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FINAL REPORT OF A MISSION

CARRIED OUT IN

CANADA

FROM 04 TO 13 OCTOBER 2010

IN ORDER TO EVALUATE THE CONTROL SYSTEMS FOR GENETICALLY MODIFIED ORGANISMS (GMOS) IN RESPECT OF SEED, FOOD AND FEED INTENDED FOR EXPORT TO THE EU

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a mission carried out in Canada from 4 to 15 October 2010 in order to evaluate the control systems for genetically modified organisms (GMO) in respect of seed, food and feed intended for export into the European Union (EU), with particular attention to the measures in place to ensure freedom from GMO in flaxseed (*Linum usitatissimum*) that are not authorised by the European Union (EU).

Canada has established detailed product based procedures and assessments for plants with novel traits, food and feed derived from biotechnology. This provides a high level of assurance with regards to the safety of such plants and products in the Canadian market.

The protocol for the export of flaxseed to the EU is being fully implemented by a combination of controls by the competent authorities and industry initiatives, including a stewardship scheme established by the Flax Council of Canada (FCC). Limited official controls have been carried out to assess the cause of the presence of CDC Triffid in flaxseed production but no evidence of the presence of CDC Triffid in the national seed supply was found. The testing regime introduced by the FCC has found widespread, low-level contamination of the flaxseed production and one significant finding of CDC Triffid has been confirmed. Action has been taken to exclude all of these from the export chain for the EU, further increasing confidence in the absence of CDC Triffid in flaxseed exported to the EU.

The widespread low-level presence of CDC Triffid found in the national production and the level of rejections both at producer and terminal elevator stages indicate that the protocol may need to remain in place for the foreseeable future to exclude the risk of CDC Triffid being present in flaxseed exported to the EU.

There is good laboratory support in Canada relating to GMOs; some shortcomings were identified in the interpretation of laboratory results, which if not addressed, may affect the reliability of the Canadian Grain Commission (CGC) certification for flaxseed exported to the EU.

Recommendations are made in the report to address the shortcomings identified during the mission.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
Accredited laboratory	In the context of the protocol - a laboratory that has been accredited to ISO17025
CCC	Canadian Canola Council
CDC Triffid	CDC Triffid event FP967 flaxseed, with the unique identifier CDC-FLØØ1-2
CFIA	Canadian Food Inspection Agency
CGC	Canadian Grain Commission
Ct Value	Cycle Threshold (real time PCR)
DG SANCO	European Commission Directorate-General for Health and Consumers (*La DG de la santé et des consommateurs*)
DNA	Deoxyribonucleic acid
Event	Transformation event
EU	European Union
FCC	Flax Council of Canada
FVO	Food and Veterinary Office of the European Commission
GM	Genetically modified
GMO	Genetically modified organism.
IP	Identity Preserved (scheme)
ISO	International Standards Organisation
PBO	Plant Biosafety Office of the CFIA
PBRA	Plant and Biotechnology Risk Assessment Unit of the CFIA
PCR	Polymerase Chain Reaction
PNT	Plant with novel trait
Proficient laboratory	In the context of the protocol – a laboratory that is listed by the CGC as proficient in carrying out the analysis for the presence of CDC Triffid.
Protocol	Protocol for the export of Flaxseed to the European Union - March 2010
RASFF	The European Union's Rapid Alert System for Food and Feed
Refuge	A non GMO crop planted alongside a genetically modified one to prevent or slow the development of predators resistant to its modified properties by purposely encouraging the mating of species across said crops
Stacked event	A GMO that includes more than one gene from another organism.
Transgenic organism	A GMO in which DNA from a different species has been inserted
Volunteer plant	Self-set plants from the previous years crop(s)

1 Introduction

The mission took place in Canada from 4 to 15 October 2010, in addition to the Food and Veterinary Office's planned mission programme following findings of a genetically modified (GM) variety of flaxseed in consignments imported to the EU from Canada, and the subsequent adoption of a protocol to reduce the likelihood of further findings (see section 4 below).

The mission team consisted of two inspectors from the FVO, one policy officer from DG SANCO and one National Expert from an EU Member State. Representatives from the Canadian Grain Commission accompanied the team throughout the mission.

An opening meeting was held on 4 October 2010 at the headquarters of the Canadian Food Inspection Agency in Ottawa, during which, the objectives and itinerary for the mission were confirmed by the team, and additional information, necessary for the conduct of the mission, was requested.

2 Objectives Of The Mission

The objective of the mission was to evaluate the control systems for genetically modified organisms in respect of seed, food and feed intended for export into the European Union, with particular attention to the measures in place to ensure freedom from GM events in flaxseed (*Linum usitatissimum*) that are not authorised by the European Union (EU).

The mission was carried out in the framework of:

- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003 in so far as they apply to the export of GMO products to the EU.
- The Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union and Addendum Sampling and Testing Protocol for flaxseed exported in containers, March 2010.

The table below lists the sites visited and meetings held in order to achieve the objective:

Competent authority visits			**Comments**
Competent authorities	Headquarters	3	Canadian Food Inspection Agency (CFIA) and Health Canada - Ottawa, Canadian Grain Commission (CGC) Winnipeg
Local offices	CFIA	1	Plant Biosafety Office (Saskatoon)
	CGC	1	Thunder Bay
Stakeholders			
Flax Council of Canada		1	Winnipeg
Canola Council of Canada		1	Winnipeg

Laboratory visits		**Comments**
Official laboratories	1	CGC Grain Research Laboratory
Proficient laboratory	1	Saskatchewan

Control sites		Comments
Flaxseed producer	1	Manitoba
Primary elevator	1	Manitoba
Terminal elevator	1	Thunder Bay
Certified Seed Sampler	1	Manitoba – exports in containers

3 Legal Basis for the Mission

The mission was carried out in agreement with the Canadian authorities, under the general provisions of EU legislation, in particular Article 46 of Regulation (EC) No 882/2004.

3.1 Relevant EU legislation

Article 46 of Regulation 882/2004/EC authorises the Commission to carry out official controls in third countries in order to verify the compliance or equivalence of third country legislation and systems with European Union feed and food law. The Article provides that such controls should have particular regard to the legislation, organization of competent authorities, diagnostic facilities and the assurance that the third country can give regarding compliance with, or equivalence to, EU requirements.

The mission team evaluated the equivalence of the assurances provided by the legislation, procedures and controls in Canada with respect to the export of seed, feed and food to the EU, against those provided for by relevant EU legislation, in particular:

- Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.
- Regulation 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation,
- Council Directive 53/2003 of 13 June 2002 on the common catalogue of varieties of agricultural plant species.
- Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

3.2 Relevant Standards

The mission team evaluated the implementation of the Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union and Addendum Sampling and Testing Protocol for flaxseed exported in containers, of March 2010 (hereafter 'the protocol').

4 Background

This was the first mission carried out by the FVO to Canada to evaluate the official controls for genetically modified organisms (GMO) in seed and food and feed intended for export to the European Union (EU). The FVO has previously carried out a series of missions to Member States and to a number of third countries on the same topic. The reports of these missions are available on

the FVO's website: http://ec.europa.eu/food/fvo/index_en.cfm

The mission to Canada was undertaken following a series of alerts reported in the European Union's Rapid Alert System for Food and Feed (RASFF – the RASFF portal is available via: http://ec.europa.eu/food/food/rapidalert/index_en.htm) for the suspected presence of a non-authorised GM event in flaxseed exported to the EU from Canada. In 2009 there were 71 alerts related to this event. There were a further 9 alerts in 2010, 7 of which were prior to the protocol coming into effect.

A molecular construct specific assay was issued by the Joint Research Centre of the European Commission on 15 October 2009, which permitted the detection of the CDC Triffid event FP967 (http://gmo-crl.jrc.ec.europa.eu/doc/Flax_FP967_verification_report.pdf) (see section 4.3. below).

Following bilateral contacts between the EU and Canada, and the agreement of the Standing Committee for the Food Chain and Animal Health (SCFCAH), the protocol for the export of Flaxseed to the EU was adopted. It was amended in order to better align with bulk and container handling procedures; the final version of the Protocol was adopted in March 2010.

The full text of the protocol is available on the website of the Canadian Grain Commission (http://www.grainscanada.gc.ca/gmflax-lingm/stpf-peevl-eng.htm).

4.1 CDC Triffid event FP967 Flaxseed

The transgenic flax variety 'CDC Triffid' was developed by the Crop Development Centre of the University of Saskatchewan. The variety has enhanced tolerance to sulfonylurea herbicide residues in soil. Such herbicides are commonly used in Canada to control weeds in cereal crops. Some formulations persist in the soil for months or even years, which precludes the planting of 'broad-leaf' (dicotyledon) crops, including flaxseed, in rotations.

The variety is referred to as CDC Triffid event FP967 and has the unique identifier CDC-FLØØ1-2. For the purposes of this report, it will hereafter be referred to as CDC Triffid.

CDC Triffid was approved for unconfined environmental release and use in animal feeds in Canada in May 1996, by Decision 98-2. The variety was also registered in 1996. Health Canada gave approval for use in food in February 1998. The variety gained similar approvals in the USA in 1998 and 1999 respectively.

The registrant for CDC Triffid voluntarily withdrew variety registration in 2001 with the intention of pre-empting potential problems with export markets (in particular the EU). The approvals of CDC Triffid for unconfined release and for use in food and feed remain extant.

At the time of the mission there were no GM varieties of flax registered in Canada.

4.2 Production

Linum usitatissimum is commonly known as flax or flaxseed in North America and linseed in Europe. It is grown either for oil (linseed) or for fibre (flax). Traditionally, the oil has been used for a variety of industrial purposes and the oil-free meal may be fed to livestock. Whole flaxseed is used extensively in baked goods in Europe.

Canada is a major producing country along with Argentina, India, the USA and Russia. The Flax Council of Canada (FCC) informed the mission team that the 10 year average annual production of flaxseed in Canada is 773,000 tonnes.

The Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA) has published a detailed document on the biology of *L. usitatissimum* (ref: BIO1994-10), which serves as a

companion document to Directive 94-08 (see section 5.2.1. below). The key elements relating to flaxseed production are:

- Cultivated flax is an annual, reproducing by means of seed; it is almost entirely self-pollinating; the nature of the pollen means that the incidence of wind-assisted and insect derived cross-pollination is almost zero. The pollen is viable for only a few hours and so there is very little out-crossing by any means.
- Flaxseed may be stored for long periods in farm conditions. The producers met by the mission team indicated that a good level of germination may be obtained even after 10 years farm storage.
- The majority of the crop is produced from non-certified 'common' seed (see section 5.1.1.2. below), although the competent authority informed the mission team that since the discovery of CDC Triffid in shipments of flaxseed exported to the EU, producers have indicated that they have increased the planting of certified seed.

The FCC informed the mission team that weather conditions (high precipitation and early frosts) in 2010 were likely to result in a significant yield reduction (>20%).

4.3 Exports

Canada is a major exporter of cereals, oilseeds and other grains. According to the Canadian Grain Commission (CGC), a total of 32.6 million tonnes of grain and wheat flour was exported from Canada in 2009.

530,200 tonnes of flaxseed were exported in 2008/2009 (August to July), 422,777 tonnes, or 80% of which, was destined for the EU. Three EU Member States accounted for all of the EU imports: Belgium (395,100 tonnes), France (8,400 tonnes) and Germany (19,300 tonnes).

Exports to the EU take place via Thunder Bay (298,000 tonnes) and the eastern seaports (124,000 tonnes).

5 Findings And Conclusions

5.1 Organisational aspects

Legal requirements:

Article 46(1)(a) of Regulation 882/2004 requires that particular regard be paid to the compliance or equivalence of third-country legislation with relevant Union legislation, which is detailed in section 3 above. Article 46(1)(b) of the same regulation requires that particular regard be paid to the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively.

Mission findings:

5.1.1 National Legislation

Provinces are competent for issues relating to land-use within each Province, with the exception of Crown and Federal lands. The Canadian Food Inspection Agency (CFIA) stated that the legislative and policy approach in Canada concerning GMOs is based on the product and not the process by which it was developed. The basis for this approach is that it is the presence of a novel trait that potentially poses an environmental risk or risk to human and animal health, rather than how the trait

was specifically introduced to the plant. Canadian legislation refers to plants with novel traits (PNTs), which are defined as:

- Plants into which one or more traits have been intentionally introduced, and
- Where the introduced trait is both new to cultivated populations of the species in Canada and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. Particular factors considered include the “five pillars”: potential to become a weed, potential consequences of gene flow, potential to become a plant pest and impact on non-target organisms and biodiversity.

PNTs may be produced using conventional plant production methods such as back-crossing and mutation induction, or through the use of genetic engineering (recombinant DNA).

5.1.1.1 Seed legislation related to GMO

The Seeds Acts is administered by the Plant Products Directorate of the CFIA and provides authority to regulate the quality, testing, inspection and sale of seeds in Canada. The Seeds Regulations, specifically Part V – 'release of seeds', defines the regulatory requirements for both confined and unconfined environmental release of PNTs in Canada (see section 5.2.1. below). Directive 94-08 on the Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, describes the procedure for the assessment of PNTs.

The Seeds Acts permit the sale of both 'pedigree' and 'common’ seed, the main difference between pedigreed seed and common seed is that the former must meet the field inspection procedures (verified by official or officially licensed inspectors) and varietal purity standards established by the Canadian Seed Growers' Association, whereas common seed is of unverified origin, which cannot be referred to by variety name, and has no varietal purity standard.

5.1.1.2 Feed legislation related to GMO

The manufacture, sale and import of livestock feeds are regulated by the Feeds Acts and Regulations. Approved feed ingredients are listed and defined in Schedules IV and V of the Feeds Regulations.

Novel feeds are considered to be those derived from an organism, or parts or products thereof that are not approved as livestock feed in Canada (i.e. are not listed in Schedule IV or V of the Feed Regulations) and/or contain a novel trait.

A novel trait is defined as a heritable characteristic of a feed that is not substantially equivalent in terms of its specific use and safety to a characteristic of a similar feed included in Schedule IV or V of the Regulation. For novel feeds derived from plant sources, a novel trait is a heritable characteristic that is new to the plant species or is an endogenous trait that has been modified, such that it differs from conventional parameters for that plant species. Similarly to the approach for plants, it is the presence of the novel trait and not the method used to introduce the trait that is considered; the trigger for a risk assessment is novelty. The authorisation process for novel feeds is covered in section 5.2.4. below.

5.1.1.3 Food legislation related to GMO

The Food and Drugs Act and Regulations cover the regulation of novel food in Canada. Novel food is defined as:

- a substance, including a micro-organism, that does not have a history of safe use as a food or;

- a food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food and which causes the food to undergo a major change (e.g. high pressure processing of fruit) or;
- a food that is derived from a plant, animal or micro-organism that has been genetically modified such that:
    - the plant, animal or micro-organism exhibits characteristics that were not previously observed in it, or
    - the plant, animal or micro-organism no longer exhibits characteristics that were previously observed in it, or;
    - one or more characteristics of the plant, animal or micro-organism no longer fall within the anticipated range for it.

Division 28 (Canada Gazette Part II, October 27 1999) requires that the manufacturer or importer provides notification prior to advertising or sale of novel foods in order that Health Canada may determine the safety of the product prior to the marketing of the novel food being authorised.

The authorisation procedure for novel food is covered in section 5.2.5. below.

5.1.1.4 Non-authorised GMOs

The seed, feed and food Acts and Regulations require mandatory pre-market assessment and authorisation of novel products prior to release or sale in Canada. The release of a novel food or feed or PNT without authorisation would constitute a regulatory non-compliance. The CFIA stated that it addresses any incidents of non-compliance with a case-by-case risk assessment and develops responsive actions commensurate with the level of risk identified. The CFIA informed the mission team that this is not normally an issue for Canada since new GM events are often registered in Canada before other markets.

5.1.2 Competent Authorities:

The Canadian Food Inspection Agency (CFIA) and Health Canada are the lead agencies responsible for the regulatory oversight of biotechnology products derived from plant sources.

The CFIA provides all federal inspection services related to food and is responsible for enforcing the food safety and nutritional quality standards established by Health Canada. The CFIA is also responsible for regulating the organic sector, which includes the oversight of organic certification and the monitoring and enforcement of organic labelling. Further information on the work of CFIA is available on their website: www.inspection.gc.ca

The Plant Biosafety Office of the CFIA is responsible for regulating the environmental release of PNTs in Canada. The PBO administers two PNT specific programmes: the confined research field trial program and the unconfined environmental release. These programmes are covered in section 5.2.1. and 5.2.2. below.

The Seeds Section of the Field Crops Division of CFIA is responsible for the regulatory management of the variety registration and seed certification; their activity is supported by the Seeds Laboratories and Operations section. The CIFA stated that it works in close cooperation with the Canadian Seed Growers Association and the Canadian Seed Institute in this regard.

The Animal Feed Division of the CFIA is responsible for the regulatory overview of livestock feeds, including feeds derived through biotechnology. The regulation of livestock feeds is covered in section 5.2.4. below. Further information on the work of the Animal Feeds Division is available on www.inspection.gc.ca/english/anima/feebet/feebete.shtml

The Food Directorate of Health Canada is responsible for assessing the safety of novel foods and novel food additives (which may include products of genetic engineering) for use in Canada. Further information on Health Canada is available on their website: www.hc-sc.gc.ca

The Canadian Grain Commission is a federal government agency; it is responsible for the inspection, weighing and issue of quality certificates for 21 types of grain, irrespective of whether they are derived from GMO or not. The CGC is based in Winnipeg, and its Grain Research Laboratory (see section 5.7.1. below) is responsible for research, development of new techniques and administers a proficiency testing programme for the purpose of the flaxseed protocol.

The export control system for grains, and in particular flaxseed, is covered in section 5.5. below. Further information on the CGC is available via its website: www.grainscanada.gc.ca

All staff of the CFIA, Health Canada and the CGC are civil servants and are subject to provisions intended to prevent potential conflicts of interest and to ensure the protection of confidential information.

The CFIA maintains a range of detailed instructions and guidelines on the above programmes, on the relevant departments websites.

The various competent authorities informed the mission team that training programmes are in place for all staff. The PBO inspectors who carry out inspections of confined field trials must already be certified as seed samplers and crop inspectors, and have experience of both before they may be trained and authorised. The staff met by the mission team reported that they had been provided with regular training and appeared to be fully competent.

5.1.3 Cooperation with industry and trade organisations

The trade is represented by various 'Councils', which are funded by the relevant industries. The Councils interact with the competent authorities on relevant policy, programming and legislative development and provide input into the CFIA's processes for the registration of new varieties. Two Councils of direct relevance to this mission were the Flax Council of Canada (FCC) and the Canadian Canola Council (CCC). The mission team met with representatives of both organisations; both reported that they enjoyed good cooperation with the competent authorities and both were actively involved in issues related to GMOs.

5.1.3.1 Flax Council of Canada

The FCC was established in 1986 with the aim of promoting Canadian flax and flax products, through market development and an emphasis on research and technical assistance. It includes representatives from all sectors of the industry. It is a non-profit organisation funded by a combination of membership fees and levies from the flaxseed industry and on flaxseed exports. Their activities include the dissemination of technical information, including stewardship schemes and the outcome of the research programmes.

The mission team noted that the FCC has been actively involved in the development of the protocol and has pro-actively developed additional measures to tackle the CDC Triffid issue, for example the development of a stewardship scheme for flax and in taking action in light of new information to protect the export chain for the EU from potential contamination through co-mingling with CDC Triffid (see section 5.6.3. below).

The FCC also presented details of the practical and financial implications of the protocol for producers and in particular the additional costs of testing and implications of risk for exporters to the EU, in particular due to the zero tolerance required by the EU. Further information on the FCC may be obtained from their website: http://www.flaxcouncil.ca

Conclusions:

There is a comprehensive legislative framework in place in Canada in relation to genetically modified seed, feed and food. The approach to GMOs differs from that taken in the EU, in that the Canadian legislation is product based, rather than process based, however there are many similarities in the implementing legislation.

There is a clear structure, and division of responsibilities for the competent authorities responsible for controls of GMOs in Canada. The competent authorities are all official bodies; their staff are subject to requirements intended to ensure that controls are carried out independently and free from potential conflicts of interest.

The competent authorities cooperate and communicate with relevant industries, which are represented by levy funded Councils. There was a good awareness of the EU requirements relating to GMOs and in particular, CDC Triffid.

5.2 GMO RELATED AUTHORISATION PROCEDURES

Legal requirements:

European Union legislation does not apply to Canada, however the following EU legislation provided a basis for the evaluation of the national system required by Article 46 of Regulation 882/2004:

- Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.
- Regulation 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation,
- Council Directive 53/2003 of 13 June 2002 on the common catalogue of varieties of agricultural plant species.

Mission findings:

5.2.1 Field trials and confined environmental release:

Confined release of PNTs may be applied for in cases where the environmental hazard of the PNT is unknown or not fully characterised. The regulatory programme focuses on environmental exposure evaluation by field trials with risk mitigation measures. The provincial authorities are notified of all field trials in their area. Health Canada's Pest Management Regulatory Agency is also notified as many new PNTs are intended for use with plant protection products that are not currently authorised in Canada.

The CFIA stated that the confined research field trial programme is intended to provide plant developers an opportunity to study the PNT and the data required to apply for unconfined environmental release, variety registration and, where appropriate, registration of plant protection products. It is not intended to be used for the production and/or multiplication of PNT seed pending authorisation. The CFIA stated that this is ensured by limiting the size and number of trials and requiring a clear intent for research in the application. At the time of approval for confined field trials, PNTs are not registered; any seed produced during the field trials is therefore not eligible for

inclusion in the plant variety registration system.

Confined trials are subject to conditions intended to prevent persistence and spread of the PNT in the environment and to prevent contamination of the food chain. Each field trial is inspected by the PBO. The CFIA informed the mission team that trial sites are usually limited to 1ha/construct and a maximum of 5 sites per Province. The minimum isolation distances and periods of post-harvest land use restrictions for confined research trials is listed, by crop type, on the CFIA website at: www.inspection.gc.ca/english/plaveg/bio/dir/dir0007e.shtml In addition, the applicant is required to keep records relating to each trial.

The mission team met with representatives of the PBO who detailed the site inspections they carry out and their record keeping systems. Each trial site is subject to inspections during the growing season (usually at flowering), after harvest and each year of the post harvest land use restriction period. The role of the inspections is to determine whether the terms and conditions stipulated for the confined research field trial have been met. The conditions depend on the biology of the crop and the novel trait. During the growing season, the reproductive isolation of the trial plants must be maintained by an isolation distance or another approved method. After harvest, the inspectors verify that the appropriate records are being kept and that plant material from the trial has been accounted for, stored, and/or disposed of in an appropriate manner. During the postharvest restriction period, appropriate measures must be in place to minimize the risk of persistent volunteers from the trial. Any volunteer plants found during the post-trial inspections are considered to be PNTs and must be destroyed before flowering. . Storage and destruction sites are also inspected. The CFIA stated that the authorised person responsible for each trial is notified of the outcome of each on-site inspection. A copy is also sent to PBO headquarters. In case of significant breaches of trial conditions, action is determined by PBO headquarters staff.

In 2010, there were 159 submissions for confined field trials; 797 field trials were approved including 649 for canola, 18 for maize and 115 for soya bean.

The CFIA informed the mission team that the PBO does have authority to take samples of PNTs to confirm the identity of the plants under trial, however this is not done as the containment conditions imposed on confined research trial sites should ensure that there is no risk to the environment.

5.2.2 Unconfined Environmental release

The regulatory approach for the environmental release of PNTs is for an environmental risk evaluation or safety assessment, to be carried out and stewardship schemes to mitigate any risks (e.g. development of resistance to a new PNT). The molecular characteristics and the biological and environmental interactions of the PNT must have been established before an application for unconfined environmental release is submitted. It is the responsibility of the applicant to determine whether a plant to be released into the environment has a novel trait or not. The CFIA has authority to require the applicant to provide scientific justification for their determination that the plant is not a PNT.

The Plant and Biotechnology Risk Assessment Unit (PBRA) of the CFIA conducts the risk/safety assessments on behalf of the Plant Biotechnology Office. The CFIA stated that the PBRA does have access to external expertise if required. Evidence must be provided that the novel trait is stably inherited and that it does not caused unintended effects on the agronomy or composition of the plant. An analysis of potential impacts of gene flow, i.e. crossing of the PNT with other plants that may occur once the PNT is released must also be provided. The potential impact of gene-flow, for example on organic production and socio-economic factors, including potential impact on export markets, are not considered during the assessment.

Based on the PBRA assessment, the PBO decides whether to authorise the release of an event, and

if so, any conditions that are required to mitigate any risks identified by the PBRA. The detection method for the PNT must be provided prior to unconfined release.

A PNT being assessed for unconfined release that could reasonably be expected to be used as feed and food may also trigger a novel food or novel feed assessment. However, since the criteria to be classified as a novel feed or food, differ from that to be considered as a PNT, not all PNTs will be classified as novel food or feed.

As a condition of authorisation for unconfined release, the applicant is required to notify any new information regarding the PNT to the CFIA. The applicant is also required to monitor compliance with any conditions imposed, in particular stewardship programmes. The CFIA stated that failures to comply with stewardship programmes, which are most frequently linked to the absence of required refuges, is dealt with by letter. The CFIA has the authority to consider previous non-compliance in the consideration of current or future approvals for unconfined release and to amend or cancel the authorisations as necessary. However, no situation to date has been found to require such action.

All decisions authorising unconfined environmental release are published on the CFIA website. The CFIA stated that it also notifies the approvals to the relevant international bodies including the Biosafety Clearing House under the Cartegena Protocol on Bio-safety.

5.2.3 Variety registration and de-registration

The aspects most relevant to this mission relate to the approval of varieties with novel traits, which fall under the authority of the Seeds Act and more specifically Part V of the Seeds Regulations. Varieties of most agricultural crops must be registered in Canada before seed of the variety may be sold and/or imported for sale. Seeds of unregistered varieties may not be sold for propagation. The CFIA informed the mission team that it could not be excluded that non-registered varieties may be being sold for planting, as common seed, for which the variety is not declared. There is a tolerance of 2-5% for unregistered varieties in common seed. The CFIA stated that some supervision is carried out to check for such cases, but no data on the number and outcome of controls was available.

The CFIA stated that imported varieties may be eligible for variety registration in Canada if they are assessed for merit according to Canadian procedures. Also, these varieties may be permitted into Canada for multiplication and re-export to the country of origin without being entered into the varietal registration system.

A list of registered varieties with PNTs is published by the CFIA (http://www.inspection.gc.ca/english/plaveg/variet/pntvcne.shtml).

Registration may be cancelled by the CFIA in specific cases, in accordance with section 74 of the Seeds Regulations section 74. The registration for a variety may also be cancelled at any time by written request from the registrant. The registration for CDC Triffid was cancelled on April 1, 2001 on the request of the registrant of the variety.

The CFIA informed the mission team that the voluntary withdrawal of registration of two further CDC flaxseed varieties Mons and Normandy, was publicly announced on 1 August 2010 following confirmation of contamination with CDC Triffid in breeders seed of both varieties. There is a three year transition period; the varieties will be de-registered as of 1 August 2013. The CFIA informed the mission team that it was not known how these two varieties became contaminated with CDC Triffid. The mission team requested a visit to the seed producer concerned, but this was not accepted.

5.2.4 Novel feed

Only feed ingredients that have been approved and evaluated by the Animal Feed division of CFIA may be used in livestock feed. The mission team met with representatives of the Animal Feed Division, who stated that the control of novel feeds is by product based measures including product registration and compositional, nutritional and contaminant standards. The Feeds Regulations were amended in 1996 to include feeds derived through biotechnology. New definitions, including Novel Feeds, were also added.

The CFIA stated that it usually takes one to two years to complete the assessment for PNT based feed. At the time of the mission, 80 novel feed and 15 novel GM microbial products had been approved, including CDC Triffid. No products of biotechnology derived animals have been approved in Canada.

The CFIA stated that there are no direct controls on GM food and feed on the market to ensure compliance with the zero tolerance for non-authorised events in Canada. Where non-compliance is identified, a risk-based approach and measures are applied. Given that most GM events are submitted for authorization in Canada before other markets, and in consideration of the wide variety of traits and genetic material that would need to be identified through specific DNA testing, the CFIA stated that control measures are targeted to cases where a potential risk has been identified, such as through notification from trading partners.

The CFIA also informed the mission team that it reviews international activities in biotechnology and monitors GM registrations in other countries through various sources including the Biosafety Portal, and that this pro-active intelligence gathering, along with cooperation in multilateral international fora (such as North American Biotechnology Initiative) and bilaterally (Canada/China and Canada/India Biotech dialogues) with foreign partners who are also developing and registering PNTs, allows Canada to focus its control measures where there is the most potential risk, and where they can be most effective.

5.2.5 Novel food

The mission team met with representatives of the Food Directorate, which forms part of Health Products and Food Branch of Health Canada who informed the team that a detailed procedure is in place for the assessment of novel foods. The Division issued detailed Guidelines for the Safety Assessment of Novel Foods in June 2006, which detail the notification procedure, other regulatory considerations and the information requirements for the safety assessment, in particular for novel foods derived from plants and micro-organisms.

The safety assessment is carried out by the Food Directorate, which stated that it has access to external expertise if required to complete the assessment. The general considerations include the history of safe use (if any), dietary exposure and nutritional, toxicological and allergenicity factors.

Following completion of the assessment the Novel Foods Section of the Division draws up a draft Food Rulings Proposal, which is then submitted to the Food Ruling Committee of Health Canada for consideration. The Committee consists of senior management from the Food Directorate and either approves or reject applications, based on the Food Rulings Proposal.

5.2.6 Stacked Events

The CFIA stated that the authorisation of a PNT for unconfined environmental release includes permission to cross the PNT with other plants to develop new varieties. Plant breeders are free to introduce a novel trait into different varieties of a crop. Similar to these new varieties, many stacked products, which are defined in Canada as plant lines developed by conventional crossing of two or more authorized PNTs, do not require further assessment of their environmental safety. The CFIA

requires notification of all stacked products before they are placed on the market, in order that regulators may determine if any conditions of authorisation placed on the parental PNTs are compatible and appropriate for the stacked plant product, or if additional information is required to assess the safety of the stacked plant product.

Conclusions:

Canada has established detailed product based procedures and assessments for plants with novel traits, food and feed. This provides a high level of assurance with regards to the safety of such plants and products in the Canadian market.

There is a comprehensive system in place for the authorising and supervising the confined and unconfined environmental release of plants with novel traits in Canada. The sale of common seed, which are not subject to systematic official controls for the presence of authorised or non-authorised varieties or genetically modified organisms, provides the potential to circumvent the authorisation and approval process for agricultural crops, that may be exported to the EU.

The approval system in place in Canada is not entirely equivalent to the system in place in the EU and therefore authorisations provided in Canada for novel foods and feed are not equivalent to authorisations under EU legislation.

5.3 Status of Transgenic crops, novel feed and food in Canada

Mission findings:

The CGC Grain Research Laboratory informed the mission team that 8.2 million hectares in Canada is planted with GM crops. Approximately 93% of canola and 70% of soya bean and maize produced in Canada are genetically modified. In addition, 15,000ha was planted with Roundup Ready tolerant sugar beet in 2009, which constitutes approximately 75% of the total sugarbeet crop.

The CFIA informed the mission team that herbicide tolerance remains the primary PNT in Canada, although traits relating to yield and nitrogen and water use efficiency have become more popular in recent years. Traits relating to resistance to pests and diseases have remained fairly constant. The CFIA maintains a database on the status of regulated plants with novel traits in Canada, including whether products have been approved for unconfined environmental release, novel livestock feed use, variety registration and novel food use on the following website: http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp. In summary:

11 GM varieties of Canola have been approved for unconfined release. The CGC informed the mission team that they had carried out sampling of the 2009 Canola harvest during loading of individual vessels at the port of export. Eleven samples were analysed for GM events by the company holding the authorisations. The majority of the samples tested positive for the withdrawn events, but with calculated concentrations below 0.9%.

CDC Triffid is the only flax variety listed in the CFIA database on the status of regulated plants with PNTs. While variety registration has been withdrawn, the safety assessments and resulting approvals for its use in food, feed and for unconfined environmental release remain in place. The withdrawal of variety registration means that the seed may not be sold for propagation.

Novel feed and foods:

80 novel feeds from plant sources and more than 15 GM microbial products have been approved. The latter include enzymes, amino acids and vitamins. No viable GM micro-organisms or products of biotechnology derived animals have been approved. CDC Triffid is the only PNT flaxseed variety, listed by the CFIA as being approved for use in feed and food.

Health Canada informed the mission team that 127 novel foods had been approved, 96 of which were GM products, including Roundup Ready Maize and Clearfield Rice.

Conclusions:

There are a significant number of GMO varieties authorised and planted in Canada compared to the EU; the majority of Canola, soya bean and sugar beet planted in Canada are GM varieties.

The Canadian grain industry has taken steps to remove GM varieties not authorised in the EU from the export chain for the EU.

5.4 MARKET CONTROLS FOR GMOS

Legal requirements:

Article 46(1)(a) of Regulation 882/2004 requires that particular regard be paid to the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation.

- Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms,
- The Labelling Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

Mission findings:

5.4.1 Seeds

The action taken in response to the alerts for CDC Triffid and the adoption of the protocol is detailed in section 5.6.2. below.

The CFIA stated that varietal purity standards for certification include tolerances for the presence of off-types, including authorised GM events. No monitoring is carried out for the presence of such events since the CFIA mandate to do so relates only to the suspected presence of non-authorised GMOs. The CFIA stated that the lack of reference material for non-authorised events means that it is difficult to carry out controls for such events.

The CFIA provided details of the extensive monitoring and surveillance programme carried out following the discovery of a non-authorised GM maize (Starlink) in Canada, which were imported by private individuals. This included the imposition of testing requirements for all US maize imports entering Canada, followed by on-going post-entry monitoring by the CGC and CFIA.

The CFIA stated that non-registered varieties may not be sold, but that the sale of common seed may provide a means by which non-registered varieties could be sold. There are no controls regarding the presence of authorised or non-authorised GMOs in non-pedigree seed since there are no varietal purity standards for non-pedigree seed.

5.4.2 Labelling

The policy in Canada is to permit voluntary positive and negative labelling with respect to GMOs provided the labels are truthful and not misleading. There is no legal requirement for food, feed or

seed derived from GMO to be labelled as such. However, Health Canada can require mandatory labelling for foods, including those derived through biotechnology, where there are health or safety concerns that could be mitigated through labelling, such as the presence of an allergen.

A National Standard for the Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering has been developed by the Canadian General Standards Board. The Standard Refers to techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Examples of the techniques used in genetic engineering include, but are not limited to, recombinant DNA, the direct introduction into the organisms of hereditary materials prepared outside the organism, and cell fusion (including protoplast fusion). Based on these definitions, Health Canada stated that few foods could be considered to be non-GM for the purposes of labelling.

The Standard establishes a 5% tolerance for which the claim genetically engineered or not genetically engineered may be made. To be labelled 'not genetically engineered' the ingredient must not contain any intentionally added genetically engineered material and also must contain less than 5% of any unintentionally introduced genetically engineered material. In multi-ingredient processed foods, the 5% allowance applies to individual ingredients in the food, that make up 1% or more of the total weight of the food. This differs significantly from the 0.9% tolerance for adventitious presence in the EU

5.4.3 Organic products

The CFIA informed the mission team that the Organic Products Regulations (OPR) 2009, protect consumers against false and misleading organic claims. In accordance with these Regulations, organic certification is based on the Canadian Organic Standards (CAN/CGSB-32.310 and 311). Section 1.4 lists the substances, methods or ingredients that are prohibited in organic production and handling and specifically prohibits all materials and products produced from genetic engineering.

The organic certification process is implemented by Certification Bodies accredited by the CFIA. These bodies are responsible for verifying compliance with the Regulation, including the absence of GMOs from organic materials and products.

Conclusions:

The competent authorities respond to identified risks relating to the presence of non-authorised GMOs in seeds for planting. However, systematic official controls are not carried out for such events in seeds, in particular non-certified 'common' seed, present in Canada.

The organic standards in place in Canada are equivalent to those in place in the EU, with regards to the prohibition on use of GMO derived materials.

The labelling requirements in Canada with respect to GMO's differ from those in place in the EU. Considering the higher tolerance and wider range of GMOs approved in Canada compared to the EU, there is potential that food and feed, labelled as free from GMOs in Canada, would not comply with the conditions for placing such food and feed on the EU market.

5.5 Export controls

Legal requirements:

The sampling and control measures for flaxseed exported to the EU are established in the Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union and Addendum Sampling and Testing Protocol for flaxseed exported in containers.

Mission findings:

Control of exports are carried out if required by importing countries; this is either through 'voluntary' Identity Preserved schemes or specific protocols.

5.5.1 Identity preserved schemes

The CGC has recently set up the Canadian Identity-Preserved Recognition System (CIPRS). It is a voluntary, generic system for certifying individual Identity Preserved (IP) systems set up by the grain exporters to meet customer demands for specific products, e.g. malt barley or bread wheat of specific varieties. It is implemented through so-called Service Providers, i.e. companies accredited by the CGC. The Service Providers, of which there currently are four in Canada, carry out audits of the participating exporter and his supply chain system against standards issued by the CGC. Based on the reports of the audits, the CGC issues the Certificate of Recognition. IP schemes exist for a number of crops including mustard seed and soya bean. The soya bean scheme includes a crop specific standard developed by the Canadian soya bean Exporters' Association. The soya bean programme is based on contracts with individual growers that include the obligation to use certified seed and implement and document measures to prevent co-mingling during production, storage and transport and to ensure a quality crop. Each farm's crop is also tested (strip test) for GM upon delivery to the elevator.

5.5.2 Flaxseed Protocol

The EU-Canada Flax Protocol details the control points in the commercial bulk handling system; sampling is required at three stages in the system. There are separate provisions for containers.

The protocol also includes a provision for the CGC to investigate the presence of CDC Triffid in the Canadian grain supply. Testing for this purpose has been carried out by the CFIA and producers/FCC as part of their stewardship scheme as detailed in sections 5.5.2.1. and 5.5.2.2. below. The sampling and controls at the three stages required in the protocol are carried out by the CGC; these are detailed in section 5.5.2.3. below.

The CGC informed the mission team that exports in containers are not normally subject to supervision/inspection by the CGC. The export controls for the purposes of the protocol are detailed in section 5.5.2.4. below. The CGC stated that the transfer elevator at the Port of Montreal is not used for flax exports to the EU due to insufficient human resources to fulfill the elements of the Protocol. Terminal elevators in Vancouver are located on the Pacific coast of Canada and are not typically used for exporting grain to the EU. The industry representatives met by the mission team stated that these constraints have a significant impact on their handling of bulk shipments.

5.5.2.1 CFIA testing for flaxseed

The CFIA informed the mission team that it has carried out a sampling and testing plan for flax seed following the findings of CDC Triffid. The CFIA stated that their mandate is limited to testing for varietal purity, and that it does not have the authority to test for the low level presence of authorized GM events at levels below the standards for varietal purity. The seed varietal purity standards for flax under the Association of Official Seed Certifying Agencies are as follows[1]: Foundation seed: 0.05%; Registered seed: 0.1% and Certified seed: 0.2%. Since CDC Triffid is approved for environmental release and use in feed and food in Canada, the CFIA sampling and testing programme therefore focused on pedigree and non-pedigree seed and for levels >0.2%.

1 a glossary of terms related to seed certification in Canada is available at: http://www.seedgrowers.ca/pdfs/Circular%206_2010/Circ6-APPENDIX%20C-ENGLISH_Rev01-5_20100128.pdf).

The CFIA inspection staff drew samples of flax seed for sowing for testing at a CFIA laboratory. Reference material was obtained from the original reference sample provided by when the variety was registered in 1996. In total, the CFIA tested 160 samples of flax seed for sowing. For samples other than Breeders seed, each sample consisted of 3,000 seeds, which the CFIA stated provided 95 percent confidence that the sample contains less than 0.1 percent of GM material if the result is negative. The following seed samples were tested for each category of seed:

- Breeder: 10 samples (x 200 seeds) (initial search for variety mislabelling)
- Select: 21 samples (x 3,000 seeds)
- Foundation: 2 samples (x 3,000 seeds)
- Registered: 19 samples (x 3,000 seeds)
- Certified: 105 samples (x 3,000 seeds)
- Common status samples: 3 samples tested (x 3,000 seeds).

The CFIA informed the mission team that three samples were found to have GM markers below 0.1% as follows:

1. One sample of certified seed: 95% confidence that the true value is less than 0.01%

The first sample of 3,000 seeds was positive and therefore a second sample of 3,000 was tested, which was found to be negative. As a result, a further 10 samples, each consisting of 3,000 seeds, were tested and all were negative.

2. One sample of certified seed: 95% confidence that the true value is less than 0.02%

The first sample of 3,000 seeds was positive and therefore a second sample of 3,000 was tested and found negative. As a result, a further 10 samples of 3,000 seeds were tested, two of which were positive.

3.One sample of common seed: GM markers detected at 0.04%

The first sample of 3,000 seeds was positive and therefore a second sample of 3,000 was tested and found negative. As a result, a further 5 samples of 3,000 seeds were tested, 4 of which were found to be positive.

The CFIA concluded that the results of their programme did not indicate that GM material was present in Canadian flax seed for sowing at levels that would bring into question the varietal purity of pedigreed seed, or that could lead to an interpretation that seed of an unregistered variety was being sold in Canada. The CFIA also noted that the presence of an authorised event at the levels described above is permitted within the varietal purity standards. The seed producers were informed of the outcome of the testing.

5.5.2.2 Flax Council controls for flaxseed exported to the EU

The FCC informed the mission team that they had introduced a stewardship scheme for flax producers on 12 March 2010. The scheme requires that producers test their seed (both pedigree and common seed) prior to planting as well as their production for the presence of CDC Triffid. Test certificates must be provided prior to, or at the time of delivery to the primary (country) elevator.

Details of the producer testing of planting material are as follows:

Seeds for planting:

Pedigree seed; a 1kg preliminary sample is taken before conditioning (i.e. cleaning, grading and treatment of the seed), 60g of which is tested. Following conditioning, a 2kg sample is taken for testing. For farm saved non-pedigree seed; a 2kg sample must be tested.

The producer is responsible for taking and submitting the samples to a proficient laboratory,

following CGC guidance and recommendations on appropriate sampling techniques in its Sampling System Handbook and Approval Guide. The 2kg sample must be taken from lots not exceeding 20 tonnes; and 4 sub-samples must be drawn from every tonne.

The samples must be sent to a laboratory accredited for the purposes of the protocol for a 4x60g grind test. If all four sub-samples are negative, then the seed may be planted. If one or more tests positive, then the seed must be removed from the export chain for the EU (i.e. destroyed or exported to destinations that do not have requirements regarding CDC Triffid).

Producer testing of flax production:

Producers must store the flax in lots of a maximum of 5,000 bushels (approximately 127 tonnes).

A 2kg sample, taken in the same way as for seed, must be taken and sent to a proficient laboratory for a 4 x 60g grind test. If all four sub-samples are negative, then the lot may be delivered to the primary elevator, and subsequent handling and testing procedures required by the protocol, and implemented by the CGC (see section 5.6.3.3 below).

The mission team met with a producer of flaxseed, who appeared to be fully familiar with the situation of CDC Triffid and the FCC stewardship programme and the flaxseed protocol. The producer had access to suitable storage bins for the purposes of the test regime detailed above.

Results:

The results of the seed and production tests are made available on a voluntary basis to the FCC. Approximately 80% of producers have agreed for the testing laboratories to share the data with the FCC, who informed the mission team that 5,845 producer samples had been entered into the FCC database at the time of the mission. To date, 230 producer samples (i.e. 3.9%) have tested positive (>0.01%) for CDC Triffid.

The FCC stated that one sample was found to be almost pure CDC Triffid. The FCC were informed by the testing laboratory, who followed up the finding with the producer. It was found that the producer had been under contract to multiply CDC Triffid (certified) seed immediately prior to the voluntary withdrawal of authorisation. As a result of a dispute between the two parties, the seed was retained by the producer for, it is believed, his own use. The FCC informed the mission team that some of the production had previously been exported to Europe. The FCC stated that two of its members bought the entire production (at an extra premium) and promptly directed it to an acceptable market.

The number of pre-planting samples that had tested positive was not known.

The FCC indicated that it, in view of the zero tolerance for CDC Triffid applied by the EU, that it has a strong preference for testing to be carried out by two laboratories that indicate 'trace' findings where the level of triffid = <0.01% (the limit of quantification). The other accredited laboratories indicate 'negative' for similar findings (see section 5.6.3. below).

5.5.2.3 Sampling and testing Protocol for flaxseed exported to the EU

The mission team met with representatives of the CGC and also carried out site visits and met with CGC staff and industry representatives concerned with the implementation of the protocol.

The CGC has an established and comprehensive control system regarding ensuring the integrity, quality and quantity of exported grains. The flaxseed protocol has necessitated that the CGC take additional samples over those normally required for quality purposes. The terminal elevator visited had installed new sampling equipment to facilitate the automatic sampling of flaxseed at the time of loading silos.

All of the CGC staff met by the mission team appeared to be fully familiar with the CDC Triffid

issue and the protocol.

The mission team visited a primary, or country, elevator in order to observe the handling and sampling procedures in place for flaxseed exported to the EU.

Primary elevator:

The certificates of testing of producer samples were presented by drivers on arrival at the elevator, which were verified by the elevator staff before the lorry was permitted to enter the facility. The producer must provide a signed declaration that the varieties are eligible for export. The declaration includes a list of varieties that are not eligible, which includes CDC Triffid. The declaration includes the conditions that the producer will be liable for all claims, damages, losses and costs resulting from a false or negligent declaration.

A sample was taken from each trailer to check for quality, before being discharged into a silo. The whole process is computer controlled; the system enables traceability from elevator to loading at the terminal elevator. The system also includes safeguards to prevent mixing of grain types or CDC Triffid positive flax with negative flax. In the event that positive and negative flax are taken, these are handled separately and the system is flushed using hard spring wheat after handling positive flax.

The elevator generally loads 100 rail-cars at a time, each of which has a capacity of 100 tonnes. The samples required for the protocol are taken at time of loading, with one 2kg sample being collected from the stream, for every 5 cars. The samples are sent to a proficient laboratory for analysis. The results are considered to be preliminary and are provided to the terminal elevator.

The FCC informed the mission team that 10% of rail car samples taken between October to December 2009 were positive, which fell to 4% for samples taken between March to September 2010.

Terminal elevator:

The mission team visited a terminal elevator at Thunder Bay, used for the shipment of flaxseed, including to the EU. The terminal elevators have been developed since the early 20th century to facilitate the bulk storage and shipment of grain: 80% of all grain exports to the EU takes place via Thunder Bay. The facility visited has a storage capacity of 210,000 tonnes and can handle 18 different commodities.

The CGC has an inspection and weighing office and technical staff within the facility to enable rapid analysis of samples and oversight and control of the discharge, storage and loading. The CGC inward procedures start with verification that the bins used to receive flax are checked and the bottom is sealed. The grain flow into the selected bin is monitored and an official sample is collected from each railcar. Once unloading is completed, the CGC seal the bin tops and a composite sample, representative of the bin, is prepared for laboratory analysis by an accredited laboratory, chosen by the exporter. The results of the analysis are sent directly to the CGC, who then informs the terminal and exporter of the results. The terminal operator must inform the CGC of the intention to load flaxseed onto a vessel. The CGC then verify the list of bins against the test results and that the seals are intact, before breaking them and permitting loading. The seals are replaced on any partially emptied bins.

The mission team noted that the terminal operator maintained detailed records of the contents of each bin, and that all bins marked as containing negative flaxseed had been sealed.

The facility visited had fitted a new, CGC approved 'cross-stream' sampler to enable automatic sampling of the seed stream. The CGC informed the mission team that a sample of 5kg was taken

from each 500 tonne lot. The sample is then subdivided in the CGC facility before dispatch to the accredited laboratory for testing. A reference sample is kept in the local CGC office.

The terminal operator informed the mission team that approximately 5% of the samples taken at the terminal elevator were positive. The CGC later confirmed that 4.6% of terminal elevator samples are found to be positive. The CGC stated that the most likely explanation for these findings, which follow earlier testing at the primary elevator, is that the automated sampling equipment in use at the terminals allows for a more representative sampling.

5.5.2.4 Flaxseed exports in containers:

The protocol was amended in order to provide for exports in containers, taking account of the logistical constraints for sampling by the CGC. The CGC informed the mission team that no flaxseed has been exported to the EU in containers since the introduction of the protocol.

The system adopted to facilitate flaxseed exports to the EU in containers is based on the CGC's Accredited Container Sampling Programme and the Certified Container Sampling Programme. Accredited and Certified Seed Samplers must satisfy the requirements of the CGC's Sampling System Standard, which requires a quality management system, documented sampling procedures and that samplers are trained and evaluated by the CGC.

Accredited third party samplers are audited annually by the CGC; Certified grain company samplers are audited annually by third part auditors, who are trained by the CGC. The audit includes an evaluation of the sampling techniques and equipment.

The sampling under the protocol includes a producer delivery sample taken by the grain company at time of delivery and a sample taken by a certified sampler or a sample taken by an accredited third party sampler. The producer delivery sample must be retained for at least 6 months.

The samples are taken before loading the container, which is then held pending the results of the laboratory analysis. The sampling method depends on the nature of the seed source (stream or trans-loading bulk to bulk or bag to bag).

The CGC stated that one company has now been certified to take samples of flaxseed in line with the amendment to the protocol. The mission team visited this company and met with the certified seed samplers. The premises had appropriate equipment for taking representative samples of consignments of flaxseed intended for export to the EU and the staff were aware of the protocol and in particular, CDC Triffid. The company informed the mission team that it only handles golden flaxseed and not brown flaxseed (which includes CDC Triffid). The seed samples taken by the company were sent to a proficient laboratory for testing. The third party auditor was also present during the visit and explained the audit procedures, which included an assessment of the sampling techniques used.

Conclusions:

The protocol for flaxseed exported to the EU has been implemented by a combination of official controls by the Government of Canada and supplemented by industry initiatives including a stewardship scheme developed by the Flax Council of Canada.

The CGC carries out the sampling and other checks required by the protocol. These controls provide a high degree of assurance with regards to the GM status of flaxseed exported to the EU.

No evidence of contamination by CDC Triffid of the seed supply have been identified, although widespread, low-level contamination of the flaxseed production and one significant finding of CDC Triffid has been confirmed. The number of seeds tested, and the frequency is not in line with the

protocol and is also too low to ensure the monitoring for CDC Triffid in pedigree seed is appropriate. Action has been taken to exclude all of these from the export chain for the EU, further increasing confidence in the absence of CDC Triffid in flaxseed exported to the EU.

The widespread low-level presence of CDC Triffid found in the national production and the level of rejections both at producer and terminal elevator stages indicate that the protocol may need to remain in place for the foreseeable future to exclude the risk of CDC Triffid being present in flaxseed exported to the EU.

The introduction of the Canadian Identity Preserved Recognition System is a positive step in enabling exporters to manage the export chain for commodities to ensure that these meet the requirements of the importing market, including the EU.

5.6 LABORATORIES

Legal requirements:

The Flaxseed Protocol, and its Addendum for containers, establishes requirements relating to the sampling and testing of flaxseed exported to the EU.

Mission findings:

The CGC publishes a list of Accredited (to ISO 17025) and proficient laboratories for the purpose of the protocol. At the time of the mission, there were 5 accredited laboratories and 14 proficient laboratories. The CFIA and CGC Grain Research Laboratory informed the mission team that, in general, accreditation of laboratories to ISO17025 is not common in Canada. As a result, all of the accredited laboratories for the protocol but one were in the USA.

5.6.1 Biotechnology Laboratory of the Canadian Grain Commission

The mission team visited the biotechnology laboratory of the CGC, which is part of the Grain Research Laboratory in Winnipeg. The laboratory is responsible for carrying out proficiency tests for CDC Triffid in proficient laboratories in both Canada and the US. In addition, the laboratory also provides testing services to third parties for commodities destined to non-EU markets only. Testing facilities for EU-exports are not provided by this laboratory.

The proficiency tests are organised together with the Grain Inspection, Packers and Stockyard Administration of the United States Department of Agriculture, which produces non-GM flax test samples as well as samples containing 0.01% and 0.05% CDC Triffid. The CGC Grain Research Laboratory organises the proficiency test and also evaluates the data obtained by the participants. Three rounds of the proficiency tests have been undertaken since 2009, using 0.05 and 0.01 test material. According to the CGC, all laboratories passed the proficiency test. The data from the participating laboratories was not provided to the mission team due to data protection requirements. The biotechnology laboratory informed the mission team that it also took part in the proficiency tests using blind samples, and achieved good results. The laboratory plans to acquire certification according to ISO 17025 at some point in 2011.

The mission team noted that the overall structure of the laboratory, with dedicated rooms for the different methodological steps of the molecular analysis, meets the requirements for ISO 17025. The laboratory also has a high level of equipment including grinding facilities, modern DNA quantification instruments, and two real time PCR machines. Procedures and the instrumentation used for grinding the samples are designed to prevent cross contamination. The sample management system provides full traceability and tracking of samples throughout the test procedure.

The biotechnology section is adequately staffed with two scientists and one technician, the laboratory manager possesses an international reputation by published articles in peer reviewed scientific journals.

DNA is extracted from ground samples according to the Protocol. Regarding the observation of this laboratory that the DNA yield differs using the commercial kit, the DNA quality is checked and the amount of DNA is determined prior to PCR and the same amount of DNA is used for the controls and samples analysed. Reactions are carried out using in two replicates per each of the four DNA-extracts targeting the NOST-Spec-construct present in CDC Triffid. The theoretical LOD of the method was assessed to be below 0.01%, which is evaluated for each PCR run using 0.05 and 0.01% positive controls. According to the laboratory, a sensitivity level of below the 0.01% level can be reached.
The mission team noted that target taxon specific reactions targeting the SAD-gene, as outlined in the "NOST-Spec construct-specific method for the detection of CDC Triffid Flax" issued by the Joint Research Centre, and required by ISO 24276 and ISO 21569 to monitor the ability for amplification of the extracted DNA, were not carried out at the time of the mission.

5.6.2 Proficient Laboratory carrying out analysis for the flax industry

The mission team visited one proficient laboratory performing analysis for the purposes of the FCC Farm Stewardship Programme. The laboratory is privately owned and offers a wide range of molecular tests for the industry and for research purposes. The laboratory employs 20 persons with experience in the field of molecular biology, the majority of whom hold relevant post-graduate qualifications. Regular training is provided for staff; the training records were presented to the mission team.

The mission team noted that the laboratory is equipped with dedicated rooms for each of the methodological steps. Appropriate technical equipment including automatic devices for DNA extraction and real-time PCR were also present. The organisational structure, the staffing and the technical equipment in place allows a high sample throughput without affecting the testing quality.

The laboratory is in the process of obtaining ISO 17025 accreditation. The mission team noted that standard operation procedures are in place for the analysis of CDC Triffid flaxseed. The documents were well organised with a clear description of each of the methodological steps. Written procedures for the interpretation of all likely results are also already in place, in line with the principles of ISO 17025.

The laboratory analyses producer samples as part of the FCC stewardship programme. Each sample gets an unique identification number allowing it to be tracked through the process, which was verified by the mission team. The test procedures for CDC Triffid are based on the protocol established by the Community Reference Laboratory. The method had been validated in-house. The laboratory had taken part in the proficiency tests organised by the CGC. The laboratory management system allowed access onto the raw data generated in the proficiency tests.

The mission team noted that the analytical tests are carried out correctly and n appropriate number of replicates are tested. There are procedures in place allowing the analysis of every sub-sample with the required sensitivity of 0.01% and below. This is ensured by evaluation of the flax housekeeping gene SAD.

The interpretation of the results of the construct specific test targeting NOST-Spec is straightforward by reporting all positive signals which occurred in one of the replicates of the sub-samples to client.

5.6.3 Interpretation of testing carried out for flaxseed exported to the EU

It became evident during the on-site visits in the private laboratory, reading test reports obtained from various parties of the Canadian flax industry, and in meetings with stakeholders during the mission, that the various proficient and accredited laboratories report divergent test results in different ways. Some of the laboratories interpret test results, with signals in the real-time PCR below the 0.01% standard, as “trace”, i.e. CDC Triffid present, while other laboratories report such results as “negative”, i.e. “CDC Triffid not detected”.

Conclusions:

The Canadian Grain Commission has established a list of accredited and proficient laboratories for performing the analysis required by the flaxseed protocol. These laboratories are regularly assessed and the laboratories visited had suitable personnel and facilities to ensure that the analysis required by the protocol is carried out correctly. However, there is variation in the interpretation of results, which may in practice result in 'false negatives' for samples where CDC Triffid is present at levels <0.01% when comparing the test sample's 'ct-values' with those obtained from the 0.01% positive reference material. This semi-quantitative approach means that samples that give a signal below the signal of the 0.01% reference material are not reported as 'CDC Triffid detected' and are therefore not excluded from export to the EU, where a zero tolerance for the presence of the event is applied.

6 Overall Conclusions

Canada has established detailed product based procedures and assessments for plants with novel traits, food and feed derived from biotechnology. This provides a high level of assurance with regards to the safety of such plants and products in the Canadian market.

The protocol for the export of flaxseed to the EU is being fully implemented by a combination of controls by the competent authorities and industry initiatives, including a stewardship scheme established by the Flax Council of Canada (FCC). Limited official controls have been carried out to assess the cause of the presence of CDC Triffid in flaxseed production but no evidence of the presence of CDC Triffid in the national seed supply was found. The testing regime introduced by the FCC has found widespread, low-level contamination of the flaxseed production and one significant finding of CDC Triffid has been confirmed. Action has been taken to exclude all of these from the export chain for the EU, further increasing confidence in the absence of CDC Triffid in flaxseed exported to the EU.

The widespread low-level presence of CDC Triffid found in the national production and the level of rejections both at producer and terminal elevator stages indicate that the protocol may need to remain in place for the foreseeable future to exclude the risk of CDC Triffid being present in flaxseed exported to the EU.

There is good laboratory support in Canada relating to GMOs; some shortcomings were identified in the interpretation of laboratory results, which if not addressed, may affect the reliability of the Canadian Grain Commission (CGC) certification for flaxseed exported to the EU.

7 Closing Meeting

A closing meeting was held on 13 October 2010 at the headquarters of the Canadian Food Inspection Agency in Ottawa, during which the main findings and conclusions of the mission team were presented. The CFIA provided clarifications and provisionally accepted these preliminary findings and conclusions.

8 RECOMMENDATIONS

The competent authorities in Canada are recommended to consider:

N°.	Recommendation
1.	Harmonising the reporting of the results of analysis performed by the proficient and accredited laboratories for the purposes of the flaxseed protocol, in particular to ensure that:the test results of all four sub-samples are provided, regardless of the -ct value obtained and that all positive real-time signals of the NOST-Spec construct, in-line with ISO 21567the limit of detection, together with a reference to the test sample, following quantification of the flax specific SAD gene
2.	Introducing controls, for commodities exported to the European Union and for which GM events have been approved in Canada, but not in the European Union, in order to establish the potential for such events being present.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_ca_2010-8788.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 1829/2003	OJ L 268, 18.10.2003, p. 1-23	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
Dir. 2001/18/EC	OJ L 106, 17.4.2001, p. 1-39	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
Reg. 1830/2003	OJ L 268, 18.10.2003, p. 24-28	Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC