresholds.

Tasmania differs from the mainland states in that it has adopted a zero-tolerance stance on GM canola entering the state; whereby zero-tolerance is defined as a negative result from the sampling and testing of canola lots such that a level of AP of GM material of 0.01 per cent would be detected with a probability of 95 per cent (discussed further below).

National Strategy for Unintended Presence of Unapproved GMOs

A risk-based national strategy to manage the unintended presence of unapproved GMOs in imported seed-for-sowing (the 'UP Strategy) has been endorsed by the Australian Government Biotechnology Ministerial Council (OGTR 2007). The OGTR is responsible for implementing the six components of the UP strategy, namely:

- risk profiling—to identify seed imports posing the highest likelihood of AP, to focus government monitoring and surveillance efforts
- quality assurance / identity preservation—to develop a program for auditing and testing industry quality assurance systems that industry has agreed to and adopted
- laboratory testing—to discuss appropriate testing methodologies with NMI

- approvals / advance risk assessments for Australia's regulatory agencies—to prepare GMO incident response documents for the 12 crops identified through risk profiling as having the highest likelihood of unintended presence in seed-for-sowing
- post market detection—to work cooperatively with industry to develop a voluntary code of conduct that aims to isolate risks as early as possible in the commercial seed supply chain
- enforcement action—to determine that in the event of the detection of unapproved GMOs appropriate responses would be decided on a case-by-case risk management basis.

State Level Regulation

Setting up the national regulatory scheme for GMOs occurred in two parts. The first was a national cooperative scheme of Commonwealth and State legislation, such legislation being complementary to the Commonwealth's *Gene Technology Act 2000*. The second was an inter-governmental agreement, called the Gene Technology Agreement (effective from 11 September 2001), to which the Commonwealth and States are all a party. The Agreement sets out the roles and responsibilities of each of the Governments in the administration and enforcement of the regulatory scheme and also establishes the GTMC (see Introduction to this Chapter).

Under the national scheme, all states and territories recognise approvals of GMOs made by the Regulator in respect of risks to human health and safety and the environment. In the development of the *Gene Technology Act*, state governments were concerned about the impact of the commercial release of GMOs on local trade and export markets and accordingly wanted to maintain the capacity to refuse to allow the release of GMOs on these grounds (Ludlow 2004). Passing of corresponding legislation by states and territories in accordance with the Gene Technology Agreement does not preclude their capacity to pass laws with respect to marketing. Further to this, the Act also enables the GTMC to issue Policy Principles relating to designating areas non-GM for marketing purposes (s21(1)(aa) of the *Gene Technology Act*).

The GTMC issued the *Gene Technology (Recognition of Designated Areas) Principle 2003*, taking effect from 5 September 2003, 'for the purposes of recognising areas (if any) designated under a State law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM and non-GM crops, for marketing purposes'.

In July and December 2003, the Regulator issued two licences for the commercial release of GM canola lines in Australia. Subsequently, all states and territories except Queensland and the Northern Territory enacted GM crop moratorium legislation, consistent with the 2003 Policy Principle, to delay the commercial production of approved GM canola until marketing and trade considerations had been addressed. It is important to note that these moratoria were not imposed on health and safety grounds. Most states have now reviewed, or are in the process of reviewing, their moratoria (Table 5.1).

Victoria

In 2004, Victoria introduced an Order under the *Control of Genetically Modified Crops Act 2004* (Vic) to prohibit the commercial production of GM canola. Following an independent review, the Victorian government announced in November 2007 that the Order establishing the moratorium on the commercial production of GM canola would be allowed to lapse on the 29 February 2008 to enable production of GM canola from the 2008 growing season.

One of the key recommendations of the review of the GM moratoria in Victoria was that 'the Victorian Government allow the market to determine whether segregation of non-GM canola from GM canola in the grain supply chain is required'.

The Victorian Government supported this recommendation deciding that there is no apparent market failure in relation to segregation to meet customer requirements, and there is therefore no case for government to intervene with sampling and testing requirements. In Victoria, it is

being left up to the supply chain and in particular the marketers to undertake any sampling and testing required to ensure that grain consignments will meet the requirements of their particular markets.

New South Wales

The NSW Parliament passed the *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) to prohibit the production of specified GM food crops (including GM canola, but excluding GM cotton). Based on the recommendations of an independent review in 2007, amendments were made to this Act to extend the period of the moratorium until 2011; replace the moratorium Order process with a blanket moratorium and scheme for approving the commercial cultivation of licensed GM food plants; and established an Expert Committee to advise the NSW Minister for Primary Industries on applications by industry for the commercial cultivation of GM food crops. On 14 March 2008, following applications from industry, the NSW Primary Industries Minister announced that approval had been granted for the commercial production of GM canola (approved by the Regulator) in NSW, having been satisfied that industry had adequately identified the requirements of key markets and could segregate GM and non-GM canola if required. The moratorium remains in place for the commercial production of all other GM food crops in NSW. The NSW Government will continue to maintain the oversight of the commercial release of GM food crops under the NSW legislation.

South Australia

South Australia introduced the *Genetically Modified Crops Management Act 2004* (SA) to ensure that the cultivation of GM crops was regulated in the State. On 8 February 2008, the South Australian Government decided to extend its current moratorium on growing GM canola in South Australia beyond the end of April 2008 when the existing regulations were due to expire. Any plant or plant material that forms part of a GM food crop grown outside South Australia, including seed for planting, harvested seed for cleaning, harvested grain for processing or export, or hay, is not permitted to enter South Australia.

The South Australian Government does not currently have sampling and testing programs for GM events in seed and grain in place; however, bulk handling companies that operate in the state may be carrying out sampling and testing for GM events in order to satisfy existing contractual obligations. The South Australian Government is currently considering how cultivation and related dealings including trade will be monitored, particularly along its borders with Victoria and NSW, where farmers could potentially be growing canola containing GM events from the 2008 growing season onwards.

Tasmania

Tasmania has been declared a GM organism-free area under the *Genetically Modified Organisms Control Act 2004* (Tas). The Act expires on 16 November 2009. In Tasmania, a Joint Select Committee was appointed to report on the most effective and appropriate policy position on the use of gene technology in agriculture that best serves the future market interests. The key recommendation from the report (released on 28 August 2008) is that the prohibition on the release of GM food crops to the Tasmanian environment for commercial purposes should be extended and reviewed after 5 years (thereby extending the moratorium until 2014). Open-air trials of food plants should continue to be prohibited in Tasmania. The report recommends a continued zero tolerance for GM canola in imported seed and grain. It recommends that devitalised GM stockfeed should be allowed to be imported into and used in Tasmania.

Import Requirement 32 (Canola Seed and Grain—Freedom from GM *Brassicaceae* Seed) of the *Plant Quarantine Manual* (Tas) requires that canola seed and grain imported into Tasmania ‘must be accompanied by a certificate or statement of analysis from an approved

laboratory that adequately identifies the lot from which the tested sample was drawn and states that the lot has been sampled and tested in manner approved by the Tasmanian Department of Primary Industries and Water such that a level of contamination by GM material of 0.01 per cent would be detected with a probability of 95 per cent and the test has returned a negative result for GM events known to have been inserted into canola.' The Tasmanian government accepts the ISTA standards for sampling and relies on screening (qualitative) as opposed to quantitative tests.

This Import Requirement is enforced by Quarantine Tasmania, which checks that all canola seed and grain arriving at the Tasmanian border carries the appropriate certification as to its GM status.

Western Australia

In Western Australia the *Genetically Modified Crops Free Areas Act 2003* (WA) prohibits the cultivation of all commercial GM crops in the State. Current Exemption Orders under the Act have been issued for small scale scientific research trials for cotton (mainly in the Ord River Irrigation Area) and canola (trial did not proceed) as well as an Exemption Order for permitting low levels of GM canola material in non-GM seed and grain for canola cultivated in 2007 and 2008. Section 19 of the Act requires the Minister to carry out a review after 24 December 2008.

Table 5.1: Gene technology moratorium legislation[4]

Jurisdiction	Legislation	Moratorium on GM canola/crops	Sunset/Expiry or Review Date
New South Wales	*Gene Technology (GM Crop Moratorium) Act 2003* (NSW)	Blanket moratorium and scheme for approving the cultivation of licensed GM food plants. Established an Expert Committee to advise the NSW Primary Industries Minister. Commercial cultivation of GM canola was approved in March 2008.	Section 43 of the Act provides that the Act expires on 1 July 2011.
Victoria	*Control of Genetically Modified Crops Act 2004* (Vic)	The Act allows the Minister to make Orders prohibiting the growing of GM Crops. The Order in place prohibiting the cultivation of GM glyphosate- and glufosinate ammonium-tolerant canola varieties was allowed to lapse on 29 February 2008.	No expiry or review provisions within the Act itself.
South Australia	*Genetically Modified Crops Management Act 2004* (SA)	The Act provides for a moratorium on the commercial cultivation of all GM food crops. The whole state is designated by Regulation as an area in which the cultivation of genetically modified food crops is prohibited. The Act allows for exemptions to be given for field trials under specific conditions.	Under Schedule 1, s1(2) of the Act, the regulation was to expire on 29 April 2008. A review announced in June 2007 recommended the Regulation be allowed to expire, but the Government decided in February 2008 to maintain its ban on GM canola.

[4] Moratorium legislation has been introduced for marketing and trade reasons only. Issues relating to human health and safety and environment are assessed and regulated by OGTR.

Jurisdiction	Legislation	Moratorium on GM canola/crops	Sunset/Expiry or Review Date
Tasmania	*Genetically Modified Organisms Control Act 2004* (Tas)	The Act provides for a moratorium on the commercial cultivation of all GM crops (including GM canola) in designated areas. A Ministerial Order designated the entire state.	Section 36 provides that the Act expires on 16 November 2009. In August 2008, a Tasmanian Government Joint Select Committee recommended that the prohibition on the release of GM food crops to the Tasmanian environment for commercial purposes should be extended and reviewed after 5 years (thereby extending the moratorium until 2014).
Western Australia	*Genetically Modified Crop Free Areas Act 2003* (WA)	The Act provides for a moratorium on the commercial cultivation of all GM crops (including GM canola) in designated areas. The Western Australia Minister for Agriculture designated whole state by Order on 22 March 2004.	Section 19 of the Act requires the Minister to carry out a review after the expiration of five years (i.e. after 24 Dec 2008). Report to be tabled in both houses of parliament before 24 Dec 2009.
Queensland	No legislation	None	N/A
Australian Capital Territory	*Gene Technology (GM Crop Moratorium) Act 2004* (ACT)	The Act allows the Minister to make Orders prohibiting the growing of GM Crops. Orders have been given prohibiting the cultivation of GM glyphosate- and glufosinate ammonium-tolerant canola varieties.	Section 39 provides that the Act expires on a date fixed by the Minister by written notice not earlier than 17 June 2006. The Act and the moratorium remain in force.
Northern Territory	No legislation	None	N/A

Import and Export Regulations – Quarantine and Food Safety

The Australian Quarantine and Inspection Service (AQIS) is part of the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF). AQIS provides quarantine inspection for (amongst other things) plants and plant products arriving in Australia in accordance with the *Quarantine Act 1908* (Cwlth). In respect to GMOs, the *Quarantine Act 1908* (Cwlth) requires prior approval (via an import permit) to import declared GM seeds and grain. In deciding whether to grant a permit to import a seed of a kind of plant that was produced by genetic manipulation, the Director of Quarantine must take into account any risk assessment prepared, and any decision made, in relation to the seed by the Regulator under the *Gene Technology Act 2000* (Cwlth). GMOs *per se* are not a quarantine concern, unless a particular GMO posed a specific quarantine risk.

AQIS also administers the imported food inspection scheme and has responsibility for inspection and sampling of imported food under the *Imported Food Control Act 1992* (Cwlth) to ensure compliance with the *Australia New Zealand Food Standards Code*. Food Standards Australia New Zealand (FSANZ) advises AQIS on food risk assessments.

Under the *Export Control Act 1982* (Cwlth), AQIS certifies exports of agrifood products and commodities. AQIS bases its certification on identification and inspection of products and commodities, and certifies they meet the requirements of the importing country. AQIS relies upon inputs from a number of sources, including industry, and state or commonwealth government agencies to verify data to underpin certification. Where industry organisations provide verification, AQIS monitors the process to ensure that certification integrity is maintained and meets both international standards and importing country requirements. AQIS does not provide any statements on the GM status or any biotechnology aspect for exported products.

If an importing country requires certification of the GM status of a product or commodity, where appropriate, AQIS will attach to the export documentation a statement from the Regulator regarding the GM crop approval status in relation to the commodity.

National Framework to Develop Co-existence Strategies for GM and Non-GM crops

A National Framework to Develop Coexistence Strategies for GM and Non-GM Crops (August 2007) has been developed jointly by the Commonwealth, states and territories as a guide for both governments and industry to establish effective coexistence strategies. The framework contains a number of fundamental principles that may be used to develop strategies to enable supply chain participants to meet the requirements of their chosen markets and ensure customers and consumers have the choice to select products according to their preferences.

Coexistence strategies depend on non-legislative collaboration between industry and government to manage GM crops through the whole supply chain. In regard to sampling and testing, the framework states: 'The maintenance of thresholds is standard industry practice as supply chain participants' aim in managing the unintended presence of all unwanted material is to manage the product to levels which are as close to zero as possible within the limits of cost, practicality and technical feasibility.' Currently, the framework has been noted by both PIMC and the Gene Technology Ministerial Council (GTMC).

Chapter 6: The Australian Industry Environment for Maintaining Product Integrity within the Seed and Grain Supply Chain

The Australian Seeds and Grains Industries

The Australian seeds and grains industries have expressed confidence that they can successfully segregate GM canola from non-GM canola in the supply chain. This cohesive view is detailed in the Single Vision Grains Australia (SVGA) report *Principles for process management of grain within the Australian supply chain: a guide for industry in an environment where GM and non-GM grain is marketed* (the 'SVGA Principles') which describes principles for the Australian grains industry to consider following the introduction of GM grains in order to ensure that all grain and grain products marketed meet customer requirements. The SVGA Principles set out the standards, quality assurance practices, other processes and testing regimes that supply chain participants may use to assist them in supplying customers with the desired grain and grain products. The SVGA Principles have been signed off on and agreed to by 29 grain supply chain participants (see Table 6.1 below).

Table 6.1: Grain Supply Chain Participants who are signatories to the SVGA initiative

ABB Grain Ltd	Grains Council of Australia Ltd
AgForce Queensland Pty Ltd	Grains Research and Development Corporation
Agrifood Awareness Australia Ltd	Monsanto Australia Ltd
Allied Mills Australia Pty Ltd	National Agricultural Commodity Marketing Association
Ausbiotech Ltd	National Farmers' Federation
Australian Food and Grocery Council	NSW Farmers' Association
Australian Oilseeds Federation	Nufarm Ltd
Australian Seed Federation	Pacific Seeds Pty Ltd
Bayer CropScience Australia Pty Ltd	PGA Western Graingrowers Committee
Cargill Australia Ltd	Pioneer Hi-Bred Australia Pty Ltd
Co-operative Bulk Handlers Ltd	Riverland Oilseed Processors Pty Ltd
CropLife Australia Ltd	South Australian Farmers' Federation
Flour Millers' Council of Australia Pty Ltd	Victorian Farmers Federation
Grain Growers Association	WA Farmers Federation Grains Section
GrainCorp Ltd	

The institutional framework for applying the SVGA Principles is the existing National Agricultural Commodities Marketing Association (NACMA), which currently is responsible for facilitating trade across the Australian grain supply chain for both domestic and export grain (Victorian Department of Primary Industries 2007).

Figure 6.1 illustrates the processes that need to be managed within the Australian supply chain. This report focuses on the sampling and testing requirements and responsibilities from the breeding to the marketing and exporting stages of the supply chain. Elements of Quality Assurance (QA) apply along the entire supply chain and include sampling and testing requirements, when needed, to verify the processes by which seed and grain made available for sale agrees with customer specifications.

The SVGA Principles do not state the specific tests nor who is responsible for sampling and testing required at each stage of the supply chain. Associated with the SVGA Principles are a number of technical documents released by industry organisations which elaborate on the process management requirements at each stage of the supply chain. These associated technical documents are summarised in Table 6.2, and referred to regularly in the remainder of this chapter.

The following discussion of the Australian seed and grain supply chain has focused on examples from the canola supply chain.

Breeding

The breeding phase of the grain supply chain is where germplasm containing the desired traits is developed into new varieties. In developing new varieties, breeders are interested in improving traits such as yield, quality, disease resistance and vigour, as well as other agronomic qualities. In the development of GM crop varieties, it is at this stage where the GM trait (i.e. herbicide resistance) would be introduced into elite varieties of the crop through conventional cross-breeding methods. Figure 6.2 below shows a typical seed breeding flow chart for the development of new canola varieties. Points at which testing for the AP of GM events is required by the ASF *Best Practice Guidelines for Management of Adventitious Presence in Canola Varieties* are highlighted. The current requirements for sampling and testing during the breeding phase of the supply chain, and the sampling and testing that industry is actually performing, is discussed in further detail below.

While seed breeding companies aim for zero AP of GM events in their non-GM seed-for-sowing, products are marketed as complying with the 0.5 per cent AP threshold for GMOs approved for commercial release by the Regulator.

Neither the SVGA Principles nor the ASF Best Practice Guidelines stipulate a specific or mandatory need to test for the presence of GM events during the nursery phase of the breeding process. The SVGA Principles require that a DNA test method be available and provided to the OGTR for the detection of the GM trait. The seed breeding company may decide to perform testing at this stage in order to ensure that any AP of GM events is not transferred to later stages of the breeding process. Additionally, the breeder may decide to test at this stage to confirm the presence of the desired Regulator-approved GMOs in the development of GM varieties.

Seed breeding companies consulted for this project reported that they test each F_1 generation plant for the presence or absence of a number of GM events. In the case of canola, companies typically test for all GM canola events that have been approved for commercial release or field trials by the Regulator, as well as common GM canola events overseas. A number of the seed companies reported the prohibitive cost of carrying out AP testing in Australia and the lack of accredited laboratories meant that samples were tested in overseas laboratories (either in the USA or EU). Laboratories testing for Roundup Ready® or Invigor® hybrid canola events must be accredited by either Monsanto or Bayer CropScience respectively.

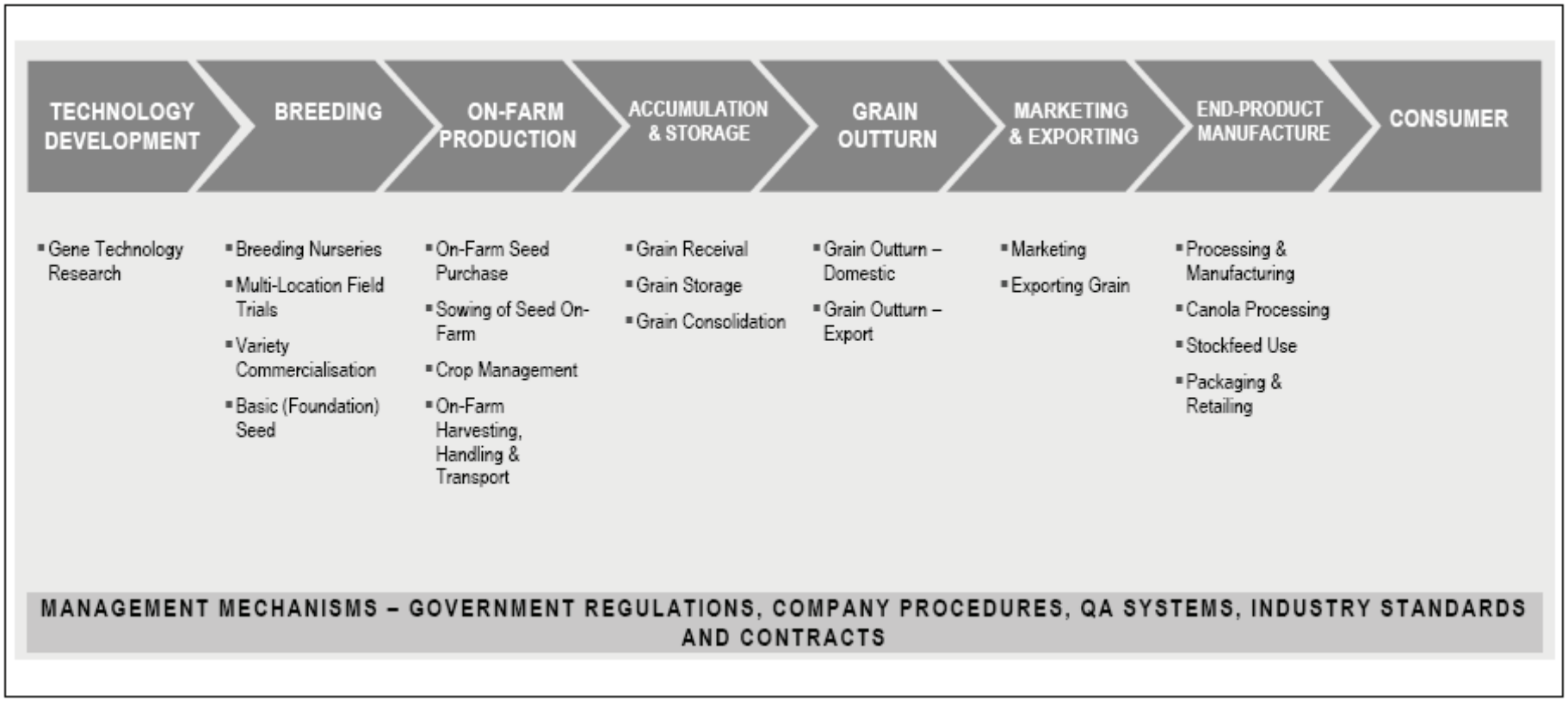

Figure 6.1: Processes to be managed within the Australian Supply Chain (Single Vision Grains Australia 2007).

Table 6.2: Key technical documents involved in the process management of genetically modified canola seed and grain in the Australian supply chain.

Document	Synopsis
Single Vision Grains Australia (SVGA) Principles for process management of grain within the Australian supply chain: A guide for industry in an environment where GM and non-GM grain is marketed (2007)	Describes principles for the Australian grains industry to consider following the introduction of GM grains in order to ensure that all grains and grain products marketed meet customer requirements.
Australian Seed Federation (ASF) Best Practice Guidelines for Management of Adventitious Presence in Canola Varieties (2006)	Responsibility for compliance with the internationally recognised standards for seed quality and purity and for testing protocols in Australia is held by the ASF. These guidelines detail the sampling and testing strategies, standards and processes that plant breeders and seed companies can apply to manage the variety development and seed production processes for canola sowing seed to comply with Australian regulatory AP requirements at state, territory and federal levels; and to comply with industry trading standards.
Gene Technology Grains Committee (GTGC) Canola Industry Stewardship Principles (2003)	The GTGC was a grains industry and supply chain body that included representatives from across the grains industry, including seed producers, growers, bulk handlers and food producers. This document provides a set of stewardship principles that define the different canola production processes which ensure different canola production systems and supply chains coexist.
ASF National Code of Practice for Labelling and Marketing of Seed for Sowing (2005)	This document ensures that consumers are provided with consistent and accurate information to enable them to make informed decisions about the suitability of seed-for-sowing.
Australian Oilseeds Federation (AOF) Quality and Trading Standard for Canola (2008)	The industry reference for Quality and Trading Standards. Use of these standards is not mandatory however they are widely used with an estimated 90 per cent of canola being traded on NACMA contracts (AOF standard).
AOF and NACMA Grains Industry Common GM Declarations (first published 2007, updated 2008)	Provides guidance on a common GM declaration to be used by industry on receipt of grain from a grower or during trade.
Roundup Ready® canola 2008 Technical Manual	Details the Roundup Ready® Canola stewardship program which is an over-arching approach to introducing and supporting Roundup Ready® Canola technology.

Document	Synopsis
Roundup Ready® canola 2008 Crop Management Plan	The purpose of this document is to implement on-farm strategies to manage risks to the integrity of grain crop supply chains and the sustainability of agricultural production.
Roundup Ready® canola 2008 Resistance Management Plan	This document sets out the implementation of management practices within a crop rotation including Roundup Ready® Canola to manage the weed population to ensure the long term sustainable use of Roundup Ready® herbicide in Australian farming systems, by minimising the risk of weeds developing resistance to glyphosate based herbicides.
Roundup Ready® canola 2008 Licensing and Stewardship Agreement (LSA)	The LSA is the first of two agreements that must be signed by growers intending to grow Roundup Ready® Canola in 2008. The LSA stipulates the regulatory and stewardship requirements governing the use of the crop and grants the grower a licence to use Roundup Ready® technology.
Roundup Ready® canola 2008 Technical User Agreement (TUA)	The TUA is the second agreement that must be signed and includes specific obligations relating to planting the crop. As part of the TUA, the proposed paddocks and resistance management assessments must be recorded along with the proposed sowing area and seed varieties.
Monsanto's Paddock Risk Assessment and Management Option Guide (PRAMOG®) 2008	Provides farmers planning to grow Roundup Ready® Canola with an individual paddock risk assessment management tool.
Customer contracts	These documents specify the grade of canola (i.e. 'Canola' or 'non-GM Canola') and whether or not Identity Preservation documentation is required.

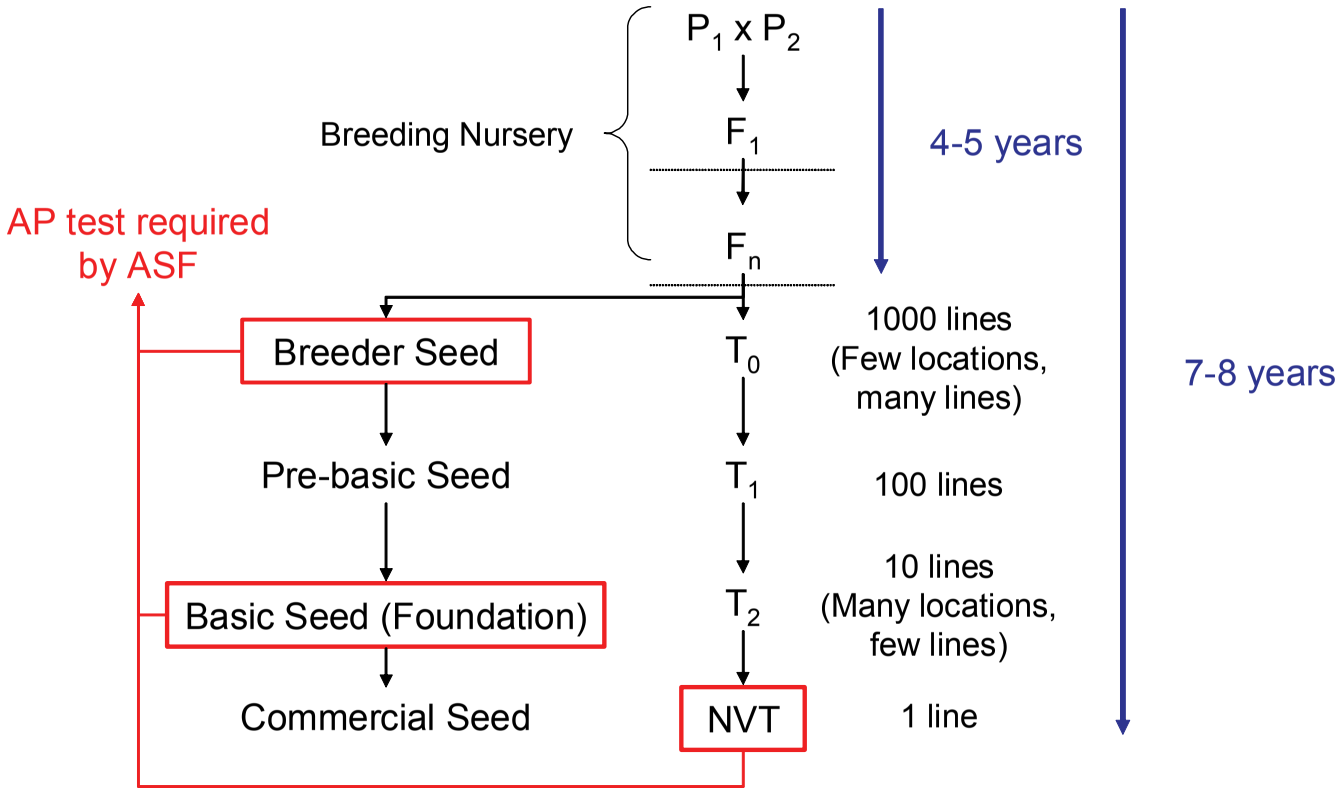

Figure 6.2: Seed breeding flow chart for the development of new canola varieties showing points at which AP testing for GM events is required by the ASF NVT, National Variety Trials; P, parental line; F, filial line; T, testing line. From the F_n stage there are two paths the seed can take: either entering field trials (T_0) where its agronomic qualities are evaluated; or through the parallel 'Breeder Seed' pathway, whereby seed from the most promising lines in the field trials is bulked up to commercial seed levels.

In Australia, it is an industry requirement that non-GM canola lines test negative for all these events if they are to proceed to the 'breeder seed' and field trial stages. For example, Roundup Ready® Canola lines should test positive only for the Regulator-approved GT73 canola event and negative for all other GM events if they are to proceed past this stage. From the F_n stage in the breeding cycle illustrated in Figure 6.2 above, there are two paths that the seed can take. It can either progress through the field trial (T_0 etc) pathway, whereby its agronomic qualities are evaluated and it will eventually end up in the National Variety Trial process; or, it can progress through the parallel 'breeder seed' pathway, whereby seed from the most promising lines is bulked up to commercial seed levels. To progress from the F_1 to T_0 or 'breeder seed' stage shown in Figure 6.2 above, it is common practice in the seed industry to 'bag' individual plants to prevent pollen flow and fertilisation between lines occurring by means of cross pollination.

If a seed company intends to commercialise a variety, it will go through a 'breeder seed' stage. At this stage, the ASF Best Practice Guidelines specify three testing options, one of which must be performed at this point. The Guidelines specify that either 'an absolute test is made where all plants producing seed intended to form the new variety are tissue sampled and tested for the presence of unintended GM events' (if GM positive plants are rejected, this provides absolute freedom from AP of GM events); *or* 'At least 7 seeds from each individual plant that will form the variety are sampled' (this will provide 99.9 per cent confidence of freedom from AP of GM events); *or* where neither of the options above are possible 'a sample based test of the variety to give at least 99 per cent confidence that any AP is below 0.01 per cent'.

Basic (or foundation) seed is the seed produced for sowing for commercial production. Certification that the seed has been variety-tested as described in the previous paragraph is a pre-requisite for seed reaching this level. There is an expectation that seed lots from these varieties will be tested to give 95 per cent confidence that they contain less than the tolerance level for approved GMOs and that no unapproved GMOs are detected. For example, for commercialisation of GM varieties, industry carries out testing to confirm the presence of the Regulator-approved GM event (e.g. GT73 for Roundup Ready® Canola) and absence of specific unapproved GM events. For non-GM varieties, testing will confirm that if a Regulator-approved GMO is present, the level at which it is present is within the established industry standards for AP in seed-for-sowing (currently 0.5 per cent).

For commercial seed lots, certification that the line has been variety-tested as described above is required under the ASF Best Practice Guidelines. The rationale behind this protocol is that because the line has already been screened during the variety testing stage, and has not been exposed to GM events either during seed production or in handling, there is no new hazard that warrants any additional testing. The ASF Best Practice Guidelines note that 'prohibiting the production of commercial seed lots in areas where unapproved GM [crops] are being grown is in recognition that it is impossible to guarantee no cross pollination or commingling in commercial seed production in these situations.' The reference to 'unapproved' GM crops in this instance is referring to those that have not been approved by the Regulator for commercial release, but have been approved by the Regulator for field trials.

The seed companies may also carry out 'bioassays' or spray-out tests on samples of seed produced for commercial sale. In a typical spray out test, three plots of a representative sample of plants of the variety to be tested are planted out. Each plot is then sprayed with a different herbicide; Roundup® (glyphosate), triazine or Basta® (glufosinate ammonium). If it is a non-GM, non-herbicide-tolerant line that is being tested, all plants in each plot would be expected to be killed by the herbicides. Likewise, if it is a Roundup Ready®, triazine-tolerant or Invigor® hybrid canola line that is being tested, all plants would be expected to survive in the plot that sprayed with their companion herbicide, and die in the other two plots. This is a simple yet effective way to make a final test for AP in the seed intended for commercial sale.

If plants survive in plots where they would be expected to die, it indicates that AP of a herbicide tolerance event may have occurred and further testing is necessary.

It is worth noting that the Australian seed companies consulted for this project all conducted sampling and testing for AP of GM events above and beyond that which is required by the ASF Best Practice Guidelines and SVGA Principles. Since the seed companies are already carrying out sampling and testing for the AP of GM events in canola, the introduction of GM canola varieties into the Australian farming system in 2008 will not present them with a significant amount of extra sampling and testing work or, indeed, extra costs depending on the extent of testing performed. Seed companies may have added logistical requirements, such as managing isolation distances between paddocks (for example 400 m) and managing rotations in these paddocks (for example canola/wheat/wheat). However, they draw the analogy to introducing a new non-GM herbicide-tolerant canola variety into their system, and point out that introducing a GM variety is not significantly different.

Seed companies are also introducing visual aids by which their products can be identified as a means of maintaining effective segregation of their product and helping to prevent human error. For example, one company uses different coloured bags for each type of canola seed it produces—conventional, triazine-tolerant and Roundup Ready®.

Since 2006, Australian seed companies have provided a GM testing declaration to the ASF, who then pass it onto the relevant state government departments if requested. In 2006 and 2007, this information included the batch numbers and testing certificates of all the lines tested. An example of the type of information provided is shown in Table 6.3 below.

Table 6.3: Information on AP testing supplied by seed companies to the ASF (EXAMPLE ONLY).

Variety	Batch Id (Raw Seed no.)	Gateway/Cert no.	Test Id / Cert no.	Test Details (i.e. PCR / primers)
1	RAWSEED A	XWZ12345	ABC12345	Taqman – Bar, Brom, Hyg, NPTII, GT73
	RAWSEED B	XWZ67899	ABC56789	As above
2	SEEDLOT 34	PQR45678	ABC54321	As above
	SEEDLOT 35	PQR56789	ABC98765	As above

From 2008 onwards, all that will be required is for a director of the seed company to send a signed statutory declaration to the ASF declaring that that all seed sold abides to the ASF Best Practice Guidelines. This declaration will then be passed on to the relevant state government departments if requested.

Sampling and testing frameworks that may be adopted by Australian seed companies

ISTA regularly publishes *International Rules for Seed Testing* (ISTA 2005). These rules include sampling guidelines and testing methods for AP of GM events. Australian seed companies may choose to abide by the internationally accepted ISTA Rules for their sampling and testing protocols, particularly as these are the methods used in evaluating seed for transactions in international trade.

The Organisation for Economic Cooperation and Development (OECD) has a scheme in place for the *Varietal Certification of Crucifer Seed and Other Oil or Fibre Species Seed Moving in International Trade* (OECD 2008). Australian seed companies are able to be

certified under this scheme, and if so, are required to periodically submit to a third party audit to verify they are adhering to the schemes directions.

Imported Seed

Seed imported for use as germplasm and in breeding lines is used under the direct supervision of the breeder. It would not be used in trials for commercial demonstration plots, or for open field seed increases. The ASF Best Practice Guidelines require the supplier of the seed to 'provide a declaration that the GM status of the seed is as described, that the supplier has in place QA procedures that minimise the risk of AP, and that to the best of the suppliers knowledge, no AP is present'.

This level of assurance is considered adequate as 'the consequences for Australia of AP in this material are minimal given that the imported seed will remain under the control of the breeder, and if it eventually contributes to a commercial variety, rigorous testing at that point will prevent AP in the commercialised variety' (Australian Seed Federation 2006).

Seed imported to produce either seed or grain in a commercial open field environment should undergo variety commercialisation testing as outlined above. Each seed lot should be tested for the presence of all commercialised GM events (in both Australia and overseas), and any that have been in, or are believed to be in, extensive field trials (in both Australia and overseas). The testing of non-GM canola lines should be sufficient to give 95 per cent confidence that any Regulator-approved GMOs, if present, are at levels below the accepted tolerance (0.5 per cent), and no unapproved GMOs are detected.

On-farm Production

The on-farm production stage is the point in the supply chain in which seed is grown to produce grain. The farmer's aim is to provide grain to the bulk handler/marketer or the processing plant that meets the requirements of the desired grade—in the case of non-GM canola, this means providing canola with less than 0.9 per cent AP of GM material. To do this the farmer needs to maintain the integrity of both the seed and the grain.

There are no industry requirements to test on-farm for the presence of GM material. In the future, lateral flow strip tests could potentially be used if there was a requirement from customers or if the farmer wanted to ensure compliance with specifications or tolerance levels. Although there are no industry requirements with regard to sampling and testing on-farm for the AP of GM events in non-GM seed and grain, there are industry requirements for growers of GM crops to undergo training and sign agreements with the technology providers to ensure proper use of the technology. There are also Crop Management Plans and Resistance Management Plans for the technology which must be followed by the grower.

Taking the 2008 release of Roundup Ready® canola as an example, there are a series of requirements from the technology provider (Monsanto) which must be met by all farmers intending to grow the crop. A summary of these is listed below:

1. Growers are required to attend an accreditation course. This focuses on 'the Resistance Management Plan for Roundup Ready® canola, providing education on the Crop Management Plan, and ensuring an understanding of the regulatory and compliance requirements'.
2. Growers must sign a Licence and Stewardship Agreement. This 'stipulates the regulatory, intellectual property and stewardship requirements for the crop'.
3. Seed must be purchased from an accredited Technology Service Provider (TSP). Prior to this the grower must complete a paddock risk assessment using the Paddock Risk Assessment Management Option Guide (PRAMOG®) for each paddock in which they intend to grow Roundup Ready® canola. They must also provide the TSP with the paddock risk assessment information, paddock areas, quantity and variety of seed they wish to purchase. This is recorded on the Technology User Agreement (TUA), which the grower must sign.

4. The seed is sown and the crop managed in accordance to the Crop Management Plan and Resistance Management Plan. Key points within this with regard to segregation include the need to:
    - keep Roundup Ready® canola separate from all other canola crops by at least 5 metres. This aims to reduce the risk of gene flow due to pollen movement from GM canola to non-GM canola crops. Alternatively, if crops are grown in adjacent paddocks (within 5 metres of each other), a narrow band (at least 5 metres) of the non-GM crop can be harvested and processed as part of the GM crop and subsequently managed as per the GM paddock for volunteer control. In addition to providing a physical separation distance between the GM and non-GM crops to prevent pollen movement, the 5 metre strip of non-GM canola also acts as a pollen trap.
    - practice good volunteer management to minimise adventitious presence in crops grown in subsequent rotations after a GM canola crop. This includes aiming to control volunteers prior to flowering, avoiding deep cultivation and adopting Integrated Weed Management practices (i.e. rotation of herbicides, and/or cultivation, and/or grazing). As part of this Integrated Weed Management (and Resistance Management Plan), Roundup Ready® canola can only be grown no more frequently than one year in three.
    - practice good seed and grain management, which includes labelling all units containing GM seed or grain as such (including trucks); keeping seed in a leak and vermin proof storage area; keep copies of seed bag labels and record where seed bag lot numbers are sown; and tarpaulins should be properly fitted to trucks transporting seed or grain.
    - practice good machinery hygiene to minimise AP. This includes cleaning down any equipment that moves seed or grain, including sowing implements, windrowers, harvesters and trucks. All clean down procedures should be conducted in the paddock that contains the specified crop (except silos and augers).
    - maintain good paddock records and continue these for at least two years after harvest.
5. Harvested grain is delivered to Grain Handlers/Marketers with a grain declaration form. On this form it must be declared that the grain came from Roundup Ready® canola and identify the particular variety. This declaration is a contractual and legal requirement. For 2008, GM canola will only be allowed to be sold to authorised Grain Marketers.

Random audits of Roundup Ready® canola fields and records maintained by growers will also be undertaken by the technology provider to ensure the paddock is in compliance with the Licence and Stewardship Agreement.

The Roundup Ready® canola Crop Management Plan is intended, in part, to reduce the level of AP of GM events in adjacent or subsequent non-GM canola crops. Levels are expected to be well below the threshold level of 0.9 per cent, enabling harvested non-GM canola to be confidently sold as non-GM. Holtzapffel et al. (2008) have considered in some detail the risk of AP of GM events through gene flow, directly from GM canola to non-GM canola or indirectly via GM canola volunteers (for example, in subsequent crops). They and other authors cited in that study, conclude that AP due to gene flow will be below threshold levels.

All the above crop management requirements are specific to Roundup Ready® canola for 2008, however it is likely similar requirements would be put in place for other future GM crops. Such industry and technology provider requirements are also unlikely to place extensive extra burdens on farmers, as much of the Crop Management Plan and Resistance Management Plan would be considered standard Best Management Practices for any crop, regardless of whether it is GM or not.

Accumulation and Storage

After leaving the farm gate, the grain is received at a storage facility. At this point of the supply chain the bulk handler consolidates grain from multiple growers prior to transporting to an export terminal or for use on the domestic market. This can involve grain being transported between small receival sites and larger storage facilities by the bulk handler.

Grain receival

Grain is delivered to the storage facility with a declaration from the grower (or the grower's agent) tendering the load, which identifies the grain type, variety, GM status and quality assurance status of the grain. Sampling and testing is conducted at the time of receival of the load to ensure the grain meets industry quality standards. These are voluntary standards which have been set by industry (for canola this is done by the AOF). The sampling procedure for oilseeds involves taking a minimum of at least three samples using either a manual or vacuum probe from each grain bin and from different locations in the bin (front, middle and rear). Additional samples are to be taken randomly throughout the load, with the total sample size determined by the delivery unit size.

Sampling rates per delivery unit size for all bulk grain commodities are for each bulk road unit, as follows: 3 x 1 litre probes for up to 10 tonnes; 4 x 1 litre probes for 10–20 tonnes; and, 5 x 1 litre probes for over 20 tonnes. It is common to receive 2 x 23 tonne units in a road train, and in this case for example, 10 probes of 1 litre each would be taken. Current tests for grain quality attributes are conducted on a half litre subsample of the primary sample which in the above example would be 10 litres in total.

Testing is then conducted for a number of parameters including oil content, moisture, defective canola and contaminants. Methodologies for sampling and testing for these parameters have been determined by the AOF, based on the American Oil Chemists' Society (AOCS) Standard Methods (Australian Oilseeds Federation 2007; consultation with stakeholders). Samples must be retained for at least two months after receival and a sub-sample may also be sent to a laboratory for further analysis or to confirm the results obtained at the receival site. Failure to meet the quality standards may result in the load being rejected or in a deduction in the price. Price adjustments may be made for certain standards such as oil, with a premium or deduction given for the lot price if the grain quality is better or worse than the standard (Australian Oilseeds Federation 2007; consultation with stakeholders; Single Vision Grains Australia 2007).

When the grain receival facility operator and the grower (or the grower's agent) are satisfied with the determination of the grain's quality, they generally both sign a delivery document that includes the date, grain variety, grain type and/or category, and the delivery point (usually identifying the silo, bin or hopper). The grain is then sent to be unloaded into the appropriate storage (Single Vision Grains Australia 2007). The storage operator checks the documentation of each load before unloading the grain. To ensure the integrity of the grain within the storage facility will be maintained, storage operators implement and monitor the cleaning of equipment and handling facilities (Single Vision Grains Australia 2007). Canola storages vary from as little as 500 tonnes (in a small vertical silo) up to 10 000 tonnes in a single shed, and as much as 20 000–30 000 tonnes in an aerated bunker.

The need for segregation and testing of grain is determined by the market's needs. For crops such as barley, there are many different grades which have different grain quality standards and reflect the market's desire for segregation. Prior to GM canola being grown in Australia, there was only one grade of canola grain, with the Standard allowing for the AP of up to 0.9 per cent of GM canola's approved for commercial release by the Regulator. However, following approval for the commercial production of GM canola in New South Wales and Victoria, industry has developed two Standards for canola. These are *CSO1 Canola*, which may or may not contain approved GMOs, and *CSO1-a Non-GM Canola*, where the AP of up

to 0.9 per cent of GM canola approved for commercial release by the Regulator is permitted. These came into force as of 1 August 2008[5]. With regard to testing for GMOs, 'there is no specific or mandatory need to test each load for the presence of GM material to ensure compliance to industry standards. Testing may occur as required by the customer or as determined by the receival site operator internal audit procedures to ensure compliance with specifications or tolerance levels set by the marketplace' (Single Vision Grains Australia 2007).

Grain consolidation

Grain is out-loaded from the original receival and storage site and transported to another storage site where the grain is consolidated prior to being transported to an export terminal or for the domestic market. Storage operators check the documentation to ensure the correct grain is moved from storage. Documentation that attests to the quality, grade description and integrity of the grain is provided to the transport operator, which in turn is given to the storage operator at the next facility. Depending on the individual bulk handler's internal procedures and Quality Assurance systems, the grain may be sampled and/or tested either prior to being outloaded from the original storage facility or on receival at the next facility (as described for *Grain receival)* (Single Vision Grains Australia 2007).

To maintain the integrity of the grain and prevent unintentional contamination, transport and storage units are inspected and cleaned. Depending on the market's requirement for segregation and tolerances for contamination, dedicated transport units may be used (Single Vision Grains Australia 2007).

Grain Outturn

The grain is out-loaded from the storage facility and transported to the domestic market or an export terminal. Segregation and sampling and testing regimes are similar to that for *Grain consolidation*, with loads of grain tested to ensure compliance with contract terms and conditions and to ensure no quality deterioration has occurred during storage. Again there is no specific or mandatory need to sample and test for the presence of GM material but this may be required by customers or internal audit procedures (Single Vision Grains Australia 2007).

For domestic markets, grain directly from farms may also be received. The end buyer would likely employ similar sampling and testing protocols as described for a grain receival facility (Single Vision Grains Australia 2007).

Marketing and Exporting

Marketing

The marketing stage of the supply chain is the sale and delivery of grain to the domestic or export market. Sampling and testing and documentation requirements are determined by the customer's needs. Customer contracts typically outline the grade, description and quality requirements of the grain. It may also stipulate the need to provide samples or analytical results from specific tests to support documentation. As noted in the SVGA Principles (2007), 'testing for the GM status or other quality attributes only occurs where the supply chain participants or marketers QA system, importing country quarantine requirements or customer contract stipulates. Declarations and processes employed through the supply chain suffice for most markets'.

[5] http://www.nacma.com.au/__data/page/227/No_20_of_08_New_Canola_Trading_Standards.pdf

Exporting grain

For grain to be exported it is loaded onto a vessel in bags, containers or in bulk, and transported to the importing country. AQIS conducts shiphold inspections to ensure there is no contamination that may impact on Australia's favourable pest status and compromise AQIS export certification. AQIS samples and inspects the grain during loading to ensure the importing country quarantine and Australian legislative requirements are met. Grain is also sampled by the export facility operator to ensure compliance with the terms and conditions as agreed with the customer. A sample may be retained for subsequent analysis (Single Vision Grains Australia 2007).

The export facility operator processes documentation to ensure the correct grain is loaded and provides this to the exporter and vessel owner for proof of grain quality.

The SVGA Principles (2007) identify that the sampling and testing needs for exporting grain are the same as for marketing.

National Residue Survey

Sampling and testing of Australian food commodities for the purpose of monitoring residues of agricultural and veterinary chemicals and environmental contaminants is currently carried out by the Australian Government National Residue Survey (NRS)[6]. The cost of this monitoring is industry-funded through levies on the animal and plant commodities that are tested. Such residue monitoring facilitates Australia's access to key export and domestic markets by underpinning industry quality assurance programs. If required by industry, there may be the potential in the future for an NRS program to monitor for the AP of GMOs in seed-for-sowing and grain commodities.

[6] For more information about the NRS, see http://www.daff.gov.au/agriculture-food/nrs

Section 3: The International Environment

Chapter 7: International Organisations, Agreements and Standards

Global trade in GM commodities continues to increase, and against this background, Australia continues to work in international fora and with trading partners to maintain and improve market access for Australian food and agricultural products, including GM products. There are a number of intergovernmental and non-governmental international organisations, agreements and standards that are relevant to world trade in GM commodities, grains and food. Any measures relating to GM commodities and products need to be consistent with international trade obligations.

Intergovernmental International Organisations and Agreements

The most important international organisations relevant to world trade and transboundary movements in GMOs (referred to as Living Modified Organisms—LMOs[7]—in agreements) are the World Trade Organization (WTO), the United Nations Food and Agriculture Organization (FAO) and the United Nations Environment Programme (UNEP). Through these organisations a number of relevant agreements have been developed.

The WTO operates a system of international rules governing trade between its members and provides a forum to settle trade disputes. Various WTO agreements set out rules for international commerce with the aim of ensuring trade flows as freely as possible.

The main WTO agreement relevant to trade in LMOs is the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). The SPS Agreement allows countries to put in place measures to protect animals and plants from pests or diseases, human health from animal- or plant-carried diseases, and human or animal health from food-borne risks.

In the case of plant health, including for seed and grain, standards for measures which countries can implement are set under the International Plant Protection Convention (IPPC), adopted in 1951. The IPPC is a general plant protection agreement that also provides its contracting parties with non-binding guidance for analysing and managing quarantine pest risks associated with LMOs. The FAO coordinates the activities of the IPPC.

In 1963, the FAO, together with the World Health Organization (WHO), established the Codex Alimentarius Commission (Codex) to develop food standards, guidelines and related documents (for example codes of practice) under the Joint FAO/WHO Food Standards Programme. The latter aims to protect the health of consumers and ensure fair trade practices in food trade, and also to promote coordination of all work undertaken by international governmental and non-governmental organisations on food standards and guidelines, including those for foods derived from LMOs. A number of Codex guidelines deal with food derived from modern biotechnology (see IPPC and Codex Standards and Guidelines below).

The UNEP Convention on Biological Diversity (CBD) was negotiated at the 1992 Earth Summit in Rio de Janeiro. The Convention seeks to sustain the rich diversity of life on Earth and promote sustainable development. In January 2000, the Conference of the Parties to the CBD adopted the Cartagena Protocol on Biosafety (CPB), to protect biodiversity from potential adverse effects of the transfer, handling and use of LMOs resulting from modern biotechnology during transboundary movement.

[7] An LMO is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000).

While there are some references to sampling and testing for GM events in some guidelines or standards produced by these organisations (see IPPC and Codex Standards and Guidelines below), there are no specified sampling and testing methods or protocols. Nevertheless, countries may sample and test for GM events in the course of implementing measures under the SPS Agreement and the CPB. Also, specific international sampling and testing standards have been developed by other non-intergovernmental international organisations.

A third agreement of potential relevance is the WTO Technical Barriers to Trade Agreement (the 'TBT Agreement'). The scope of this agreement is not intended to cover sanitary and phytosanitary measures under the SPS Agreement, but technical measures for a wide range of other purposes, such as to protect consumer interests, for the welfare of animals, and purposes such as car safety and energy-saving devices. In terms of food, measures such as labelling requirements (unless for sanitary and phytosanitary purposes), nutrition claims and concerns, quality and packaging regulations are not regarded as sanitary or phytosanitary measures and are subject to the TBT Agreement.

The potential relevance to LMOs, standards and sampling and testing is, therefore, that if a labelling requirement for a GM food commodity and/or any associated sampling and testing are deemed to be for non-SPS Agreement purposes (for example to allow consumer choice) then it is a measure which falls within the scope of the TBT Agreement. Labelling requirements dealing with food safety are considered to be SPS measures.

Agreement on the Application of Sanitary and Phytosanitary Measures

The Agreement sets out the rules for international trade in food, animals and plants and their products, and governs the use of SPS measures applied to protect human, animal and plant life or health. The basic principles of the SPS Agreement state that SPS measures must be based in science, not be more trade restrictive than necessary to protect life or health, and not be arbitrary or disguised restrictions on international trade.

The SPS Agreement encourages harmonisation, by encouraging governments to base their SPS measures on international standards, guidelines and recommendations developed by three 'relevant' international organisations (the Office Internationale des Epizooties (OIE), the IPPC and Codex). This promotes the establishment, recognition and application of common SPS measures. Where such international standards, guidelines and recommendations do not exist or a WTO Member country chooses not to use them, the Member must base its SPS measures on a scientific risk assessment. A risk assessment under the SPS Agreement must take into account the risk assessment techniques developed by the three relevant international standard setting bodies (IPPC, OIE and Codex).

Whilst the SPS Agreement itself does not specifically refer to LMO seed or grain, the standards, guidelines and guidance documents on food safety and plant health (and set by the IPPC and Codex) are relevant to grain and seeds that are LMOs. The standards developed by the IPPC and Codex (see IPPC and Codex Standards and Guidelines below) are generally deemed to be consistent with the SPS Agreement.

Cartagena Protocol on Biosafety

The CPB establishes an advanced informed agreement procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of LMOs into their territory. The Protocol also establishes a Biosafety Clearing House to facilitate the exchange of information on LMOs and to assist countries in the implementation of the Protocol (ACIL Tasman 2007).

The Protocol came into force in September 2003 and as of August 2008, 147 countries were Parties to the Protocol, including most of the major grain-importing countries. However, some of the main grain exporting countries—Argentina, Australia, Canada and the United States of America—are not Parties. There are no Articles or measures required under the Protocol

specifically in regard to sampling and testing for GM events. However, a country may decide that sampling and testing may be necessary at the border for GM events in traded grain commodities and imported seed, where these could contain unapproved GMOs or be contaminated with LMO seed of another species.

LMOs intended for direct use as food, feed, or processing (including grain and seed), are required under Article 18(2)(a) to be clearly identified during transboundary movement that they 'may contain' LMOs. In 2006, the Third Meeting of the Parties to the CPB made a decision on information that is required to be included in existing documentation that accompanies transboundary shipments of LMOs for food, feed or processing during handling and transportation. However, the decision does not specify any related standards or provide guidelines or guidance on sampling or testing for approved or unapproved GMOs (and hence the CPB is not discussed further in the section below).

The CPB leaves room for possible future development of standards for handling, packaging, transport and identification of LMOs by the Meeting of the Parties to the CPB. Furthermore, the issue of the acceptability and harmonisation of sampling and testing techniques more broadly (particularly in regard to testing for unapproved GMOs) continue to be discussed at the Meeting of the Parties to the CPB, including reference in discussions to existing international standards (next sections). The Secretariat of the CBD administers a range of programs including for technology transfer and capacity building, such as regional training workshops including for the detection and sampling methods for different LMOs[8].

Relevant IPPC and Codex Standards and Guidance Documents

International Plant Protection Convention

WTO members are required to base phytosanitary measures on international standards, guidelines and recommendations developed within the framework of the IPPC. These standards—International Standards for Phytosanitary Measures (ISPMs)—are developed under the auspices of the IPPC Secretariat and, by providing these standards, the IPPC (a protection agreement which makes provision for trade) complements the SPS Agreement (a WTO trade agreement which makes provision for plant protection).

The ISPM relevant to crops as LMOs is ISPM 11—*Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms* (2004). The types of LMOs that a country's National Plant Protection Office may assess as a potential phytosanitary risk are not only LMOs used, for example, as biological control agents or in bioremediation, but also the parent organism of crops for food and feed which, in themselves are not normally regarded as pests (a phytosanitary risk). In the latter, an assessment may need to be made to determine if the genetic modification (a gene, new gene sequence that regulates other genes, or gene product) results in a new trait that may present a plant pest risk.

Should an LMO crop be regarded or assessed to be a potential phytosanitary risk, a country could implement measures (including sampling and testing of commodities at the border) to prevent import. An example would be where a GM crop plant was assessed to pose an unacceptable and/or unmanageable weed risk.

Codex Alimentarius Commission

Codex is the international food standards-setting body recognised under the SPS Agreement and the TBT Agreement for internationally traded food. The standard specifically relevant to foods derived from LMO crops is the global consensus document—*Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (2003). The

[8] UNEP/CBD/BS/COP-MOP/4/10, Risk Assessment Risk Management (Articles 15 and 16), http://www.cbd.int/doc/meetings/bs/mop-04/official/mop-04-07-add1-en.doc accessed 25 September 2008.

Guidelines address safety and nutritional aspects of foods consisting of, or derived from, plants that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits. In assessment, the intention is to identify and assess any new or altered hazards relative to the conventional counterpart of the food. The Guidelines do not address animal feed derived from an LMO crop or animals fed with such feed.

The more recent Codex *Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food* (2008) addresses assessment in the situation where a GM food has been approved (passed a food safety assessment according to the Codex Guidelines) in an exporting country but has not yet been assessed by an importing country that may be importing the food occasionally at low levels.

In July 2008, Codex approved new work to be undertaken by the Codex Committee on Methods of Analysis and Sampling to develop Guidelines on *Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology* by 2011. The current draft of these Guidelines includes protocols for the validation of both quantitative and qualitative PCR and protein-based testing methods. The draft Guidelines also refer to the need to develop appropriate sampling plans in order to help minimise errors that can be attributable to sampling, noting that sampling error can be expected to contribute significantly—if not dominate—the overall uncertainty of an analytical result, particularly when considering raw commodities.

In the case of LMO grains and seed imported for food or processing, should the grain or seed be regarded or assessed to be unsafe for use in food, a country could implement science-based measures (including sampling and testing of commodities at the border) to prevent import. A theoretical example is where a GM crop plant had been modified to produce an industrial compound and this became a contaminant in a conventional food commodity of the same species.

Codex also sets standards that are TBT Agreement-related, for example for food-labelling. The Codex Committee on Food Labelling has been considering the need and recommendations for the labelling of foods and food ingredients derived from modern biotechnology for ten years but recommendations have yet to be agreed. If labelling requirements for LMO grain and seeds imported for food or processing eventuate, the issue of the need for standards for sampling and testing could arise in this context also.

While some consider that standards for sampling and testing methods and protocols need to be developed by IPPC and Codex, others draw attention to the need to avoid duplication where existing standard-setting bodies exist, in particular the International Organization for Standardization (ISO) and, relevant to grains and seeds, the non-government International Seed Testing Association (ISTA). These bodies have already been active in developing specific sampling and testing standards relevant to LMOs.

Non-Governmental Specific International Sampling and Testing Standards

International Organization for Standardization (ISO)

ISO is a network of the national standards institutes of 157 countries and develops and publishes International Standards in a wide range of areas including agriculture, construction, mechanical engineering, medical devices and the newest information technology developments. ISO has published a number of standards relevant to sampling and testing for GMOs, shown in Tables 7.1 and 7.2 below.

Table 7.1: Relevant ISO sampling standards.

Standard	Title
ISO 542:1990	Oilseeds – Sampling
ISO 13690:1999	Cereals, pulses and milled products – Sampling of static batches
ISO 6644:2002	Flowing cereals and milled cereal products – Automatic sampling by mechanical means
ISO 2859-1:1999	Sampling procedures for inspection by attributes

ISO 542:1990 and 13690:1999 specify general conditions relating to sampling for the assessment of the quality of oilseeds (542:1990) and cereals, pulses and milled products from cereals and pulses (13690:1999). ISO 542:1990 specifies the limitation of the size of the lot, methods of taking samples, packaging and labelling of samples, the dispatch of samples and requirements of the sampling report. ISO 13690:1999 is applicable to the manual or mechanical sampling of static bulk grain up to a depth of 3 m. For static bulks exceeding 3 m in depth and up to a maximum of 12 m, mechanical sampling methods are necessary. For bulk grain exceeding 12 m in depth, it is necessary to sample grain when flowing (see ISO 6644:2002). Standard 13690:1999 is not applicable to sampling for microbiological, mycotoxin and pesticide residue analysis.

ISO 6644:2002 specifies requirements for the automatic sampling, by mechanical means, of cereals or of milled cereal products moving in bulk for the assessment of their quality. The purpose of ISO 2859-1:1999 is to specify an acceptance sampling system for inspection by attributes. This Standard aims to induce a supplier through the pressure of lot non-acceptance to maintain a process average at least as good as the specified acceptance quality limit (i.e. this may be a threshold), while at the same time providing an upper limit for the risk of the consumer accepting the occasional lot beyond that limit.

Relevant ISO testing standards are shown in Table 7.2 below.

Table 7.2: Relevant ISO testing standards

Standard	Title
ISO 24276:2006	Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – General requirements and definitions
ISO 21569:2005	Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Qualitative nucleic acid based methods
ISO 21570:2005	Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Quantitative nucleic acid based methods
ISO 21571:2005	Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid extraction
ISO 21572:2004	Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Protein based methods

The general Standard ISO 24276:2006 specifies how to use the standards for nucleic acid extraction (21571: 2005), qualitative nucleic acid analysis (21569:2005), quantitative nucleic acid analysis (21570:2005) and protein-based methods (21572:2004), and explains their relationship in the analysis of genetically modified organisms in foodstuffs. The Standard contains general definitions, requirements and guidelines for laboratory set-up, method

validation requirements, description of methods and test reports. It has been established for food matrices but could also be applied to seed, feed and plant samples.

The main focus of ISO 21569:2005 is on PCR-based amplification methods. This Standard gives general requirements for the specific detection and identification of target DNA sequences and for confirmation of the identity of the amplified DNA sequence. As with ISO 21569:2005, the focus of ISO 21570:2005 is on PCR-based amplification methods. This Standard defines the general requirement for the specific amplification of target DNA sequences in order to quantify the relative GMO-derived DNA content and to confirm the identity of the amplified DNA sequence. The guidelines laid down in these Standards are intended to ensure that comparable, accurate and reproducible results are obtained in different laboratories.

ISO 21572:2004 provides general guidelines and performance criteria for methods for the detection and/or quantification of specific proteins derived from GM plant material. These guidelines address existing antibody-based methods but accept that other methods may also be used to detect the protein.

GMO testing laboratories may also choose to be certified under ISO 17025:2005 – *General requirements for the competence of testing and calibration laboratories*. This Standard specifies general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

International Seed Testing Association (ISTA)

The seed industry standard-setting body, ISTA, publishes the *International Rules for Seed Testing* (the Rules) annually. The Rules include a chapter on seed sampling protocols. These have been adopted by many national bodies around the world as the sampling protocol for testing seeds for GMOs. Another chapter includes rules for the detection, identification and quantification of GMOs in conventional seed lots. This chapter does not provide specific methods, but rather defines general principles for testing and reporting results and specifies the minimum requirements for the performance of laboratories carrying out such tests. Due to the complexity of specified trait testing, the approach adopted by ISTA to ensure worldwide reliability and accuracy of results is founded on a Performance Based Approach under which laboratories are free to choose the methods they use, with the Rules setting minimum requirements for the performance of laboratories carrying out such tests. It is expected that ISTA Member Laboratories demonstrate their competence in specified trait testing to provide accurate and reproducible results.

Laboratories must be accredited by ISTA in order to report test results for specified traits on the International Seed Analysis Certificate. One of the requirements of accreditation is successful participation in the ISTA GMO Proficiency Tests. The Proficiency Tests are designed to check the ability of individual laboratories in detecting GM seeds and in quantifying and identifying their presence in ‘blind’ samples of conventional seeds. As of June 2008, 10 tests had been conducted since 2002, with each test focusing on a single species and either one or two GM varieties (for example, the maize test, with samples either containing no transgenic events, the GM MON863 variety and/or the GM NK603 variety). Species used to date include maize, soybean, canola and cotton.

ISTA also conducts training and workshops on GM Seed Testing. These have been held in various locations around the world and have focused on both testing methodologies and statistical aspects of GMO detection.

American Association of Cereal Chemists International (AACC International)

AACC International[9] is a non-profit organisation of members who are specialists in the use of cereal grains in foods. The Association was previously known as simply the AACC, and publishes the *Approved Methods of the American Association of Cereal Chemists*. The current Approved Methods (10th Edition) includes the following methods for the detection of GM cereals:

- 11-10 Bt Cry1Ab-modified Corn in Corn Flour—ELISA Method
- 11-20 StarLink™ Corn in Corn Flour and Corn Meal—ELISA Method
- 11-21 ELISA Method for StarLink™ Corn in Corn Flour and Corn Meal

American Oil Chemists' Society (AOCS)

AOCS[10] is an international organisation with 4 000 members across 90 countries that focuses on the science and technology of fats, oils, surfactants, detergents and related materials fields.

AOCS currently produce certified reference material for detecting transformation events in canola, sugar beet, potato, corn (maize), rice and cottonseed.

Association of Official Seed Analysts Inc. (AOSA)

AOSA[11] is an organisation of member laboratories, which include official state, federal, and university seed laboratories across the United States of America and Canada. Its primary functions are to establish the AOSA *Rules for Testing Seeds*; contribute to the refinement and modification of the AOSA rules and procedures for seed testing, and ensure that testing procedures are standardised between analysts and between laboratories.

The AOSA has produced the *Association of American Seed Control Officials Handbook on Seed Sampling*, which provides protocols and methods for sampling seed.

[9] http://www.aaccnet.org/about/default.asp accessed 29 May 2008

[10] http://www.aocs.org/tech/crm/ accessed 29 May 2008

[11] http://www.aosaseed.com/sampling.htm accessed 29 May 2008

Chapter 8: International Initiatives to Establish Sampling and Testing Protocols or Frameworks to Maintain Product Integrity or Coexistence Strategies

Internationally, initiatives to deliver coexistence for GM and non-GM crops are diverse and generally do not take the form of a single official strategy or framework. In countries that have adopted a more regulatory approach to coexistence (for example the EU-27), the guidelines tend to be embedded in legislation; whereas in countries that have adopted a market-based approach (for example Canada and the USA), the guidelines for coexistence are described in industry Best Practice Guidelines or the equivalent. Some reports about coexistence, including those relating to the EU-27, acknowledge that given the limited practical experience with GM crops, coexistence strategies are adapted from existing segregation practices, such as those techniques for certified seed production (Commission of the European Communities 2006). Sampling and testing for the AP of GM events is referred to in some of these documents, but often only as a minor component of the overall strategy or framework.

This Chapter discusses the sampling and testing components that were found in existing and proposed coexistence strategies in the major countries to which Australia exports canola and cottonseed. In some European countries where coexistence strategies have been articulated, they are discussed separately from the blanket EU-27 framework. Initiatives in New Zealand and the USA to establish accredited testing protocols and sampling regimes are also discussed.

Based on the research conducted for the domestic section of this report, it is likely that sampling and testing for GM events in overseas countries will also be an extension of existing sampling and testing activities and not represent significant extra effort. Only limited mention of sampling and testing for GM events was found in the overseas coexistence strategies. The detail in the overseas coexistence strategies was focused on managing gene flow, through separation distances, or managing physical admixture, through handling methods, as opposed to sampling and testing for GM events *per se*. It has been acknowledged that most national coexistence regulations are based on isolation distances (Lecroart et al. 2007). This may be because the discussion of coexistence tends to focus on coexistence on farms and, at this level, it was found that sampling and testing for GM events is not a common requirement.

EU-27

European Commission (EC)

The majority of EU Member States have decided to take a legislative approach to coexistence and most Member States have either adopted or drafted national coexistence measures (CEC, 2006). EC Recommendation 2003/556/EC[12] was developed to assist Member States establish GM, non-GM and organic coexistence strategies/arrangements at a national level. In addition, COEX-NET has been created by the EC to facilitate the exchange and coordination of information concerning coexistence of GM, conventional and organic crops (United States Department of Agriculture - Foreign Agricultural Service 2006b).

[12] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (notified under document number C(2003) 2624).

For many Member States in the EU the development of coexistence strategies and good practice guidelines relates to a future hypothetical scenario because there is limited availability of GM crops authorised for cultivation (United States Department of Agriculture - Foreign Agricultural Service 2006b). A report released by the European Commission in 2006 concluded that EU-wide regulations on coexistence are not justified at present due to the limited experience in implementing national measures (United States Department of Agriculture - Foreign Agricultural Service 2007c). Austria, Denmark and Italy have pressed the Commission to adopt an EU-wide regulation for coexistence and, along with Germany, each of these countries has drafted coexistence laws which are quite restrictive (United States Department of Agriculture - Foreign Agricultural Service 2007c). The approaches to coexistence taken by Germany, Spain, the Netherlands and Belgium are outlined below.

A subsequent EC Recommendation on technical guidance for sampling and detection of GMOs and material produced from GMOs in seed, food and feed products (2004/787/EC[13]) highlights some conditions Member States should take into account in order to fulfil the requirements set out in Regulation (EC) 1830/2003[14]. Although they are general principles, there is specific mention of sampling and testing including:

- the need to consider heterogeneity and places in the supply chain where testing takes place
- acknowledging that alternative sampling strategies to those recommended in the guidance may be applied
- acknowledging that alternative testing strategies to those recommended may also be applied, provided such methods are approved by the Community Reference Laboratory (established under Regulation (EC) 1829/2003[15])
- suggesting that harmonised sampling procedures (for seed, food, feed etc) should be used for the purpose of estimating the presence of GMOs
- highlighting that protocols for sampling seed should be developed in accordance with specific legislation for seeds, whereas strategies for sampling bulk commodities, food and feed products are addressed in 2004/787/EC
- identifying that sampling of seeds and other plant propagating material should follow ISTA rules and the ISTA Handbook on Seed Sampling
- listing the ISO standards which should be taken into account when sampling bulk commodities
- suggesting that 'a multiple-step protocol is recommended in order to minimise cost and maximise statistical power according to pre-defined acceptance levels'
- a list of analytical test protocols and testing methods, including laboratory requirements and sample preparation.

For bulk agricultural commodities, sampling should be conducted in accordance with ISO Standards 6644 and 13690 (grains), 2859 (fruit, rhizomes, potatoes, pre-packaged food) and 542 (oilseeds). The analytical test protocols state that testing should be conducted by a

[13] Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003.

[14] Regulation (EC) No 1830/2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced From Genetically Modified Organisms.

[15] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

laboratory accredited according to ISO 17025/2005 (*General requirements for the competence of testing and calibration laboratories*) or certified to an appropriate scheme. It should be carried out in accordance with the draft European standard prEN ISO 24276:2002 (since the release of the Recommendation, this standard has been accepted as an ISO standard - ISO 24276:2006[16]). Whenever possible, laboratories should use a method validated according to internationally recognised criteria and include the use of certified reference material.

Regulation (EC) No 1830/2003 regarding the traceability and labelling of GMOs also identifies that Member States carry out measures for the inspection and monitoring of products and this includes sampling and quantitative and qualitative analyses of food and feed (Europa 2007).

In the regulation of seed grown for sale in Europe, statutory measures exist to minimise genetic contamination and maximise variety purity.

European Commission's Joint Research Centre (JRC)

The JRC provides 'scientific and technical support for the development of policy and regulations for genetically modified organisms (GMOs) and biotechnology'. The Unit for Biotechnology and GMOs within the JRC has responsibility for developing methods of GMO detection and quantification, validation of detection methods and strengthening the harmonisation of qualitative and quantitative GMO analysis. To achieve these responsibilities, the JRC has set up the European Network of GMO Laboratories, runs the Community Reference Laboratory for GM Food and Feed and the Community Reference Laboratory for GMOs, maintains a GMO Methods Database, and conducts research into biotechnology and sampling.

- ENGL

  The European Network of GMO Laboratories (ENGL) is an organisation of more than 100 national enforcement laboratories representing all EU members as well as Norway and Switzerland. ENGL is a platform through which laboratories across Europe can discuss technical issues with regard to GMO analysis and attempt to harmonise and standardise methods for sampling, detection, identification and quantification of GMOs or derived products.

- CRL-GMFF

  The Community Reference Laboratory for GM Food and Feed (CRL-GMFF) was instituted by the European Regulation (EC) No 1829/2003. The CRL-GMFF roles include distributing appropriate control samples for use in GMO analysis to ENGL laboratories, and testing and validating methods of detection and identification of GMO events. For all validated methods, a testing protocol has been produced.

- CRL-GMO

  The Community Reference Laboratory for GMOs (CRL-GMO) has been established under European Regulation (EC) No 882/2004. The CRL operates at the level of control of GM food and feed in real market situations. Its objectives include:

  'solving scientific issues related to harmonisation and communication of scientific data among laboratories, monitoring the quality levels of the analytical laboratories for GMO

[16] Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – General requirements and definitions.

detection, [and] levelling the capacities through training, workshops and any common scientific normative tool available'.[17]

- GMO Methods Database

  The JRC has also developed the GMO Methods Database, which contains analytical methods for the detection, identification and quantification of genetically modified organisms. All methods have been published in peer-reviewed journals or in reports from collaborative studies.

- Sampling

  Research has been undertaken by the JRC into sampling for GMOs in conventional grain and seed lots. Generally the distribution of GM material within lots is assumed to be random in order to use binomial distribution to make inferences. This assumption had never been verified in practice, with no data available on the distribution of GMOs. KeLDA (Kernel Lot Distribution Assessment) is an ENGL collaborative project, coordinated by JRC. The project assessed the real distribution of GM materials in soybean grain lots and estimated the amount of variability of distribution patterns among lots. All of the 15 lots analysed showed significant heterogeneity, indicating that randomness cannot be assumed. The project concluded sampling protocols need to be developed based on statistical models free of distribution requirements.

European Committee for Standardisation (CEN)

CEN is an organisation which represents national standard bodies from 30 European countries. CEN produces voluntary technical standards which promote free trade, the safety of workers and consumers, interoperability of networks, environmental protection, exploitation of research and development programmes, and public procurement.

CEN developed the series of standards for methods of analysis for the detection of genetically modified organisms and derived products that were adopted as ISO standards. CEN has also developed a standard for sampling (CEN/TS 15568:2006 *Foodstuffs—Methods of analysis for the detection of genetically modified organisms and derived products – Sampling strategies*), which is free from distribution assumptions, and therefore applicable in cases of heterogeneity. This CEN standard has not been accepted at the ISO level.

Germany

Germany's Genetic Modification Act 2005 is the legal basis for the cultivation of GM plants in Germany (Co-Extra 2008c). The *Genetic Modification Act – Amendment (2005)* aims to implement Directive 2001/18/EC and to ensure GM-free production and the coexistence of GM and non-GM crops. The Amendment provides three instruments including compliance with 'Good Farming Practice' in the cultivation of GM crops.

The codes of Good Farming Practice include measures to help farmers reduce AP between GM and non-GM plants. So far, codes have been described in only general terms with reference to, for example, separation distances between GM and non-GM fields, use of natural pollen barriers and the need for farmers to document they are familiar with coexistence measures (Co-Extra 2008c). The legislation also includes liability legislation and stipulates GM crop growers must be able to prove they have the appropriate knowledge about GM crops before they can cultivate them (United States Department of Agriculture - Foreign Agricultural Service 2006b).

The German Bundesrat approved the Amendment on February 15, 2008 and it became effective in May 2008. Some of the key features of the Amendment for farmers are the

[17] http://bgmo.jrc.ec.europa.eu/ accessed 30 October 2008

implementation of isolation distances for GM corn (maize) and the change to the definition for the use of the 'without biotech' food and feed label (United States Department of Agriculture - Foreign Agricultural Service 2008).

Guidance on Good Farming Practices has also been provided by the seed industry for the cultivation of GM maize; including rules about separation distances (20 metres) and care to avoid admixing during planting, harvesting, transport, storage and cleaning of machines (Co-Extra 2008c). In 2005, the success of the separation system was evaluated and samples were taken at grain receival points from all incoming maize loads as well as from points further along in the supply chain. 'The results showed that the maize harvested more than 20 metres from GM maize fields consistently stayed well below the 0.9 percent labelling threshold' (Co-Extra 2008c).

Germany has a decentralised system for testing and controlling the illegal entry of GM products. Sampling is primarily done at the wholesale and processing level (United States Department of Agriculture - Foreign Agricultural Service 2007d).

Spain

Spain has drafted a royal law to harmonise coexistence practices in the country (drafts prepared by Spanish authorities in 2005 and 2006). The draft proposes compulsory training courses for GM crop growers or all operators dealing with GM crops (United States Department of Agriculture - Foreign Agricultural Service 2006b). To date, farmers rely on the Good Agricultural Practices developed by the Spanish Association of Seed Producers (APROSE) but have been working towards a royal law to harmonise coexistence practices in the country (GMO Compass 2007). The Good Agricultural Practices for Cultivation of Bt-maize (developed by the seed industry) addresses insect resistance management practices, coexistence recommendations and traceability and labelling obligations (Novillo et al. 2007).

However, coexistence in Spain is mainly an issue in the case of GM crops intended for the human food sector, and the Spanish starch industry currently tests all loads of non-GM maize before receival at processing plants (Brookes and Barfoot 2003). As in Australia, seed-for-sowing is tested prior to sale, in order to rule out the possibility of seed impurities being a source for AP of GM events.

While organic maize crops in Spain are not subject to systematic testing for AP of GM events, the regional certification authorities are believed to conduct some tests each year. These are based on their perceptions of where a risk of AP could occur (Brookes and Barfoot 2003).

Netherlands

In 2004 the Dutch Coexistence Committee, which consists of umbrella organisations in the Netherlands representing agriculture, plant breeders and consumers, developed a set of coexistence guidelines that received consensus from all relevant stakeholders. The guidelines in the report were designed to keep the adventitious mixing of GM and non-GM agricultural products at an absolute minimum, thereby guaranteeing coexistence and ensuring consumers' freedom of choice (Co-Extra 2008a). The Committee settled on appropriate distances for separating GM and non-GM maize, sugar beets and potatoes. The Dutch Main Board of Arable Crops set up regulations based on these agreed coexistence guidelines.

There is not a large sampling and testing component in these guidelines, although the committee did recommend in the monitoring protocol that samples should be collected before, during and after cultivation to provide assurance that monitoring is carried out correctly; and that a sample of the harvested product should be analysed first. If there is evidence of AP of GM events found in this initial sample, the other samples can be analysed in order to trace its cause (van Dijk 2004). It is suggested that monitoring and control should be frequent in the initial three years of GM cultivation and it may be reduced if it is found that product integrity is being maintained (van Dijk 2004). It is intended that these guidelines, which have been

developed in the form of Codes of Good Practice, will eventually be legislated for (United States Department of Agriculture - Foreign Agricultural Service 2006b).

Belgium

The two Belgium Regions, Flanders and Wallonia, are responsible for formulating and implementing coexistence policy and, respectively the Flemish and Walloon governments decide upon the regulations (United States Department of Agriculture - Foreign Agricultural Service 2006a). The Walloon Government approved the coexistence regulations in 2006. However, the technical details of the regulations have not been determined (United States Department of Agriculture - Foreign Agricultural Service 2006a).

Japan

As outlined in the next Chapter, there are several regulations, including labelling requirements, which apply to the marketing or import of GM products to Japan. Presently, the sampling and testing component of guidelines issued by the Japanese Ministry for Agriculture, Forestry and Fisheries (MAFF) regarding the coexistence of field trials states that at least 10 000 seeds should be harvested and tested through analytical techniques, such as PCR, to confirm if cross-pollination has taken place between a GM and non-GM plant (United States Department of Agriculture - Foreign Agricultural Service 2007f).

In addition to these coexistence guidelines for field trials, local government regulations exist regarding agricultural biotechnology in Japan. Within these regulations, when an application for growing GM crops is made to the Governor's office, they require precise information on the 'means for testing for biotechnology contamination' (United States Department of Agriculture - Foreign Agricultural Service 2007f). There is no specific mention of what sampling or testing should take place, but there is an acknowledgement that the farmer needs to be aware of these methods.

Japan has programs in place to sample and test both imported shipments and processed food products at the retail level for the presence of GM events. All testing is performed according to sampling and testing criteria set by the Japanese Ministry of Health, Labor and Welfare (United States Department of Agriculture - Foreign Agricultural Service 2007f).

Pakistan

Pakistan has Biosafety Guidelines and Rules but at present the Government of Pakistan has not formulated a policy on coexistence between GM and non-GM crops (United States Department of Agriculture - Foreign Agricultural Service 2007g). The objective of the guidelines is to prevent unintentional negligence and prevent possible adverse impact on human health and the environment. As such, the focus is more related to research of GMOs and commercial release and does not discuss coexistence. The Development of the National Biosafety Centre will provide the requisite setup for the implementation of the Biosafety Rules and Guidelines[18]. To date in Pakistan, no GM crops have been approved for cultivation on a commercial basis (United States Department of Agriculture - Foreign Agricultural Service 2006c; 2007g).

China

China has a variety of regulations in place for managing the marketing approval and import of GMOs (see Appendix A). However, no specific mention of coexistence guidelines or strategies was found among these regulations.

[18] www.environment.gov.pk accessed 30 May 2008

Bangladesh

Bangladesh currently has a National Biotechnology Strategy (but is yet to establish a regulatory framework) and Draft Biosafety Guidelines (United States Department of Agriculture - Foreign Agricultural Service 2007a). The Guidelines contain standards and codes of practice related to the 'risks' associated with the environmental release of bioengineered products.

UK

In 2006, the British Department for Environment Food and Rural Affairs (DEFRA) published a consultation paper setting out proposed coexistence measures for GM and non-GM crops (Department for Environment Food and Rural Affairs 2006). The British government aims to use this document as the basis to establish coexistence rules. Public feedback on this document was sought and has been published (Department for Environment Food and Rural Affairs 2007). The government intends to introduce coexistence measures prior to the commercial cultivation of GM crops despite the coexistence regulations still being in a state of development (Co-Extra 2008b). In the consultation paper, there are no specific sampling and testing components mentioned; however, it does note the testing methods for GM presence (i.e. PCR methods) and the important role that sampling plays in this process.

In the UK, all farm-scale trials of GM crops are required to comply with the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) guidelines which, among other things, specify practices for the storage and planting of seed, harvesting and on-farm separation distances (Brookes 2004).

It is worth noting that Scotland has its own distinct policy on GMOs. The Scottish government has indicated that they intend to maintain a moratorium on planting GM crops in Scotland due to consumer demand for locally-produced conventional and organic food. Accordingly, there is no intention to develop a coexistence strategy for GM and non-GM crops.

The Welsh Assembly Government takes a restrictive stance towards GM crops and aims to develop policies in accordance with this stance and express them in the UK and EU contexts. The Assembly Government is a member of the GM-Free Network of Regions but they acknowledge under EU legislation all forms of agriculture are allowed to exist and a total ban on GM crop cultivation would be illegal (Welsh Assembly Government 2008). It is intended to issue a consultation paper on the Welsh Assembly Government's coexistence proposals and allow stakeholders to comment on the plans.

Ireland

In 2005, a Working Group in Ireland reported on the coexistence of GM and non-GM crops in Ireland and recommended that a national coexistence strategy should be a combined mandatory and voluntary arrangement, with mandatory measures given legal status and voluntary measures specified in a code of Good Farming Practice (Department of Agriculture and Food 2005). The report advised users of home-saved seed to test for GMO content prior to planting, and that sampling and testing may be necessary to monitor for compliance to the coexistence strategies. In addition to inspection for compliance, the report suggests it may be necessary to carry out a program of crop sampling and analysis to isolate a cause of admixture. It is acknowledged that the use of certified seed will ensure seed purity. They recommend all certified non-GM seed should be tested by the seed producers and that the Irish Department of Agriculture, Fisheries and Food (formerly Department of Agriculture and Food) should conduct sampling and testing. The Department should also conduct sampling and testing of a proportion of imported seed lots (Department of Agriculture and Food 2005).

India

No mention of coexistence was found in India's rules relating to the manufacture, use, import, export and storage of genetically engineered organisms (see Appendix A).

Canada

Coexistence between GM and non-GM crops is not regulated by the government in Canada and, due to the market-based approach to coexistence, the responsibility is placed on the producers (United States Department of Agriculture - Foreign Agricultural Service 2007b). No specific GM and non-GM coexistence plans were considered or implemented at the time of commercial release of GM canola in Canada (Van Acker et al. 2003).

However, farmers are provided with 'Technology Use Guides' or 'Crop Stewardship Guides' from GM seed suppliers which provide recommendations on coexistence issues such as pollen movement and the use of buffer crops and barriers (Brookes and Barfoot 2004). Although specific sampling and testing protocols could not be identified in publicly available documents, there is guidance regarding the timing of sampling, for example, if sampling is required to confirm harvest standards, samples should be submitted prior to harvest to determine crops status. Grid-sampling and submitting samples separately are also suggested if AP of GM events is suspected (Croplife Canada 2008).

Organic certifiers offer advice to non-GM growers on ways of ensuring product integrity, such as implementation of procedures and plans regarding seed, site selection, neighbour relations, harvest and storage (Brookes and Barfoot 2004). Within this advice, similar mention of grid-sampling is highlighted, as well as the need to keep copies of test results.

The National Standard of Canada: *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* was developed to ensure that any claim about GM status is informative and verifiable. The Standard identifies that the verification that food is GM or non-GM may include testing and detection methods; and where testing and detection methods are used, validated methods of sampling and analysis are to be used as appropriate for the product in question. The preference is for methods to follow Canadian standards, then international ones (Canadian General Standards Board 2004).

The Canadian Grain Commission has developed the Canadian Identity Preserved Recognition System (CIPRS). This is a voluntary tool for industry to provide third party assurance of the processes they are using to deliver their specific quality attributes to both domestic and international markets (Agriculture and Agri-Food Canada 2006). CIPRS ensures that the quality management system of a company meets the Standard created by the Canadian Grain Commission and this Standard is designed to be compatible with quality management systems such as those developed by the ISO.

USA

There are no specific legislative-based coexistence strategies in the USA although there are a number of government-based services which standardise sampling and testing (see below) as well as a general Coordinated Framework for the Regulation of Biotechnology (Appendix A). As there is a market-based approach to managing coexistence of GM and non-GM crops in the USA, it is reliant on industry programs for identity preservation.

The Association of Official Seed Certifying Agencies (AOSCA) has developed an IP certification program to assist in preserving the genetic and/or physical identity of a product. Any grain produced by an AOSCA IP grain program will have been produced under a third-party verification program involving a coordinated system of inspections, audits, sampling and testing. All AOSCA programs are peer-reviewed (Thompson and Miller 2004). Specific AOSCA IP protocols have been developed to address transgenic crops with a '99.5% Non-

GMO Soybean Grain Program'[19] and a '99% Non-GMO Corn Grain Program'[20]. Both these protocols have requirements for sampling and testing for GMOs.

Ag Processing Inc (AGP), a cooperative soybean processor, has developed an IP program for non-GM soybean, which includes price premiums for providing grain free of GMOs. The IP program involves a combination of grower requirements, declarations and testing. The testing component requires all loads to be tested for GMOs upon delivery to the elevator (where available) and again when brought to the AGP processing plant. If either test results in detection of more than 0.1 per cent GMO, all non-GMO premiums are deducted (BASF and ASA 2003).

Organic certifiers also offer advice to farmers on ways of maintaining product integrity. As in Canada, this advice requires farmers to implement procedures and plans that incorporate a variety of methods regarding seed, site selection, neighbour relations, harvest and storage (Brookes and Barfoot 2004). Within this advice, only a small reference to sampling and testing for GM events is made and it refers to the need to submit samples prior to harvest for GM testing and states that grid sampling and submitting samples separately should be undertaken if AP of GM events is considered a risk. It also suggests that samples are tested for all applicable GM events and copies of test results are kept (Brookes and Barfoot 2004).

Grain Inspection, Packers and Stockyards Administration (GIPSA)

GIPSA, part of the United States Department of Agriculture's Marketing and Regulatory Programs, has a number of roles in standardising sampling and testing for GM oilseeds and grains in the USA. These include: evaluating the performance of rapid tests developed to detect biotechnology-derived grains and oilseeds; conducting a Proficiency Program for organisations testing for biotechnology-derived grains and oilseeds; providing guidelines on sampling; and, developing a number of specific testing protocols for GM events.

- Rapid Tests Performance Evaluation Program

  To ensure that reliable, rapid tests are commercially available for testing the presence of genetically modified grains and oilseeds, GIPSA provides a program to verify the performance of commercial test kits[21]. The test manufacturers submit a data package to support their claims, which is reviewed by GIPSA staff. GIPSA also conducts in-house performance verification, and if it matches the manufacturer's claims, a Certificate of Performance is issued[22].

- Proficiency Program

  The Proficiency Program run by GIPSA aims to help organisations testing for biotechnology-derived grains and oilseeds improve their testing capability and reliability[23, 24]. Participants in the voluntary program receive corn (maize) or soybean samples for testing from GIPSA which contain various combinations and concentrations of transgenic traits. The testing organisations then provide qualitative and/or quantitative results and the testing technology used. Scoring of the participant's results is then done by computing the 'percentage of correctly reported transgenic traits' in the samples. A

[19] www.identitypreserved.com/handbook/aosca-nongmosoy.htm

[20] www.identitypreserved.com/handbook/aosca-nongmocorn.htm

[21] www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=iws-rtk accessed 30 May 2008

[22] www.gipsa.usda.gov/GIPSA/documents/GIPSA_Documents/9181-2.pdf accessed 30 May 2008

[23] http://archive.gipsa.usda.gov/reference-library/directives/9181-3.pdf accessed 30 May 2008

[24] www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=iws-prof accessed 30 May 2008

performance report is provided to all participants[25]. Participants typically include organisations from Africa, Asia, Europe, North America and South America, with the program run at least twice a year.

- Sampling guidelines

  GIPSA's *Grain Inspection Handbook* (Book 1, *Grain Sampling*) and *Rice Inspection Handbook* (Chapter 2, *Sampling*) contain instructions for taking samples from static lots, such as trucks, barges, and railcars, and for taking samples from grain streams. The sampling procedure for testing for GM events in a consignment is the same as the sampling for any other characteristics in grain. GIPSA has also developed a spreadsheet to help in the design of sampling plans for qualitative testing for GM grains. The spreadsheet can be used to calculate appropriate sample sizes (in terms of both number of grains and mass) for given confidence levels.

- Testing Protocols

  GIPSA has devised a protocol for sampling and testing rice, which is being exported to the EU, for the presence of the GM herbicide-tolerant LibertyLink® trait[26]. The protocol was developed in response to EC measures that require all imports of USA long grain rice to be tested for the presence of the trait. The measures were adopted after the USDA Food and Drug Administration announced in 2006 that trace amounts of LibertyLink® rice had been detected in commercial long grain rice.

  Under the protocol, all USA long grain rice to be shipped to the EU must be sampled by GIPSA in accordance to the established sampling procedures listed in *Rice Inspection Handbook* (Chapter 2, *Sampling*). Samples are then tested by PCR using the 35S:BAR method (for detecting the 'basta resistance' event) developed by Bayer CropScience and verified by both GIPSA and the CRL-GMO. The lot is considered negative only when all sample results are negative.

  A sampling and testing protocol has also been developed for testing corn (maize) for the presence of StarLink™ corn[27]. StarLink™ is a GM insect-resistant corn variety (expressing the Bt protein Cry9C) that was approved in the USA for use in animal feed, but not for human consumption. In 2000, the StarLink™ event was detected in taco shells, indicating that it had entered the human food supply. In response, testing for the Cry9C protein has been conducted on both domestic consignments used for food and consignments for export[28]. Sampling procedure follows the *Grain Inspection Handbook* (Book 1, *Grain Sampling*). Testing is conducted with one of two lateral flow test kits; the EnviroLogix Cry9C QuickStix™ Test Kit No. AS 008 BG or the SDI Trait✓ BT9 Lateral Flow Test Kit No. 7000012.

  It has been suggested the there is no longer a requirement for sampling and testing for the Cry9C protein as it has been sufficiently removed from the human food supply that continued testing provides no added public health protection[29].

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[25] http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=iws-prof-rep accessed 30 May 2008

[26] http://archive.gipsa.usda.gov/reference-library/directives/9181-4.pdf accessed 30 May 2008

[27] http://archive.gipsa.usda.gov/reference-library/directives/9181-1.pdf accessed 30 May 2008

[28] http://archive.gipsa.usda.gov/biotech/starlink/protocol.htm accessed 30 May 2008

[29] http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2007-0832 accessed 30 May 2008

Agricultural Marketing Service (AMS)

While GIPSA provides services to bulk grain and oilseed markets, the AMS performs a similar role for food commodities such as fruit and vegetables, as well as fibre commodities. AMS conducts evaluations of commercially available test kits to detect the presence of GM events in food (other than grains) and fibre commodities. AMS is also developing a proficiency program, similar to the program run by GIPSA, for evaluating and verifying the capabilities of independent laboratories to screen food and fibre products for the presence of GM material.

Republic of Korea

To date no GM crops have been commercialised for cultivation in the Republic of Korea (United States Department of Agriculture - Foreign Agricultural Service 2007i) and no coexistence strategies exist to facilitate parallel cultivation of GM and non-GM crops. Organic agricultural production is provided for in regulations focused on the components of the final product and the Korean Food and Drug Administration (KFDA) maintains a zero-tolerance policy for AP of GM events in processed organic products (United States Department of Agriculture - Foreign Agricultural Service 2007i). Korea also released proposed consolidated guidelines in June 2007 to deal with import, export and production of LMOs. The guidelines include provisions to cover agricultural biotechnology products subject to in-country field tests. In-country field tests are required for LMOs used for planting seed and may be required for imported LMOs used for food, feed and processing (United States Department of Agriculture - Foreign Agricultural Service 2007i).

New Zealand

Biosecurity New Zealand

Currently, no GM crops have been approved for commercial growing in New Zealand and no coexistence strategies have been developed. GM seed cannot be imported without approval from New Zealand's Environment Risk Management Authority. All other seed must be accompanied by a supplier's declaration that the seed is not GM (MAF Biosecurity New Zealand 2007b).

Biosecurity New Zealand has developed sampling and testing protocols for imported seed-for-sowing of crops that are grown in New Zealand and for which there are GM varieties grown overseas. Protocols are provided for *Zea mays* (maize and sweet corn), *Glycine max* (soybean), *Brassica napus* var. *oleifera* (canola) and *Medicago sativa* (lucerne/alfalfa). The protocols do not apply to seeds imported for processing and, in the case of lucerne/alfalfa, nor to seed imported for animal or bird feed because such seed is devitalised on import (MAF Biosecurity New Zealand 2007b).

Every consignment of imported seed-for-sowing of the above species must be tested for the presence of GM seeds, unless otherwise stated (i.e. seed imported from a country that the New Zealand Ministry for Agriculture and Forestry (MAF) has granted 'area freedom from commercial GM production') (MAF Biosecurity New Zealand 2007b). Sampling and testing must be carried out by an organisation accredited according to MAF Biosecurity New Zealand *Standard Approval of Laboratories for Genetically Modified Organism Testing* (MAF Biosecurity New Zealand 2007a). Sampling and testing procedures need to be able to detect with 95 per cent confidence the inadvertent presence of one GM seed in 10 000 seeds.

Importers can either:

- have the consignment sampled and tested at the border, or
- provide certification that all seed lines/varieties in the consignment have been tested individually prior to shipping.

For sampling, the protocols list both the standard ISTA and the AOSA methodologies for seed sampling as acceptable. For testing, a qualitative PCR test must be performed to determine the presence or absence of GM seeds in the sample. Quantitative PCR tests are not acceptable by themselves and are only accepted if a negative result is also clearly reported on the certificate. The PCR methods used must be capable of detecting GM seed in the seed sample at the lowest reliable limit of detection, currently accepted to be 0.01 per cent GM. Biosecurity clearance for a consignment will be given only if no GM seeds are detected (MAF Biosecurity New Zealand 2007a).

Regardless of whether or not there is a specific testing protocol for GM seeds, MAF will investigate any consignments for which the presence of GM seeds is suspected. An example of this was a consignment of cotton seeds from Australia intended for stock feed that was stopped at the border in October 2001 because there were no assurances that it did not contain GM seeds. For the consignment to proceed past the border, the seeds were required to be either processed so that they were not viable, or tested for GM seeds.

Section 4: Sampling and Testing Methods and Protocols for Canola, Cotton, Soybean and Maize to Meet Thresholds Set by Australia and/or Its Trading Partners

Throughout this section, references are made to the approval processes for GMOs in Australia's main trading partners for the four crops of interest. The approval process for GMOs and the language used to describe the process differs from country to country. Most countries, including Australia, approve GMOs for a specified use. In Australia, the Regulator licenses dealings involving intentional release of GMOs, which includes approval of GMOs for commercial release. FSANZ approves foods derived from GM crop lines. The EU authorises GM events for marketing, where authorised for marketing means that the product is reviewed and approved for sale for a specified use including import, cultivation, processing, food, feed and/or industrial. In the USA, GM plants are not approved for cultivation but rather they are 'regulated articles' until they have been favourably reviewed by the relevant agencies. A GM plant that has been 'reviewed for cultivation' and has received a positive assessment is granted 'non-regulated' status and is no longer subject to oversight by USA regulatory agencies. GM plants are similarly 'reviewed for human consumption (or food)' and 'for animal consumption (or feed)'.

Chapter 9: Methods and Protocols for Sampling and Testing GM Events in Seed and Grain

Regulatory requirements for canola

In Australia, eight GM canola lines have been approved for commercial release by the Regulator, as well as some hybrids of these lines (i.e. GMOs in which two transformation events have been combined by crossing) (Appendix B, Table B1). Food derived from these approved GMOs has also been approved by FSANZ. To date, only one GM canola line (glyphosate-tolerant canola—Roundup Ready® canola GT73) has been commercially grown in Australia. The technology provider (Bayer CropScience) for the other approved GM lines (glufosinate ammonium-tolerant canola—InVigor® hybrid canola) will not commercialise all Regulator-approved lines; Bayer CropScience has indicated that it does not intend to commercialise the lines T45, Topas 19/2, MS1, RF1 and RF2 (or hybrids containing these) in Australia (OGTR 2006a). Approvals for these GM lines were nevertheless sought to obtain consistency with overseas regulatory approvals.

Consumers and some markets require the integrity of non-GM seeds and grain to be maintained. This may require labelling. Maintaining 100 per cent product purity is not practical and/or cost-effective, and governments around the world have therefore introduced thresholds for GM presence (for approved events) in non-GM seed and grain, below which the seed and grain can still be labelled as non-GM.

In Australia, as discussed previously, industry has adopted a threshold level for labelling of non-GM canola grain and seed which may contain some GM seed and grain approved by the Regulator. Adventitious presence (AP) thresholds are 0.9 per cent GM canola in non-GM canola grain and 0.5 per cent GM canola in non-GM canola seed-for-sowing.

Exports

The Australian canola industry is strongly export oriented. Approximately 60–75 per cent of the crop is exported in any given year, the majority to markets in which Australia competes predominantly with Canada (Alcock 2005; Apted et al. 2005; Foster and French 2007). The

major customers (in terms of the share of total Australian canola exports in the five years to 2006/07) were: Japan (67.5 per cent); Pakistan (25 per cent); Bangladesh (9 per cent); China (3 per cent); UK (2 per cent); Nepal (1 per cent) and other EU countries (0.5 per cent).

For export of non-GM canola to these countries, the regulatory requirements and approval status for GM canola within each country, which are summarised below, must be considered in relation to the allowable threshold levels and approval status of GMOs within Australia. Appendix A contains more detailed information for each of these countries.

Japan

Under the Japanese Food Sanitation Law, if the GM content of the top three ingredients in foods exceeds 5 per cent of the total weight of the foods, they must be identified with either the phrase 'Biotech Ingredients Used' or 'Biotech Ingredient Not Segregated' if the raw material is not accompanied by certificates of identity preservation handling. Under the Japan Agricultural Standards law, Japan has set an informal tolerance level of 5 per cent for GM ingredients in products that are identified 'Non-Biotech' provided that the event(s) have been approved in Japan.

The 5 per cent tolerance level applying to GM canola is above the threshold for non-GM canola set within Australia (Appendix B, Table B2). Therefore, canola meeting Australia's domestic threshold requirements, would also meet Japan's non-GM importing requirements.

Five of the eight GM canola lines that have been approved in Australia for commercial release by the Regulator, as well as the GM hybrid intended for commercial production, have also been approved in Japan for food and feed and so can be exported to Japan. Three canola lines (MS1, RF1 and RF2) that have been approved in Australia have not been approved in Japan. However, the resulting hybrids from these parent lines (MS1xRF1, MS1xRF2) have been approved for food and feed in Japan. GM canola with any of these three GM events are not intended to be grown commercially in Australia (OGTR 2003a).

China

China has placed its listed agricultural GMOs (soybean, maize, canola, cotton and tomato) under a mandatory labelling system. China requires that all products derived from listed GM crops be labelled and prohibits the importation and sale of any unlabelled or mislabelled GM products. China has not approved any of the GM canola varieties licensed in Australia for commercial growing in China; however, since GM canola is a 'listed GMO' in China's regulatory scheme, it may still be imported and used for oil and meal provided its products are labelled appropriately as being derived from a GMO.

EU

The EU has set a threshold level of 0.9 per cent for AP of GM events authorised in the EU for food and feed use, with labelling required for products above this level. For GM events that have not been authorised but have received a positive EU risk assessment, the adventitious presence level is set at 0.5 per cent, while products containing GM events above this level are not allowed into the EU market. GM events without a positive safety assessment are not permitted at any level in the EU.

All of the GM canola lines and hybrids approved for commercial release in Australia have also been authorised in the EU for use in food (Appendix B, Table B2). Authorisation for the cultivation and placing on the market of GM events MS1, RF1, RF2 and Topas 19/2 was withdrawn in the EU from 18 April 2007, as varieties containing these events were no longer offered for sale on a global basis and Bayer CropScience indicated to the European Commission that it had no intention to submit an application for renewal of the authorisation (European Union 2007c; b; a). AP of this event will still be tolerated in the EU at a level of up

to 0.9 per cent until 25 April 2012 (European Union 2007c) and, after this date, at a level up to 0.5 per cent. Again, GM canola varieties with these events are not intended to be commercially grown in Australia.

Other countries

Bangladesh, India, Nepal and Pakistan do not set a tolerance for AP of GM events in non-GM commodities (Appendix B, Table B2). These countries have not formally approved any of the GM canola varieties approved for commercial release in Australia. However, these countries import GM canola from Canada.

Imports

Imports of non-GM canola seed from overseas, such as New Zealand, Japan, Canada and the USA, are permitted. New Zealand does not grow GM canola. While all of the GM canola events currently approved for commercial release in Australia have been approved for cultivation in Canada and reviewed for cultivation in the USA, there are four events either approved in Canada and/or reviewed for planting in the USA, that have not been approved by the Regulator under the *Gene Technology Act 2000* (Cwlth) for commercial release in Australia (Appendix B, Tables B1 and B2). These are GM canola events 18, 23, GT200, and Westar-oxy-235; not considered for approval in Australia because applications have never been made to the Regulator. Two (event 18 and GT200) of these four events, however, even though approved in Canada and the USA have not been commercialised there (Biotechnology Industry Organization 2008) and the other two events have not been sold in North America for a number of years.

Canola testing options and capabilities

Test protocols for GM events will differ depending on the sampling point along the supply chain and the commodity being sampled. Protocols may not involve monitoring for all events at each sampling point. In the majority of cases where testing is required, one approach is for an initial screen to be conducted. If any GMO was detected in the screen, the level of GM presence may need to be determined to ensure that it is below the specified threshold. Identification of the specific GM event could be required, for example to confirm if it is approved in Australia or not.

There are twelve GM canola events relevant to Australia's domestic and international trade (eight of the events are approved in Australia and four of the events are approved overseas but unapproved in Australia). There is no single genetic element that is present in all twelve GM canola events relevant to Australia. To detect all twelve GM events, a combination of at least three screens would be required. A similar number of screens would be required to only detect the GMOs approved in Australia (Appendix B, Table B1).

In the first instance, a combination of screening tests is most suitable for detecting unapproved GM canola varieties (example in Figure 9.1). If these results indicate GM material is present, possible GMOs present in the sample can be deduced from the pattern of results. In the case of GT73 and GT200, further testing may be required if an initial screen suggests that one of these two GM events is present; one (GT73) is Regulator-approved and the other (GT200) is not, so confirmation would be needed about which one is present. AP of unapproved GT200 GMOs would require this additional testing, preferably using a validated event-specific method for conclusive evidence.

For detection of approved GMOs, a combination of screening tests (example in Figure 9.2) would be most suitable in the first instance. If the correct number of working samples with the required number of seeds is analysed at the screening stage, these results could be used to estimate whether or not any AP of GM seed in the seed lot is above the threshold level.

Samples falling above the threshold would most probably require further testing to confirm and identify the GM event present in the sample.

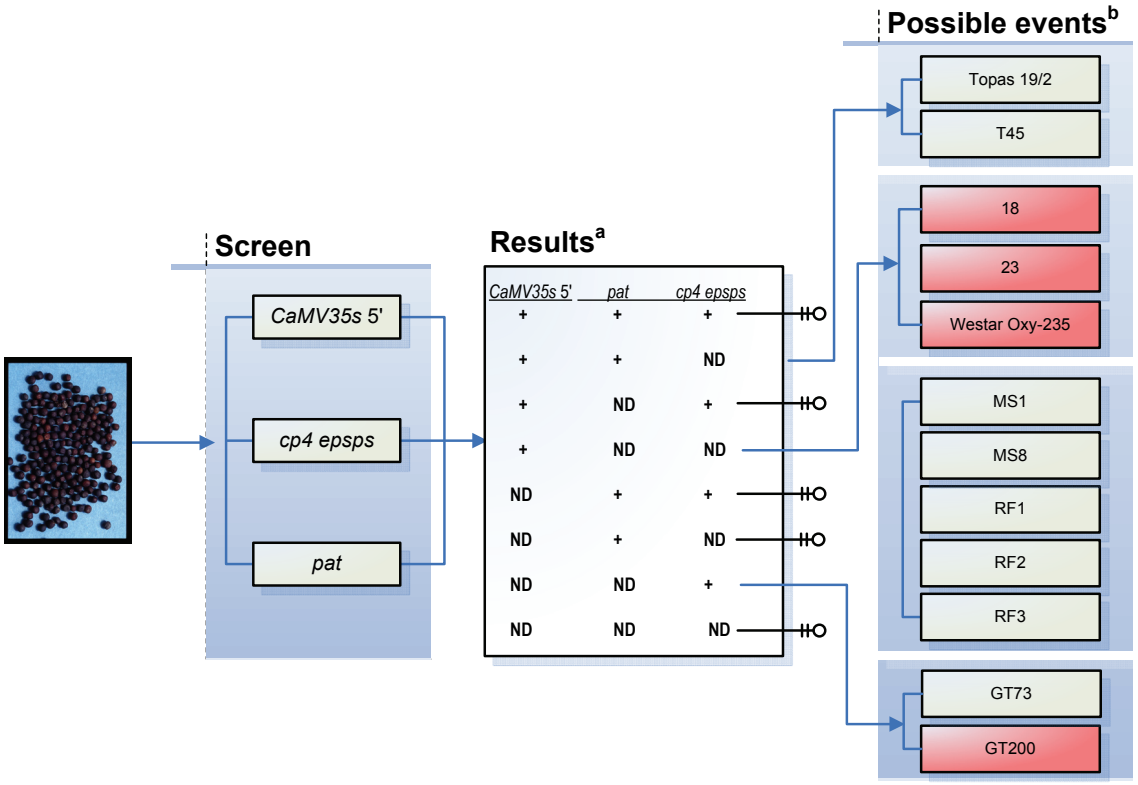

Figure 9.1: Flow chart representing the process to screen canola seed imported from the USA and Canada for unapproved GMOs. This flowchart has been developed assuming possible adventitious presence of a single unapproved GMO in non-GM plant seed based on a desktop evaluation of genetic elements within events. Unapproved GMOs are shaded in red.

ND, not detected. Flow lines extending from Results table and terminating with a circle indicate that there is no single GM event that can result in the observed combination of screening results.

[a] A positive result for the CaMV35s 5′ may indicate the presence of the Cauliflower Mosaic Virus itself and not a GM event.

[b] The approved GMOs, MS1, MS8, RF1, RF2 and RF3 are not detected using this screening combination.

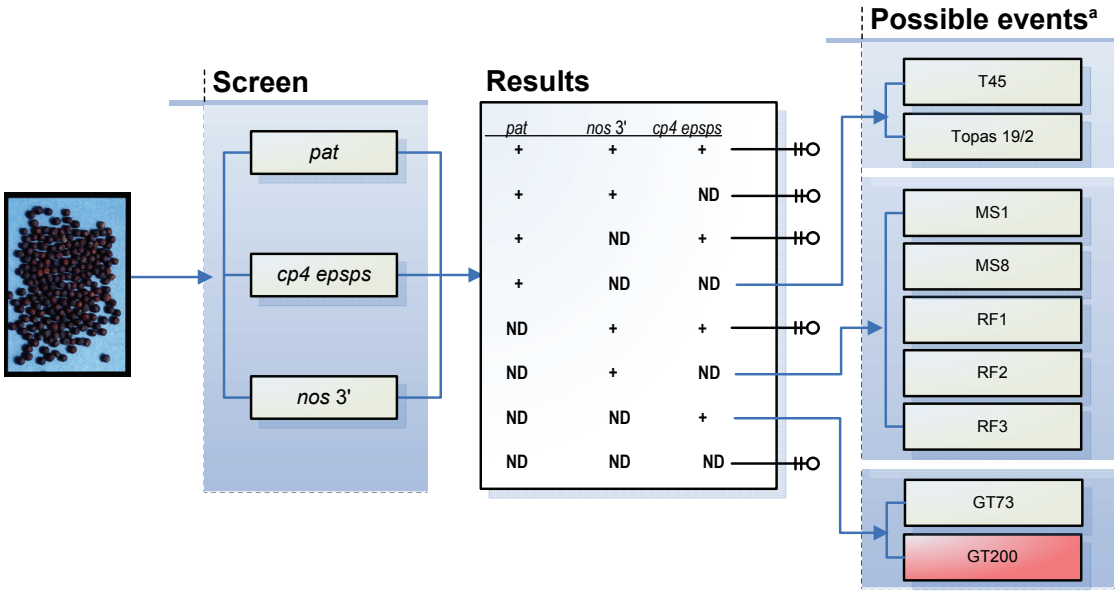

Figure 9.2: Flow chart representing the process to screen canola seed for approved GMOs. This flowchart has been developed assuming possible adventitious presence of approved GM canola in non-GM canola seed based on a desktop evaluation of genetic elements within events.

ND, not detected. Flow lines extending from Results table and terminating with a circle indicate that there is no single GM event that can result in the observed combination of screening results.

[a] Unapproved GMOs that would be detected using this screen are shaded in red.

If a quantitative PCR method is used for determining the level of AP of GM events, the method needs to be event-specific (Table 9.1), although in some cases a construct-specific method is also suitable. It is not valid to use a screening method to quantify the level of AP of GM events.

Table 9.1: Genetic elements of GM canola suitable for DNA-based screening methods

Event(s)	Target DNA for screening						
	CaMV35s 5'	*nos 3'*	*nptII*	*CMoVb35s 5'*	*pat*	*bar*	*cp4 epsps*
18 23	✓	-	✓	-	-	-	-
GT73 GT200	-	-	-	✓	-	-	✓
MS1 RF1 RF2	-	✓	✓	-	-	✓	-
MS8 RF3 MS8xRF3	-	✓	-	-	-	✓	-
T45 Topas 19/2	✓	-	-	-	✓	-	-
Westar-Oxy-235	✓	✓	-	-	-	-	-

Note: Shading denotes those GMOs not approved in Australia by the Regulator for commercial release.

Regulatory requirements for cotton

The major customers for Australia's exported cottonseed (note this is traded as a distinct commodity to cotton fibre) as a share of total exports in the five years to 2006/07 were Japan (79.9 per cent), the Republic of Korea (19.7 per cent) and Taiwan (0.4 per cent). For export of cotton to the small niche markets that require non-GM, the regulatory requirements and approval status for GM cotton within the relevant country should be considered. In Australia, five GM cotton varieties (three with stacked events) have been approved for commercial release by the Regulator (Appendix B, Table B3).

All GM cotton crops approved for commercial release in Australia have been approved in Japan and they have also been approved in Korea for food and feed. The tolerance levels for approved GM ingredients in non-GM consignments in Japan (5 per cent w/w) (United States Department of Agriculture - Foreign Agricultural Service 2007f; i) also apply to GM cottonseed.

The Republic of Korea applies a 3 per cent tolerance level for the AP of GM material in non-GM raw agricultural products (i.e. grain) used to produce processed foods and for products

used for animal feed. However, the tolerance level does not apply to the processed product itself (e.g. cottonseed oil) and applies only to the 20 raw agricultural products approved by Korea, including canola, maize, soybean and cottonseed. A 0.5 per cent tolerance level is currently applied to all other, non-approved, raw agricultural products (but see below).

Recently proposed changes to the Republic of Korea's KFDA GM labelling regime, which are yet to come into force, include:

- processed foods that contain any GM agricultural ingredients must be labelled
- previously exempt products (i.e. highly processed food such as soy sauce or cottonseed oil) must be labelled (a three year grace period for this requirement is proposed)
- GM-free labelling will be available but there will be zero tolerance for unintentional GM presence
- GM-free labelling cannot be applied to products that can't be tested for GMOs (i.e. highly processed foods such as soy sauce or cottonseed oil)
- GM labelling will also apply to alcoholic beverages.

Cotton testing options and capabilities

There is no single assay which will detect all GM cotton events relevant to Australia's domestic and international trade. However, all five GM cotton varieties approved by the Regulator for commercial release in Australia contain the *CaMV35s* 5' DNA sequence and four of the five events contain the *nos* 3' sequence (Table 9.2). Therefore, a single DNA screen is sufficient to detect all GMOs approved by the Regulator and our major trading partners for cottonseed. A combination of two or more assays will provide additional information regarding the specific events that may possibly be present in a sample.

In some cases, available screening tests will not distinguish approved from non-approved GMOs. For instance, the approved GMO MON1445 event and the unapproved GMO MON1698 event both contain the same DNA targets for screening, so a PCR screen will not distinguish between these two events. An event-specific test (PCR or other) would be required.

Dealings with GMOs are illegal in Australia unless authorised under the *Gene Technology Act 2000* (Cwlth). Hence, if unauthorised GMOs are detected in seed lots there is no need to determine the level of GM presence, because any level is illegal.

Currently, the only cotton varieties that have been commercialised in another country but are not approved in Australia are varieties with the 281 or 3006 events, and varieties (with stacked events) containing at least one of these events (Appendix B, Table B3). Since both of these events contain the *pat* gene which is not present in any of the Regulator-approved GMOs, a simple *pat* screen could be used to monitor for AP of these events in approved GM cottonseed. Confirmation of presence of the specific unapproved GMO would require additional testing, preferably using a validated event-specific method for conclusive evidence.

Lateral flow strip assays would be suitable screens for monitoring the AP of approved GM cottonseeds in non-GM cotton provided that the detection limit of the assay is taken into account. Alternatively, a single PCR screen to detect the *CaMV35s* 5' DNA sequence would be suitable (Table 9.2).

Table 9.2: Genetic elements of GM cotton suitable for DNA-based screening methods and laboratory capabilities.

Event(s)	Target DNA for screening					
	CaMV35s 5'	*nos 3'*	*nptII*	*CMoVb35s 5'*	*pat*	*bar*
MON1445	✓	✓	✓	✓	-	-
MON1698						
MON531	✓	✓	✓	-	-	-
LLCotton25	✓	✓	-	-	-	✓
MON15985	✓	✓	-	-	-	-
10211 10222 31807 31808 BXN MON757	✓	-	✓	-	-	-
MON88913	✓	-	-	✓	-	-
COT102	-	✓	-	-	-	-
MON1076	-	-	✓	✓	-	-
281 3006 MXB-13	-	-	-	-	✓	-
19-51a COT67B	-	-	-	-	-	-

Note: Shading denotes those GMOs not approved by the Regulator for commercial release in Australia.

Regulatory requirements for soybean

Australia imports soybean grain from the USA for processing and some seed. Ten GM soybean events have currently been reviewed and approved for cultivation in the USA (Appendix B, Table B4). There have been no applications for commercial release of GM soybean in Australia.

The Regulator has approved import and processing of GM soybean grain under Dealings Not Involving Intentional Release (DNIR) licences. These licences have included conditions to prevent the accidental or deliberate release of the imported grain into the environment, including transportation in sealed vehicles and processing so the grain is devitalised (i.e. made non-viable). DNIR licences are time-limited and do not confer general ongoing approval for import.

Currently, four of the GM soybean lines that have been reviewed in the USA for cultivation have been approved by FSANZ for use in food (Appendix B, Table B4). According to the relevant agricultural biotechnology companies, GTS 40-3-2 is the only GM soybean event that has been commercialised, although the commercialisation status of MON89788 was not supplied in the database (Biotechnology Industry Organization 2008).

Soybean testing options and capabilities

In Australia, the Regulator has not licensed any GM soybean lines for release into the environment (i.e. field trials or commercial release). Importation of viable soybean seeds for breeding or for seed-for-sowing could therefore be the primary sampling point along the supply chain for GM AP testing; if a GMO was detected, there would be no need to determine the level of GM seed or grain because any level of presence in such seed would be illegal. Where GM soybean lines have been approved for import and processing under DNIR licences,, they are permitted in grain for processing. For the GM soybean events that have been reviewed for cultivation in the USA, there is no single assay which will detect them all.

Nine GM soybean events have been approved by the USA for planting. Eight GM soybean varieties (including the three GM lines derived from event 206.05) contain the *CaMV35s* 5' DNA sequence, and the remaining variety contains the *cp4 epsps* gene (Table 9.3). So the minimum screening approach to detect all the relevant GM events and lines is a combination of two PCR assays that target the *CaMV35s* 5' and *cp4 epsps* genes (example in Figure 9.3). Not all soybean events reviewed in the USA have been approved by FSANZ (Table 9.3), and there is no screening combination that will differentiate all FSANZ-approved GM lines from those not approved by FSANZ (Table 9.3).

There are no PCR screening options that will distinguish the FSANZ-approved soybean lines, A2704-12 and A5547-127, from the unapproved lines, A2704-21, A5547-35 and GU262. If this is required, further testing would need to be undertaken if the initial screen suggested that a sample may contain one of these five GM events (Table 9.3), although methods to distinguish between these events are limited.

The suggested screening option (Figure 9.3) does not therefore distinguish between FSANZ-approved and unapproved GM events. Further testing, such as for the *bar* and *pat* genes, would be required to determine if the AP, in this case, was due to a GM line that was approved by FSANZ.

Table 9.3: Genetic elements of GM soybean suitable for DNA-based screening methods and laboratory capabilities.

Event(s)	Target DNA for screening				
	CaMV35s 5'	*nos 3'*	*bar*	*pat*	*cp4 epsps*
W62 W98	✓	✓	✓	-	-
GTS 40-3-2	✓	✓	-	-	✓
[a] 260-05 G94168 G94-1 G94-19	✓	✓	-	-	-
[b]A2704-12 A2704-21 A5547-35 A5547-127 GU262	✓	-	-	✓	-
MON89788	-	-	-	-	✓

Notes: Shading denotes those GM lines not approved in Australia by FSANZ for use in food. [a] G94168, G94-1 and G94-19 are lines derived from the event 260-05; [b] Screening options will not distinguish FSANZ-approved GM lines from those not approved by FSANZ.

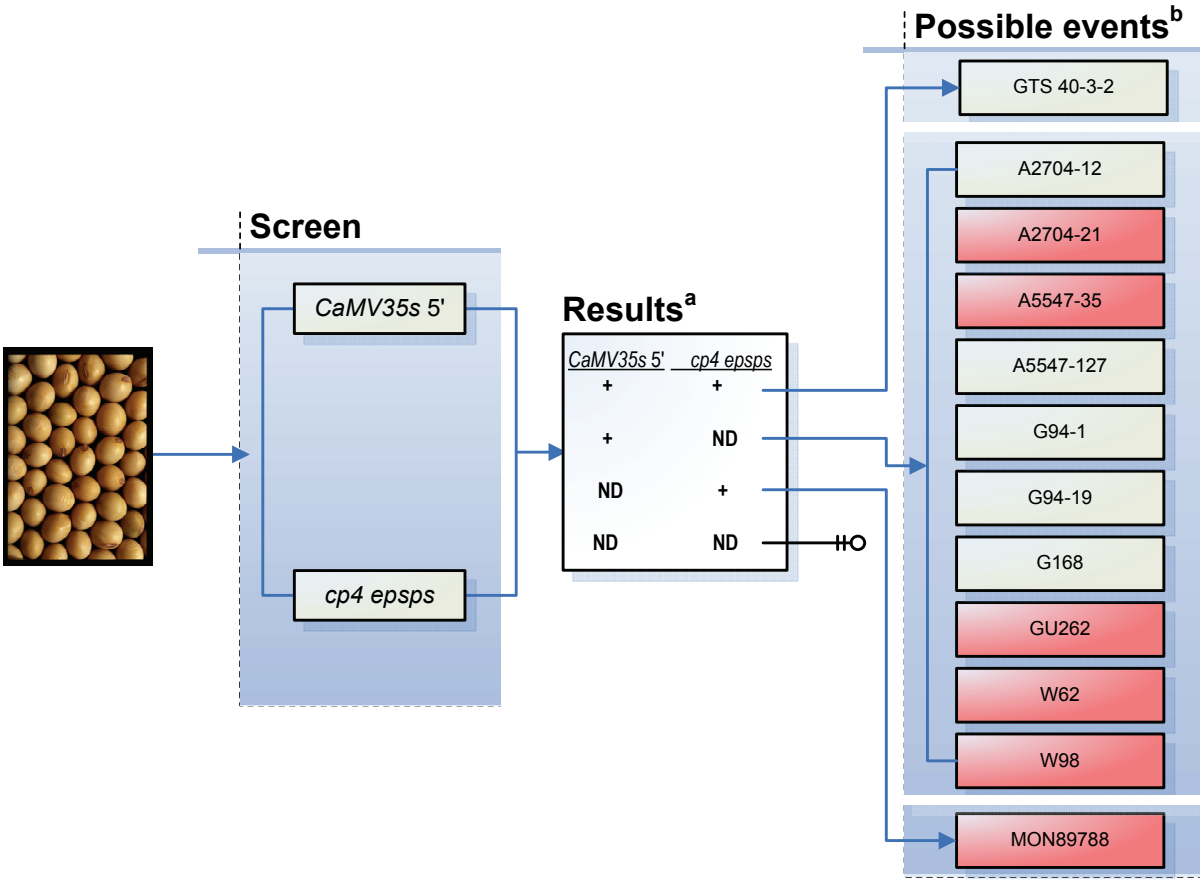

Figure 9.3: Flow chart representing the process to screen soybean seed and grain imported from USA for GM events. This flowchart has been developed based on possible presence of a single GM event in non-GM plant seed based on a desktop evaluation of genetic elements within events. None of these GMOs are approved for commercial release by Regulator.

ND, not detected. The flow line extending from Results table and terminating with a circle indicates that there is no single GM event that can result in the observed combination of screening results.

[a] A positive result for the CaMV35s 5′ may indicate the presence of the Cauliflower Mosaic Virus itself, and not a GM event.

[b] GM lines that have not been approved by FSANZ are shaded in red.

Regulatory requirements for maize

Australia imports small amounts of maize seed (mainly from New Zealand, which does not grow GM crops) and grain for processing (from the USA, where twenty-five GM maize events and one stacked event (MON88017 / MON810) have been reviewed for use in food and feed and seventeen events have been reviewed for cultivation). In Australia, no GM maize varieties have been approved for commercial release by the Regulator, therefore the presence of any GM maize events in imported maize seed-for-sowing is illegal. Where GM maize lines have been approved for import and processing by the Regulator under DNIR licences, the licences are time-limited and do not confer general ongoing approval for import. As in the case of imported GM soybean grain, licences include conditions to prevent the accidental or deliberate release of the imported grain into the environment.

Currently, thirteen of the GM maize lines reviewed in the USA for cultivation are approved by FSANZ for use in food in Australia (Appendix B, Table B5). Based on the information available, only two lines that have not been approved by FSANZ—DLL25 and T14—have been commercialised and grown in the USA.

Maize testing options and capabilities

As with soybean, because dealings with GMOs are illegal in Australia unless authorised under the *Gene Technology Act 2000* (Cwlth), imported maize seed-for-sowing could be one of the primary sampling points along the supply chain for GM testing. If unauthorised GMOs were detected in imported seed, there would be no need to determine the specific level of AP of the GM event; any level of presence is illegal.

Testing of maize for the presence of GM material could commence with an initial screen. If any GMO is detected, identification of the specific GMO may be required to determine if it is an unapproved event.

Twenty-one of the twenty-four GM maize events reviewed for use in the USA contain the *CaMV35s* 5' DNA sequence or a modification of this sequence (Table 9.4). Based on a desktop evaluation, a combination of two screens, for the *CaMV35s* 5' and *nos* 3' DNA sequences, should detect twenty-three of the twenty-four GM maize events (Table 9.4; example in Figure 9.4). However, there is no single screen available to detect the Ly038 event. Event-specific methods are available to identify and quantify the majority of GM maize events.

Table 9.4: Genetic elements of GM maize suitable for DNA-based screening methods and laboratory capabilities

Event(s)	Target DNA for screening					
	CaMV35s 5'	*nos 3'*	*bar*	*cry1Ab*	*pat*	*cp4 epsps*
MS3 MS6	✓	✓	✓	-	-	-
Bt-11	✓	✓	-	✓	✓	-
[a]MON802 MON809 MON80100 (MON801) MON88017 / MON810	✓	✓	-	✓	-	✓
MON810	✓	✓	-	✓	-	-
MON88017 NK603	✓	✓	-	-	-	✓
MON863	✓	✓	-	-	-	-
Bt-176	✓	-	✓	✓	-	-
[a]6275 DBT418 DLL25 (B16)	✓	-	✓	-	-	-
[a]676 678 680 T14 59122 1507 T25	✓	-	-	-	✓	-
GA21 MIR604	-	✓	-	-	-	-
LY038	-	-	-	-	-	-

Notes: Shading denotes those GM lines not approved in Australia by FSANZ for use in food. [a] Screening options will not distinguish FSANZ-approved GM lines from those not approved by FSANZ; to do this an event-specific test would be required.

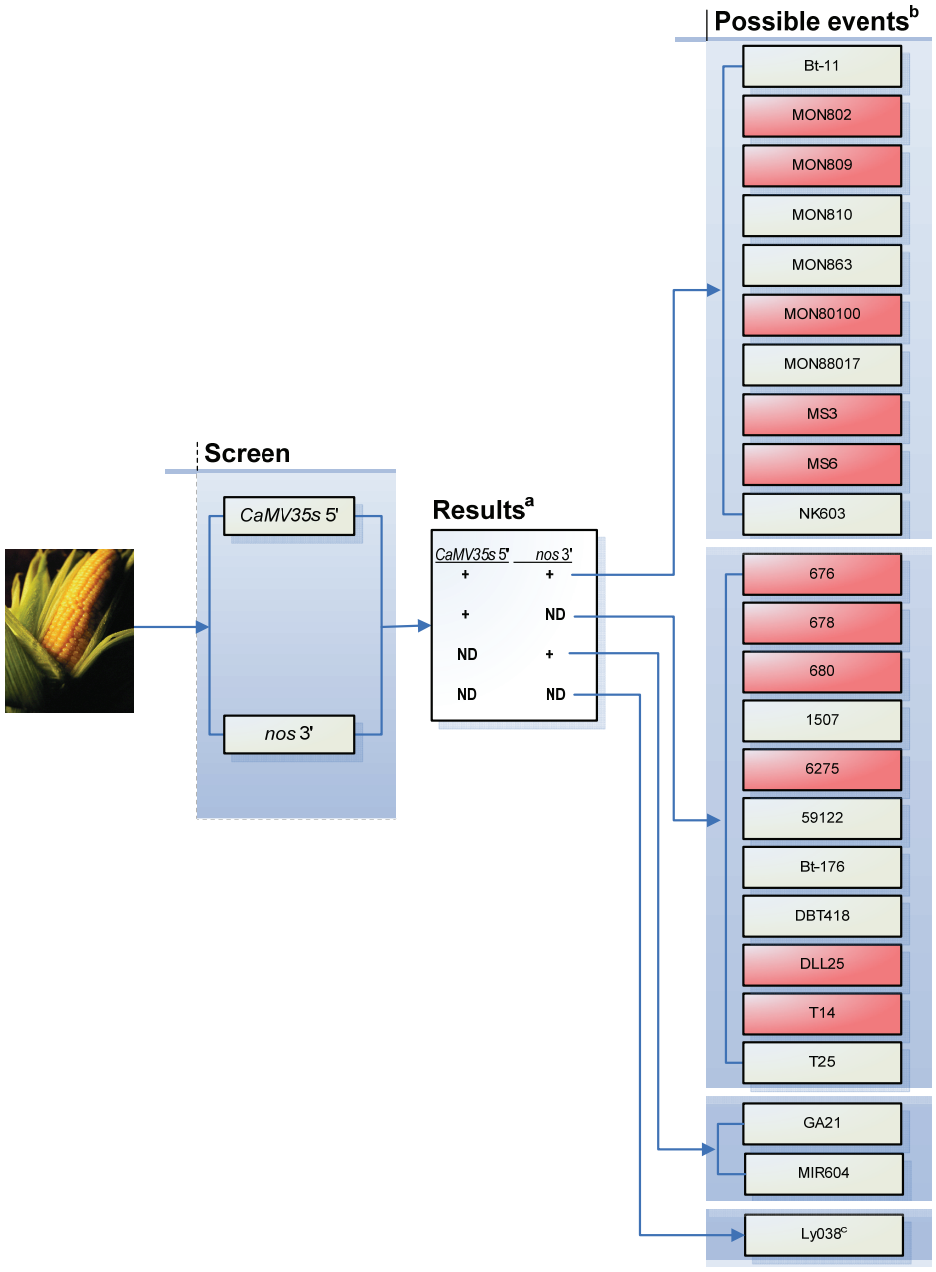

Figure 9.4: Flow chart representing the process to screen maize seed and grain imported from the USA for GM events. This flowchart has been developed based on possible presence of a single unapproved GM line in non-GM maize seed based on a desktop evaluation of genetic elements within events. None of these GMOs are approved for commercial release by the Regulator.

ND, not detected.

[a]A positive result for the CaMV35s 5′ may indicate the presence of the Cauliflower Mosaic Virus itself, and not a GM event;

[b]GMOs that have not been approved by the FSANZ are shaded in red; [c]Event Ly038 cannot be detected using common screens.

Section 5: Sampling and Testing Needs for Maintaining Product Integrity where both GM and non-GM grains are marketed

Chapter 10: Harmonisation, Standardisation and Accreditation in GMO Testing and GMO Laboratory Testing Capabilities

Harmonisation and standardisation of methods used in GMO testing laboratories

A major issue in testing for the presence of GMOs is that crops are tested using a variety of methods and instruments and in many different laboratories, in diverse countries. Results need to be accurate and comparable.

The choice of method can add variability to analytical results. Many different methods may be available to test for the same thing. Not only are there published methods, but custom methods are also commonly developed within a given laboratory. Bodies such as ISO, Codex, CRL-GMO and the JRC have the express aim of standardising testing methodology. They develop, validate and/or publish 'standard methods'. These methods have been shown to work and be fit-for-purpose, and are made available with the intention that they be used as common methodology among laboratories.

Certified reference materials are used to verify that both standard methods and laboratory developed methods are able to produce results that are accurate and comparable. A reference material is a substance whose value (i.e. per cent GMO content) is known, and is used to ensure that the detection method is capable of giving the correct results. There are commercially available reference materials for genetically modified crops that can be purchased as intact seed, ground seed, and extracted DNA, provided with a Certificate of Analysis specifying the GM content. However, reference materials are not available for all approved GM crops, let alone for unapproved crops. Also, there are only very limited sources of GM reference materials that are certified appropriately to ISO Guide 34:2000[30] (International Organization for Standardization 2000) so that the supplied value can be trusted (see below—Accreditation in GMO Testing Laboratories). Certified reference materials are available from AOCS in the USA or the Institute for Reference Materials and Measurements in the EU. Import and use of these reference materials in Australia is costly and as the materials are designated as quarantine materials, strictly controlled. Australia does not currently produce or supply reference materials.

The absence of reference materials in Australia is a major limitation to the development of standard protocols for seed testing. This is because a lack of reference materials may negate the ability to use quantitative PCR methods (i.e. real-time PCR) and is a major issue in regard to being able to evaluate the reliability of tests against false positives and negatives.

Any method used, whether it is a standard method or a method designed within the laboratory, should be shown to be capable of repeatedly producing accurate results and to be appropriate for the intended use. This is done through the process of validation. Standard methods have already been validated, but it should be verified that the results achieved are as expected when applied within the laboratory. This is generally done by assay of reference

[30] General requirements for the competence of reference material producers.

materials. The validation process in laboratory-designed methods is more in-depth, and guidelines have been published by the JRC that define the minimum performance requirements of a GMO analytical method. Before a GM food or feed can be authorised in the EU, there needs to be an analytical method for its detection validated to these requirements. The CRL-GMO maintains an online register of these validated methods for use as standard methods. GIPSA's Rapid Tests Performance Evaluation Program performs a similar validation function for commercially available lateral flow strip test kits.

Inter-laboratory collaborative studies are where multiple laboratories perform the same analytical method on 'identical' sample materials. These are an integral part of the validation of a method, proving that the method is robust enough to be applied between laboratories and still achieve accurate and reproducible results. Inter-laboratory proficiency testing schemes are where multiple laboratories perform their own method of analysis on 'identical' sample materials. This has the purpose of demonstrating the competency of the participating laboratories to accurately perform the analysis. Participation in proficiency studies is paid for by the participating laboratory. ISTA and the Food Analysis Performance Assessment Scheme are the main suppliers of this service for GMO analysis, conducting proficiency testing schemes multiple times per year.

Accreditation in GMO testing laboratories

The techniques described in the above section are used within a GMO testing laboratory to achieve harmonisation and standardisation of analytical techniques. The use and effectiveness of these techniques are demonstrated in industry by accredited compliance with the appropriate International Standard. 'ISO/IEC 17025:2005(E). General requirements for the competence of testing and calibration laboratories' (International Organization for Standardization 2005) was initially issued by ISO in 1999 and updated in 2005, and is the main standard used by testing and calibration laboratories.

ISO/IEC 17025:2005(E) is a tool for a testing laboratory to demonstrate their competence on an international scale in both laboratory management and technical capability. Accreditation to ISO/IEC 17025:2005(E) is not a blanket endorsement. Accreditation is only given for specific methods that have been audited and shown to conform to the standard. Accredited methods are reassessed periodically to ensure their continued compliance, and accreditation can be rescinded if the requirements of the standard are not met. If a laboratory is not accredited, it does not mean that it is incapable of doing the testing, but it means that it has not demonstrated its capability to the accrediting body. To maintain accreditation, laboratories are required to participate in relevant proficiency testing programs.

Testing laboratories demonstrate their compliance with ISO/IEC 17025:2005(E) by gaining accreditation from the relevant National Accreditation Body (Figure 10.1). In Australia, the National Association of Testing Authorities (NATA) is the only National Accreditation Body, and it is also a member of the International Laboratory Accreditation Cooperation (ILAC). ILAC is an international organisation with the aim of facilitating trade by promotion of acceptance of accredited test and calibration results. The ILAC Mutual Recognition Arrangement provides a peer-reviewed evaluation that accreditation bodies maintain conformance with their own relevant ISO standard (ISO/IEC 17011), and in so doing ensure that laboratories accredited by them are truly compliant with ISO/IEC 17025:2005(E). A similar function is performed by the Asia Pacific Laboratory Accreditation Cooperation (APLAC), but APLAC membership is restricted to National Accreditation Bodies within the Asia Pacific Region.

In the USA there are multiple national accreditation bodies capable of accrediting to ISO/IEC 17025:2005(E), including the American Association for Lab Accreditation (A2LA), Assured Calibration and Laboratory Accreditation Select Services (ACLASS), the International Accreditation Service, Inc (IAS), the National Voluntary Laboratory

Accreditation Program (NVLAP) and the Laboratory Accreditation Bureau (L-A-B). Canada has the Standards Council of Canada (SCC).

There are many national accreditation bodies in the European Union providing accreditation to ISO/IEC 17025:2005(E) including the United Kingdom Accreditation Service (UKAS) in the United Kingdom, in Germany the Deutches Akkreditierungssystem Prufwesen (DAP), and in Belgium BELAC, the Belgian Accreditation Structure.

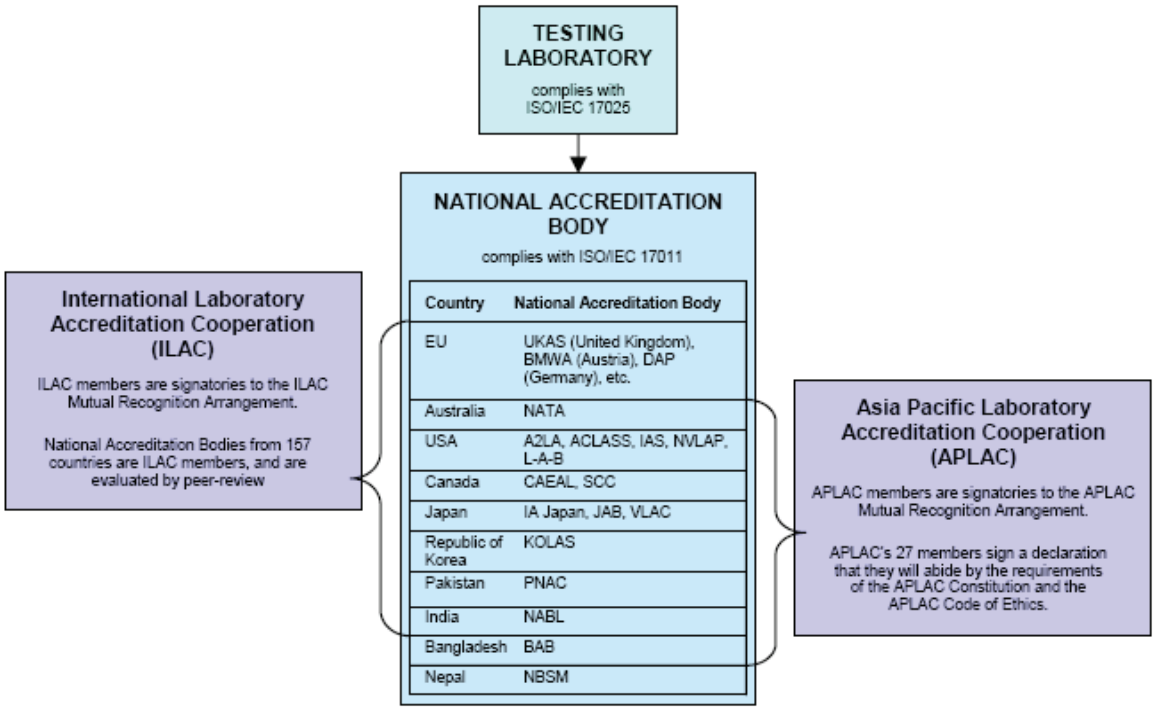

Figure 10.1: Laboratory accreditation process.

Limitations to use of sampling and testing methods

There are intellectual property restrictions on the use of analytical methods designed within individual laboratories for the detection and/or quantification of GM adventitious presence. Unpublished methods are the property of the laboratory that developed them, whereas standard methods or published methods have no restrictions on their use.

GMO laboratory testing capabilities

Three laboratories in each of Australia, North America (USA/Canada) and the EU (nine in total) were surveyed by NMI for this study to give an indication of GM testing capabilities in these countries. The information included in this section indicates only whether any of the laboratories surveyed within these regions has indicated a capability to conduct GM testing methodologies.

Laboratory testing capabilities for screening methods

Screening techniques are conducted to narrow down the possibilities of which adventitious GM events could be present by identifying groups of events with common elements. The capabilities of the surveyed laboratories to conduct screening techniques are not consistent between Australia, North America and the EU (Table 10.1). Not all of the screens recommended in the best practice screening packages described in Chapter 11 are currently able to be conducted within the Australian laboratories surveyed.

The ‘screening packages’ described in the following chapter are for sampling and testing for AP of GM events at several points along the supply chain. They outline details such as the stage in the supply chain, seed lot details, sampling protocol, analysis details and assay protocol. Depending on the situation and also on market demand, the packages could be used to screen for GMOs approved in Australia and for unapproved GMOs in imported commodities.

Table 10.1: Canola, Cotton, Soybean and Maize—laboratory testing capabilities using screening methods.

Target genetic element	Screening Package (Chapter 11)	Screening method available?		
		Australia	USA/Canada	EU
Canola				
CaMV35s 5′	Table 11.1	–	✓	✓
nos 3′	Table 11.1, 11.3	✓	✓	✓
CMoVb35s 5′		✓	–	✓
nptII		✓	✓	✓
cp4 epsps	Table 11.1, 11.2, 11.3	–	✓	✓
bar		✓	–	✓
pat	Table 11.1, 11.2, 11.3	✓	✓	✓
Other		✓	✓	✓
Cotton				
CaMV35s 5′	Table 11.4	✓	✓	✓
nos 3′		✓	✓	✓
CMoVb35s 5′		✓	–	✓
nptII		✓	✓	✓
cp4 epsps		✓	–	✓
bar		✓	–	✓
pat		✓	–	✓
Other		✓	–	✓
Soybean				
CaMV35s 5′	Table 11.5	✓	✓	✓
nos 3′		✓	✓	✓
cp4 epsps	Table 11.5	–	✓	✓
bar		✓	–	✓
pat		✓	✓	✓
Other		✓	–	✓

Target genetic element	Screening Package (Chapter 11)	Screening method available?		
		Australia	USA/Canada	EU
Maize				
CaMV35s 5′	Table 11.6	✓	✓	✓
nos 3′	Table 11.6	✓	✓	✓
nptII		✓	✓	✓
cp4 epsps		–	✓	–
bar		✓	✓	✓
pat		✓	✓	✓
cry1Ab		✓	✓	✓
Other		✓	–	✓

Notes: Laboratories were not requested to provide details on sampling protocols in relation to analytical test methods. Screening Packages described in Table 11.1, 11.2 and 11.3 (canola), Table 11.4 (cotton), Table 11.5 and 11.6 (soybean and maize); ✓, screening method available. –, screening method not available.

Once screening methods have been used to narrow down the possibilities of what adventitious GM events may be present in a lot, either trait-specific (protein) or event-specific (DNA) testing methods can be used to identity which event(s) are present within the seed sample submitted to the testing laboratory. For the laboratories surveyed, trait-specific or event-specific testing methods are not available for every canola, cotton and soybean event of interest to Australia's national framework. However, there is at least one trait-specific or event-specific testing method available for all maize events of interest in the laboratories surveyed.

Laboratory testing capabilities for trait-specific and event-specific methods

The laboratory capabilities identified by NMI do not appear to allow for comprehensive GM AP testing solely within Australia, but this does not mean that these capabilities are not present in other Australian laboratories not surveyed for this study.

Canola

From the 2008–09 season, Australia will be growing both GM and non-GM canola. If required, it may be necessary to test—for the purpose of meeting customer requirements in both domestic and export markets—declared non-GM canola grain for the AP of Regulator-approved GMOs. Australia also imports canola seed for breeding, and potentially grain from time to time, from countries where GM canolas are commercially grown. As discussed previously in this report, Australian seed breeding companies already carry out comprehensive AP testing in generating commercial seed-for-sowing so additional testing may be required only to confirm the integrity of imported non-GM canola grain.

Based on the laboratories surveyed, it appears that ten of the fifteen canola events of interest cannot be identified by trait or event-specific methods within Australia, and two of these cannot be identified within the USA, Canada and the EU (Table 10.2). However, it is important to note that in the laboratories surveyed, there is a qualitative and quantitative event-specific test available in Australia for the GM canola lines intended for commercial release in Australia and approved by the Regulator (GT73, MS8 and RF3). Five other GM canola events have been approved for commercial release by the Regulator (T45, Topas 19/2, MS1, RF1 and RF2); and, as mentioned above, there are no intentions to commercialise these

lines in Australia at this time. Of the remaining lines in Table 10.2, some (GT200 and 18) were never commercialised, and others have not been sold in North America for a number of years (T45, last seed sales in 2005; Topas 19/2, MS1, RF1 and RF2, last seed sales in 2003; Westar-Oxy-235, last seed sales 2001; and 23, last seed sales 1998)[31].

Table 10.2 Canola—testing capabilities in the surveyed laboratories for trait and event-specific methods.

Approval for cultivation in Australia[a]	Canola event	Trait-specific method available			Event-specific method available					
					Qualitative			Quantitative		
		Australia	USA/Can	EU	Australia	USA/Can	EU	Australia	USA/Can	EU
Approved	GT73	–	✓	–	✓	✓	✓	✓	✓	✓
	MS1	–	✓	–	–	–	–	–	–	–
	RF1	–	✓	–	–	–	–	–	–	–
	RF2	–	✓	–	–	–	–	–	–	–
	MS8	–	✓	–	✓	✓	✓	✓	✓	✓
	RF3	–	✓	–	✓	✓	✓	✓	✓	✓
	MS1xRF1[c,]	–	✓	–	–	–	–	–	–	–
	MS1xRF2[c,]	–	✓	–	–	–	–	–	–	–
	MS8xRF3	–	✓	–	✓	✓	✓	✓	✓	✓
	T45[b]	–	✓	–	✓	✓	✓	✓	✓	✓
	Topas 19/2[c]	–	✓	–	–	✓	–	–	–	–
Unapproved	18[e]	–	–	–	–	–	–	–	–	–
	23[f]	–	–	–	–	–	–	–	–	–
	GT200[e]	–	✓	–	–	✓	–	–	–	–
	Westar-Oxy-235[d]	–	–	–	–	✓	–	–	✓	–

Notes: Laboratories were not requested to provide details on sampling protocols in relation to analytical test methods. [a]All events approved for cultivation plus Westar-Oxy-235 are also approved by FSANZ for use in food. [b]Last seed sales in North America – 2005. [c]Last seed sales in North America – 2003. [d]Last seed sales in North America – 2001. [e]Never commercialised, but may have been used in field trials. [f]Last seed sales in North America – 1998. ✓, testing method available. –, testing method not available.

[31] www.biotradestatus.com, accessed 11 August 2008

Lateral flow test strips (trait-specific) may be commercially available for some GM canolas of interest; however, the Australian laboratories surveyed for this report did not report that they had such tests available. This does not mean that such tests are not used by other Australian laboratories not surveyed for this study.

Cottonseed

Australia imports cottonseed for use as germplasm in domestic cotton breeding programs. However, as discussed earlier, such germplasm would be extensively tested by the seed breeding companies to ensure that it is either non-GM, or, if it is intended to be GM, that only the intended GM events are present and that there is no AP of unintended GM events. Traditionally, Australia has not imported bulk shipments of cottonseed for processing into food and feed. As the majority of domestically produced cottonseed comes from GM cotton, if required by the market it may be necessary to test any identified non-GM cottonseed intended for export markets for the AP of Regulator-approved GMOs. There does not appear to be a demand for non-GM cottonseed in the domestic market. Of the laboratories surveyed by NMI, it appears that fourteen of the nineteen cotton events of interest cannot be identified by trait or event-specific methods within Australia, two of which also cannot be identified within the USA, Canada and the EU (Table 10.3). However, from Table 10.3, it is important to note that in the Australian laboratories surveyed, there are event-specific methods available to test for all the GM cottons except for MON88913 (Roundup Ready Flex®) approved by the Regulator for commercial release in Australia. Some other GM cottons may have been used in field trials but have never been commercialised[32].

Soybean

Australia may import soybean seed for use as germplasm in breeding programs and grain for processing (crushing). Soybean seed imported for use as germplasm undergoes extensive testing by seed companies for the AP of GM events. As stated earlier, no GM soybean is approved by the Regulator for commercial release in Australia.

Of the laboratories surveyed by NMI, it appears that of the twelve soybean events of interest, ten cannot be identified by trait or event-specific methods in Australia and eight of these events also cannot be identified within the USA, Canada and the EU (Table 10.4). This does not mean that the remaining events cannot be tested by other laboratories not surveyed. Further, it is important to note that a number of these events, whilst they may have been reviewed for planting in the USA, have never been commercialised[33].

[32] www.biotradestatus.com, accessed 11 August 2008

[33] www.biotradestatus.com, accessed 11 August 2008

Table 10.3: Cotton—testing capabilities in the surveyed laboratories for trait and event-specific methods.

Approval for food or cultivation in Australia	Cotton event	Trait-specific method available			Event-specific method available					
					Qualitative			Quantitative		
		Australia	USA/Can	EU	Australia	USA/Can	EU	Australia	USA/Can	EU
Approved for food and cultivation	LLCotton25	–	✓	–	✓	✓	✓	✓	✓	✓
	MON531[b]	–	✓	–	✓	✓	✓	✓	✓	✓
	MON1445	–	✓	–	✓	✓	✓	✓	✓	✓
	MON15985	–	✓	–	✓	✓	✓	✓	✓	✓
	MON88913	–	✓	–	–	✓	–	–	✓	–
Approved for food only	10211	–	–	–	–	–	–	–	–	–
	10222	–	–	–	–	–	–	–	–	–
	COT102	–	–	–	–	–	–	–	–	–
	MON757	–	✓	–	–	✓	–	–	–	–
	MON1076[a]	–	✓	–	–	–	–	–	–	–
	MXB-13	–	✓	–	✓	–	✓	✓	–	✓
Unapproved for either cultivation or food	19-51a[a]	–	–	–	–	–	–	–	–	–
	281	–	✓	–	–	✓	✓	–	✓	✓
	3006	–	✓	–	–	✓	✓	–	✓	✓
	31807	–	✓	–	–	–	–	–	–	–
	31808	–	✓	–	–	–	–	–	–	–
	BXN	–	–	–	–	✓	–	–	–	–
	COT67B	–	✓	–	–	–	–	–	–	–
	MON1698[a]	–	✓	–	–	✓	–	–	–	–

Notes: Laboratories were not requested to provide details on sampling protocols in relation to analytical test methods. [a]Never commercialised, but may have been used in field trials. [b]Not grown in Australia since 2004–05. ✓, testing method available. –, testing method not available.

Table 10.4: Soybean—testing capabilities in the surveyed laboratories for trait and event-specific methods.

Approval for food in Australia	Soybean event	Trait-specific method available			Event-specific method available					
					Qualitative			Quantitative		
		Australia	USA/Can	EU	Australia	USA/Can	EU	Australia	USA/Can	EU
Approved	A2704-12[a]	–	✓	✓	✓	✓	✓	✓	✓	✓
	A5547-127[a]	–	✓	–	–	–	–	–	–	–
	G94-1[a]	–	–	–	–	–	–	–	–	–
	G94-19[a]	–	–	–	–	–	–	–	–	–
	G168[a]	–	–	–	–	–	–	–	–	–
	GTS 40-3-2	–	✓	–	✓	✓	✓	–	✓	✓
	MON89788	–	✓	–	–	✓	–	–	–	–
Unapproved	A2704-21[a]	–	✓	✓	–	–	–	–	–	–
	A5547-35[a]	–	✓	✓	–	–	–	–	–	–
	GU262[a]	–	✓	–	–	–	–	–	–	–
	W62[a]	–	–	–	–	–	–	–	–	–
	W98[a]	–	–	–	–	–	–	–	–	–

Notes: Laboratories were not requested to provide details on sampling protocols in relation to analytical test methods. [a]Never commercialised, but may have been used in field trials in the USA. ✓, testing method available. –, testing method not available.

Maize

Australia may import maize seed for use as germplasm in breeding programs or as grain for processing (crushing). Maize seed imported for use as germplasm undergoes extensive testing by seed companies for the AP of GM events. As stated earlier, no GM maize is approved by the Regulator for commercial release in Australia.

Of the laboratories surveyed by NMI, it appears that fifteen of the twenty-five maize events of interest cannot be identified by trait or event-specific methods within Australia. Considering also the capabilities of the laboratories in the USA, Canada and the EU, all of the maize events of interest can be identified (Table 10.4). It is important to note that although the GM maize events below may have been approved for commercial production overseas, many of them were never used for commercial seed production, so a capacity for testing all the listed events would probably not be needed.

In addition to using trait-specific and event-specific methods to identify GM events, there are other techniques currently available and in the process of development (Chapter 4). These include microarrays, dynamic arrays and DNA fingerprinting techniques, but laboratory capabilities for these techniques were not evaluated in the laboratory capabilities survey for this report.

Table 10.4: Maize—testing capabilities in the surveyed laboratories for trait and event-specific methods.

Approval for food in Australia	Maize event	Trait-specific method available			Event-specific method available					
					Qualitative			Quantitative		
		Australia	USA/Can	EU	Australia	USA/Can	EU	Australia	USA/Can	EU
Approved	1507	–	✓	✓	✓	✓	✓	✓	✓	✓
	59122	–	✓	–	✓	✓	✓	✓	✓	✓
	Bt-11	–	✓	✓	✓	✓	✓	✓	✓	✓
	Bt-176	–	✓	✓	–	✓	✓	–	✓	✓
	DBT418[a]	–	✓	✓	–	✓	–	–	✓	–
	GA21	–	–	✓	✓	✓	✓	✓	✓	✓
	LY038	–	–	–	–	✓	–	–	–	–
	MIR604	–	✓	✓	✓	✓	✓	✓	✓	✓
	MON810	–	✓	✓	✓	✓	✓	✓	✓	✓
	MON863	–	✓	–	✓	✓	✓	✓	✓	✓
	MON88017	–	✓	–	–	✓	–	–	✓	–
	MON88017 / MON810	–	✓	✓	–	✓	–	–	–	–
	NK603	–	✓	–	✓	✓	✓	✓	✓	✓
	T25	–	✓	✓	✓	✓	✓	✓	✓	✓
Unapproved	676[b]	–	✓	–	–	–	–	–	–	–
	678[b]	–	✓	–	–	–	–	–	–	–
	680[b]	–	✓	–	–	–	–	–	–	–
	6275[b]	–	✓	–	–	–	–	–	–	–
	DLL25 (B16)[a]	–	✓	✓	–	✓	–	–	✓	–
	MON802	–	✓	–	–	–	–	–	–	–
	MON809[b]	–	✓	✓	–	–	–	–	–	–
	MON80100 (MON801)[b]	–	✓	✓	–	–	–	–	–	–
	MS3	–	✓	–	–	–	–	–	–	–
	MS6	–	✓	–	–	–	–	–	–	–
	T14[a]	–	✓	✓	✓	✓	✓	–	✓	–

Notes: Laboratories were not requested to provide details on sampling protocols in relation to analytical test methods. [a]Last seed sales in North America 1999. [b]Never commercialised, but may have been used in field trials. ✓, testing method available. –, testing method not available.

Chapter 11: Discussion and Analysis

This report has found that sampling and testing is already an integral part of maintaining product integrity in Australia's seed and grain supply chain. This section will address the important questions:

- What are the best points in the supply chain for sampling and testing for AP of GM events in order to maintain product identity?
- What could best practice sampling and testing screening packages look like?
- Can we look towards sampling and testing regimes in overseas coexistence models in order to be better prepared for an environment in which both GM and non-GM grain is marketed?
- What are the priority needs that should be addressed by the Australian seed and grain industry in regard to sampling and testing?

Recap on coexistence, segregation and thresholds

The National Framework to Develop Co-existence Strategies for GM and Non-GM Crops (see Chapter 5) summarises the factors which determine the thresholds established and maintained by industry as including:

- thresholds established in export markets by customers and if premiums will be paid for achieving those levels
- the technical and practical ability of the supply chain management system to process and deliver product consistently to levels below the threshold
- availability of appropriate testing technology.

For canola in Australia, the thresholds which have been adopted by the peak industry bodies, the Australian Oilseed Federation and the Australian Seed Federation, are 0.9 per cent GM canola grain in non-GM canola grain and 0.5 per cent GM canola seed in non-GM seed-for-sowing. Thresholds established by current and potential international trading partners in export markets are equal to or above the Australian industry thresholds. Therefore, providing Australian industry thresholds are met, other countries' thresholds should not present any barriers to trade, and growing GM canola in Australia would not be expected to impede access to markets.

This report has emphasised that managing segregation and working with thresholds is not new to the Australian seed and grain supply chain. For example, growers already manage for a threshold level of 0.4 per cent for barley in wheat, significantly lower than the 0.9 per cent threshold set for GM and non-GM canola. Growers also manage the segregation of products that cannot be differentiated by visual inspection, such as malting barley and barley used for animal feed which attract a significant price differential. The malting barley supply chain delivers a varietal purity standard of 98 per cent to maltsters.

The technical and practical ability of supply chain management systems to process and deliver product consistently to levels below thresholds has therefore been demonstrated in Australian agriculture. Thresholds are met and product integrity is maintained through effective segregation practices. In the case of the canola industry and GM/non-GM coexistence, segregation practices have been identified for canola seed breeders, growers and grain handlers to ensure that the AP of GM canola in non-GM seed and grain is below the 0.9 per cent threshold for GM canola in non-GM canola (Tables 6.1 and 6.2, and Fig. 6.1). Provided these canola coexistence practices are upheld, AP thresholds would be met, with

human error being perhaps the most likely potential risk (for example, a truck with GM seed being accidentally directed to unload into a non-GM silo at a grain receival site).

The National Framework also refers to specific coexistence strategies to incorporate 'access to sampling and testing regimes, with the aim of confirming, or providing evidence, that market and regulatory requirements are being met'. Sampling and testing confirms that segregation is being managed adequately and that the product's integrity has been maintained.

Current sampling and testing for GM in the supply chain

Australia currently imports canola seed for breeding purposes, use by seed companies for seed increase, and also as grain for processing for food or feed or for oil extraction. Grain and seed of soybean and maize are also imported, mainly for crushing for processing for food or feed but also small quantities for breeding or for seed increase. Most imported canola and maize is from New Zealand. Cotton germplasm is imported for breeding from time to time. Imported seed of maize, soybean and cotton (but not canola) require quarantine because they are 'quarantine restricted species'; restrictions relate to disease and pest risks, not to any risks arising from potential AP of GM events.

Some of the countries from which the seed and grain is imported have either commercialised or are in the process of reviewing for commercial release GM events for these four commodities. No sampling and testing for AP of GM events in imported bulk commodities is required at the border; and no quarantine risk associated with a specific GM event has been identified with any type of import of these commodities. The *Quarantine Act 1908* (Cwlth) requires prior approval via an import permit to import declared GM seeds and grain. AQIS relies on the declaration by the importer as to a shipment's GM status.

In the case of canola seed currently imported for plant breeding (germplasm enhancement), testing for the presence of both Australian-approved and unapproved GMOs is undertaken by industry.

Only GM events approved by the Regulator are allowed to be bred into canola, maize, cotton and cotton breeding lines. Any imports of seed which are GM would require a licence from the Regulator, unless already approved for commercial release in Australia. Conventional non-GM seed imported into Australia by seed companies would be certified seed.

At the time of writing, the only GM broadacre crop in Australia to have been grown commercially and processed through the complete supply chain is GM cotton. GM and non-GM cottonseed was segregated by the Australian cotton industry when GM cotton was first introduced, but following the lack of significant market demand for non-GM cotton, the latter is now delivered in a single supply chain. As a result, there is no requirement for the cotton industry as a whole to segregate or to carry out sampling and testing for AP of GM events past the seed breeding stage. There are few examples of non-GM cotton being segregated.

The Australian Bureau of Agricultural and Resource Economics (ABARE) reported that in 2005 around 20 000 t of Australian cottonseed was certified as derived from non-GM cotton and virtually all of this was exported (Foster and French 2007). For this reason, the cotton industry does not serve as an example or model for GMO sampling and testing needs and capabilities in a coexistence framework, or for managing segregation, for the Australian grain supply chain generally or for the canola supply chain specifically.

An AP threshold does not apply to cotton production in Australia. Furthermore, no GM soybean or maize is grown in Australia. Therefore, the only crop for which there is an AP threshold for GMOs in a non-GM crop is canola. Australian seed companies carry out appropriate sampling and testing of imported non-GM seed for breeding to ensure that it is free from the AP of any GMOs not approved by the Regulator. Sampling and testing is

performed according to the ISTA guidelines and their own internal protocols (see Chapter 6). Such sampling and testing maintains the integrity with respect to the non-GM status of the commercial non-GM seed supplied to growers.

In summary, the only part of supply chains where sampling and testing of conventional non-GM seed and grain for AP of GM material is currently conducted is in breeding and supply of certified seed by breeders and seed companies, as this is a critical stage where unapproved GMOs could enter supply chains.

Importing seed-for-sowing without testing would be a potential source for the introduction of unapproved GMOs into farm production systems, if the seed was imported from a country which grew GM crops and was intended for direct use by farmers in farm production. However, we are unaware of any canola, soybean, maize or cotton seed that is imported into Australia for such direct use by farmers; but if it was, it would need to be certified seed. Seed is imported in small quantities either for breeding or for seed increase by seed companies; or, in the case of soybeans and sometimes maize, in larger quantities for processing for food or feed. All imports of GMOs require authorisation under the *Gene Technology Act 2000* (Cwlth) and any release of a GMO to the environment requires a licence from the Regulator.

Potential future sampling and testing points for GM events in the seed and grain supply chain – Where?

Canola

For the 2008 season, about 10 000 ha of GM canola have been sown in NSW and Victoria. The crop is expected to yield 10 000–15 000 t of grain depending on the seasonal conditions. All harvested grain will be sold to appointed marketers and delivered to pre-determined receival points. For this season, GM canola grain will be stored separately from non-GM canola, and will be marketed by only specified companies. Other segregation arrangements of GM/non-GM canola would be expected to be made as larger amounts of GM canola are cultivated in coming seasons.

Extensive adoption by farmers of GM canola could see the need for sampling and testing for AP of Regulator-approved GM events introduced to points in the supply chain other than seed breeding. This would be dependent on whether there is a market for segregated non-GM canola and, if so, the size of the non-GM market relative to the total market and whether the market was domestic or export.

So, where else could sampling and testing occur in a GM/non-GM canola coexistence system, and how? To answer this question, this study has examined sampling and testing from a practical and scientific perspective and also considered if approaches developed overseas could be adapted to meet the Australian canola grain and oilseed industry needs.

Importantly, from the 2008 canola growing season onwards in Australia, the 'Canola' standard will be defined as a combination of GM and non-GM canola grain (see Chapter 6). If the market requests differentiation, 'non-GM canola' grain will be identified as a distinct commodity[34]. If, or where, there is a need to provide non-GM grain, sampling and testing practices along the supply chain would need to be sufficient to confirm that the presence of GM material above the threshold in non-GM grain can be detected.

As noted above, there is routine sampling and testing for GM events at the canola seed breeder stage. Seed industry stakeholders have indicated that the optimal point for sampling and testing for AP of GM events at the breeder stage is the point at which the seed breeding

[34] http://www.nacma.com.au/__data/page/227/No_20_of_08_New_Canola_Trading_Standards.pdf

flowchart (see Figure 6.2) splits into the 'breeder seed' and 'field trial' pathways, as this represents a 'testing gateway' where both the number of lines being tested and the volume of seed is small (discussed Chapter 6). Sampling and testing for AP of GM events is most practical at this point, especially for checking that GMOs not approved by the Regulator and/or by FSANZ are absent, so that the GM status of all seed exiting this point can be confirmed. The relevant screening package is shown in Table 11.1. Screening would need to be followed by more specific testing to distinguish approved and unapproved events. Such specific tests are outside the scope of this report.

Furthermore, if unapproved GMOs have not been detected in either imported seed used in early breeding or at the seed increase stage for seed-for-sowing, the need to test for unapproved GMOs further down the supply chain is greatly reduced and, we suggest, eliminated. Hence subsequent screening activities could be simplified because they could focus on the AP of approved GMOs in non-GM commodities (where there is market demand).

To date, there has been no need for sampling and testing to be conducted on-farm by growers, or at later stages in the supply chain, for AP of approved GMOs. Nor would on-farm sampling and testing in non-GM crops be needed in farming systems growing both GM and non-GM canola, provided farmers can be confident of the certified non-GM seed supply (above) and provided farmers comply with industry-developed crop management plans during on-farm production (see Chapter 6) so that the threshold of 0.9 per cent of GM grain in non-GM grain is maintained. An exception to the absence of a need for on-farm testing would be where a particular grain bulk handler(s) decided to require documentation of testing from farmers.

Marketers and exporters may in the future require documentation of testing of supplied grain from bulk handlers, and so the potential need for sampling and testing post-farm gate arises. Sampling and testing for a range of different quality characteristics of grain is already carried out routinely by bulk handlers, marketers and exporters. It would therefore be practical for any future sampling and testing for AP of GM events in canola to be integrated into the existing sampling and testing practices, that is, at grain receival at a silo and/or at grain outturn. The relevant screening packages are shown in Tables 11.2 and 11.3. Screening would need to be followed by more specific testing if there was a need to distinguish approved and unapproved events. Such specific tests are outside the scope of this report.

Cotton

Seed imported for breeding purposes is the key identifiable point for sampling and testing for events not approved by the Regulator. Imported seed could be tested using a simple *pat* gene screen to monitor for AP of unapproved events (see the 'Cotton testing options and capabilities' section, Chapter 9). Confirmation of presence of the specific unapproved GMO would require additional testing, preferably using a validated event-specific method for conclusive evidence.

Exported non-GM cotton could be tested for all GM events approved by the Regulator using a single DNA screen to detect the *CaMV35s* 5' DNA sequence (Table 9.2), in order to confirm non-GM status. The relevant screening package is shown in Table 11.4. Screening would need to be followed by more specific testing if there was a need to distinguish approved and unapproved events. Such specific tests are outside the scope of this report.

Soybean and maize

No GM soybean or maize lines are approved for commercial release in Australia and therefore no GM events should be present in any imported soybean or maize seed. Sampling and testing (for any GM events at all) at, or at any stage before, the breeder seed/field trial 'testing gateway' would confirm imported seed was non-GM. Relevant screening packages

are shown in Tables 11.5 and 11.6. Screening would need to be followed by more specific testing if there was a need to distinguish FSANZ-approved and –unapproved events. Such specific tests are outside the scope of this report.

In the case of GM soybean or maize grain imported for processing, a DNIR licence is required from the Regulator and approval from FSANZ is required for use in food.

Potential future sampling and testing for GM events in the seed and grain supply chain – How?

Several points for sampling and testing in current supply chains have been identified which seem practicable (discussed in the previous section). In the case of canola, cotton, soybean, and maize seed imported into Australia as new germplasm for breeding purposes, the key point is at the early seed breeding stage and also, at least, at the breeder seed/field trial 'testing gateway'. Sampling and testing at these points eliminates the prospect that unapproved GMOs can enter domestic production streams for non-GM commodities or, therefore, exported commodities or domestically produced food streams, from varieties or lines bred in Australia.

In the case of imported shipments of these commodities for seed-for-sowing, sampling and testing of seed at some stage before it was sown, either in the originating country and/or in Australia, would confirm the non-GM status of the seed (or, in the case of GM canola varieties approved for commercial release in Australia, confirm the GM variety) and this would further confirm that GM events not approved by the Regulator are absent. A risk-based national strategy to manage the unintended presence of unapproved GMOs in imported seed-for-sowing is in place (OGTR 2007).

Because a threshold for the AP of a GMO in a non-GMO commodity in domestic supply chains has been set only for canola, sampling and testing for AP is relevant to non-GM canola grain at bulk handling and/or grain supply stages, including supply for domestic food production and for export, to meet any non-GM market demand. In the case of cotton, although there is no domestic demand for a non-GM supply and therefore no need to sample and test for AP of GMOs; there could be a need for sampling and testing in the case where a niche overseas market required non-GM cottonseed.

In practical terms, the canola industry has indicated that bulk handling companies could monitor non-GM canola for the presence of GM grain at grain receival should markets require segregated product, as sampling and testing for other characteristics is routinely carried out at this stage. The initial step would be to determine the presence or absence of any GM grain in grain to be marketed as non-GM so that it can be appropriately unloaded at the receival point—this could involve a set of industry-designed protocols including declarations and/or testing. Segregations could then be tested at various points as determined by industry protocols and then tested again at grain outturn to meet customer requirements. Depending on these requirements, testing at some points of the supply chain could variously require sophisticated tests (including if there is a need to quantify GMO presence), or perhaps lateral flow test strips may be sufficient in some cases.

It is important to note that GM canola grain would be classed as Standard 'Canola' CSO1 (see Chapter 6), and thus it would not be necessary to test every load of grain at receival points: only those that were to be segregated as CSO1-a Standard ('Non-GM Canola').

Model sampling and testing screening packages

The matrix of unapproved and approved GMOs in the four commodities under consideration is complex, and becoming more complicated as more GM varieties are introduced into

commercial production. It is complicated because there may be approvals in the country from which we receive imports of seed and/or grain, but not in Australia—and even though approvals for commercial cropping may have been given in a country, the GM crop may never have actually been commercially grown. Further, approvals may be for food in Australia, but not for field release (commercial or trial), or there may be an AP threshold overseas but not in Australia (and vice versa).

In this report we have analysed: the current GM events which exist in canola, cotton, soybean and maize varieties in North America; their approval status in Australia (for food and for commercial field release); the production supply chains in Australia; thresholds in place in our major export markets; and, sampling and testing methods and technology. In this context, we have developed model sampling and testing screening packages (below) for potential use across the four crops at the identified sampling and testing points discussed above.

Whilst the specific screening packages provide feasible options for screening in the current context, it is important to note that they may not reflect what is needed and/or applied in the commercial or regulatory environment. Their currency will depend on which new GM varieties are introduced overseas or in Australia, and at what rate. The screening packages presented in this report could, however, be used as a model approach to ensure continued product integrity in the seed and grain supply chain. They also highlight the potential complexity of sampling and testing for specific purposes.

The sampling process described in Chapter 4 involves taking a number of primary samples from a seed lot, combining these to form a composite sample and reducing it (if it is too large) into a submitted sample to be sent to the laboratory. Key factors associated with this process are the confidence level and relative uncertainty. Understanding the confidence one can have that the results are correct and how far away the actual value could be from the calculated results plays a fundamental role when deciding a sample size. In regard to testing, qualitative PCR tests are the most reliable detection tests and so are to be recommended for determining presence/absence.

The sampling and testing screening packages below have taken the above factors into account when suggesting sampling and testing protocols, target confidence levels and the relative uncertainty (specified in each case).

Depending on the testing results, different decisions will need to be made. For example, if no GM events are detected in a certified non-GM seed or grain lot, it could continue to the next stage in the supply chain with no further sampling and testing requirements. For seed or grain lots, if the screen suggests that a GM event may be adventitiously present in a non-GM lot, further testing could be conducted to determine if the GMO(s) present is Regulator-approved and, if so, the level of GM presence (i.e. is it above or below the permitted AP threshold). Such further testing would require the availability of event-specific methods as discussed previously (Chapters 4 and 8). The outcomes would determine subsequent actions: for example the lot may no longer be classified as non-GM.

Canola

The following screening package (Table 11.1) has been developed for the situation where canola seed (for example, for germplasm enhancement or seed increase to commercial quantities) imported from the USA is tested to confirm that the seed lot does not contain AP of GMOs that have not been approved by the Regulator. This example uses the maximum permitted seed lot recommended by ISTA for canola of 10 tonnes. Since analytical testing to a zero presence level is not possible, this package is designed to confirm with a confidence level of 99 per cent that the seed lot contains less than 0.1 per cent GM seed which has not been approved by the Regulator for commercial release.

Table 11.1: Sampling and testing screening package for the scenario of an imported shipment of canola seed from the USA

Scenario: Imported shipment of canola seed from the USA	
Purpose of testing:	Monitoring for presence of GMOs not approved for commercial release by the Regulator, in imported shipments
Regulatory approval status:	Eleven GM events and three hybrids successfully reviewed in the USA for planting. Three of these GMOs are not approved in Australia
Threshold level:	No threshold (any presence level of unapproved GMOs is illegal)
Target confidence level:	99% confidence level that shipment contains less than 0.1% GM seed of unapproved GMOs
Seed lot details (see Chapter 4 for further information)	
Size of shipment:	10 tonnes (this is the maximum permitted lot size for canola seed based on ISTA guidelines)
Seed lot composition:	Assumed low level of heterogeneity
Target confidence level for sampling:	99% confidence level that laboratory sample is representative of the seed lot to within 10% of the true GM content at 0.1% GM seed
Sampling protocol	
Collect twenty primary samples of 0.5 kg each (Kruse 2004). Combine primary samples to produce a composite sample of 10 kg. Thoroughly mix and reduce by means of a suitable divider to a laboratory sample of at least 2.7 kg	
Critical factors: Sampling according to ISTA guidelines Thorough mixing of composite before dividing to minimum of 2.7 kg (based on data from Figure 4.2 and assuming an average canola grain weight of 5 mg)	
Analysis details (see Figure 9.1 for screening tests)	
Detection method:	Qualitative PCR detection of *CaMV35s* 5′, *pat* and *cp4 epsps* DNA sequences
Method LOD:	One GM seed in at least 1 000 seeds
Target confidence level for analysis:	99% confidence level that composite sample contains less than 0.09% GM seed (0.09% is the lower limit of sampling uncertainty for a sample with 10% uncertainty from a lot containing 0.1% GM)
Assay protocol	
Mix submitted sample using a riffle box. Collect six working samples of 1 000 seeds each (Remund et al. 2005). Extract DNA from each sample and analyse using the three DNA screening methods detailed above	
Critical factors: Submitted sample mixed prior to splitting	

Method validation and LOD estimation includes entire assay process Number of working samples required based on 5% false negative rates at the assay LOD	
Result	**Conclusion**
CaMV35s 5′, *pat* and *cp4 epsps* not detected in any working sample.	GM events not detected
Either *CaMV35s* 5′, *pat* or *cp4 epsps* detected in at least one working sample.	Screen suggests sample contains a GM event. Confirmation required through identification, based on Figure 9.1, of the event(s) present using event-specific methods

The following screening package (Table 11.2) has been developed for the situation where non-GM canola seed has been grown in Australia and is tested at grain receival to confirm that the seed lot (a 500 tonne silo lot) does not contain AP of Regulator-approved GM canola at a level above the 0.9 percent threshold. The screening package has been tailored to take advantage of the current sampling and testing practices that are already occurring at the grain receival point of the canola supply chain. The latter makes this an attractive point for sampling and testing grain, allowing early detection of misidentified GM canola being added to non-GM grain.

Different sampling rates for current testing of bulk grain commodities are specified for each bulk road unit, varying depending on the bulk road unit size. In the package below, sampling at 3 x 1 litre probes per 10 tonnes has been identified to cover this situation of varying bulk road unit sizes. The 500 tonne silo lot into which road unit lots are pooled is assumed to be highly heterogeneous. Excess sample material from that already collected for grain quality determinations is combined to form the basis of the composite sample required for this screening package. If the Australian grains industry were to adopt this type of sampling and testing screening package it would represent relatively little extra sampling work as the grain is already being sampled at this point to ensure it meets quality parameters. Extra testing would be three DNA screening tests for each bulk sample (a 500 tonne silo lot).

Table 11.2: Sampling and testing screening package for the scenario of receival of non-GM grain into storage by a bulk handling company

Scenario: Non-GM canola grain at receival into storage	
Purpose of testing:	Monitoring for adventitious presence of Regulator-approved GM canola in non-GM canola grain early in the grain supply chain (at grain receival)
Regulatory approval status:	Eight GMOs (and hybrids derived from some of these GMOs) approved for commercial release by the Regulator
Threshold level:	0.9%
Target confidence level:	99% confidence level that the storage unit contains less than 0.9% GM grain
Seed lot details (see Chapter 4 for further information)	
Size of lot:	500 tonnes This is the maximum lot size recommended by ISO. Larger storage sites could be treated as multiple 500 tonne silos
Seed lot composition:	Assumed highly heterogeneous due to incorporation of one or more misidentified bulk road units of GM grain 95% of GM material localised in 5% of the lot

Target confidence level for sampling:	99% confidence level that laboratory sample is representative of the seed lot to within 10% of the true GM content
Sampling protocol	
Sample each bulk road unit at the rate of three probes per 10 tonnes of grain (minimum of three probes). Thoroughly mix the contents of the probes and, to produce a bulk sample representative of the silo, combine increments consisting of 100 g from each probe (a total of 1.5 kg for a 500 tonne silo). Thoroughly mix the entire bulk sample according to ISO 13690:1999 (Ramsey and Ellison 2007) and reduce by means of a suitable divider to a laboratory sample of at least 0.3 kg	
Critical factors: Increments of equal size representing each probe on material added to the storage site Thorough mixing of bulk sample before dividing to minimum 0.3 kg (based on data from Figure 4.2 and assuming an average canola grain weight of 5 mg)	
Analysis details (see Figure 9.2 for screening tests)	
Detection method:	Qualitative PCR detection of *nos* 3′, *pat* and *cp4 epsps* DNA sequences
Method LOD:	One GM seed in at least 1 000 seeds
Target confidence level for analysis:	99% confidence level that composite sample contains less than 0.81% GM seed (0.81% is the lower limit of sampling uncertainty for a sample with 10% uncertainty from a lot containing 0.9% GM)
Assay protocol	
Mix laboratory sample using a riffle box. Collect three working samples of 600 seeds each (Remund et al. 2005). Extract DNA from each sample and analyse each extract using the three DNA screening methods above. Two or more positive results for a given event constitute a positive finding	
Critical factors: Laboratory sample mixed prior to splitting Method validation and LOD estimation determined based on the entire assay process Number of working samples required based on 5% false negative rate at the assay LOD	
Result	**Conclusion**
Neither *nos* 3′, *pat* nor *cp4 epsps* detected in any working sample.	GM events not detected
nos 3′, *pat* or *cp4 epsps* detected in at least two working samples.	Screen suggests sample contains GM event. Approximately 40% of samples containing 0.1% GM will give a positive result. Confirmation required through identification, based on Figure 9.2, and quantification using event-specific method

An alternative or additional point for monitoring canola for AP of GM events is at the grain outturn from country storages (see Figure 6.1). The following screening package (Table 11.3) has been developed for the situation where non-GM canola grain in a 200 tonne lot is tested to

confirm that any AP of Regulator-approved GM canola is below the AP threshold level for GM canola grain of 0.9 per cent. The lot is assumed to be highly heterogeneous. Such heterogeneity means that bulk samples should be prepared from a high number of increments. The preferred sampling method is therefore to use automated sampling equipment operating on the flowing grain as it leaves the silo. A qualitative PCR test with the ability to detect one GM seed in one thousand is recommended as opposed to using lateral flow test strips, because PCR testing is more sensitive. Sampling of the grain in the package accords with ISO guidelines.

Table 11.3: Sampling and testing screening package for the scenario of outturn of non-GM canola grain from a country storage site

Scenario: Non-GM canola grain at outturn from a country storage site	
Purpose of testing:	Monitoring for adventitious presence of Regulator-approved GM canola in non-GM canola grain at grain outturn from a country storage site
Regulatory approval status:	Eight GMOs (and hybrids arising from some of these GMOs) approved for commercial release by the Regulator
Threshold level:	0.9%
Target confidence level:	99% confidence level that shipment contains less than 0.9% GM grain
Seed lot details (see Chapter 4 for further information)	
Size of shipment:	200 tonnes (this is within the maximum lot size recommended by ISO of 500 tonnes)
Seed lot composition:	Assumed highly heterogeneous 95% of GM material localised in 5% of the lot
Target confidence level for sampling:	99% confidence level that laboratory sample is representative of the seed lot to within 10% of the true GM content
Sampling protocol	
Use an automatic sampler according to ISO 6644:2002 to collect 100 equal sized increments of between 0.1–1 kg each from flowing grain. Combine all increments to produce a bulk sample. Thoroughly mix the entire bulk sample according to ISO 6644:2002 (Ramsey and Ellison 2007) and ISO 13690:1999 (Ramsey and Ellison 2007) and reduce by means of a suitable divider to a laboratory sample of at least 0.3 kg	
Critical factors: Sampling according to ISO guidelines with a large number of increments Thorough mixing of bulk sample before dividing to minimum 0.3 kg (based on data from Figure 4.2 and assuming an average canola grain weight of 5 mg)	
Analysis details (see Figure 9.2 for screening tests)	
Detection method:	Qualitative PCR detection of *nos* 3′, *pat* and *cp4 epsps* DNA sequences
Method LOD:	One GM seed in at least 1 000 seeds
Target confidence level for analysis:	99% confidence level that composite sample contains less than 0.81% GM seed (0.81% is the lower limit of sampling uncertainty for a sample with 10% uncertainty from a lot

	containing 0.9% GM)
Assay protocol	
Mix laboratory sample using a riffle box. Collect three working samples of 600 seeds each (Remund et al. 2005). Extract DNA from each sample and analyse each extract using the three DNA screening methods above. Two or more positive results for a given event constitute a positive finding	
Critical factors: Laboratory sample mixed prior to splitting Method validation and LOD estimation determined based on the entire assay process Number of working samples required based on 5% false negative rate at the assay LOD	
Result	**Conclusion**
Neither *nos* 3′, *pat* nor *cp4 epsps* detected in any working sample.	GM events not detected
nos 3′, *pat* or *cp4 epsps* detected in at least two working samples.	Screen suggests sample contains GM event. Approximately 40% of samples containing 0.1% GM will give a positive result. Confirmation required through identification, based on Figure 9.2, and quantification using event-specific method

From an industry perspective, the sampling at grain receival is unlikely to represent a significant extra sampling burden as sampling is carried out at this point to test for other grain characteristics. However, the costs of PCR tests are high, and this would place extra costs on the processing of the grain, and hence, depending on the extent of testing, the final cost of non-GM grain in the domestic or international market. Sampling for GM events at grain outturn also incurs the extra costs of PCR tests.

Other potential challenges which could be presented by adopting the above screening packages include:

- delay in results could be a problem if outturned grain goes straight to the crusher; testing at grain receival, before storage, would therefore be better
- payment of farmers—if farmers are being paid a premium for non-GM grain (although, there is currently no indication in markets that there will be significant global demand for non-GM grain), but supply GM grain, this may not be known by the time farmer payments need to be made. Also, payments to farmers who actually supplied non-GM grain into the silo lot could be disadvantaged.

For some varieties, there is potential to avoid delays at the grain handling terminal by performing more rapid tests, either earlier in the supply chain or at the time of grain receival. Lateral flow strip tests are available for Roundup Ready® canola, and, while this remains the only commercially grown GM canola variety in Australia, these tests could form a part of a sampling and testing package. However, the robustness of the Roundup Ready® lateral flow strip tests under field conditions would need to be verified as studies on the efficacy of other lateral flow strip tests in the field have indicated unacceptable levels of false positive readings and variances in the LOD between the laboratory and the field.

Cotton

The following screening package (Table 11.4) has been developed to meet the situation where non-GM cottonseed is exported to a niche market overseas. The seed lot is tested prior to

export to confirm that any AP of GM cottonseed is present at a level of less than 0.1 per cent. This example uses a 20 tonne lot size which is less than the maximum permitted seed lot recommended by ISTA for cotton of 40 tonnes. The screening package is designed to confirm with a confidence level of 99 per cent that the seed lot contains less than 0.1 per cent GM seed.

Table 11.4: Sampling and testing screening package for the scenario of export of non-GM cottonseed for a niche market

Scenario: Export of non-GM cottonseed for a niche market	
Purpose of testing:	Monitoring for presence of Regulator-approved GM cotton in non-GM cottonseed for export
Regulatory approval status:	Five GMOs approved for commercial release by the Regulator
Threshold level:	0.1% tolerance level for adventitious presence
Target confidence level:	99% confidence level that shipment contains less than 0.1% GM seed
Seed lot details (see Chapter 4 for further information)	
Size of shipment:	20 tonnes (this is within the maximum lot size recommended by ISTA of 40 tonnes)
Seed lot composition:	Assumed low level of heterogeneity
Target confidence level for sampling:	99% confidence level that submitted sample is representative of the seed lot to within 20% of the true GM content at 0.1% GM seed
Sampling protocol	
Collect forty primary samples of 0.4 kg each (Kruse 2004). Combine primary samples to produce a composite sample of 16 kg. Thoroughly mix and reduce by means of a suitable divider to a laboratory sample of sufficient size for assay protocol (suggested size at least 1.5 kg)	
Critical factors: Sampling according to ISTA guidelines with a minimum composite sample of 15 kg (based on data from Figure 4.2 and assuming an average cottonseed weight of 110 mg) Thorough mixing of composite before dividing to submitted sample	
Analysis details	
Detection method:	Qualitative detection of *CaMV35s* 5′ DNA sequence
Method LOD:	One GM seed in at least 1 000 seeds
Target confidence level for analysis:	99% confidence level that composite sample contains less than 0.08% GM seed (0.08% is the lower limit of sampling uncertainty for a sample with 20% uncertainty from a lot containing 0.1% GM)
Assay protocol	
Mix submitted sample using a riffle box. Collect seven working samples of 1 000 seeds each (Remund et al. 2005). Extract DNA from each sample and analyse using the above DNA screening method	
Critical factors: Submitted sample mixed prior to splitting	

Method validation and LOD estimation includes entire assay process Number of working samples based on 5% false negative rate at the assay LOD A positive result may indicate presence of the Cauliflower Mosaic Virus itself, and not a GM event, so should be confirmed with additional testing	
Result	**Conclusion**
Negative result for all assays	GM events not detected
Positive result on at least one working sample.	Screen suggests sample contains GM event. Confirmation required to identify the GM event(s) present using event-specific methods

For the scenario of imported shipments of cottonseed, a simple *pat* screen could be applied to test for the presence of the two GM events not approved in Australia but approved and commercialised in the USA (see Chapter 9). Such testing (for example, by pre-breeders) would give confidence that unapproved events are not entering the Australian cotton production system. A sampling and testing package has not been developed for this scenario.

Soybean and maize

No GM soybean or maize varieties have been approved by the Regulator for field trials or commercial release in Australia. Six GM soybean lines (three derived from the same event) have been approved by FSANZ for use in food in Australia. FSANZ have also approved 13 GM maize lines for use in food. The import into Australia of GM soybean or maize for processing requires a DNIR licence[35] from the Regulator.

The following screening package (Table 11.5) has been developed to meet the situation where imported non-GM soybean in bulk is tested to confirm that it does not contain GM soybean. This example uses a 25 tonne seed lot which is less than the maximum permitted seed lot recommended by ISTA for soybean of 40 tonnes. Since analytical testing to a zero presence level is not possible (see Chapter 4), this package is designed to confirm with a confidence level of 99 per cent that the seed lot contains less than 0.1 per cent GM seed. The screen also provides the basis for further sampling and testing (beyond the scope of this report) to distinguish between GMOs which have FSANZ approval as GM foods and those which do not.

Table 11.5: Sampling and testing screening package for the scenario of an imported shipment of non-GM soybean from the USA

Scenario: Imported shipment of non-GM soybean from the USA	
Purpose of testing:	Monitoring for presence of GM soybean in non-GM soybean
Regulatory approval status:	No GMOs approved by the Regulator
Threshold level:	No threshold (any presence level of unapproved GMOs is illegal)
Target confidence level:	99% confidence level that shipment contains less than 0.1% GM seed
Seed lot details (see Chapter 4 for further information)	

[35] A DNIR licence may be issued by the Regulator for dealings NOT involving the intentional release of GMOs into the environment.

Size of shipment:	25 tonnes (this is within the maximum seed lot size recommended by ISTA of 40 tonnes)
Seed lot composition:	Assumed low level of heterogeneity
Target confidence level for sampling:	99% confidence level that submitted sample is representative of the seed lot to within 20% of the true GM content at 0.1% GM seed
Sampling protocol	
Collect forty primary samples of 0.7 kg each (Kruse 2004). Combine primary samples to produce a composite sample of at least 27 kg. Thoroughly mix and reduce by means of a suitable divider to a submitted sample of sufficient size for assay protocol (suggested size at least 3 kg).	
Critical factors: Sampling according to ISTA guidelines with a minimum composite sample of 27 kg (based on data from Figure 4.2 and assuming an average soybean weight of 200 mg) Thorough mixing of composite before dividing to submitted sample	
Analysis details (see Figure 9.3 for screening tests)	
Detection method:	Qualitative PCR detection of *CaMV35s 5′* and *cp4 epsps* DNA sequences
Method LOD:	One GM seed in 1 000 seeds
Target confidence level for analysis:	99% confidence level that laboratory sample contains less than 0.08% GM seed (0.08% is the lower limit of sampling uncertainty for a sample with 20% uncertainty from a lot containing 0.1% GM)
Assay protocol	
Mix laboratory sample using a riffle box. Collect seven working samples of 1 000 seeds each (Remund et al. 2005). Extract DNA from each sample and analyse using both DNA screening methods	
Critical factors: Laboratory sample mixed prior to splitting Method validation and LOD estimation includes entire assay process Number of working samples based on 5% false negative rate at the assay LOD	
Result	**Conclusion**
Neither *CaMV35s 5′* nor *cp4 epsps* detected in any working sample.	GM events not detected
Either *CaMV35s 5′* or *cp4 epsps* or both detected in at least one working sample.	Screen suggests sample contains GM event. Confirmation required through identification, based on Figure 9.3, of GM event present using event-specific methods

The following screening package (Table 11.6) has been developed to meet the situation where non-GM maize is imported. Since there are no GM maize varieties approved by the Regulator for commercial release in Australia, the seed lot is tested to confirm that it does not contain

any GM maize. This example uses a 25 tonne seed lot which is less than the maximum permitted seed lot recommended by ISTA for maize of 40 tonnes. Since analytical testing to a zero presence level is not possible, this package is designed to confirm with a confidence level of 99 per cent that the seed lot contains less than 0.1 per cent GM seed. The screen also provides the basis for sampling and testing to distinguish between GMOs which have FSANZ approval as GM foods and those which do not, in maize shipments for food and feed.

Table 11.6: Sampling and testing screening package for the scenario of an imported shipment of non-GM maize from the USA

Scenario: Imported shipment of non-GM maize from the USA	
Purpose of testing:	Monitoring for presence of GM maize in non-GM maize
Regulatory approval status:	No GMOs approved by the Regulator
Threshold level:	No threshold (any presence level of unapproved GMOs is illegal)
Target confidence level:	99% confidence level that shipment contains less than 0.1% GM seed
Seed lot details (see Chapter 4 for further information)	
Size of shipment:	25 tonnes (this is within the maximum seed lot size recommended by ISTA of 40 tonnes)
Seed lot composition:	Assumed low level of heterogeneity
Target confidence level for sampling:	99% confidence level that submitted sample is representative of the seed lot to within 20% of the true GM content at 0.1% GM seed
Sampling protocol	
Collect forty primary samples of 0.9 kg each (Kruse 2004). Combine primary samples to produce a composite sample of at least 34 kg. Thoroughly mix and reduce by means of a suitable divider to a submitted sample of sufficient size for assay protocol (suggested size at least 3 kg).	
Critical factors: Sampling according to ISTA guidelines with a minimum composite sample of 34 kg (based on data from Figure 4.2 and assuming an average maize kernel weight of 250 mg) Thorough mixing of composite before dividing to submitted sample	
Analysis details (see Figure 9.4 for screening tests)	
Detection method:	Qualitative PCR detection of *CaMV35s* 5′ and *nos 3′* DNA sequences
Method LOD:	One GM seed in 1 000 seeds
Target confidence level for analysis:	99% confidence level that laboratory sample contains less than 0.08% GM seed (0.08% is the lower limit of sampling uncertainty for a sample with 20% uncertainty from a lot containing 0.1% GM)
Assay protocol	
Mix laboratory sample using a riffle box. Collect seven working samples of 1 000 seeds each (Remund et al. 2005). Extract DNA from each sample and analyse using both DNA screening methods	

Critical factors: Laboratory sample mixed prior to splitting Method validation and LOD estimation includes entire assay process Number of working samples required based on 5% false negative rate at the assay LOD	
Result	**Conclusion**
Neither *CaMV35s 5′* nor *nos 3′* detected in any working sample.	GM events not detected
Either *CaMV35s 5′* or *nos 3′* detected in at least one working sample.	Screen suggests sample contains GM event. Confirmation required through identification, based on Figure 9.4, of GM event present using event-specific methods

Testing capabilities

Three laboratories in each of Australia, North America and the EU were surveyed for this study to give an indication of the GM testing capabilities in these countries. Australian laboratory testing capabilities identified in this report include event-specific testing capacity for all GM cotton and GM canola varieties approved by the Regulator for commercial release in Australia. While capabilities do not appear to include capacity to test for all GM events approved overseas, capabilities may exist in overseas and Australian laboratories not surveyed for this study.

The difference in cost for GMO testing between Australia, the USA and the EU is significant. For example, the cost of a qualitative PCR assay in the USA can be as little as US$12.75–209 (AUD$19.03–312), whereas in Australia and the EU it could cost between $400–680 and 109–222€ (AUD$209–426) respectively[36]. This cost differential in testing for AP of GM events is a major reason why Australian seed breeding companies currently send their seed samples for testing to accredited USA and European laboratories. It is also a reason why the bulk handling companies look towards using the lateral flow test strips as opposed to qualitative PCR testing. At about AUD$6–7 per strip test, using lateral flow test strips is significantly cheaper than engaging an accredited Australian laboratory to perform the testing.

Event-specific PCR primer sequences for the GM events are often held as Commercial-in-Confidence by the technology providers and only made accessible to a limited number of accredited laboratories around the world. This could explain why industry may not be able to undertake much qualitative PCR testing in-house. If the cost of testing for AP of GM events in accredited Australian laboratories could be reduced, this could lower overall costs to Australian industry of maintaining product integrity in a GM/non-GM canola coexistence framework, should such segregation be required in the market.

In issuing a licence for dealings involving an intentional release of a GMO into the environment (DIR licence), the Regulator can impose conditions. For DIR licences issued to date, the Regulator has required that "the licence holder must provide a written instrument to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence in a recipient organism." This testing methodology constitutes intellectual property of the licence holder and as such cannot be shared with commercial testing laboratories.

[36] Currency conversions correct as of 18 November 2008.

The international experience – can it inform Australia's sampling and testing needs for managing adventitious presence?

Approaches to the coexistence of approved GM and non-GM crops in different countries essentially fall into three groups. Some countries, for example the USA, Canada and Australia have adopted a non-legislative approach to coexistence. A second group, such as some EU countries, take a legislative approach (see Chapter 8), and a third group comprises the many countries that are still in the process of considering, developing, or formalising their approach to coexistence.

Coexistence experiences overseas could be instructive about how to address sampling and testing for AP of GM events in non-GM seed and grain. In this study (Chapter 8), we therefore looked for sampling and testing components in existing and proposed coexistence strategies in the USA, Canada, EU27 countries and the countries to which Australia exports significant volumes of canola and cottonseed.

With the exception of the EU, we found few sampling and testing components that formed part of legislation-based strategies. As highlighted in Chapter 8, strategies often focus mostly on managing physical admixture through handling methods and gene flow at the on-farm level though physical isolation (or separation) distances between GM and non-GM crops; sampling and testing for GM events is not a common requirement. Whether the coexistence approach is legislative-based or non legislative-based, the specific sampling and testing protocols and methods to be employed are not prescribed, consistent with the approach by, for example, ISTA. However, principles and/or guidance may be provided and international standards referenced, and, if in a legislated framework context, there may be a recommendation or a statutory requirement to comply with them.

Contrasting approaches are exemplified by the following two documents. First is the EC Recommendation on technical guidance for sampling and detection of GMOs and material produced from GMOs in seed, food and feed products (2004/787/EC), which fulfils requirements set out in Regulation No. 1830/2003 on the traceability and labelling of GM organisms and the traceability of food and feed products produced from GMOs (see Chapter 8). Second is the SVGA Principles—and associated technical documents, particularly the ASF Best Practice Guidelines (see Chapter 6).

The first document illustrates an approach that is statute-based, with detailed reference in a guidance document to strategies, standards and processes relevant to sampling and testing. The latter documents illustrate an industry-based self-regulatory approach, which also includes detailed reference to strategies, standards and processes. In both these examples, the guidance/recommendations are detailed. The essential difference in approach is whether or not there is associated government intervention through legislation. The industry self-regulated approach relies on breeding programs and seed companies to have in place quality management systems to ensure compliance and so meet any market demand for segregated product.

The international experience with coexistence models and sampling and testing for GM events can help inform Australia's needs, but does not provide any 'off-the-shelf' approach that can or should be adopted. This is because approaches to coexistence are determined and constructed around two drivers—market-specified demands and statutory regulatory requirements; these vary by commodity and by country, and so sampling and testing needs can become commodity- and country-specific. The sampling and testing needed is that which delivers the commodity which meets the market-specified and/or legally-specified requirements.

In the case of coexisting approved GM crops (approved both for commercial field release and for food) and non-GM crops, the sampling and testing issue is not one of ensuring that some safety threshold has not been exceeded or that an unapproved GMO(s) is absent. One view is,

therefore, that the market should determine whether or not there is a need for a coexistence strategy, industry should be responsible for any strategy, and AP thresholds themselves should be what are realistically practical. AP thresholds for approved GM events in non-GM commodity tend to be set at about 0.9% for grain or higher, across different countries.

This is essentially the approach that applies in Australia in the case of canola, although Tasmania has effectively set a zero presence threshold, while acknowledging it is not possible to sample and test to zero presence. The sampling and testing packages presented in this report are examples of the kinds of best practice packages that can be constructed. However, packages need to be tailored to the specific combination of the following: the AP threshold to be met; the target confidence levels for the test accuracy, representativeness of the sample, and analysis; the seed lot size; and, the particular commodity (taking into account grain size and weight).

In the case of the sampling and testing that is needed to determine the absence of unapproved GMOs or the absence of any GMOs, the AP threshold is presence. However, analytical testing to zero is not possible, because methods are limited by their sensitivity. Sampling and testing packages for any given commodity therefore need to acknowledge the limits of detection of the methods to be used and to specify the number of seeds to be sampled in a test working sample. A realistic testing plan would specify at least 99% confidence that any AP is below 0.1%.

As described in Chapters 7 and 8, both non-government (ISTA and ISO) and government (for example, the USDA GIPSA and the European JRC and CEN) standard setting bodies already produce comprehensive relevant rules and standards and accredit and certify laboratories. While sampling theory and methodology are well established, testing methodology continues to evolve. More efficient, effective and economic testing methodology is continually being developed. Any organisation or laboratory involved in testing therefore needs to be aware of current testing methods and select the most appropriate test to meet the purpose required.

Needs that could be addressed by the Australian seed and grain industry in regard to sampling and testing

The SVGA process resulted in the grains industry agreeing to the *Principles for process management of grain within the Australian supply chain: a guide for industry in an environment where GM and non-GM grain is marketed*. This document underpins the Australian grains industry approach to coexistence (Chapter 6; Tables 6.1 and 6.2), describing the Principles that the industry will adopt in order to maintain their product integrity and meet domestic and export customer requirements in any grains commodity. This document contains the standards, quality assurance practices and sampling and testing regimes which supply chain participants may use to meet customer requirements.

Reference to specific sampling and testing regimes in the SVGA document is currently limited, due to the desire not to impose a specific sampling and testing regime across the entire industry. This approach acknowledges the fact that a sampling and testing regime that works in one sector of the industry may not necessarily be practical in another.

The sampling and testing screening packages for AP of GM events presented in this report provide a level of detail and transparency that may be of benefit to the grains industry, their customers and others. They could also serve as models or be adapted or refined, as appropriate, for use by industry (for example the sampling and testing screening package for canola grain at the grain receival or grain outturn points). Successful development of packages now, when there is no significant GM canola production in Australia to warrant extensive testing of non-GM canola grain, could position industry for a potential future need, should markets require ongoing segregation.

The need to work towards harmonisation of sampling and testing protocols for GM events was also raised earlier in this report (Chapter 9). Harmonisation stems from the need to judge that results are reliable and comparable. Appropriate reference materials are required in order to verify that testing methodologies used in different laboratories are able to produce accurate and comparable results. For example, in an ideal harmonised system, the sampling and testing carried out by an Australian bulk handling company at its grain receival points should be comparable with, and use the same testing methodologies as, the sampling and testing carried out on the grain received at port by an importing country. This would help ensure consistency in results when testing the same seed lot.

In addition to establishing consistency through harmonisation, sampling and testing practices will need to be adapted as future GM crops enter the marketplace. The points in the supply chain where seed and grain should be tested for AP may need to be reassessed in a given commodity, and procedures for sampling may also need to be changed accordingly, with changed characteristics of the seed and grain.

Concluding Statement

In an environment of growing global trade in GM commodities, understanding the sampling and testing protocols of other countries and their diverse contexts, and appreciating the varied systems and standards and levels of harmonisation that exist, will become an increasingly important aspect of the sampling and testing approaches that need to be applied within the Australian seed and grain supply chain. The sampling and testing screening packages presented in this report could be used as a model approach to continue maintaining product integrity in the seed and grain supply chain.

In regard to coexisting GM and non-GM varieties of a crop in a farming system, the sampling and testing needs of the Australian seed and grain industry for AP of GM events in non-GM seed and grain will ultimately depend on the market demand for differentiated products.

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Appendix A – Regulatory Arrangements for GMOs and GM products in Australia and Australia's Major Export Markets for Canola and Cottonseed

Australia

Table A1: Australia – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	The *Gene Technology Act (2000)* (Cwlth) (the Act) and the Regulations and corresponding state and territory laws provide a nationally consistent system to regulate development and use of gene technology in Australia. Dealings with GMOs (including research, manufacture, production, transport, destruction, commercial release and import) are regulated by the Gene Technology Regulator (the Regulator) supported by the Office of the Gene Technology Regulator (OGTR) under the Act. The object of the Act is to protect human health and safety and the environment by identifying and managing potential risks posed by gene technology through regulating certain dealings with GMOs. Dealings with GMOs are illegal in Australia unless authorised under the Act.
Marketing approval	The Regulator has approved certain lines of GM cotton, canola and carnations for unrestricted commercial release into the environment. GM products (products which are derived from a GMO but that are not a GMO; for example a purified protein derived from a GM bacteria) are not regulated under the Act unless there is no existing product regulator (however, the GMO producing the product would need to be approved by the Regulator). The use of GM products is regulated by other regulatory agencies, for example Food Standards Australia New Zealand (FSANZ), the Therapeutic Goods Administration (TGA), and the Australian Pesticides and Veterinary Medicines Authority (APVMA). FSANZ regulates food produced using gene technology, meaning a food which has been derived or developed from an organism which has been modified by gene technology. FSANZ is responsible for carrying out safety assessments of GM foods on behalf of the Australian Government, the state and territory governments of Australia and the Government of New Zealand (under Food Standard 1.5.2—Food Produced Using Gene Technology). As of July 2008, FSANZ has approved 35 GM foods/food ingredients from seven crops: soybean, canola, maize (corn), potato, sugar beet, lucerne and cotton.
Imports	GM seed-for-sowing and grain imported into Australia must be declared to the Australian Quarantine and Inspection Service (AQIS). AQIS provides quarantine inspection for (amongst other things) plants and plant products arriving in Australia in accordance with the *Quarantine Act 1908* (Cwlth). The *Quarantine Act 1908* (Cwlth) requires the importer to obtain prior approval (via an import permit) to import declared GM seeds and grain. In deciding whether to grant a permit to import a seed of a kind of plant that was produced through genetic manipulation, the Director of Quarantine must take into

	account any risk assessment prepared, and any decision made, in relation to the seed by the Regulator under the Act. The importation of GM seed-for-sowing to Australia intended for commercial release or for release in an open-environment field trial requires authorisation under the Act and actual release requires a licence from the Regulator. To date, imports of GM grains for processing and use in food and/or feed but which have not been approved for commercial release, have been authorised under licences for 'dealings not involving an intentional release' (DNIR). The licences include conditions to prevent release of the GMO, including requiring containment during transport and storage, and devitalisation of the grain.
Labelling	Labelling of approved GM food is required to indicate that it is GM or contains GM ingredients. The purpose of labelling is for consumer choice, and not for food safety reasons. There are some instances where labelling of approved GM foods or ingredients is not required, for example in highly refined foods where the effect of the refining process is to remove novel DNA and/or novel protein, or where the approved GM food is unintentionally present in the food, ingredient or processing aid at a concentration of no more than 10g/kg (1 per cent) per ingredient. The FSANZ Food Standard 1.5.2—Food Produced Using Gene Technology—and the labelling requirements under that Standard apply only to food for humans and do not apply to animal feed. Stockfeed legislation in Australia is the responsibility of State and Territory jurisdictions and jurisdictions each have their own stockfeed legislation. There are no labelling requirements in regard to animal feed that is a GM crop or contains feed ingredients derived from a GM crop. To date, for GM crops approved for commercial release the Regulator has concluded that they are as safe (for human health and the environment) as their conventional counterparts and may be used in the same manner, including for animal feed. In Australia, industry has adopted threshold levels for the labelling of non-GM canola grain and seed-for-sowing which may contain the adventitious presence (AP) of GM canolas approved by the Regulator. The AP thresholds are 0.9 per cent GM canola in non-GM canola grain and 0.5 per cent GM canola in non-GM canola seed-for-sowing. Above these thresholds the canola must be labelled as GM canola.

Japan

Table A2: Japan – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	In Japan, commercialisation of GM crop plants requires environmental, food and feed approvals. Four Ministries are involved in the regulatory framework – the Ministry of Agriculture, Forestry and Fisheries (MAFF), the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT).
Marketing approval	Based on the Food Sanitation Law (FSL), the MHLW is responsible for the food safety of GM products. All GM foods must undergo a safety assessment prior to being awarded certification for distribution to the domestic market. The Food Safety Commission (FSC) performs food and feed safety risk assessments for MHLW and MAFF. As of February 2008, Japan had approved 88 GM events in seven crops (potato, soybean, sugar beet, maize, canola, cotton and alfalfa) for use in food products; 52 GM events in six crops (canola, maize, soybean, cotton, sugar beet and alfalfa) for use in animal feed; and 14 GM events for use in producing six food additives (α-amylase, rennet, pullulanase, lipase, riboflavin and glucoamylase).
Imports	It is illegal to import GM products that have not been approved. To assure compliance, a sampling program is in place to test both import shipments and processed food products at the retail level. Testing of imported foods at ports is handled by the MHLW directly. All testing is performed according to sampling and testing criteria set by the MHLW. The testing is normally carried out by a Japanese Government Agency called FAMIC—Food and Agricultural Materials Inspection Center. MAFF monitors quality and safety of imported feed ingredients at the ports. Japan ratified the Cartagena Protocol on Biosafety in November 2003.
Labelling	Labelling of GM foods is legislated under two laws—the FSL and the Japan Agricultural Standards (JAS). Under the FSL, if the GM content of the top three ingredients in these foods exceeds 5 per cent of the total weight of the foods, they must be labelled with either the phrase 'Biotech Ingredients Used' or 'Biotech Ingredient Not Segregated' if the raw material is not accompanied by certificates of identity preservation handling. In order to be labelled 'Non-Biotech', the processor must be able to show that the ingredient to be labelled was identity-preservation-handled from production through to processing. Under the JAS law, Japan has set an informal tolerance of 5 per cent for GM ingredients in products that are labelled 'Non-Biotech'. This tolerance only applies to events that have been approved in Japan. If MAFF or MHLW finds a product labelled 'Non-Biotech' that has a

	GM content of greater that five per cent, it is determined that the identity preservation handling has not been carried out correctly and the product must be re-labelled as ‘Biotech Ingredients Used’.

United States Department of Agriculture – Foreign Agricultural Service (2007f).

Pakistan

Table A3: Pakistan – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	The responsible government ministries are: Environment; Food, Agriculture and Livestock; Science and Technology; and Health and Education.
Marketing approval	National Biosafety Guidelines were approved in April 2005; however, to date no GM crop has been approved for cultivation on a commercial scale. The implementation and monitoring mechanisms of the proposed guidelines are built upon a three tier system comprising the National Biosafety Committee (NBC), a Technical Advisory Committee (TAC), and the Institutional Biosafety Committees (IBCs) at the level of distinct organisations. The Secretary of the Ministry of Environment heads the NBC and is responsible for overseeing all laboratory work and field trials, and authorising the commercial release of GM products.
Imports	Pakistan has signed the Cartagena Protocol on Biosafety. Biotechnology products are sold in all segments of society. Industry and consumers are using GM soybean, soybean oil and other processed food products.
Labelling	Pakistan does not have any labelling requirements for food or feed derived from GMOs.

United States Department of Agriculture – Foreign Agricultural Service (2007g).

China

Table A4: China – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	The Ministry of Agriculture (MOA) is China's primary governing body over agricultural biotechnology issues. The MOA Ministerial Decrees 8, 9 and 10 create the legal framework under which GM products are regulated. Other government agencies, such as the General Administration on Quality Supervisions Inspection and Quarantine (AQSIQ) and the State Environmental Protection Administration (SEPA) are also involved.
Marketing approval	China has commercialised five GM plants domestically since 1997 (cotton, tomato, sweet pepper, petunia and papaya). The MOA is chiefly responsible for approval of GM crops for import and domestic production. SEPA is the lead authority for negotiation of the Cartagena Protocol on Biosafety. AQSIQ is responsible for the nationwide management of the inspection and quarantine for entry and exit of all GM products; Ministerial Decree 62 governs the steps that importers or exporters of GM products need to take at customs. The National Biosafety Committee (NBC) evaluates applications for safety certificates for GM products for different uses as submitted by both domestic and foreign seed developers. The National Technical Committee for Standardisation of Biosafety Management of Agricultural GMOs is responsible for drafting and revising technical standards for agricultural GMOs including standards for safety assessment and sampling and testing.
Imports	China ratified the Cartagena Protocol on Biosafety in 2005. The MOA must approve GM products that are intended for import into China. The approval process varies depending on the product's intended use and the potential risk to human or animal health and the environment. For importation of GM products as processing materials, a foreign seed developer must apply for an agricultural GMO safety certificate from MOA's Agricultural GMO Biosafety Office. The regulations require applicants to have certification that the exporting country has allowed the use and sale of the GM products in its domestic market and that they have undergone tests there showing no harm to human or animal health or the environment. The MOA also requires environmental and food safety tests conducted by Chinese institutions, to verify data provided by the seed developer. All these documents are reviewed by the National Biosafety Committee before the MOA can issue a safety certificate. China has approved four GM crops for import as processing materials (soybean, maize, canola and cotton). The safety certificate of a food crop is valid for three years and that of a non-food crop is

	valid for five years.
Labelling	Governed by the MOA, China requires approved GM products be labelled and prohibits the importation and sale of any unlabelled or mislabelled products. The regulations spell out the type of labelling as well as the language required to be used.

United States Department of Agriculture – Foreign Agricultural Service (2007h).

Bangladesh

Table A5: Bangladesh – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	The Ministries of Agriculture (MOA), Science and Information technology (MOSICT) and Environment and Forest (MOEF) are jointly responsible for the development of a biotechnology policy and regulatory framework. MOSICT is the lead agency for biotechnology research and development, and MOEF is the lead agency for biosafety. In 2006 Bangladesh approved a National Biotechnology Policy that emphasises protection of indigenous knowledge, collective innovation and community rights. The Secretary of the MOEF heads the National Technical Committees on Biosafety (NCB). The principal role of the NCB is to draft legislation and measures to ensure the environmentally safe management of modern biotechnological development. The draft Biosafety Guidelines developed in 2000 under the leadership of the MOSICT, contain standards and codes of practice related to 'risks' associated with the environmental release of GMOs. They propose a decision-making framework that will allow experimental field-testing based on: the testing agency's familiarity with the plant and genetic modification; the ability to confine the GM plant; and, the perceived environmental impact should the GM plant escape confinement.
Marketing approval	Bangladesh has yet to establish a regulatory framework for agricultural biotechnology, and as such no GM crop has yet been approved for commercial cultivation. Bangladesh does not differentiate between GM or non-GM agricultural commodities.
Imports	Bangladesh is a signatory to the Cartagena Protocol on Biosafety. It ratified the Protocol in 2004, but rules to implement the protocol have not yet been formulated. There are no GM-specific barriers on imports.
Labelling	Bangladesh has no regulations governing the labelling of GM products.

United States Department of Agriculture – Foreign Agricultural Service (2007a).

EU-27

Table A6: EU-27 – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	There are two EU laws under which technology providers can file an application for the authorisation of GM products – Regulation (EC) No 1829/2003 (under the control of the Directorate General for Health and Consumer Protection (SANCO)) and Directive 2001/18/EC (under the control of the Directorate General for the Environment).
Marketing approval	Under Regulation (EC) No 1829/2003 a company can file a single application for a GM event and all its uses by submitting it to the competent authority of the Member State where the product will first be marketed. The Member State will then forward the application to the European Food Safety Authority (EFSA) for review. EFSA conducts a single risk assessment and may grant a single authorisation for a GM event and all its uses. The findings of the EFSA review apply to all EU Member States. If EFSA issues a positive risk assessment, the application is then forwarded to the European Commission (EC), which has responsibility for risk management. The EC will then present a proposal to Member States recommending they authorize the marketing of the product. The Member States then review and vote on the proposal in a regulatory committee. A qualified majority (QM) is required to approve the proposal. If the proposal fails to get a QM, it then goes to the Agriculture Council of Ministers for review. If the Council fails to make a decision within three months, the EC may then authorise the marketing of the product. Under Directive 2001/18/EC, a company may file an application for the marketing of a GM event for cultivation, importation and processing into different products. This procedure differs from that under Regulation (EC) 1829/2003 in that when the application is submitted in the Member State, that country's competent authority performs the safety assessment (as opposed to the EFSA). If a favourable assessment is issued, then the results are shared with EC and all other Member States who may approve the GM event for marketing within the EU or may raise objections. If objections are raised by other Member States, the EC will ask the EFSA to conduct a risk assessment. The approval procedure is then as for Regulation (EC) 1829/2003, except that the Environment Council of Ministers is responsible for reviewing EC proposals if Member States cannot reach an agreement.
Imports	The EU is a signatory to the Cartagena Protocol on Biosafety. See above for requirements for importing GMOs into the EU.
Labelling	All food and feed products containing GMOs and or produced from GMOs, including products that no longer contain detectable traces of GMOs, must be labelled. Before a product can be labelled as GM, the European Commission must review its safety and authorise its marketing. EFSA must also issue a positive risk assessment.

	Labelling regulations for products containing or consisting of GMOs are presented in Regulation (EC) No 1830/2003, article 4B. These regulations apply to bulk agricultural commodities such as whole grains and oilseeds. Labelling regulations for food and feed products that are produced from GMOs are presented in Regulation (EC) No 1829/2003— Articles 12–13 for food and Articles 24–25 for feed. The adventitious presence level for EU-approved varieties of GMOs for use in food and feed is set at 0.9 per cent. Above this level, all products must be labelled. For GMOs that are not formally approved but which have received a positive EU risk assessment, the adventitious presence level is set at 0.5 per cent. Above this threshold, the product is not allowed on the EU market. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labelling. No threshold for the adventitious presence of GM seeds in conventional seed lots has been established, meaning any seed lot containing GM seed authorised for cultivation must be labelled as containing GMOs. Seed lots containing GM seed that is not authorised for cultivation cannot be marketed in the EU and must be returned to point of origin or destroyed.
Traceability	Under Regulation (EC) No 1830/2003, business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of placing on the market. This information must be transmitted throughout the commercial chain and must be retained for five years. The regulation covers all products, included food and feed, containing or derived from GMOs that have received an EU authorisation. For GMOs intended for deliberate release in to the environment operators must transmit specified information on the identity of the individual genetic modifications the product contains. For GMOs intended for food, feed or processing operators may either transmit the specified information or transmit a declaration that the product shall be used only as food or feed or for processing together with the identity of the GMOs from which the product was derived. For food and feed produced from GMOs, operators must inform the next operator in the chain that the product is produced from GMOs. The EC has also established a system for the development and assignment of unique identifiers for GMOs (Commission Regulation 65/2004). Under this system, a unique identifier is assigned to each GMO as a means of tracking its presence and indicating the specific GM event covered by the authorisation for it to be marketed in the EU.

United States Department of Agriculture – Foreign Agricultural Service (2007c).

India

Table A7: India – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	The regulatory framework for GM events and products in India is governed under the Environmental Protection Act (EPA) 1986. This covers research, development, large-scale use as food or feed and imports. There are six competent authorities for handling the responsibilities under this Act.
Marketing approval	The Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forest (MOEF) is the nodal agency responsible for implementing the 'Rules for manufacture, use / import / export and storage of hazardous micro-organisms / genetically engineered organisms or cells, 1989' (the 'Biotech Rules') under the EPA. The Department of Biotechnology (DBT) under the Ministry of Science and Technology (MST) provides guidelines and technical support to the GEAC. The DBT also evaluates and approves the safety assessment of GM research and development in India. The Ministry of Agriculture (MOA) evaluates and approves the commercial release of transgenic crop varieties through multi-location trials conducted for assessing agronomic performance. The Ministry of Health and Family Welfare (MHFW) evaluates and approves the safety assessment of GM crops and products for human consumption. Currently, there are no restrictions on the marketing of domestically produced GM cottonseed oil and meal for consumption.
Imports	India ratified the Cartagena Protocol on Biosafety in 2003. India has approved imports of soybean oil derived from Roundup Ready® soybean for consumption after refining. No other food products are officially permitted for commercial import. All imports containing GM events or products must receive prior approval from the GEAC and complete a mandatory declaration. The import of GM seeds is regulated by the national Bureau of Plant Genetic Resources under the Plant Quarantine Order (PQO) 2003.
Labelling	India supports the mandatory labelling of GM foods in the Codex Alimentarius. It has not yet enacted a GM food labelling regulation(s).

United States Department of Agriculture – Foreign Agricultural Service (2007e).

United States of America

Table A8: USA – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	Established in 1986, the *Coordinated Framework for Regulation of Biotechnology* describes the Federal policy for regulating products developed using modern biotechnology. The USA Government Agencies responsible for implementing this Framework are: • The United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS); • The United States Environmental Protection Agency (USEPA); and • The Department of Health and Human Services' Food and Drug Administration (FDA). USDA-APHIS is the lead agency for ensuring the safety of release of GMOs into the environment, but shares with USEPA the responsibility for the release of GM crops modified to express pesticides (for example GM insect resistant cotton).
Marketing approval	The FDA is the lead agency for food safety assessment of GMOs.
Imports	The import of GMOs into the USA is permitted with the joint approval of all three agencies. The USA (like Australia) is not a signatory to the Cartagena Protocol on Biosafety.
Labelling	If the FDA rules that a GMO is 'substantially equivalent' to its conventional counterpart, labelling is not required. However, labelling would be required if the FDA considers consumers need to be alerted to a potential safety issue. There are no GMOs that require labelling currently on the market in the USA.

United States Regulatory Agencies Unified Biotechnology Website (n.d.) and Foster and French (2007).

Republic of Korea

Table A9: Republic of Korea – regulatory arrangements for GMOs and GM products

Experimental and commercial release into the environment	The Korean Ministry for Food, Agriculture, Forestry and Fisheries (MiFAFF) regulates labelling of unprocessed GM products and is responsible for conducting environmental risk assessments (ERA) of GM crops. The Korean Food and Drug Administration (KFDA) is responsible for the food safety approval of GM crops and the labelling of processed food products that contain GM components. The Ministry of Knowledge Economy (MKE) is the responsible authority for implementation of Korea's obligations under the Cartagena Protocol on Biosafety (CPB). No GM crops have been commercialised in Korea and as a result, the process for crop and food approval has only been applied to imported products to date.
Marketing approval	Currently, food safety approvals for GM crops are mandatory but ERAs are voluntary. When Korea's *Act on Transboundary Movement of Living Modified Organisms* (LMO Act) takes effect (expected in 2008), it will implement Korea's obligations under the CPB and ERAs will become mandatory. The scope of Korea's ERAs has so far been limited to approval of GM crops for unintentional release into the environment. As of July 2007, 50 GM events had received food safety approval and 21 had completed ERAs. Food safety approval has been given to GM varieties of soybean, maize, cotton, canola, potato and sugar beet.
Imports	Korea has ratified the CPB, and is expected to start implementing its provisions in 2008. Korea imports both GM crops and processed products derived from GM crops. Maize imported for human consumption is nearly all identity-preserved non-GM. Soybean imported for food processing (not vegetable oil), for example tofu, bean paste, bean sprouts, is nearly all identity-preserved non-GM. The KFDA maintains a zero-tolerance policy for the unintended presence of GM events in organic produce. Korea still requires a 'Starlink-free' certificate and 'Starlink-free' statement to accompany all maize imports intended for food use from the USA. Korea also requires multiple testing of all shipments of rice from the USA to confirm the absence of LibertyLink® rice. Korea's MiFAFF requires that two separate tests be carried out prior to loading and the KFDA requires a third test upon arrival. Once the rice is released into the market, the MiFAFF conducts a fourth test to verify the absence of LibertyLink® rice.
Labelling	Unprocessed GM crops intended for human consumption that have been approved by the KFDA are required to carry GM labels. A 3 per cent adventitious presence of a GM event in a non-GM consignment is allowed and this tolerance level applies to 20 raw agricultural products approved by Korea including cottonseed, canola, soybean

	and maize. Vegetable oils and processed sugar are exempt from labelling requirements. For processed products, labelling for GM components is required for 27 different food categories if either of the following apply: GM soybean or maize comprise one or more of the top five ingredients in the final product; or Foreign protein or DNA inserted into the product using modern biotechnological methods is still present in the final product. The KFDA has recently proposed expanding mandatory GM labelling to GM cotton, canola and sugar beets (see note below). In April 2007, MiFAFF introduced GMO labelling requirements for animal feed. Under these requirements, retail-packaged animal feed products are required to carry a GMO label on the packaging if GMO ingredients have been used.

United States Department of Agriculture – Foreign Agricultural Service (2007i).

Note: The recently proposed changes to the Republic of Korea's KFDA GM labelling regime, which are yet to come into force, include:

- processed foods that contain any GM agricultural ingredients must be labelled
- previously exempt products (i.e. highly processed food such as soy sauce or cottonseed oil) must be labelled (a three year grace period for this requirement is proposed)
- GM-free labelling will be available but there will be zero tolerance for unintentional GM presence
- GM-free labelling cannot be applied to products that can't be tested for GMOs (i.e. highly processed foods such as soy sauce or cottonseed oil)
- GM labelling will also apply to alcoholic beverages.

Appendix B

Table B1: Canola events—approval status in Australia and Canada, and status of review for planting in the USA

GM event	Alternative name or derived line	Modified trait[a]	Approval status[b]				Commercialisation status[c]
			Australia		Canada	USA	
			Food (FSANZ 2008)	Crop (OGTR 2008)	Crop (CFIA 2008)	Crop (USDA-APHIS 2007; USDA 2008)	
18		FAP	NA	NA	NA	✓	NC
23	23-18-17, 23-198	FAP	NA	NA	✓	✓	NC
GT73	RT73	HT	✓	✓[d]	✓	✓	✓
GT200	RT200	HT	NA	NA	✓	✓	NC
MS1	B91-4	HT / HB	✓	✓[e]	✓	✓	✓
MS1xRF1	PGS1	HT / HB	✓	✓	✓	✓	✓
MS1xRF2	PGS2	HT / HB	✓	✓	✓	✓	✓
MS8		HT / HB	✓	✓[e]	✓	✓	✓
MS8xRF3		HT / HB	✓	✓[e]	✓	✓	✓
RF1	B93-101	HT / HB	✓	✓[e]	✓	✓	✓
RF2	B94-2	HT / HB	✓	✓[e]	✓	✓	✓
RF3		HT / HB	✓	✓[e]	✓	✓	✓
T45	HCN28	HT	✓	✓[e]	✓	✓	✓
Topas 19/2	HCN10, HCN92	HT	✓	✓[e]	✓	✓	✓
Westar-oxy-235		HT	✓	NA	✓	NA	✓

Notes: [a]FAP, Altered fatty acid profile of oil; HB, hybrid breeding system; HT, herbicide tolerance. [b]✓, Approved or, in the case of USA, reviewed; NA, Not approved. [c]✓, currently or previously commercialised in at least one country; NC, never commercialised (Biotechnology Industry Organization 2008). [d] OGTR (2003b). [e] OGTR (2003a).

Table B2: Thresholds relevant to Australia's national framework for canola

GM event	Import from USA or Canada		Domestic production		Export of grain to[a]						
	Grain	Seed for sowing	Grain	Seed for sowing	Bangladesh	China	EU-27[b]	India	Japan[c]	Nepal	Pakistan
GT73	0.9%	0.5% (proposed 0.1%)	0.9%[d]	0.5% (proposed 0.1%)	NS	NA[f]	0.9%	NS	5%	NS	NS
MS1							0.9%[e]		1%		
MS1xRF1							0.9%[e]		5%		
MS1xRF2							0.9%[e]		5%		
MS8							0.9%		5%		
MS8xRF3							0.9%		5%		
RF1							0.9%[e]		1%		
RF2							0.9%[e]		1%		
RF3							0.9%		5%		
T45							0.9%		5%		
Topas 19/2							0.9%[e]		5%		
18	Any presence level of unapproved GMOs is illegal						Zero tolerance		1%		
23									1%		
GT200									5%		
Westar-oxy-235									1%		

Notes: [a] NS, not stated. [b] refers to the percentage of GM–DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes (Lecroart et al. 2007). [c] refers to % (w/w). Note: These labelling requirements are for corn (maize) and soybean. At the time of preparing this report, it was not possible to confirm whether these thresholds also applied to canola and cotton but this has been assumed in this table (United States Department of Agriculture - Foreign Agricultural Service 2007f). [d] refers to % (w/w). [e] withdrawn from EU market but adventitious presence tolerated till 25 April 2012 (Europa 2007; European Union 2007d). [f] NA, not approved for commercial cultivation — however, as a 'listed GMO', GM canola grain may be imported into China for use as oil or meal provided that it is labelled appropriately as being derived from a GMO.

Table B3: Cotton events—approval status in Australia, Japan and the Republic of Korea, and status of review for use in the USA

GM event	Commercialisation status[a]	Approval status[b]											
		Australia			USA			Japan			ROK		
		Food[e]	Feed	Crop[f]	Food[g]	Feed[h]	Crop[h]	Food[i]	Feed[i]	Crop[i]	Food[j]	Feed[j]	Crop
LLCotton25	✓	✓	✓[c]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON531	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON1445	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON1445 / MON531	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON15985	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON15985 / MON1445	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON88913	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
MON88913 / MON15985	✓	✓	✓[d]	✓	✓	✓	✓	✓	✓	✓	✓	✓	NA
19-51a	NC	NA	NA	NA									
281 (281-24-236)	✓	NA	NA	NA									
3006 (3006-210-23)	✓	NA	NA	NA									
281 / 3006	✓	NA	NA	NA									
281 / 3006 / MON1445	✓	NA	NA	NA									
281 / 3006 / MON88913	✓	NA	NA	NA									
31807 (BXN Plus Bt)	ND	NA	NA	NA									
31808 (BXN Plus	ND	NA	NA	NA									

Bt)													
BXN	ND	NA	NA	NA									
BXN10211	ND	✓	✓	NA									
BXN10222	ND	✓	✓	NA									
COT67B	ND	NA	NA	NA									
COT102	ND	✓	✓	NA									
LLCotton25 / MON15985	✓	✓	✓	NA									
MON757	ND	✓	✓	NA									
MON1076	NC	✓	✓	NA									
MON1698	NC	NA	NA	NA									
MXB-13	ND	✓	✓	NA									

Notes: [a]✓, currently or previously commercialised; NC, never commercialised, ND, no data supplied (Biotechnology Industry Organization 2008); ROK, Republic of Korea; [b]✓, Approved or, in the case of USA, reviewed; NA, Not approved; [c] OGTR (2006a); [d] OGTR (2006b); [e] FSANZ (2008); [f] OGTR (2008); [g] USDA (2008); [h] USDA-APHIS; USDA (2007; 2008); [i] United States Department of Agriculture – Foreign Agricultural Service; Japan – Biosafety Clearing House (2007f; 2008); [j] Korea – Biosafety Clearing House (2008).

Table B4 : Soybean events—approval status in Australia and status of review for use in the USA

GM event	Modified trait[a]	Approval status in Australia[b]		Reviewed uses in USA[b]			Commercialisation status[c]
		Food (FSANZ 2008)	Crop (OGTR 2008)	Food (USDA-APHIS 2007; USDA 2008)	Feed (USDA-APHIS 2007; USDA 2008)	Crop (USDA-APHIS 2007; USDA 2008)	
A2704-12	HT	✓	NA	✓	✓	✓	NC
A2704-21	HT	NA	NA	NA	NA	✓	NC
A5547-35	HT	NA	NA	NA	NA	✓	NC
A5547-127	HT	✓	NA	✓	✓	✓	NC
[d]G94-1, G94-19, G168	OA	✓	NA	✓	✓	✓	NC
GTS 40-3-2	HT	✓	NA	✓	✓	✓	✓
GU262	HT	NA	NA	NA	NA	✓	NC
MON89788	HT	NA	NA	✓	✓	✓	ND
W62	HT	NA	NA	NA	NA	✓	NC
W98	HT	NA	NA	NA	NA	✓	NC

Notes: [a] HT, herbicide tolerance; OA, Increased oleic acid content. [b] ✓, Approved, or in the case of USA, reviewed; NA, Not approved. [c] ✓, currently or previously commercialised in at least one country; NC, never commercialised, ND, no data supplied (Biotechnology Industry Organization 2008). [d] G94-1, G94-19 and G168 are lines derived from the event 260-05.

Table B5: Maize events—approval status in Australia and status of review for use in the USA

GM event	Modified trait[a]	Approval status in Australia[b]		Reviewed uses in USA[b]			Commercialisation status[c]
		Food (FSANZ 2008)	Crop (OGTR 2008)	Food (USDA-APHIS 2007; USDA 2008)	Feed (USDA-APHIS 2007; USDA 2008)	Crop (USDA-APHIS 2007; USDA 2008)	
676	HT / MS	NA	NA	✓	✓	✓	NC
678	HT / MS	NA	NA	✓	✓	✓	NC
680	HT / MS	NA	NA	✓	✓	✓	NC
1507	HT / IR	✓	NA	✓	✓	✓	✓
6275	HT / IR	NA	NA	✓	✓	NA	NC
59122	HT / IR	✓	NA	✓	✓	✓	✓
Bt-11	HT / IR	✓	NA	✓	✓	✓	✓
Bt-176	HT / IR	✓	NA	✓	✓	NA	✓
CBH-351	HT / IR	NA	NA	NA	✓	NA	ND
DBT418	HT / IR	✓	NA	✓	✓	NA	✓
DLL25 (B16)	HT	NA	NA	✓	✓	✓	✓
GA21	HT	✓	NA	✓	✓	✓	✓
LY038	Lys	✓	NA	✓	✓	✓	ND
MIR604	IR	✓	NA	✓	✓	✓	✓
MON802	HT / IR	NA	NA	✓	✓	NA	ND
MON809	HT / IR	NA	NA	✓	✓	NA	NC
MON810	IR	✓	NA	✓	✓	✓	✓
MON863	IR	✓	NA	✓	✓	NA	✓
MON80100 (MON801)	IR	NA	NA	✓	✓	NA	NC
MON88017	HT / IR	✓	NA	✓	✓	✓	✓
MON88017 / MON810	HT / IR	✓	NA	✓	✓	✓	ND
MS3	HT / MS	NA	NA	✓	✓	✓	ND
MS6	HT / MS	NA	NA	✓	✓	✓	ND
NK603	HT	✓	NA	✓	✓	✓	✓

T14	HT	NA	NA	✓	✓	✓	✓
T25	HT	✓	NA	✓	✓	✓	✓

Notes: [a]HT, herbicide tolerance; IR, Insect resistance; Lys, Increased lysine content; MS, male sterility. [b]✓, Approved, or in the case of the USA, reviewed; NA, Not approved. [c]✓, currently or previously commercialised in at least one country; NC, never commercialised; ND, no data supplied (Biotechnology Industry Organization 2008).

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