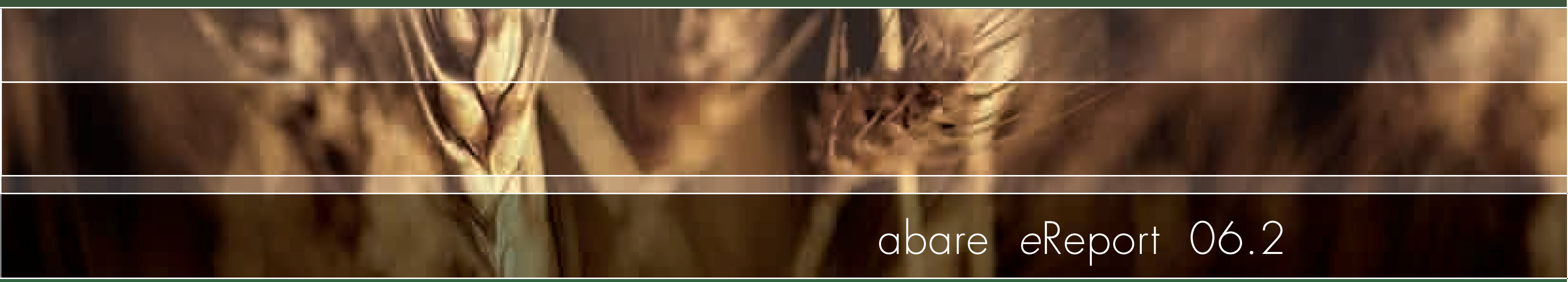
biosafety protocol

implications of the documentation regime



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foreword

The technologies of genetic modification offer great potential to raise the welfare of the world community through lowering the cost of food and fibre production, raising the quality of agricultural products and facilitating the adoption of agricultural production practices that are environmentally friendly. In particular, genetic modification technologies offer the hope to the world's less developed countries of feeding their growing populations in the face of increasingly binding resource constraints and of generating the exportable surpluses that can raise their standards of living.

A range of policy institutions has been developed throughout the world in response to perceptions that the introduction of genetically modified organisms raises new human and environmental safety issues. One of the potentially most important of these institutions is the Cartagena protocol on Biosafety to the Convention on Biological Diversity. This international agreement seeks to address the biodiversity implications of cross border movements of living modified organisms that can replicate in the environment.

The aim in this report to address one of a number of the aspects of the Biosafety Protocol that has be yet to finalised — the export documentation requirements for cargoes with living modified organisms that are intended for food, feed and processing. The report is an assessment of the implications of alternative export documentation regimes that have been proposed by different interest groups of countries. It is hoped that the report will contribute to the development of an export documentation regime that assists in realising of the full potential of genetic modification technologies.

BRIAN S. FISHER
Executive Director
February 2006

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Advance Informed Agreement (AIA) procedure

The procedure under the Biosafety Protocol that applies to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the party of import. The AIA procedure includes steps of notification by an exporting Party or exporter, acknowledgment of notification and risk assessment and decision making by an importing Party.

Biosafety Clearing House (BCH)

Established under Article 20 of the Biosafety Protocol in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist parties to implement the protocol.

Cartagena Protocol on Biosafety (Biosafety Protocol)

An international agreement negotiated and adopted under the Convention on Biological Diversity. The objective of the protocol is to contribute, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Clearing House Mechanism (CHM)

Mechanism established under Article 18.3 of the Convention on Biological Diversity to promote and facilitate technical and scientific cooperation. The Biosafety Clearing House is established as part of the Clearing House Mechanism.

Competent National Authority

Authority (or authorities) designated and authorised by a government to be responsible for performing the administrative functions required by the Biosafety Protocol, and to act on their behalf with respect to those functions.

Conference of the Parties (COP)
: The intergovernmental supreme decision making body with regard to the implementation of the Biodiversity Convention, consisting of Parties to the Convention.

Conference of the Parties serving as the meeting of the Parties to the protocol (COP/MOP)
: Consists of all Parties to the protocol. Its main functions are to review the implementation of the protocol and make decisions necessary to promote its effective implementation.

demurrage
: A fee levied by the shipping company on the port or supplier for not loading or unloading the vessel by a specified date agreed by contract. Usually, assessed on a daily basis after the deadline.

DNA
: Deoxyribonucleic acid. This molecule carries the genetic information for most living systems.

GMO
: Genetically modified organism. An organism whose genetic structure has been altered using genetic engineering techniques.

genetic engineering (also genetic modification)
: The selective, deliberate altering of the genetic material of organisms through the adding or removal of genes.

International Organisation for Standardisation (ISO)
: Global network made up of 156 national measurement institutes whose aim is to identify and implement international standards required by business, government and society.

ISO 9000
: Set of international quality management standards (www.iso.org/iso/en/iso9000-14000/understand/selection_use/selection_use.html).

identity preservation
: Process by which a crop is grown, handled, delivered, and processed under controlled conditions to assure the customer that the crop has maintained its unique identity from farm gate to end use.

International Grain Trade Coalition (IGTC)
: Formed in 2001 in recognition that the protocol could have a profound impact on maintaining a low cost bulk handling system to ensure an inexpensive food supply for world consumers. It has seventeen members representing more than 1000 organisations in more than 80 countries.

living modified organism (LMO)
: Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (genetic engineering).

risk assessments
: Environmental reviews of LMOs generated by a regulatory process, and carried out in accordance with article 15 and annex III of the protocol.

traceability
: Ability to trace and follow a food, feed, food-producing animal or substance intended to be or expected to be incorporated into a food or feed in all stages of production, processing or distribution.

transgenic organism
: An organism whose genetic structure has been augmented by genetic material from another species, using genetic engineering techniques.

unique identifier
: An alphanumeric code (usually 9-digit) that is given to each transgenic (or genetically engineered) plant that is approved for commercial use, including planting and food/feed use.

World Trade Organisation (WTO)
: International organisation dealing with the rules of trade between nations, with the goal of helping producers of goods and services, exporters, and importers conduct their business. To this end, there are a number of WTO agreements dealing with different aspects of the world trading environment, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments.

summary and conclusions

Cartagena Biosafety Protocol

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity came into force in September 2003 and has so far has been ratified by 131 countries. Essentially, the protocol is a set of rules aimed at making countries aware of shipments containing living modified organisms (LMOs) that can replicate in the environment entering (or attempting to enter) their borders. This enables countries to protect the conservation and sustainable use of the biodiversity of their country.

Australia and a number of other major agricultural exporters, including the United States and Canada, are not signatories to the protocol. This is partly because a number of aspects of the protocol are yet to be finalised. Prominent among these is the nature of the documentation that should accompany shipments of LMOs not intended to be released into the environment but rather to be used directly for food, feed and processing. A range of documentation regimes have been proposed but there is controversy over their impacts.

The aim with this report is to assess the implications of alternative documentation regimes. The emphasis in the report is on grains, particularly cereals and oilseeds, because this is where most of the commercialisation of agricultural genetically modified organisms (GMO) has taken place to date and is likely to occur in the near future.

Background

World trade in living organisms is nearly US$130 billion a year. The bulk of this trade is grains, fruit and vegetables. Currently, around three quarters of the total value of world imports are accounted for by countries that are signatories to the protocol. (Around 63 per cent of Australian exports of living organisms go to signatory countries.) A number of other important food importing countries, including the Republic of Korea have flagged their intention to sign the protocol.

Over 100 different forms of GM plants have been commercialised throughout the world. Each of these different forms is called a 'transformation event'. With the exception of rice, world trade in grains is dominated by countries that have commercialised GM grains — most notably the United States, Canada, Argentina and Brazil. The main GM crops commercialised are soybeans, corn, cotton and canola.

The only other LMOs that have entered world trade to date are potatoes, tomatoes and papayas. GM rice could be commercialised in the next few years in China.

Australia has commercialised GM cotton (producing cottonseed as a byproduct) and various forms of carnations. A number of GM varieties have also been brought to an advanced stage of development (particularly canola, field peas and lupins) in Australia, but have not been commercialised.

While there has been extensive experimentation with genetic modification of livestock, there has been no commercialisation. It is possible that some GM fish (mainly ornamental) will enter world trade. A number of GM micro-organisms (mainly attenuated vaccines) have been developed but the implications of this trade from the point of view of the protocol are probably not immediate.

At least some consumers have concerns about GM crops, even after they have been assessed by government authorities to be safe for humans and the environment. The extent of consumer concerns have been enough to hold up commercialisation of a number of GM crops, including GM wheat. These concerns have also led to a range of market access conditions being imposed in many countries throughout the world, quite apart from the protocol. The main conditions are the mandating of labeling for products where the level of presence of GM material exceeds specified thresholds. The European Union has probably the most exacting market access conditions for GM products.

The documentation issue

The protocol documentation issue is a particular problem for grains because accidental presence of LMOs can occur in bundles of non-LMO grain, originating through cross pollination in the field and through co-mingling in the harvesting, bulk handling and storage system. It is a particular problem keeping large parcels of grain free from unintended presence because they are usually accumulated from many different farms and pass through storage and transport systems that are repeatedly used to move different types of grain.

Two documentation regimes have been proposed by parties to the protocol. The first is what can be termed the simple, 'low cost' regime. Under this regime a cargo from a country with a commercialised LMO of that commodity species will be documented as 'may contain' LMO's. However, such documentation would not be required when either the exporting country does not have a commercialised LMO of that species, or there is a contractual arrangement for a non–LMO shipment with assurance that the shipment achieves a minimum of 95 per cent of non–LMO content (provided that definition does not conflict with the regulations of the importing country).

Under this regime, statements about the presence of LMOs are simply part of the normal commercial invoice that accompanies a grain cargo — no stand alone documentation is required. The proponents of this approach point to a tripartite agreement between Mexico (a signatory to the protocol), Canada and the United States as evidence of the practicality of their approach.

The other case is a complex, 'prescriptive' regime, usually associated with the European Union and Norway, whereby exporters would be required to detail all the GM events that are contained in a shipload of grain. This 'does contain' regime would require extensive and costly testing of each grain shipment. Proponents of the complex regime also suggest that statements of LMO content would be a stand alone document, certified by an appropriate government agency.

There is zero tolerance for the presence of unapproved GM events with both these regimes.

There are general concerns about documentation regimes. The main concern is that any additional documentation requirement adds to costs of trading grain. One cost is testing to identify what GM events are in the cargo. In many cases a separate test is required for each GM event so countries that have the most commercialised GM events face higher documentation costs than those that have fewer or no commercialised GM events. The testing costs are essentially the same for a large shipment of grain as for a small one so the testing cost per tonne could be much higher for small shipments of grains.

There is also the problem of 'false positives' that arises from the use of GM tests and sampling methods with associated errors. For example, tests at the exporting position may indicate no GM presence but virtually the same tests conducted at the import position may find GM presence. Differences in results can cause problems such as delays in unloading grain that usually incur demurrage costs. The problem could be avoided if there is agreement to test only at the point of loading.

Another concern with documentation is that it is imposing a label that may be misunderstood. It is possible that it could cause delays at some import positions because customs officials are not equipped or trained to process the documentation.

Protocol documentation also draws attention to the GM content of a cargo which may affect demand. Unintended presence of GM material is certainly of concern to marketers of wheat and barley in Australia because they believe that accidental presence of GM canola seed in wheat and barley shipments could jeopardise some of their markets.

The 'may contain' approach avoids many of the costs and problems associated with unintended presence in non-LMO cargoes. Given a tolerance for unintended presence of 5 per cent, the overwhelming proportion of non-LMO grain shipments would not need to be tested. Therefore, the costs are likely to be minimal (Kalaitzandonakes 2004; JRG Consulting Group 2004).

On the other hand, the 'does contain' approach would impose testing costs on virtually every shipment of grain where there is the possibility of unintended GM presence. To avoid labeling would require elaborate identity preservation arrangements (including testing) to avoid unintended presence. (Identity preservation is the process by which a crop is grown, handled, delivered and processed under controlled conditions to assure the customer that the crop has maintained its unique identity from farm gate to end use.) The identity preservation option is costly compared with the option of simply testing and labeling, and identity preservation costs are higher the lower is the tolerance for unintended presence. It is widely accepted that identity preservation arrangements that deliver a zero level of unintended presence in regions that produce both GM and non-GM grains would be very costly. The need for identity preservation will grow as the number of LMOs expands.

Implications of documentation regimes

The implications of the simple and complex documentation regimes obviously depend on the extent to which costs of delivering grain are raised. Because world markets for agricultural commodities are competitive, it means that any additional costs will be passed on to consumers in the form of higher prices. The largest adverse welfare effect from higher prices is likely to be in less developed countries where expenditure on food makes up a much larger proportion of total income than in more developed countries.

Because documentation costs are largely fixed, irrespective of the size of the shipment, the cost per tonne would be higher for small shipments than for large ones. This could mean that the burden of documentation would be higher on consumers in the smallest importing countries.

One of the key unknowns in any assessment of the implications of documentation regimes is the extent to which exporters of non-LMO grains will increase the level of identity preservation to avoid levels of unintended presence of LMOs that trigger protocol documentation requirements. This could occur in response to concerns over adverse demand effects or lingering liabilities for damage associated with documenting unintended presence of

LMOs. It seems likely that a documentation regime with a low trigger level will increase the level of identity preservation.

It should be noted that quite separately from the protocol, marketers are already dealing with mandatory labeling regimes in many countries, requiring labeling if GM presence exceeds specified thresholds. There are also importers who require non-GM grain. However, a zero tolerance trigger with the 'does contain' regime is much more exacting than most mandatory labeling tolerances in existence throughout the world at present.

If documentation requirements do change supply costs, patterns of world trade in agricultural commodities would be changed in complex ways. First, any documentation regime that raises transaction costs shifts the balance of comparative advantage in favor of countries that either do not produce GMOs or have relatively few GM events commercialised, such as the European Union bloc of countries. Second, raising the cost of delivering living organisms is an incentive for processing grain before export or using it as feed for livestock, rather than exporting it in a living form. This means, for example, that the competitiveness of livestock industries in countries that rely on imports of grain will be adversely impacted.

Documentation costs would also impact on adoption of GMOs because it imposes additional costs, probably on both GM and non-GM producers and marketers. The debate over the commercialisation of GM canola in Australia since approval for unrestricted release into the environment by the Office of the Gene Technology Regulator in 2003 saw key interest groups in Australia opposing the commercialisation because of these concerns. Nonadoption means that the agronomic benefits of GM crops will be forgone and consumers will not benefit from resultant lower prices.

Conclusions

The main impact of the protocol is likely to be on producers of non-GM grains in countries that produce a mix of GM and non-GM grains. However, this impact is probably very small if the 'may contain' regime is adopted. This is also the conclusion of other economic research conducted into the implications of various proposed documentation regimes under the protocol.

The cost impact increases as the tolerance for unintended presence is lowered. This is because the need for testing is increased and there is greater incentive for identity preservation to avoid documenting a cargo as 'does contain' LMOs. The main cost implications of protocol documentation regimes depend on the extent to which additional identity preservation is adopted; with a trigger level of zero unintended presence, the additional identity preservation is likely to be substantial.

In summary, the proposed ‘does contain’ documentation regime with the protocol is likely to distort world markets for grains and raise the cost of food to consumers by more than a ‘may contain’ regime. The ‘does contain’ regime would advantage the grain exporting countries that have not commercialised GM crops and lower the welfare of consumers, particularly in less developed countries.

1

introduction

An international agreement called the Cartagena Protocol on Biosafety to the Convention on Biological Diversity seeks to set the rules for movements across international borders of living genetically modified organisms (LMOs) that may affect the conservation and sustainable use of biodiversity. The protocol came into force on 11 September 2003 and so far has been ratified by 131 countries (see appendix A). However, some provisions of the protocol such as documentation requirements, and liability and redress arrangements have yet to be agreed. It is also unclear how Parties to the Protocol will implement the protocol, and concerns are being expressed that implementation by some countries will be not be consistent with obligations under WTO agreements.

Countries that are not party to the protocol include Australia, the United States, Canada and Argentina. Australia has no timetable for consideration of accession to the protocol but it is recognised that the protocol could have important impacts on Australian trade — both exports and imports — and on the development of GM technologies in Australia.

The aim in this research is to assess the implications of possible documentation regimes under the protocol. The documentation requirements have the potential to increase the costs of trading living organisms generally, not just modified ones, because it may mean increased identity preservation, testing and certification, and insurance.

Australia has undertaken to share the results of this study with parties and nonparties at the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP–MOP3) in March 2006.

2

biosafety protocol

Overview of the protocol

Essentially, the protocol is a system aimed at making countries aware of when shipments containing living modified organisms (LMO) that can replicate in the environment enter their borders. This enables countries to take appropriate action to prevent adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

The protocol deals separately with living modified organisms (seed, fish, trees and animals) intended for direct release into the environment and those intended for food, feed and processing (so-called LMO commodities). Complete details of the protocol are available at www.biodiv.org/biosafety.

The basis of the protocol is a prior notification and consent regime — Advanced Informed Agreements (AIA) — implemented via an internet based Biosafety Clearing House that provides information on national biosafety risk assessment summaries and final decisions about LMOs.

An exporting country must notify the importing country in writing of the first transboundary shipment of the LMO intended for direct introduction into the environment. An importing country would then make the decision about importing an organism, on the basis of a science based assessment of the risk to the environment, within a time limit specified under the protocol.

An important characteristic of the protocol is that its provisions are couched in terms of the precautionary approach, which holds that 'Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question …… in order to avoid or minimize such potential adverse effects.' In other words, a country could reject an LMO on the grounds that not enough is known about its impact on biodiversity; concrete evidence of harm is not necessary. This is a controversial aspect of the protocol, with concerns being expressed that it could be used to impose unjustifiable restrictions on trade and weaken the scientific basis of risk assessment. As Hathcock (2000) says 'attempts to apply this concept [precautionary principle] to "proof of safety" for new food ingredients or products has led to the impossible demand of establishing the "absence of harm", with a level of evidence that avoids uncertainty'.

LMOs intended for direct use as food, or feed, or for processing, such as bulk grains, are exempt from the advanced informed agreement procedure; it will be sufficient for the importing country to have notified the Biosafety Clearing House of its approval for the domestic release of LMO commodities that may enter world trade. Transboundary shipments of LMOs must be

1 Cartagena Biosafety Protocol – Timeline of negotiations

Date	Event
June 1992	Convention on Biological Diversity signed by 150 governments at the Rio Earth Summit
November 1995	Second meeting of the Conference of the Parties to the Convention on Biological Diversity establish Open Ended Ad Hoc Working Group of Biosafety to develop a draft protocol on Biosafety
January 2000	Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted
September 2003	Protocol entered into force 90 days after the 50th country completed the process of ratifying it
February 2004	First meeting of the Conference of the Parties of the Convention serving as the meeting of the Parties to the Protocol
March 2005	Meeting of the Open-ended Technical Expert Group on Identification Requirements of LMOs intended for direct use as food, feed, or for processing held
May/June 2005	Second meeting of the Conference of the Parties of the Convention serving as the meeting of the Parties to the Protocol
March 2006	Third meeting of the Conference of the Parties of the Convention serving as the meeting of the Parties to the Protocol

accompanied by 'appropriate' documentation but the final form for this documentation is not yet decided.

Similarly, the terms of arrangements for liability and redress if transboundary movements of LMOs cause damage are still not decided under the Protocol.

Relationship to existing international agreements

The protocol is not supposed to affect the rights and obligations of governments under any existing international agreements.

One potential area for inconsistencies is with the World Trade Organisation's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS) which establishes members' rights to take SPS measures necessary for the protection of human, animal or plant life or health, provided such measures are not inconsistent with the agreement.

Another potential area for inconsistencies is the WTO's Agreement on Technical Barriers to Trade (TBT), covering issues such as packaging, marking and labeling requirements, that seeks to ensure that technical regulations do not create unnecessary obstacles to trade. This is particularly relevant to a documentation regime that could be construed as a label.

Biosafety Clearing House

The Biosafety Clearing House (BCH) is an internet based information exchange mechanism established by the protocol. It is aimed at facilitating the exchange of scientific, technical, environmental and legal information on, and experience with LMOs. A key role of the BCH is to publish final decisions by countries regarding the domestic use of a living modified organism (LMO) that may be subject to transboundary movements. Under Article 20.3 of the protocol, each party shall make available to the BCH details of relevant information on domestic use of an LMO. For example:

- any existing laws, regulations and guidelines for implementation of the protocol
- any relevant details of bilateral, regional and multilateral agreements and arrangements

- summaries of risk assessments and environmental reviews of LMOs and
- parties' final decisions on the importation or release of LMOs.

Unique identifiers

To facilitate the Clearing House Mechanism, each GM event of interest is given a unique identifier consisting of an alphanumeric code. This aims to avoid confusion in the exchange of information between national authorities.

At the First Meeting of the Conference of Parties in February 2004, it was decided that a system of unique identifiers for plants developed by the OECD could be useful in the context of the Biosafety Protocol. The basis of the OECD system is a nine digit alphanumeric code. More details of this system, including an online database, are available at OECD (2005a). (The European Union had already adopted the OECD guidance as its system for generating unique identifiers for plants under Commission Regulation (EC) no. 65/2004 of January 2004.)

Documentation requirements

Article 18.2 of the protocol states that each party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned.

(c) Living modified organisms that are intended for intentional introduction into the environment of the party of import and any other living modified organisms within the scope of the protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

Article 24 of the protocol suggests that signatory countries should require that imports from nonsignatory countries comply with the protocol's documentation requirements.

The exact details of documentation required for category (a) of LMOs listed above are still unresolved, despite lengthy negotiations at meetings of parties and expert groups. Given the date of entry into force of the protocol (11 September 2003), the Conference of the Parties have not met the timeframe for agreement on documentation requirements of two years.

3

trade in living organisms

World

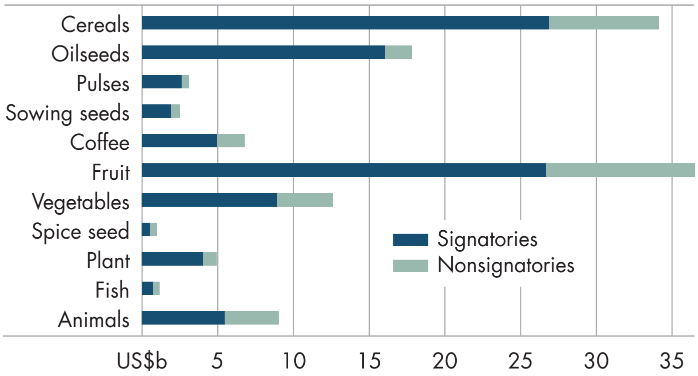
Based on data from UN Statistical Division (2005), the value of world imports of living organisms (excluding micro-organisms) averaged US$129 billion in the three years to 2003. The main components of this trade were cereals, fruit and oilseeds, with countries that are signatories to the Protocol accounting for 76 per cent of the total value (figure A). A number of other countries have flagged their intentions to sign the protocol when domestic regulatory arrangements for GM products are finalised including the Republic of Korea.

2 World trade in living organisms of the plant kingdom for which there are GM events

		Value of world trade (GM and non-GM)			
	GM events	2001	2002	2003	Average
	no.	US$m	US$m	US$m	US$m
Cereal					
Maize	25	8 585	9 471	10 902	9 652
Rice (in husk)	2	261	305	485	350
Flower					
Carnation	14	na	na	na	na
Fruit					
Papaya	1	155	167	185	169
Oilseed					
Cottonseed	13	233	229	217	227
Flax (linseed)	1	223	244	321	262
Rapeseed/canola	15	1 905	1 739	2 101	1 915
Soybean	8	11 074	11 012	16 168	12 751
Vegetable					
Chicory	1	na	na	na	na
Potato	20	1 517	1 733	1 944	1 732
Squash	2	na	na	na	na
Sugar beet seed	2	262	269	363	298
Tobacco	1	na	na	na	na
Tomato	2	4 308	4 975	5 867	5 050

Sources: Agbios (2005); UN Statistics Division (2005); OECD (2005b); ABARE.

A **Value of world imports of living organisms**
average three years to 2003



The living modified organisms from the plant kingdom that have been cleared for unrestricted release into the environment in at least one country in the world are shown in table 2, along with the value of world trade in these commodities (both GM and non-GM). Each form of genetic modification is called a transformation 'event',— for example, there are 25 GM events with maize. The United States and Canada have the most GM events that have been granted unrestricted release (table 3).

However, some of the GM varieties listed in table 2 have not been commercialised — for example, wheat, rice, sugar beet and flax (linseed). A key reason for this is that at least some consumers have concerns about GM products, despite them being assessed by government authorities to be safe for humans and the environment.

Existing market access conditions for LMOs

Stated concerns over the safety of GMOs for humans and the environment have led to a range of market access conditions for LMOs, even without the Protocol. In most cases, governments are making arrangements under the Biosafety Protocol consistent with these existing arrangements.

The European Union has the most stringent market access restrictions for GM products. Prior to 1978, the EU approved a number of GM varieties of soybeans and corn for import into member countries but then applied a virtual moratorium on further approvals until it had put in place a range of market requirements aimed at dealing with the issues of consumer choice and food and environmental safety. This meant that it was not until late 2004 that additional GM varieties were approved for import into the European Union. The European Union has a tolerance of 0.5 per cent for the unintended presence of GM materials not yet approved for import into the European Union, but which have been assessed as safe for consumption by the European Food Safety Authority.

The market requirements in the European Union include mandatory labeling of food products that contain more than 0.9 per cent by weight GM materials, including animal feedstuffs. There are also strict traceability requirements, meaning that marketers and processors must have documentation showing the nature and source of materials that they use in the food making process. The claim is that traceability arrangements facilitate the operation of the labeling regime and ensure that products can be removed from the supply chain if unforeseen safety concerns emerge (European Commission nd).

3 Number of different GM events in selected countries, by crop type

	Argentina	Australia	Brazil	Canada	China	European Union	India	United States
	no.	no.	no.	no.	no.	no.	no.	no.
Alfalfa				1				1
Canola		5		13				9
Carnation		2				2		
Chicory						1		1
Corn	8			16		2		18
Cotton	2	4	1	2	1		1	12
Linseed				1				1
Papaya								1
Potato				4				4
Rice								1
Soybeans	1		1	3				6
Squash								2
Sugar beet				1				3
Tobacco								1
Tomato								6
Total	11	11	2	41	1	5	1	66

Source: Based on data in Agbios (2005).

However, there are still many other countries that do not have mandatory labeling requirements for GM products including the United States and Canada. Moreover, the European Union is one of the few countries that require mandatory labeling of GM feed materials and, as yet, no country requires labeling of products obtained from animals fed on GM feedstuffs (though this was mooted at one stage in the European Union). The European Union is also almost unique in that its regulations require labeling of all products containing GM materials whereas most other countries only require labeling if modified DNA is detectable in the product. More details on the labeling requirements for key countries in the world grain trade are contained in Foster, Berry and Hogan (2003).

The 'detectable DNA' condition has important implications. It means, for example, that oils derived from GM oilseeds do not require labeling outside the European Union because there is no modified DNA in the oil. The oil meal remaining after the oil extraction process is mostly used as animal feed so it also largely escapes labeling requirements.

The estimated proportions of world grain trade imports, by grain type, that are subject to each GM labeling threshold (or tolerance) for adventitious presence of GMOs are shown in table 4. (It is assumed that a 0.5 per cent tolerance would apply in the European Union with canola that contained quantities of 'unapproved' GM canola.) It can be seen that around 83 per cent of world canola trade enters countries that have mandatory labeling regimes. However, the 'detectable DNA' condition means that mandatory labeling only applies to around a third of world canola trade, 45 per cent of soybeans, and 21 per cent of cottonseed. The effective proportion is also much lower for maize because around 70 per cent of maize is consumed as animal feed.

All countries have zero tolerance of unintended presence of unapproved GM events. There have been a number of recent cases where unapproved GM grains have entered the supply chains of other grains. One occurrence was in 2001 when a GM variety of corn called Star-

4 Proportions of world unprocessed grain imports subject to each GM labeling threshold, by grain type a

Labeling threshold/tolerance	Canola	Cottonseed	Maize	Soybeans
	%	%	%	%
Zero	24.9	9.4	2.9	24.4
0.5 per cent	33.6	20.7	b	b
0.9 per cent	0.0	0.0	3.8	35.4
1 per cent	0.1	0.0	0.1	0.2
2 per cent	0.1	0.0	1.8	1.0
3 per cent	–	7.9	11.8	2.8
4 per cent	0.0	0.2	1.1	1.7
5 per cent	24.5	13.7	29.1	16.3
Total, all thresholds	83.2	51.9	50.6	81.8
No labeling	16.8	48.1	49.4	18.2

a Averages based on imports for the three years to 2004-05. Includes intra-EU trade. **b** Not identified.

Link that was approved for feed use but not food use was found in US supplies of food corn. Another occurrence was in 2005 when another variety of corn called Bt-10 that was developed in the United States but had no regulatory approval was found in supplies of conventional corn. In both cases, testing regimes were implemented to enable diversion of the grain from food markets with zero tolerance of unintended presence of the unapproved event. The StarLink episode caused disruption to the US export corn trade until testing regimes and seed and product recalls were able to reassure customers and regulatory agencies throughout the world about unintended presence of this variety (Lin, Price and Allen 2001; Carter and Smith 2004).

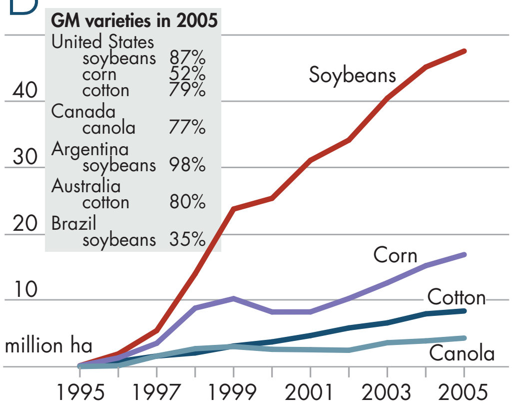
GM grains

The grain crops that have been successfully released are soybeans, maize, canola (rapeseed) and cotton (producing both cottonseed and lint). Genetically modified varieties account for around 24 per cent of total world plantings of these crops in 2005. Plantings are largely confined to the United States, Argentina, Canada and Brazil and China but adoption in these countries has been very rapid (figure B). Apart from small quantities of GM maize in Spain, the European Union is not a producer of GM crops.

Despite supposed concerns over GM products, GM producing countries dominate world exports of grains (figure C; US Department of Agriculture 2005a).

There is a component of world grain trade that is based on demand for grain that is certified to be non-GM. However, this grain represents a relatively small niche in world grain markets, apart from in the European Union and, to a lesser extent, in Japan and the Republic of Korea. The conclusion of Foster, Hogan and Berry (2003) was that

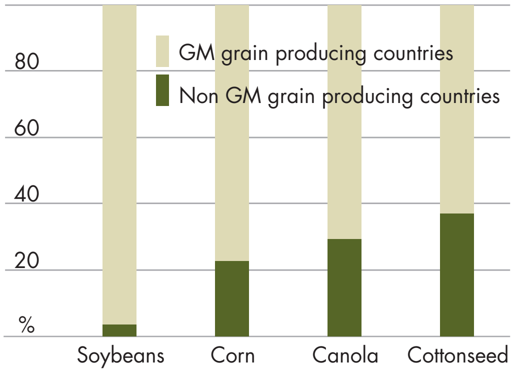
B Estimated areas harvested of GM crops



the great bulk of world grain users are not prepared to pay the higher prices necessary for certified non-GM (identity preserved) grain.

The main trade flows of certified non-GM grain are soybeans to the European Union and Brookes, Craddock and Kniel (2005) say the share is around 14–17 per cent of total soybean use of around 15 million tonnes a year in that bloc of countries. (The Brookes et al. definition of non-GM appears to be grain that has GM content of less than 0.9 per cent, the threshold for mandatory labeling in the European Union.) The Brookes et al. conclusion was that prices for non-GM soybean in the European Union averaged 2–5 per cent higher than for noncertified soybeans over the past two years.

C Shares in world grain trade
three years to 2004-05. Excludes intra-EU trade



There is also demand for non-GM soybeans in Japan related mainly to more direct food use (such as tofu), rather than for crushing for oil and meal. Imports of non-GM soybeans by Japan could be as high as 1 million tonnes a year out of total imports of around 4.5 million tonnes a year.

GMOs in the pipeline

There is a range of GMOs in development but not currently commercialised.

There are indications that China will commercialise GM rice as early as 2006. China is by far the largest consuming country of rice in the world but accounts for only around 5 per cent of world exports of rice (based on US Department of Agriculture 2005a for the three years to 2004-05).

A GM variety of wheat with herbicide tolerant traits has been developed in North America. However, the developer has chosen not to commercialise the GM wheat at this stage until uncertainties about impacts on existing markets for Canadian and US wheat are cleared up. US Wheat Associates, the US wheat industry's market development organisation, and the Canadian Wheat Board have detailed the conditions that they consider must be met before commercialisation of GM wheat goes ahead (US Wheat Associates 2005; Canadian Wheat Board 2005).

There has been extensive experimentation with GM (or transgenic) livestock throughout the world but as yet there have been no commercial applications at the farm level. Of most relevance to the protocol debate are GM food production animals with improved production traits such as growth potential, disease resistance, environmental adaptation and lower environmental contamination potential. There has also been the engineering of animals, such as cows, to produce pharmaceuticals, blood proteins and antigens (for vaccine production) in their milk. Another aim with GM animals is to produce transplant organs for humans from animals such as pigs, without the organ rejection problems. More details on GM livestock are available in Pew Initiative (2002) and Baskur and King (2005).

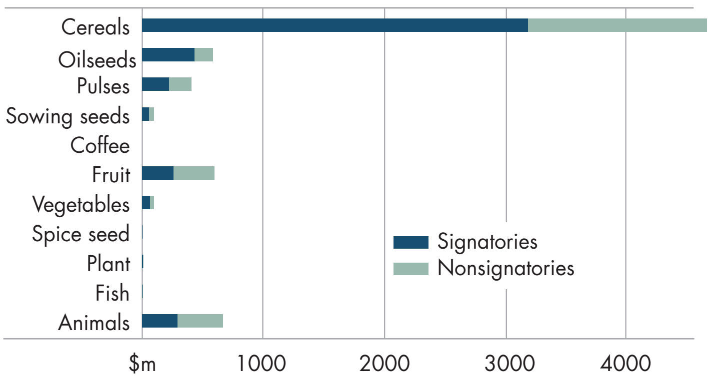
With fish, there is a GM salmon that grows at twice the rate of a conventional salmon through the insertion of a growth hormone gene from another fish. However, concerns over the impact on wild salmon populations have prevented commercialisation of this fish. There is also a GM zebra fish (an ornamental fish) that has been engineered to fluoresce in different colors through the insertion of genes from jelly fish and sea anemone. A sterile fish of this form is on sale in Chinese Taipei.

Living micro-organisms — for example, bacteria, yeasts and moulds — are used extensively in food processing that involves fermentation processes. Some products where micro-organisms are employed in manufacturing processes are bread, cheese, yogurts, fermented milk, beer and wine. There are a number of micro-organisms that have been genetically modified to increase the efficiency of these manufacturing processes. In some cases, LMOs may be present in the final product. This is particularly likely with dairy products, such as yogurts or the live microbial (usually *Lactobacillus* species) dietary supplements that are intended to have a beneficial effect on the metabolic activity of the flora of the gastrointestinal tract (FAO 2004). In the main, however, living micro-organisms are used mainly as processing aids and are not likely to survive in the finished products.

There are also vaccines based on the use of live but harmless GM viruses or bacteria. Live attenuated vaccines are generally superior to deactivated ones because they produce a more robust immunological response but they could conceivably pose a threat to biodiversity because of the possibility of reverting back to virulence (Rogan and Babiuk 2005). However, one of the advantages of GM techniques with live vaccines is that they are lowering this risk by lowering the pathogenicity.

Insects have been genetically modified in the laboratory but technical and regulatory issues suggest it will be at least five years at the most optimistic before unrestricted release of a GM insect and perhaps as much as 25 years at the most pessimistic (Pew Initiative 2004). One possibility is GM male insects that are fertile but engineered to pass on a gene that makes their progeny sterile. This has the potential to be a more effective form of insect control than the current method of releasing male insects that have been sterilised through the use of radiation. Another theoretical possibility is fully fertile insects that pass on a gene that stops transmission of malaria. There has also been experimentation with genetically altering the microbes that live symbiotically within insects (symbionts), a form of genetic engineering called paratransgenesis (Pew Initiative 2004). For example, GM forms of symbionts could be used to prevent host insects from transmitting a pathogen.

D **Estimated annual value of Australian exports of living organisms** average three years to 2003



Australia

The annual value of Australian exports of living organisms (excluding micro-organisms) averaged $7.2 billion in the three years to 2004, around 63 per cent of which is accounted for by countries that are signatories to the protocol. Grains (cereals, pulses and oilseeds) are the main components of these exports (figure D; ABS 2005).

The composition of Australia's trade in unprocessed grains is summarised in table 5. The only GM broadacre crop in Australia is cotton, which was commercially released in 1996. An estimated 80 per cent of Australia's cotton plantings in 2004-05 were of GM varieties. Australian exports of cottonseed are substantial (table 5).

5 Composition of Australian exports of unprocessed grain

Average, three years to 2004.

	Total exports a		Major customers
	Volume kt	Value $m	(share of total exports in the three years to 2004)
Cereals			
Barley			
– malting	1 677	412	China (64%), Japan (14%), Saudi Arabia (7%), Colombia (4%), Korea, Rep. (3%), Chinese Taipei (3%), Peru (1%), South Africa (1%), Ecuador (1%)
– feed	2 755	528	Saudi Arabia (53%), Japan (24%), Iran (7%), United Arab Emirates (5%), Kuwait (4%), Chinese Taipei (2%), Oman (1%), China (1%), Qatar (1%)
– other barley	15	4	Japan (93%), China (3%), Kuwait (1%), Chinese Taipei (1%), New Zealand (1%)
Maize	48	9	Chinese Taipei (29%), New Zealand (29%), Korea, Rep. (23%), South Africa (6%), Japan (6%), Papua New Guinea (2%), Malaysia (2%), Sri Lanka (1%), United Arab Emirates (1%)
Oats	175	41	Confidential (81%), Japan (5%), Philippines (3%), Hong Kong (3%), China (2%), United Arab Emirates (1%), Korea, Rep. (1%), India (1%)
Rice (paddy)	45	10	Turkey (100%)
Sorghum	370	73	Japan (79%), Papua New Guinea (9%), New Zealand (8%), Chinese Taipei (2%), Philippines (1%)
Wheat	14 218	3 582	Indonesia (15%), Egypt (11%), Iraq (10%), Japan (8%), Korea, Rep. (8%), Iran (6%), China (5%), Malaysia (4%), Sudan (4%)
Other cereals	25	5	New Zealand (33%), Japan (31%), Philippines (10%), China (7%), Italy (3%), French Polynesia (3%), Belgium–Luxembourg (2%), Belgium (2%), Portugal (1%)
Oilseeds			
Canola	1 059	467	Japan (47%), Pakistan (23%), China (12%), Bangladesh (9%), United Kingdom (2%), Germany (1%), Belgium (1%), India (1%), Nepal (1%)
Cottonseed	266	80	Japan (53%), United States of America (34%), Korea, Rep. (12%)
Safflower	4	2	Chinese Taipei (19%), France (17%), United States (12%), Belgium (10%), Portugal (8%), Netherlands (7%), Philippines (6%), United Kingdom (4%), Belgium-Luxembourg (3%)
Soybean	6	4	Japan (37%), Chinese Taipei (24%), Papua New Guinea (11%), New Zealand (9%), New Caledonia (7%), Malaysia (6%), Philippines (3%), Sri Lanka (1%), Korea, Rep. (1%)
Sunflower	2	5	Philippines (26%), Pakistan (19%), Thailand (13%), Korea, Rep. (10%), New Zealand (6%), Sudan (5%), South Africa (4%), Japan (4%), China (4%)

Other oilseeds	17	24	Netherlands (35%), United States (21%), United Kingdom (8%), New Zealand (8%), Germany (8%), Japan (8%), Canada (5%), Fiji (1%), Austria (1%)
Pulses			
Chickpea	127	62	Bangladesh (50%), India (26%), Pakistan (11%), United Kingdom (4%), United Arab Emirates (2%), Sri Lanka (1%), Saudi Arabia (1%),Nepal (1%)
Faba bean	189	69	
Field pea	199	66	India (56%), Bangladesh (17%), Sri Lanka (8%), Malaysia (5%), Pakistan (4%), Mauritius (2%), Fiji (2%), Belgium (1%), Philippines (1%), Chinese Taipei (1%)
Lentils	159	86	Confidential
Lupins	428	101	Korea, Rep. (47%), Netherlands (16%), Spain (13%), Japan (11%), Chinese Taipei (6%), Egypt (2%), Thailand (2%), Philippines (1%), Malaysia (1%)
Other legumes			Egypt (53%), Saudi Arabia (13%), Belgium (6%), United Arab Emirates (5%), Indonesia (3%), Philippines (3%), Sri Lanka (2%), India (2%), Italy (2%), Chinese Taipei (2%)

Source: Based on data from ABS (2005).

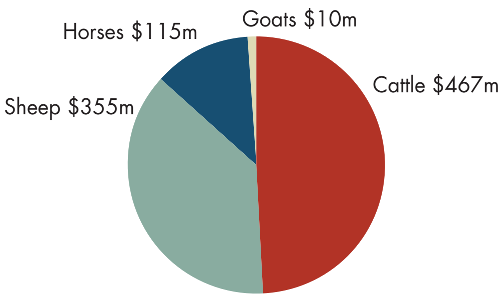
GM carnations have also been commercialised in Australia. GM canola has been licensed for environmental release by the Office of the Gene Technology Regulator but there are moratoriums for differing lengths of time on commercial growing of GM food crops including canola in all states and territories other than Queensland (which is not a canola producing state) and the Northern Territory.

There has been GM research in Australia into grains, oilseeds, pulses, sugar cane and a range of GM horticultural crops, including bananas, carrots, celery, cucumbers, flowers, lettuces, mangoes, papayas, pineapples, pome fruits, potatoes, tomatoes and grape vines. More details about gene technology and horticultural crops in Australia are available in Agrifood Awareness Australia (2005a).

There has also been experimentation with GM animals in Australia but no GM animals have been commercialised. For example, pigs were modified in the 1980s to have an extra growth gene that meant they were more efficient in converting feed to body weight than conventional pigs. More details of the use of gene technology with livestock in Australia are available in CSIRO (2004) and Agrifood Awareness Australia (2005b).

Australia's live animal trade is mostly in cattle, sheep, horses and pigs (figure E; ABS 2005). The main markets are in the Middle East and Asian countries such as Brunei, Indonesia and Malaysia. Dairy cattle for breeding purposes have been an increasing component of this export trade in recent years.

E **Value of Australia's live animal exports**
average three years to 2003-04



4

the documentation issue

Documentation issue overview

The aim of the documentation provisions of the Biosafety Protocol are to ensure sufficient information about LMOs in import cargoes is made available to importing countries so that they can make appropriate arrangements to manage any risks that the LMOs pose to biodiversity.

The issues of documentation of LMOs intended for contained use or release into the environment are reasonably straightforward (articles 18.2b and 18.2c) but are more complicated and controversial with for cargoes of LMOs intended for direct use as food, feed and for processing uses that comprise the great bulk of world trade in LMOs (article 18.2a). Complications arise mainly because there can be unintended presence of LMOs in non-LMO cargoes and it usually requires elaborate testing procedures to detect these, particularly in grains when the concentrations of LMO presence are low. Documentation costs can differ according to the extent to which importers are prepared to tolerate levels of unintended presence. This has led to a divergence of views over documentation requirements, essentially between GM producing countries and non-GM producing ones.

The aim in this chapter is to detail the nature of the documentation issue with cargoes of living organisms intended for direct food, feed and processing uses.

Unintended (or adventitious) presence of LMOs

It is difficult to keep unintended presence of LMOs out of cargoes in mixed production and marketing systems of GM and non-GM organisms. The unintended presence comes through cross breeding with plants and animals, or through co-mingling in the handling, storage and transport process.

The grain industry routinely deals with unintended presence of foreign seeds in grain lots and a system of tolerances has evolved. For example, the tolerances for canola in wheat set by AWB Limited in Australia are 0.6 per cent by weight with milling wheat grades and 1.2 per cent with general purpose and feed grades (see AWB Limited 2005). The tests are largely visual ones, often based on a sieving process that takes account of differences in sizes of different grains.

However, because there is usually no readily discernible difference in appearance between conventional and GM organisms of the same variety, the presence of GM material is detected through modified DNA or the unique proteins that the GM plants produce. To minimise the possibility of unintended presence, segregation or identity preservation arrangements are often put in place to keep GM and non-GM organisms strictly separate in the handling and storage process.

Testing procedures

Testing for the presence of GM materials is costly and separate tests are often required for each GM event. There are simple strip tests costing around US$5–10 that take 5–10 minutes to provide a yes/no answer on the presence of GM material. These are ELISA–type tests (see box 1) that look for the proteins that are common to a range of GM events, such as herbicide tolerance, but they cannot differentiate between some GM events. There is also a quantitative ELISA test that costs around $15–40 a test in the United States and around $35 a test in Australia.

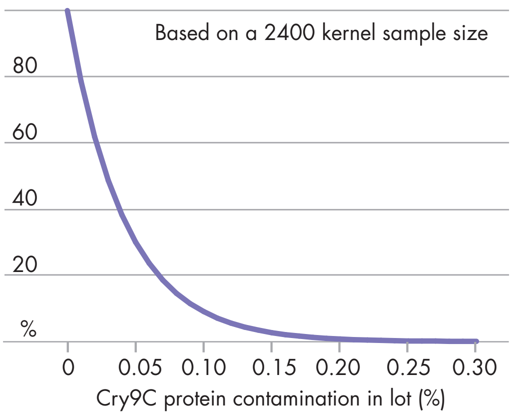
More elaborate tests such as Polymerase Chain Reaction (PCR) tests can take days and cost around US$150 a test in the United States or a minimum $500 a test in Australia but can provide quantitative measures of the level of presence of GM material and resolve some of the ambiguities associated with ELISA tests. More details on tests for GM presence are outlined in box 1.

In many cases, a quick yes/no test will be undertaken and, if the presence of GM material is indicated, more comprehensive testing will be carried out using the quantitative ELISA or PCR tests, either to confirm the result or, if required, to quantify the level of GM material present or identify the event.

There is the possibility of error with any test of the qualities of a grain cargo. Sources of error are sampling techniques, sample preparation (the possibility of contamination) and analytical method. Methods for sampling for detection of GM grains are described, for example, in GIPSA (2000) and Viljoen et al. (2005). However, there are no internationally standardised methods for sampling and analysing GMOs (Toepfer International 2004). The sources of error mean, for example, that a cargo with a small GM presence could be found not to contain GM presence (a negative result) at the export position but could be tested again at the import destination and be found to contain GM presence, even if exactly the same sampling protocols and analytical tests are employed. This is usually termed a 'false negative'. False positives are also possible through, for example, contamination of the test sample.

This issue is illustrated with the case of StarLink corn where the indicator protein to be detected in samples is Cry9C. In figure F is shown the probability of accepting a grain sample as not containing Cry9C at different actual levels of presence of Cry9C, based on statistical confidence levels calculated by the Grain Inspection, Packers and Stockyards Administration (GIPSA 2004) for approved StarLink testing procedures. It can be seen that the probability of accepting a grain sample as not containing Cry9C when the protein is in fact present — a false negative — increases as the level of Cry9C presence decreases. For example, if Cry9C is present in the sample at a concentration of 0.2 per cent, the probability of accepting the sample as not containing Cry9Cis around 0.8 per cent. However, the probability of a false negative increases to 30 per cent when the actual level of Cry9C presence is 0.05 per cent. It should be noted that the curve in the figure is based on a sample size of

F **Probability of accepting a corn shipment**



Box 1: Tests for presence of GM material

A review of the technologies for detecting GM materials in commodities and food is provided by Griffiths et al. (2003). The three main forms of tests for GM material are: bioassays, PCR (polymerase chain reaction) tests and ELISA (enzyme linked immunosorbent assay) tests.

A bioassay can be used with herbicide tolerant crops. It involves growing the seeds to be tested and then spraying the growing plants with the herbicide to which they are thought to be resistant. The plants that survive are likely to be genetically modified (though it is possible that some nongenetically modified plants can also have herbicide resistance).

The PCR test detects modified DNA, while the ELISA test detects the unique proteins produced as a result of the genetic modification. There are elaborate forms of each of these tests that enable quantitative assessments of the presence of GM material (what proportion of the sample is GM material, and simpler strip or dipstick tests that essentially allow qualitative assessments to show the presence of the target GM material).

Neither PCR nor ELISA can detect some processed products derived from GM crops — for example, oil derived from herbicide tolerant canola — because the processing has removed the modified DNA or the unique protein.

The characteristics of these tests under US conditions are summarised in the table below according to what they are able to detect, cost per sample, speed of test and sensitivity. It can be seen that there are various tradeoffs involved with these tests. For example, a strip test is faster and less costly than a PCR test. However, the sensitivity of the strip test is much lower than with a PCR test, being able to detect only a one in two hundred presence compared with the one in ten thousand presence capability of the PCR test. A searchable online database, maintained by the Joint Research Centre of the European Commission, provides GM event & specific details of analytical methods for DNA and protein detection and quantification (see Joint Research Centre 2005).

In Australia, the minimum cost for a PCR test appears to be around $500, with $100 for each additional screen. The typical turnaround time is 1–3 days, though at least one testing laboratory is offering an express service of 24 hours at a 100 per cent surcharge.

For the ELISA test in Australia, the cost appears to be around $35 per test. However, this is only for a minimum number of ten samples (reflecting that the smallest test plate contains ten wells).

Analytical test to detect traits introduced into plants through genetic modification

Test type	Target	Cost per sample (US$)	Speed	Sensitivity	Current traits
Bioassay	Herbicide tolerance	40	7-14 days	Quantitative	RR, LL, BXN, STS, IMI
Strip tests	Protein	5-10	10 minutes	Qualitative; 1/200 to 1/1000	RR, LL, Bt corn
ELISA	Protein	15-40	4 hours	Quantitative	RR (CP4), Bt corn
PCR	DNA	150-200	1 day	Qualitative; 1/10000	All commercial events
Quantitative PCR	DNA	250-325	1 day	Quantitative; 1/10000	All commercial events

RR: Roundup Ready; LL: Liberty Link; STS: Sulfonylurea tolerant soybeans; IMI: Imidazolinone tolerant; BXN: Buctril tolerant.
Source: Sundstrom, Williams, Van Deynze and Bradford (2002).

2400 kernels. Reducing the sample size would shift the curve out so that the probability of a false negative is increased at all levels of actual presence (see, for example, Johnson and Lin 2005).

Certification of grain quality

It is usual for buyers of grain to require certification of the qualities of the grain that they purchase. More details about the nature of the grain inspection and quality certification arrangements are provided in appendix B.

Grain exporters could provide their own inhouse test results to customers. This can work effectively when there is a relationship of trust between buyer and seller—for example, where there has been a long relationship. However, it is likely that many purchasers require third party certification of quality characteristics of a cargo— that is, confirmation of the quality from a party that is recognised as being independent from the buyer and seller. The certification process is based on a traceable and auditable identity preservation system and/or a robust and reliable testing regime.

The third parties could be government or private organisations. Governments in a number of countries such as Australia, Canada and the United States have established government agencies to carry out grain inspections. In other major grain exporting countries, such as Argentina and Brazil, inspections are carried out by third-party surveyors. There are many countries throughout the world that prefer government certification to private certification, especially in the cases requiring certification of the presence of LMOs or GM material.

There are a number of cases where governments are requiring certificates with GM grain cargoes. A recent example is where the Japanese Government is requiring certificates from an accredited laboratory stating that cargoes do not contain a GM feed corn variety termed Bt-10 that has accidentally been grown in the United States but which has not been approved for distribution. So far, nine cargoes of feed corn to Japan with accidental presence of Bt-10 have been detected and turned back. An earlier example of certification requirements was with the Starlink corn variety in the early 2000s.

Possible documentation regimes

The key issue is that the documentation requirements could add significantly to the costs of shipping living organisms. The additional costs are not confined to LMO cargoes because of the possibility of unintended presence of LMOs in conventional cargoes. In particular, there could be additional documentation costs for those countries that have production mixes of conventional and genetically modified organisms. The costs are likely to be much smaller for countries that do not have commercial releases of genetically modified organisms because they avoid testing and identity preservation costs.

The costs depend on the nature of the documentation requirements, which is still being negotiated under the protocol. A number of documentation regimes have been proposed.

At one end of the spectrum is a practical, low cost regime whereby the documentation accompanying export shipments of LMOs would be required to say 'may contain' LMOs where an LMO of that commodity species is authorised in, or sold from, the exporting country. However, details of every GM event present in the shipment would not need to be listed as part of the documentation. The 'may contain' documentation would not be required when the exporter and importer have contractually defined a 'non–LMO shipment', provided that such a shipment achieves a minimum of 95 per cent non – LMO content, and that such definition does not conflict with regulations of the importing country. Documentation requirements would be accommodated within the existing system of commercial invoices.

This is essentially the documentation regime proposed by the International Grain Trade Coalition (IGTC) which is made up of seventeen members representing around 1000 individual companies in more than eighty countries. The IGTC was set up specifically in 2001 to address the concern that the protocol could be implemented in such a way that it undermines the benefits of a low cost bulk handling system for commodities for the world's food, feed and processing industries (AWB Limited 2003b). Some key members of the IGTC are Australian Wheat Board Limited, Canada Grains Council (including the Canadian Wheat Board), Chamber of Grain Exporters of the Argentinean Republic, COCERAL (association representing the European cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats trade), Grain and Feed Trade Association, National Corn Growers Association, North American Export Grain Association, US Grains Council and US Wheat Associates.

The tripartite agreement between the United States, Canada and Mexico signed in October 2003 (see Agriculture and Agri-Food Canada 2003) provides a working example of a 'may contain' documentation regime. Under this agreement, the 'may contain' language will simply appear on the commercial invoice; a separate document about the LMO status of the cargo is not required. The last exporter prior to the transboundary movement and the first importer are named on the invoice as the contact points for further information.

At the other end of the spectrum is a complex, prescriptive 'does contain' regime whereby shippers must include the precise list of GM events that are present and in what quantity. Some countries are proposing zero tolerance for unintended presence before documentation is required. This could be costly if tests have to be undertaken for each possible GM event. Some countries are also proposing stand alone documentation — probably a government to government document — rather than using existing commercial invoices. The countries usually identified with documentation regimes that approach the 'does contain' one are the European Union and Norway and a bloc of African countries.

There is an argument that there may not be additional documentation costs attributable to the protocol with all international grain trades (Foster 2001). With grains, for example, commercial trading activities may already be requiring documentation of LMO presence in many countries because of mandatory labeling and other market access conditions (discussed earlier; see also Foster et al. 2003). However, the adoption of a prescriptive documentation regime under the protocol might mean that all trades attract additional documentation costs, not just some.

GM livestock may pose less of a problem in terms of transaction costs than do grains because the latter are handled through a central grain bulk handling system. However, it is possible that if a country had livestock populations that were a mix of conventional and GM animals that some sort of testing regime or 'trace back' regime may be necessary to assure customers who wanted to avoid GM animals.

A National Livestock Identification Scheme (NLIS) is already operating in Australia that enables traceability of cattle throughout the supply chain through a database that records cattle transactions from producer to retailer.

The US Department of Agriculture is developing a National Animal Identification System (NAIS) that is intended to enable tracing of the movements of animals. The main aim of the system is to ensure rapid disease containment (US Department of Agriculture 2005b). Participation in the scheme is voluntary.

5

estimation of grain documentation costs

There are essentially two documentation options open to grain marketers. The first option is simply to test and label as appropriate under the Protocol arrangements. The second option is to implement an identity preservation scheme with the grain to ensure that unintended presence is contained to levels at which Protocol-consistent labeling is not required. Testing is an integral part of the identity preservation arrangements as verification that the process is delivering grain that meets the standards required. The advantage of this second option is that it avoids the stigma and liability associated with identifying cargoes as containing LMOs. An important component of the cost of identity preservation is testing costs to verify that the process is delivering the target quality standard.

With both of these options there is the possibility that under some proposals with the protocol negotiations government certification of documentation will be required. Inextricably linked with each of these options are risks and liabilities associated with GM presence.

In summary, there are four possible components of estimating documentation costs:

- cost of testing to identifying the GM quality characteristics of the grain
- possible requirement for certification by a government agency
- coordination costs or identity preservation costs and
- risks and liabilities associated with testing errors.

Testing costs

The cost of testing and certification are mainly laboratory testing expenses but also include the costs of collecting and maintaining samples and communicating with the laboratories and third party certifiers. As Kalaitzandonakes (2004) acknowledges, the costs other than laboratory testing are difficult to quantify.

The costs are likely to vary according to the number of possible GM events that are to be detected. Countries such as the United States and Canada could have relatively large costs because so many GM events have been commercialised in these countries. For example, JRG Consulting (2004) points out 31 events (now 32) would have to be tested for in Canada and says that the cost per test for each event is around C$150.

The testing costs could be approximately doubled if there is a need for importers to also carry out laboratory tests at the destination port. (Costs associated with risks introduced with a dual testing regime are discussed further below.)

It can be seen from table 6 that because the testing cost is largely the same for small cargoes as for large cargoes, the cost per tonne of testing declines as cargoes get bigger. For example,

6 Relationship between testing costs per tonne and grain cargo size

	Lateral flow test, costing US$10/event			PCR test, costing US$150/event		
	Number of events to be tested:			Number of events to be tested:		
Cargo size	1	5	30	1	5	30
Tonnes	US$/t	US$/t	US$/t	US$/t	US$/t	US$/t
100	0.10	0.50	3.00	1.50	7.50	45.00
1 000	0.01	0.05	0.30	0.15	0.75	4.50
5 000	0.00	0.01	0.06	0.03	0.15	0.90
10 000	0.00	0.01	0.03	0.02	0.08	0.45
50 000	0.00	0.00	0.01	0.00	0.02	0.09

a Assumes only the exporter tests for GM events.

the cost of testing for five GM events using the PCR method would be around US$7.50 a tonne with a cargo of 100 tonnes but only US$0.02 with a 50 000 tonne cargo. It is likely that many less developed countries, particularly small island economies, fall into the category of smaller shipment sizes.

Using the case study of corn, Kalaitzandonakes (2004) estimates that if the protocol required a quantitative assessment of the specific LMO events in each cargo of US and Argentinean corn, the annual cost of laboratory testing could be around US$4.4 million. (Kalaitzandonakes did not attempt to estimate costs other than laboratory costs.) However, Kalaitzandonakes points to the possibility that the European Union would require around twenty separate tests for each grain shipment, with the implication that estimated laboratory testing costs could be as high as US$87 million a year. However, no evidence was found of such an onerous requirement with GM testing on the web site of the Joint Research Centre of the European Commission, the organisation charged with providing a sound scientific basis for workable legislation on traceability and the cultivation and consumption of GMOs in the European Union.

Certification by government agencies

Some countries may require certification of LMO content by a government agency. There are a number of countries that prefer third party certification by government agencies, most notably Japan. The nature of grain inspection and certification arrangements in the key grain exporting countries is outlined in appendix B.

Government agencies already exist in most countries to administer arrangements under the World Trade Organisation's Agreement on Sanitary and Phytosanitary Measures (SPS). The SPS agreement establishes members' rights to take SPS measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the Agreement. Member countries are encouraged to use existing international standards, guidelines and recommendations. For food safety, the relevant organisation is the joint FAO/WHO Codex Alimentarius Commission. For plant health, the standards are based on the Food and Agriculture Organisation's International Plant Protection Convention; for animal health, the standards are based on those of the Office International Epizooties.

There are countries where government agencies are involved in grain inspection, such as Australia (Australian Quarantine and Inspection Service), Canada (Canadian Grain Commission) and the United States (Grain Inspection, Packers and Stockyards Administration). These agencies do not usually carry out testing for GM presence. Rather, the testing is carried out by accredited laboratories, with the role of the government agency involved in grain inspection being to certify that the documentation is valid and that unintended LMO presence is not introduced in ship loading operations. In many cases — certainly with Australia, Canada and the United States — agencies charge for providing grain inspection services and are likely to be required to recover any additional costs associated with providing the certifying service in regard to GM presence.

Certification by a government agency is more difficult in other main grain exporting countries such as Brazil and Argentina where government agencies are not directly involved in grain inspection. Instead, the governments in Brazil and Argentina accredit private surveyors to perform inspection. Nevertheless, there are government agencies in these countries that issue phytosanitary certificates, based on assessments by the private surveyors.

The fees charged by the appropriate government agencies for phytosanitary certificates with grain exports are likely to be an indication of the cost of providing government certification of stand alone documentation of LMO presence. The bases on which fees for phytosanitary certificates in the main grain exporting countries are charged are shown in table 7.

7 Fees charged for phytosanitary certificates by government agencies in the main grain exporting countries, 2005

Country	Agency	Fee charging basis
Argentina	El Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)	US$0.17/t plus about $0.03/t for overtime and travel expenses (GIPSA 2004)
Australia	Australian Quarantine and Inspection Service (AQIS)	$0.023/t for bulk shipments or $0.26/t with containerised shipments. There is also cost of producing documentation (phtyosanitary certificate, export permit and other documents) of $10 for each consignment
Brazil	Ministry of Agriculture	Annual charges of US$300/entity plus US$100/product are proposed (GIPSA 2004)
Canada	Canadian Grain Commission	C$24 for a letter of assurance on export cargoes (Canadian Grain Commission 2004)
United States	Grain Inspection, Packers and Stockyards Administration	US$0.21/t for inspection and weighing services (US Government 2005)

Identity preservation

Identity preservation is the process by which a crop is grown, handled, delivered and processed under controlled conditions to assure the customer that the crop has maintained its unique identity from farm gate to end use (United Soybean Board 2001). The process involves keeping grain with the desired traits separate from other grains, right from the seed stage to end use which incurs additional costs.

Identity preservation costs differ from grain to grain and from country to country according to the natures of their grain supply chains. Usually grain is identity preserved in relatively small lots so there is often a sacrifice of the economies of scale that characterise large bulk shipments. Generally, in a mixed production system of GM and non-GM, the cost of putting together an identity preserved cargo increases as the target for unintended presence is lowered.

There have been a number of studies that have estimated costs related to achieving different levels of unintended presence; these are summarised in table 8. The estimates are compiled under different assumptions and are only available for Canada and Argentina. (ABARE is in the process of developing identity preservation cost assessments for Australia.) A rough calculation based on these estimates is that meeting a 5 per cent threshold adds 3 per cent to the cost of delivering grain to the end user. The cost rises to around 8 per cent with a target threshold of 1 per cent.

The only experience with identity preservation with non-GM grains in Australia is with cottonseed. The estimated size of the market for non-GM cottonseed from Australia in 2004-05 is around 20 000 tonnes out of total Australian production of 912 000 tonnes. In the Darling Downs region of Queensland in 2005, identity preserved cottonseed was estimated to cost an additional $60 a tonne compared with conventional cottonseed when exported in 20 foot shipping containers (Rod Wolski, Managing Director, A&B Grains, personal communication 14 September 2005). This represents an increase of around 20 per cent in the export supply price (free on board) of cottonseed and mainly reflects extra cleaning at the cotton gin and grain storage and handling facilities.

8 Previous studies: Summary of estimated costs to achieve specified thresholds of unintended presence

Study	Nature	Cost estimates
SAGPyA and FAO (2004)	Assessment of the cost of separating conventional and GM corn in the Argentinean grain export system	US$2.90/t, if the target threshold is 5 per cent, increasing to US$8.30 a tonne if the threshold is set at 0.9 per cent (the threshold level for labeling in the European Union)
Huygen, Veeman and Lerohl (2003)	Identity preservation with non-GM wheat in Canada	US$6.82/t at a threshold of 5 per cent, increasing to $13.29/t if the tolerance is 0.1 per cent
Carter, Berwald and Loyn (2004)	Non-GM wheat in Canada	Depending on assumptions, US$2.86/t to US$4.05/t at a 0.5 per cent threshold
Canada Grains Council (2003)	Assessment of the cost of implementing an identity preservation system with the current Canadian bulk handling system (does not include estimates of farm costs).	Depending on the system, US$4.50/t to US$15.35/t at a threshold of 5 per cent

Risks and liabilities

There may be heightened risks and liabilities associated with the documentation regime of the Protocol. The main risk is that test results at the export position for a grain cargo may differ from tests taken at the import position, because of the various sources of error (discussed earlier). Divergences between the two tests — if a second test is carried out — could mean delays in ship unloading or even the ship being turned away from the intended port. Delays or diversions mean additional costs, such as demurrage.

Demurrage is the daily penalty rate that the charterer pays the owner if the vessel has not been loaded within the time allowed in the charter party (US Grains Council 2004). Demurrage largely reflects the daily value of the vessel. US Grains Council (2004) gives the example of a daily demurrage rate of US$12 000–20 000 for a 50 000 tonne deadweight vessel with a daily value of US$14 000.

A second risk is that a non-LMO cargo that arrives at a port without protocol-consistent documentation could be required to be tested if there is any suspicion that there is presence of

LMOs. This could cause delays in ship unloading, with the delays likely to be especially large with less developed countries or small importing countries where appropriate testing facilities are less readily available than in more developed or large importing countries.

A third risk is that the additional information will cause customs officers or importers at the destination port to delay or reject a grain shipment because of the presence of LMOs. Some world trade in grain may be taking place in ignorance of [despite] the presence of LMOs; protocol documentation removes this ignorance.

Another risk that protocol documentation heightens is liability and redress for any damage that LMOs do to biodiversity in the destination country. There is the possibility that this can occur long after the buyer accepts the grain shipment. This is referred to by JRG Consulting Group (2004) as 'lingering liability' and they reported that grain exporters considered that this risk could add significant costs to exporters. Like the documentation provisions, the final form of the liability and redress provisions of the protocol are still to be finalised. JRG Consulting Group (2004). Parties to the protocol have not come to a common understanding of 'damage'.

If the protocol documentation regime leads to perceptions of increased risk to exporters and importers, this could mean that additional risk premiums are built into grain prices. It could be argued that because the costs associated with the risks are greater with trade with less developed countries and small importers, the risk premium could be higher for this group of countries.

Summary of previous studies

A number of studies provide estimates of the costs of meeting the documentation requirements under the protocol.

As discussed earlier, Kalaitzandonakes (2004) found that the cost of testing alone with the 'does contain' regime with Argentinean and US corn exports ranged from US$4.4 million to US$87 million, according to the number of samples from each shipment to be tested. Kalaitzandonakes concluded that the additional costs associated with the 'may contain' regime were small.

JRG Consulting Group (2004) looked at the cost for Canada of complying with various tolerances for unintended presence under the Protocol. The additional costs were mainly testing costs but importantly it was assumed that exporters would carry out identity preservation arrangements to meet the specified tolerances. The study also took into account costs associated with additional grain inspections by the Canadian Grain Commission, lost grain blending opportunities and rejection or redirection of grain shipments. Costs were estimated only with grain shipments to countries that have ratified the protocol.

The JRG Consulting Group conclusion was that the cost of complying with a 'may contain' regime with a tolerance for unintended GM presence of 5 per cent was low because it would require little change from existing operational requirements.

With the 'does contain' regime, the estimated additional costs for Canada with the JRG Consulting Group (2004) study were, according to scenario:

- C$67 million, for a threshold of 1 per cent, with exports of non-GM wheat and barley
- C$33 million, for a threshold of 1 per cent, with exports of corn, soybeans and canola (all crops that have commercialised GM events in Canada)
- C$40 million, for a zero threshold, with exports of corn, soybeans and canola
- C$14.5 million, for a zero threshold, with exports of wheat and barley.

6

economic implications of documentation regimes

Market impact of increased documentation requirements

The protocol has implications for a range of plant and animal industries but it is likely that the main impact of the protocol in the short run will be on the international grain trade where GM varieties are a large component of world trade in soybeans, corn, cottonseed and canola.

The implications of the various proposed documentation regimes depend on the extent to which the costs of delivering export grains are raised. Because world markets for agricultural commodities are competitive ones, it means that inevitably, in the long run, any additional costs will be passed on to consumers in the form of higher prices. Adverse welfare effects from higher prices are likely to be highest in less developed countries where expenditure on food makes up a much larger proportion of total income than in more developed countries.

Costs associated with testing and with providing documentation separate from a commercial invoice can be estimated with reasonable certainty. As discussed earlier, for large grain shipments these costs expressed per tonne are very small — around US$0.02 a tonne for a 50 000 tonnes cargo of grain. However, because they are largely fixed irrespective of the size of the cargo they could be large for small grain shipments — around $7.50 a tonne with a 1000 tonne cargo of grain.

The key unknown in any assessment of the implications of any protocol documentation regime is the extent to which it changes the level of identity preservation in world grain markets. If associated with LMO presence in non-LMO cargoes there is a stigma effect with grain consumers or exposure to liability, then this creates an incentive for grain exporters to identity preserve grain to levels of unintended presence that do not trigger protocol documentation requirements. The economically rational response of an exporter could be to carry out additional identity preservation up to the point at which the marginal cost of doing so is just equal to the cost of providing protocol-consistent documentation plus the perceived cost of the adverse demand effect and lingering liability exposure.

As discussed earlier in this report, grain marketers throughout the world are already dealing with many countries on existing mandatory labeling regimes for GM products in many countries that are unrelated to the protocol. The requirement that all GM events present be identified implies a zero threshold with labeling. This is a much more exacting threshold than currently exists with many countries' mandatory labeling regimes. It also needs to be remembered that in many countries (with the notable exception of the European Union) most products made from existing GM inputs effectively do not require labeling with existing mandatory labeling regimes because there is no modified DNA present in the final product.

In response to changes in costs associated with documentation requirements, patterns of world trade in agricultural commodities would be changed in complex ways.

Price relativities for grain types are changed so there would be some substitution out of the grains that are made more expensive into the grain and nongrain food and feedstuffs — whether genetically modified or not — that are left relatively inexpensive. Industries that use grains directly as inputs would contract in response to higher grain prices.

The raised costs of delivering cargoes that contain LMOs provide incentives for increased processing of products before they are exported. For example, instead of exporting an oilseed, any additional costs associated with the Protocol could be avoided through exporting the oilseed in the processed forms of oil and meal. This would disadvantage countries with low labor costs, such as developing countries, that have industries based on sourcing raw materials from imports.

The protocol also has the potential to alter the pattern of world livestock production because it shifts comparative advantage in favor of feeding GM grains to local livestock (whether for domestic consumption or export), rather than exporting the GM grain. This means that the competitiveness of domestic livestock industries in countries that rely on imports of grain would be adversely affected.

The additional export documentation requirements would also have an impact on adoption of GMOs because it imposes additional costs on both GM and non-GM producers. The debate over the commercialisation of GM canola in Australia in 2003 resulted in key exporters of wheat and barley in Australia opposing the commercialisation because of these concerns. Nonadoption means that the agronomic benefits of GM crops will be forgone and that consumers will not benefit from the resulting lower grain prices.

Market advantage and documentation regimes

There are motivations other than protection of biodiversity for pushing for a 'does contain' documentation regime.

First, any documentation regime that raises costs for shipping LMOs shifts the balance of comparative advantage in favor of grain exporting countries that either do not produce GMOs or have relatively few GM events commercialised. This is a possible explanation for why non-GM producers and exporters of grains such as the European Union are pushing for a 'does contain' documentation regime.

Another possible motivation for pushing for the 'does contain' regime is that it provides a *de facto* regulatory system for countries that do not have the resources to maintain such a system. For example, the documentation regime might help a developing country in Africa to maintain its market access to the Europe Union for its corn. This is because it helps in the process of ensuring that GM corn varieties that are not approved for import into the European Union do not become established from corn that the developing country imports from GM producers. (There are GM corn varieties that are produced in some GM producing countries, such as the United States, that are not approved for import into the European Union.) The issue is whether a particular country is seeking to impose documentation requirements on the rest of the world that it feels are necessary to protect market access for its products but that are in excess of what is needed to protect biodiversity throughout the world.

Some conclusions

A quantitative assessment was not undertaken with this analysis because the levels of costs depends on the extent to which the level of identity preservation changes with each proposed protocol documentation regime and there is currently very little basis for determining this. This may be an area for future research if these data uncertainties can be overcome. Nevertheless, it is still possible to arrive at some reasonably robust conclusions about the impact of the protocol regimes.

The view of JRG Consulting Group (2004) and Kalaitzandonakes (2004) seems reasonable that the impact on world trade in grains would be minimal for a 'may contain' regime with a tolerance for unintended presence of 5 per cent. Most exporters of non-GM grains would be able to keep unintended presence of GM material under this limit without major changes to grain handling operations or levels of identity preservation. Arguably, it is a regime that is equivalent to, or more tolerant, than all the mandatory labeling regimes that currently exist throughout the world.

As the tolerance for unintended presence is reduced, more and more of a country's grain would need to be tested for LMO presence; at a zero threshold (the 'does contain' documentation regime), just about all grain from GM producing countries would need to be tested. However, as discussed earlier, the changes in per tonne export costs from testing alone would generally be low, so the changes to the pattern of world trade in grain and products using grain as inputs would be slight.

Also as the tolerance for unintended presence is lowered, the incentive for identity preservation of non-GM grain increases and, hence, so do costs. For example, based on the review of literature in chapter 5, it appears that identity preserving grain to a threshold of 1 per cent would add 8 per cent to the cost of supplying grain. No information is available on how much additional identity preservation would occur but a general impression is that it is likely to be substantial, raising the prices of a range of grains to consumers.

countries that have ratified the Cartagena Biosafety Protocol

As at 13 February 2006

Albania
Algeria
Antigua and Barbuda
Armenia
Austria
Azerbaijan

Bahamas
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bhutan
Bolivia
Botswana
Brazil
Bulgaria
Burkina Faso

Cambodia
Cameroon
Cape Verde
China
Colombia
Croatia
Cuba
Cyprus
Czech Republic

Democratic People's Republic of Korea
Democratic Republic of the Congo
Denmark
Djibouti
Dominican Republic

Ecuador
Egypt
El Salvador
Eritrea
Estonia
Ethiopia

Fiji
Finland
France

Gambia
Germany
Ghana
Greece
Grenada
Guatemala

Hungary

India
Indonesia
Iran
Ireland
Italy

Japan
Jordan

Kenya
Kiribati
Kyrgyzstan

Lao People's Democratic Republic
Latvia
Lesotho
Liberia
Libya
Lithuania
Luxembourg

Madagascar
Malaysia
Maldives
Mali
Marshall Islands
Mauritania
Mauritius
Mexico
Mongolia
Mozambique

Namibia
Nauru
Netherlands
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norway

Oman

Palau
Panama
Papua New Guinea
Paraguay
Peru
Poland
Portugal

Republic of Moldova
Romania
Rwanda

Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
Senegal
Seychelles
Slovakia
Slovenia
Solomon Islands
South Africa
Spain
Sri Lanka
Sudan
Swaziland
Sweden
Switzerland
Syria

Tajikistan
Thailand
The Former Yugoslav Republic of Macedonia
Togo
Tonga
Trinidad and Tobago
Tunisia
Turkey

Uganda
Ukraine
United Kingdom
United Republic of Tanzania

Venezuela
Viet Nam

Yemen

Zambia
Zimbabwe

grain inspection and certification

The aim in this appendix is to outline the arrangements for grain inspection and certification of grain quality in world markets. There is a mix of government and private agencies involved in this task.

Government export inspection

Governments have important roles in grain inspection in the main grain exporting countries but the extent of this involvement varies from country to country.

Australia

In Australia, the key government agency that performs a certification role is the Australian Quarantine and Inspection Service (AQIS) that, under the *Quarantine Act 1908*, regulates imports into Australia of all animal, plant and biological products that may pose a pest or disease risk.

Under the *Export Control Act 1982*, AQIS also certifies that exports of products from Australia meet the requirements of importing country governments in accordance with the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organisation arrangements. Information that underpins the certification process is also drawn from third party sources such as Commonwealth or state government agencies or testing laboratories.

AQIS is required to recover the costs of the service that it provides. For bulk shipments, certification assurance is charged at $0.023 for each tonne; the charge for containerised grain is $0.26 a tonne (AQIS 2004a). There is a $10 fee per consignment for producing the certification.

In Australia, organic and biodynamic produce is prescribed under the Export Control (Organic Produce Certification) Orders, which requires AQIS to conduct audits of approved certification organisations to ensure ongoing compliance against legislation, the national standard and importing country requirements (see AQIS 2004b). Where an organisation satisfies these requirements, it is given the authority by AQIS to issue organic produce certificates for export purposes.

The AQIS practice on certification of the GM status of a commodity for which there has been no GM release in Australia has been to attach to its export certification a statement from the Office of the Gene Technology Regulator (OGTR) that there has been no commercial release of a GM form of that commodity in Australia. AQIS does not do testing for GM presence and it only adds an OGTR sourced statement when there is a government to government requirement.

The National Measurement Institute (NMI) has responsibility for the Australian Government's measurement functions as described in the *National Measurement Act 1960*. NMI assists participants in the food chain with GM testing of food and grains, particularly cottonseed, offering a range of methods accredited by the National Association of Testing Authorities to

ISO/IEC 17025 standards (National Measurement Institute 2005). NMI has a program aimed at enhancing Australia's capability in the identiification of GM materia.

United States

In the United States, export grain inspection is mandatory by the Federal Grain Inspection Service (FGIS) of the US Department of Agriculture's Grain Inspection, Packers and Stockyards Administration (GIPSA). With grains, FGIS provides grain quality verification and weighing services. GIPSA is required to cover the costs of its operations through the fees that it charges for grain inspections.

The key additional roles performed by GIPSA on GM grains and oilseeds are sampling guidelines (see GIPSA 2000) and the evaluation of the performance of rapid tests for all GM grains and oilseeds (Rapid Test Performance Evaluation Program). A list of rapid test kits for the analysis of GM grains is provided in GIPSA (2005a). GIPSA also intends to provide voluntary testing services using rapid test kits that GIPSA has verified (GIPSA 2005b).

GIPSA also provides what it terms 'transgenic status' statements—for example, 'There are no transgenic wheat varieties for sale or in commercial production in the United States' or 'The United States Department of Agriculture has deregulated two varieties of transgenic herbicide-tolerant rice (*Oryza sativa*); but based upon information provided by the developer, these varieties were not available for sale as of February 28, 2005' (GIPSA 2005c).

In an apparent response to the issues raised by GM grain and increasing demand for value enhanced grains, GIPSA is exploring the feasibility of providing a voluntary 'Process Verification Program' to facilitate the marketing of grains and other agricultural commodities (GIPSA 2005b).

Canada

Grain inspection in Canada is carried out by the Canadian Grain Commission, a federal government agency. The Commission has a number of roles in the regulation of grain handling systems in Canada. Like GIPSA, it provides quantity and quality assurance to purchasers of Canadian grains and oilseeds. Certification by the Canadian Grain Commission is the basis of the Canadian Identity Preserved Recognition System.

The Canadian Grain Commission recovers its costs from industry through the fees that it charges for its services. Grading certificates based on unofficial samples are issued for C$15.10 for wheat and corn, C$21.70 for other grains and C$24.40 for oilseeds. A statement of verification from the Commission costs C$16.00.

Brazil

The Brazilian grain inspection system is based on the use of private surveyors, accredited and periodically audited by the Ministry of Agriculture. (Grain inspection was privatised in 2000.) The Ministry of Agriculture issues phytosanitary certificates, based on inspections provided by the private surveyors. No fee was charged by the Ministry of Agriculture for phytosanitary certificates until 2005, when annual charges were introduced of $300 for each entity plus US$100 for each product.

There are currently around 30 private surveyors with sampling, inspection and quality assurance procedures being based on guidelines set by the Grain and Feed Trade Inspection Association (GAFTA) and the Federation of Oils, Seeds and Fats Association (FOSFA) (GIPSA 2004).

There is already extensive testing for the presence of GM grain at the ports of Paranagua and Rio Grande in the Brazilian state of Parana. This is because the Governor of Parana has declared the state as 'biotech free' and grain receipts at those ports are rejected if they contain LMOs.

According to GIPSA (2004), private surveyors in Brazil charge US$120–160 for PCR tests for the presence of LMOs.

Argentina

Grain inspection services were privatised in Argentina in the late 1980s with the services now being performed by around 27 private surveyors accredited by a government agency, El Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA, roughly translated as the National Health and Agrifood Service). All accredited surveyors follow GAFTA/FOSFA inspection guidelines (GIPSA 2004).

SENASA issues phytosanitary certificates, based on the inspections carried out by private surveyors. The charge for issuing this is around $0.20 a tonne (GIPSA 2004).

Private certification and laboratory services

A large proportion of international sales of grain are bought and sold under the terms and conditions of the standard contracts of the Grain and Feed Trade Association (GAFTA), an organisation established in 1878 and comprising international grain traders in over 80 countries. GAFTA maintains a list of GAFTA-registered 'Superintendents' that carry out: inspections, verifications, examinations and assessments of quality and condition of grain traded under GAFTA contract terms (see www.gafta.com/superintendents.asp). GAFTA also maintains a Register of Approved Analysts that consists of grain analysts that comply with GAFTA standards (see www.gafta.com/analysts.asp). Approved analysts can provide certification on the quality for grain, animal feedstuffs, pulses and rice, traded under GAFTA contract terms.

There is a network of laboratories throughout the world that provide testing services related to GMOs and the presence of GM materials. A number seem to have been established in recent years in response to the introduction of GM crops. The natures of selected laboratories and/or certifiers are outlined in table 9.

The general mechanism is for private agencies to be accredited by an independent agency as meeting standards set by reputable organisations such as the International Organisation for Standardisation (ISO). The system for certification is subject to auditing by an accrediting agency. Accreditation uses criteria and procedures specifically developed to determine technical competence, thus assuring customers that the test, calibration or inspection data supplied by the laboratory or inspection service are accurate and reliable. In Australia, the National Association of Testing Authorities, is the federal government endorsed provider of accreditation for laboratories and similar testing facilities.

For GM testing laboratories, the most widely used international standard appears to be ISO/IEC 17025:2005 which specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, nonstandard methods, and laboratorydeveloped methods. Accreditation to ISO/IEC 17025 requires that the laboratory has: a quality system meeting requirements of ISO 9001; adequate equipment to perform its testing or calibration tasks; and adequate laboratory personnel with the competence to perform the calibration and testing. As part of the accreditation process, most certifiers are required to participate in what are termed 'ring trials' and proficiency testing programs, organised by independent bodies, such as the Food Standards Agency in the United Kingdom, or GIPSA in the United States.

9 Selected certification organisations in Australia and the rest of the world

Country and laboratory	Nature	Accreditation
Australia		
AgriQuality	Owned by the New Zealand government, provides laboratory GMO services in Melbourne. Does not provide GM testing facilities.	National Association of Testing Authorities accreditation to ISO/IEC 17025 for technical and quality management systems
Benchmark Group	Australian owned and based certification company with operations throughout Australia, New Zealand, China, Korea, India, Malaysia, Indonesia and the Middle East.	No known
Agrigen Biotech	Australian owned and based company offering bio-analytical services to the food industry and agribusiness in Australia.	Not known
Agrifood Technology Pty Ltd	A subsidiary of the AWB Group in Australia, provides analytical services to assist AWB's marketing program but also to external clients in the food and feed related industries.	Accreditation by National Association of Testing Authorities (NATA, an Australian association) to ISO 17025 standard.
Rest of world		
Genetic ID Inc.	Global headquarters in Fairfield, Iowa, as well as testing laboratories in Japan and Germany, offices in Argentina and Brazil, and the Global Laboratory Alliance (of which Agrifood Technology is a part) of affiliated laboratories and representatives spanning five continents. Parent company of Cert ID	Accredited to BS/EN/ISO/IEC 17025 by the United Kingdom Accreditation Service
Genescan	Molecular biological testing for GMOs in food, feed and agricultural raw materials. Majority shareholder is the Eurofins Group, the international bioanalytical service provider.	Accredited to ISO/IEC 17025 standards by the American Association for Laboratory Accreditation (A2LA)
FASMAC (Food Assessment and Management Center	Established in 2001 in Japan. Provides a range of testing for food, primarily GMOs.	Not known
SGS	One of the world's leading inspection, verification, testing and certification companies, with a network of around 1000 offices and laboratories around the world. Services for grains include identity preservation programs and issuance of non-GM certificates.	Not known

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