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TECHNICAL CONSULTATION ON LOW LEVELS OF GENETICALLY MODIFIED (GM) CROPS IN INTERNATIONAL FOOD AND FEED TRADE

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Technical Background Paper 1

Low levels of GM crops in food and feed: Regulatory issues

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Low levels of GM crops in food and feed: Regulatory issues

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Note

The country-specific information and data provided in the paper are based on the responses submitted through the FAO survey. As the survey responses have been submitted by the national authorities, FAO considers that they are official responses. However, owing to the differences in methods, frequency and precision of monitoring applied to LLP/AP incidents, the data may not perfectly correspond to the actual events monitored elsewhere.

Acronyms

AA	asynchronous approvals
AOSCA	Association of Official Seed Certifying Agencies
AP	adventitious presence
APHIS	Animal and Plant Health Inspection Service (USA)
Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
DNA	deoxyribonucleic acid
EC	European Commission
EPA	Environmental Protection Agency (USA)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (USA)
GM	genetically modified
GMO	genetically modified organism
IICA	Inter-American Institute for Cooperation on Agriculture
ISA	International Seed Testing Association
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LLP	low level presence
LMO	living modified organism
NGO	non-governmental organization
NGS	next-generation sequencing
OECD	Organisation for Economic Co-operation and Development
RASFF	Rapid Alert System for Food and Feed
r-DNA	recombinant deoxyribonucleic acid
RNA	ribonucleic acid
USDA	United States Department of Agriculture

1. Introduction

In recent years, there have been a number of trade-related incidents involving low levels of genetically modified (GM) crops reported by multiple sources. Sources include the international survey results of the Food and Agriculture Organization of the United Nations (FAO, 2014), the Rapid Alert System for Food and Feed (RASFF) of the European Commission (EC) (European Commission, 2009) and the reports of various industry associations (e.g. Landmark Europe, 2009; CropLife, 2014) and non-governmental organizations (e.g. GeneWatch UK and Greenpeace International, 2006) on the occurrence of low levels of unapproved GM crops in global food and feed supply chains. The present paper describes the background of these incidents and discusses the relevant terminology, food and feed regulatory and policy issues, the needs and concerns of developing countries, and possible future trends that may affect the frequency and type of incidents.

2. Working definitions using the Codex terminology

In this paper, some technical terms and acronyms are applied that are based on the terms generally used in various Codex documents (http://www.codexalimentarius.org/). They differ among countries, and translations in various languages may increase the confusion associated with the terminology. The following working definitions have been adopted for the purpose of this paper. Readers should note that these are not official FAO definitions but terms that have been used in this paper in an attempt to minimize possible misunderstanding.

GM Crops: A genetically modified (GM) crop refers to a recombinant-deoxyribonucleic acid (r-DNA) plant. An r-DNA plant is a plant in which the genetic material has been changed through *in vitro* nucleic acid techniques, including r-DNA injection and direct injection of nucleic acid into cells or organelles.

Low Level Presence (LLP): LLP refers to the detection of low levels of GM crops that have been approved in at least one country on the basis of a food safety assessment according to the relevant Codex guidelines. Readers should note that low level presence (LLP) is not specifically defined by Codex, however in the context of the Codex guidelines it is referred to as LLP.

Adventitious Presence (AP): AP refers to detection of the unintentional presence of GM crops that have not been approved in any countries on the basis of a food safety assessment according to the relevant Codex guidelines.

3. Trade incidents

In 2013, FAO conducted a survey to increase understanding of the extent of trade disruption caused by LLP/AP incidents. A questionnaire was developed to collect information from FAO member countries to serve as a basis for the analysis. In this section, some trade incidents reported through the survey are described; the full analysis and report of the survey results are available elsewhere (FAO, 2014).

In the last two decades there have been a number of incidents related to LLP/AP (Annex 1). According to the FAO survey, more than 20 out of the 74 countries (excluding European Union) that returned the questionnaire reported that they have encountered at least one LLP/AP[1]. Early reports (2001/2002) implicate mixtures of seed batches that were detected by a company. From 2001 an increase was observed, with only a few incidents in the first few years and 2009 being the year in which, so far, the greatest number of incidents has been reported. Survey results indicate that incidents have involved maize, rice, soy, linseed, papaya, flax and canola. Furthermore, it may be observed that European countries tend to report more incidents, but incidents have also been reported by many other countries from all over the world.

Another observation is that the number of countries involved in the production of GMO varieties and the detection and identification of LLP/AP incidents is increasing. Initially, only a few countries were large producers of new GM crop varieties that could end up as LLP/AP in batches in countries that had not (yet) approved these varieties. However the picture in recent years is much more diverse, with many more countries from many parts of the world producing new GM crops, and more countries implementing routine monitoring programmes to detect and identify LLP/AP incidents.

AP incidents

According to the responses to the FAO survey, examples of AP include:

- the unintended production of Bt10 maize in relatively large quantities, reported by, *inter alia*, Canada, France and the Netherlands;
- a mixture of low quantities of Bt63, LL601 and KeFeng rice varieties, reported by European countries;
- a mixture that included the Amadea potato in potato fields in Sweden in 2010 (Jordbruksverket, 2011).

In the cases involving Bt63, LL601, Kefeng rice varieties, the Amadea potato and the herbicide-resistant wheat plants, the respective varieties are likely to have been derived from plant breeding programmes in which other varieties may have been developed further for marketing.

LLP incidents

According to the responses to the FAO survey, examples of LLP include the following:

- 59122 maize (2007) that was already approved for the market in the United States of America, but not in Europe;
- FP967 linseed (2009) that was already approved for the market in Canada, but not in Europe and Japan;
- virus-resistant papaya that had already been approved in the United States of America, but not in Europe.

[1] As the number of the responses to the survey was limited, the actual number of LLP/AP incidences could be far greater.

In the case of LLP, most of the examples have been linked to an **asynchronicity** of approval systems that leads to varieties being authorized in one country but not yet in the other country, for example in the case of 59122 maize. However, there are also cases in which companies have decided to seek approval for a GM variety in some countries, but (so far) not in others (e.g. FP967 linseed, GM papaya).

4. Factors contributing to the occurrence of LLP/AP incidents

Once a GM crop has been released, trace amounts of the crop may become mixed with other varieties of crops at various stages: field production (including field trials), processing, packing, storage and transportation. The movement may stop in the same country or continue to another country. Furthermore, the GM crop may move between provinces, states or prefectures within a large country where state-to-state movement is regulated or different policies towards GM crop approvals are enforced. More specifically, unintentional mixing with GM crops could occur in the following instances, eventually leading to the occurrence of LLP/AP incidents:

- During manufacture of seed for sowing (or other starting materials, such as tubers), so that the seed provided to farmers may contain trace levels of certain GM crops not allowed onto the market in the importing nations;
- During the cultivation of the crop by the farmer, through events such as cross-pollination, mixing of seed with GM volunteer plants (surviving from previous field trials in or near the crop field), or illegal cultivation of unapproved GM crops;
- Post-harvest, by combining harvest of conventional non-GM crops with that of GM crops or by accidental mixing of residual trace amounts of GM crops previously stored, transported, or processed in the same facilities in which the harvested crop is handled.

AP occurrence

Incidents of AP may have both domestic and international dimensions, depending on the circumstances. The following are possible scenarios for the occurrence of AP.

1) If the mixed GM crop is authorized only for a field trial in the producing country, a **domestic AP incident** may occur in spite of the containment measures taken, for example following cross-pollination of this GM crop with commercially produced crops (for seed production or agricultural production), emergence of plants from the seeds of GM crops remaining in the field soil during cultivation of follow-up crops, or accidental mixing of the harvests from the experimental fields with those from commercial fields. Stringent containment measures are usually required in the frame of the authorization procedures for experimental work with GM crops in the field, which should also help to prevent these possible scenarios of AP.
2) If the mixed GM crop is authorized only for a field trial in the producing country, and if it is accidently exported to another country, an **international AP incident** may occur.
3) If the mixed GM crop is unapproved and grown illegally in the field on a commercial scale and is exported to another country, both a domestic and an international AP incident may occur.

<u>Factors contributing to AP incidents</u>

All of the above AP patterns could be avoidable and manageable if the producing country implements a strict regulatory framework to separate field trials from commercial fields. However, concerns remain because accidents cannot be prevented completely. The factors that may contribute to AP incidents include:

1) lack of clear field trial policies and protocols;
2) ineffective regulations on field trials, and ineffective enforcement;

3) failure to implement good practice;
4) insufficient monitoring.

LLP occurrence

By definition, **LLP incidents** refer to the international setting. Although the possible scenarios are similar to those described above for AP, the implicated GM crop is commercially approved and cultivated in at least one country. In addition, scenarios of post-harvest mixing caused by the presence of trace amounts of approved GM crops remaining in the facility (e.g. on equipment, in storage bins) could lead to an LLP incident.

Factors contributing to LLP incidents

In addition to the factors listed above for AP incidents, the patterns of LLP incidents may lead to further challenges to appropriate management. The following additional factors may contribute to the occurrence of LLP incidents.

1) Asynchronicity: Different timings of authorization of the GM crop between the exporting and importing countries may lead to it being approved in the first and approval still pending in the second. This may relate, for example, not only to different durations of the authorization procedures (e.g. administrative procedures, consultations, political decision-making) but also to different time points for submission of applications, for example as a result of corporate strategies or the need for either the applicant or the country's authorities to generate country- or region-specific data.
2) Divergence among national authorization processes: A few countries, for example Vietnam, have legal provisions that allow them to take into account the approval status and regulatory risk assessments of specific GM crops that have been assessed in other countries. At a more general level, some countries align their authorization procedures and risk assessment guidance for GM crops with that of other countries. Examples include certain Balkan and Black Sea countries attuning their GM safety policy to that of the EU, or Moldova to that of the Russian Federation (FAO, 2014). Another example is Paraguay, which, as a land-locked country, ensures that the GM crops it exports have also been approved in the surrounding countries which the exported crop crosses while in transit to its final destination (IICA, 2013). Although the mutual recognition is not formally incorporated in regulations, in practice the assessments made by importing countries in LLP situations often refer to safety assessments already conducted by other countries. Various initiatives leading towards exchange of information in LLP incidents are underway, including the FAO GM Foods Platform (http://fao.org/gm-platform), an international information-sharing platform requested by the Codex Alimentarius Commission, and a proposal within the Organisation for Economic Co-operation and Development (OECD) Task Force for the Safety of Novel Foods and Feeds.
3) Different or no LLP policy and regulations: Countries may have different strategies on how to deal with LLP incidents. One may focus on the technically feasible detection of "zero" presence while others are ready to accept other countries' safety assessments conducted according to Codex guidelines until their own assessment of the implicated GM crop has been finalized. In addition, countries may not have laid down LLP-specific rules and/or may lack detection facilities for verifying the occurrence of LLP.
4) Different inspection regimes: The frequency of inspections to detect LLP may vary among countries, depending on factors such as schemes with scheduled inspections or intensification of inspections. The FAO survey results indicated that more frequent inspections lead to a higher number of occurrences of LLP detected.
5) Different methods used for detection: The types of analyses used to detect the presence of genetically modified organisms (GMOs) may differ among countries and among different segments of the food and feed production chains, which will also depend on the

requirements, regulatory framework and analytical capacity of each country. In the field and at processing/transport facilities, for example, harvested grain can be tested rapidly using lateral diffusion devices (strip tests) which are usually designed to be specific for specific recombinant proteins. This contrasts with DNA-specific detection methods that have high specificity and sensitivity and which can be designed to target specific recombinant events. The DNA-specific detection methods require the use of laboratory facilities (such as applied in the European Union [EU] by the European Commission's Joint Research Centre and Member States). In addition, the detection methods have inherent differences, including whether tests are qualitative (absent versus present) or quantitative (exact percentage), as well as differences in their specificity and sensitivity. In theory, it is therefore possible that an exporting country and an importing country may obtain different results from the inspection of the same batch, thereby leading to an LLP/AP incident.

5. Food and feed regulatory issues

International level

There are various stages in the food and feed production chains at which regulatory and other policy measures can help to prevent and manage LLP/AP incidents. Depending on the stage at which LLP/AP incidents occur, different kinds of regulatory and other risk management measures may be applied. To this end, both international and national legal instruments may be available to the decision-makers for application to scenarios in which LLP/AP incidents occur in internationally traded crops or crop-derived food and feed. These legal instruments can be either legally binding or non-binding. An example of a legally binding instrument is a treaty signed by various countries, such as the Convention on Biological Diversity (CBD), while non-binding instruments include internationally harmonized guidelines for safety assessment such as Codex guidelines, which nevertheless can serve as a key international reference.

The food and feed production chains start with the seeds, tubers or other starting materials produced by breeding companies; these are provided to farmers for sowing and further agricultural production. The requirements for "seed purity" in various internationally binding documents are generic and deal with different kinds of impurity that can be present in a seed batch, such as inert materials (e.g. stones) and seeds from other plant varieties (not necessarily GM) or species (weeds). For example, OECD has established Seed Schemes for certification of internationally moved seeds of crops and trees, including requirements for "varietal purity" (OECD, 2014). Seed certification is performed by competent authorities, including members of the Association of Official Seed Certifying Agencies (AOSCA), while analysis of seed purity has been standardized by the International Seed Testing Association (ISTA). It is worthwhile to note that AOSCA has a programme in place for alfalfa which takes into account the possibility of LLP. Another situation involving "seed purity" has been encountered by producers of GM crops, who have had to demonstrate that the seed is "pure" for the intended GM trait with no LLP of other non-intended GM traits (OECD, 2014).

Various occurrences of LLP/AP reported to the FAO survey have been due to LLP in seed provided to farmers. This may be caused, for example, by accidental cross-hybridization between GM crops (commercial, precommercial or experimental) and compatible crop plants grown in nearby fields by those involved in breeding programmes and commercial production of seed for sowing. One of the documents published by OECD states that "most countries have not to date developed explicit rules or policies to address LLP situations in the environment. However, a few have published policies and guidelines or elaborated more general strategies to limit the occurrence of unauthorized transgenic plants in the environment including that from LLP situations" (OECD, 2013). Relevant discussions are ongoing in some countries, taking into account the differences between cross-pollinating crops on one hand and vegetatively propagated and self-pollinating crops on the other.

Sowing seeds are considered to be living organisms and, if transported and traded internationally, therefore fall under various rules for phytosanitary health and biodiversity conservation, in addition to international and national standards for seed purity.

Binding international legal instruments that are relevant to LLP/AP are the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD). The CBD deals with the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The Cartagena Protocol aims to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs). With the single exception of LMOs that are used as pharmaceuticals for humans and are addressed by other relevant international agreements or organizations, all transboundary movements, transit, handling and use of LMOs are within the scope of the CPB. In particular, among other provisions, the CPB foresees: a) the requirement for countries to finalize an advance informed agreement with the receiving country before any intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import; and b) the requirement for parties authorizing the domestic use of LMOs in their territory to inform the other parties through the Biosafety Clearing House if the LMOs may be subject to transboundary movement for direct use as food or feed, or for processing. The Cartagena Protocol also requires that environmental risk assessments be carried out for the LMOs implicated in both cases described above (CBD, 2012).

Harvested produce (e.g. seeds, tubers, fruits or other viable plant parts) that is still viable also must be considered to comprise living organisms, and similar phytosanitary and other environmental biosafety provisions should also apply to these. Processed products that are no longer viable are considered to comprise non-living organisms. International agreements and guidelines pertaining to food and feed commodities, including principles and relevant guidelines (Codex) specific to GM crops, are in effect for these products. The Codex guidelines for the safety assessment of foods derived from GM plants outline the safety assessment of GM crops, employing a comparative approach with the conventional counterpart. Many countries follow the guidelines, and implement the regulations and measures accordingly. Some examples of examinations carried out during a safety assessment performed according to these guidelines are:

- Key chemical and biochemical constituents are analysed;
- Molecular changes caused by both intentional and unintentional genetic modification of DNA, RNA and proteins are characterized;
- Changes found under the two previous bullets (e.g. newly expressed proteins) are assessed further for their safety. This procedure generally includes assessment of their potential toxicity, allergenicity and nutritional impact.

Annex 3 of the Codex guidelines foresees the possibility of conducting a safety assessment in the case of an LLP incident and provides guidance on the elements that such an assessment should contain. While the same issues, including comparative data, potential toxicity and allergenicity and nutritional impact, are to be assessed as in a GM event, the data required for an LLP situation may be more restricted on several points, such as detailed molecular data on transgene expression, because the particular Annex refers to many but not all of the items discussed in the main guidelines. The Codex guidelines also state that data on safety assessments for GM crops, as well as the available detection methods, should be provided to an international database to be hosted by FAO (FAO GM Foods Platform; http://fao.org/gm-platform/) so that Codex members can access these data when an LLP incident occurs (Codex Alimentarius, 2008).

National and sub-national levels

At the national and sub-national levels, various regulations and measures aimed at preventing and managing LLP/AP incidents may be put in place.

During cultivation of a crop in the field, a mixture may develop from cross-pollination with pollen from GM plants flowering in neighbouring fields. Another cause of such mixing may be the presence of GM plants growing in the same field, originating from seed that had remained in that field after previous cultivation of that particular GM plant. Certain measures, both legal and voluntary, seek to keep production "GMO-free", including the designation of GMO-free regions (e.g. by farmers' cooperatives) and legal and sectional requirements for organic farming. Given that these measures are not specifically focused on AP/LLP but are of a more generic nature, or serve a different purpose, they are not discussed further in detail here.

Information on national policies/legislation/regulations on GM foods provided by national focal points of the FAO GM Foods Platform (FAO, 2014) and the outcome of a survey conducted by the Inter-American Institute for Cooperation on Agriculture (IICA, 2013) show that there is wide divergence among countries. Examples are given below.

- Several countries have fully fledged regulatory systems and detection facilities installed, as well as advisory bodies and institutions that can be called upon for expertise on biosafety issues (e.g. Argentina, members of the EU, Canada, Japan, Kenya, Malaysia and the United States of America).
- Some countries have no legislation in place that would cover the issues related to GM food or feed. However, a number of these countries (e.g. Jamaica) have scientific advisory and risk assessment bodies that are able to track developments in the field of biotechnology and advise their authorities on these matters, so that they are able to act if called upon in specific situations where the safety of such foods might be in question. In several countries (e.g. Ghana), there is already experience with field trials with GM crops and the development of GM food-specific legislation is envisaged for the future. Moreover, several countries have analytical facilities for GMO detection so as to align, for example, with the requirements of the Cartagena Protocol (e.g. Lebanon, Liberia). Other countries, such as Iceland, focus only on labelling and traceability in their legislation.
- Countries that have specific regulations in place relating to GM crops may differ in the way that they treat stacked events (a "stack" describes GM crops that have been crossed using conventional breeding, thus combining multiple "events" into one plant). In some legislations (e.g. the EU, Japan, the Philippines), a stacked event is considered to be a new GMO and separate regulatory approval will be needed for its marketing. In other legislations, the decision as to whether a particular stack needs to be assessed for safety and authorized will depend on the novelty of the stacked event when compared with each single event. Given that experimental methods are being developed that can help to distinguish stacked events from other combinations of single events (e.g. single-seed analysis), the divergent authorization requirements for stacks may raise LLP issues.

6. Policy issues and relevant considerations

In this chapter, LLP is the focus of discussion because all the policies explained in this chapter are related particularly to LLP incidents. As of January 2014, only a few countries and regional groupings have a clear policy to regulate LLP.

Country examples

Various authorities around the globe have proposed LLP-related policies and measures while at the same time continuing to warrant the safety of food and feed products. Examples of these policies and measures are described below.

Technical–analytical zero: European Union

The EU applies a zero-tolerance policy as regards the presence of non-authorized GMOs on its territory. GMOs can be placed on the EU market for food and feed use only after they have been authorized on a case-by-case basis, following a stringent risk assessment that has demonstrated their safety for human and animal health and for the environment. In 2011, the EC adopted a new regulation to harmonize the implementation of the zero-tolerance policy for non-authorized GM material in feed (Commission Regulation [EU] No 619/2011). One aim of this regulation was to harmonize the way in which EU laboratories sample feed materials for analysis of the presence of GMOs and interpret the outcomes of these analyses according to the EU legislation on feed controls. More specifically, the regulation sets the "technical zero" level at 0.1 percent, the lowest level of GM material which is considered by the EU Reference Laboratory for the validation of quantitative methods. This level has been set for the detected presence in feed of GM material authorized for commercialization in a third country, and for which an authorization procedure has been pending for more than three months in the EU (provided that it has not been identified by the EU as likely to have adverse effects on health or the environment, a quantitative method has been validated and published by the EU Reference Laboratory, and the certified reference material is available), or for which the previous marketing authorization in the EU has expired. The laboratories of EU Member States are required to report instances in which they detect the presence of such GMOs, and whether positive detections below 0.1 percent occur regularly or sporadically; measures are taken instantly if levels detected are above 0.1 percent.

Two-tier approach with an action level and threshold level to manage LLP: Canada's proposal

Canada has a policy in place to address LLP incidents. The presence of an unapproved GM product, including LLP, constitutes non-compliance with current Canadian legislation. This triggers a risk assessment and risk management response to bring the situation back into compliance. The Government of Canada recognizes that there is a potential rise in LLP incidents and considers a predictable and risk-based approach to manage LLP incidents to mitigate trade disruptions (Agriculture and Agri-Food Canada, 2012). A two-tier approach to the management of LLP incidents has been proposed. The proposal includes the setting of an action level, to be set at not higher than 0.2 percent, for LLP of GM crops not approved in Canada that have undergone a safety assessment consistent with the Codex guidelines in at least one country. Therefore Canada considers that LLP below the action level would be unlikely to pose a risk to food, feed and environment, and would not trigger enforcement action. The proposal includes setting threshold levels, which would be higher than the action level. The threshold levels would be set to reflect Canada's achievable levels for unintentional presence of LLP based on international best management practices and respecting the realities of the grain handling and transportation systems in place. These thresholds would only be applicable if an LLP risk assessment carried out in advance has determined that the presence of the indicated GM crop at the proposed level is unlikely to pose a risk to food, feed or the environment. While Canada's proposal focuses on all imported grain, food and feed products which contain LLP, the proposed policy would not apply in certain cases such as seed intended for propagation in the

environment, AP, GM fruits and vegetables, GM animals and micro-organisms, as well as GM crops modified to produce plant-derived pharmaceutical or industrial products, unless approved for food and feed use.

Case-by-case approach based on safety and legal requirements: United States of America
An example of a flexible approach to dealing with LLP incidents without setting threshold levels is the practice of the United States of America. In the United States, three agencies (the Animal and Plant Health Inspection Service [APHIS], Food and Drug Administration [FDA] and Environmental Protection Agency [EPA]) work together through the Coordinated Framework for the Regulation of Biotechnology to exercise regulatory authority over GM crops and food/feed derived from them. The ways in which the United States responds to LLP incidents may depend on the nature of the indicated GM crops detected as LLP and the applicable laws and regulations. The United States has not experienced an LLP incident. However, US regulatory agencies have responded to domestic AP incidents and they might approach an LLP incident in a similar way, i.e. on a case-by-case basis and by relying on relevant safety assessment information and applying relevant legal requirements. These legal requirements may include consideration of whether the substance added to the food was an unapproved food additive or whether the food contained an unlawful plant-incorporated protectant (a pesticidal substance). The FDA has published guidance regarding an early food safety assessment programme (FDA, 2006) intended to help resolve food and feed safety concerns prior to any unintentional LLP incidents.

Existing policies

Three categories may be identified among the currently available policies.

- **A zero-tolerance policy:** This is currently the regulatory situation in many importing countries. The consequence of a zero-tolerance policy is that trace amounts of unauthorized GMOs should trigger action by inspection services, followed by further analyses and management actions, of which the costs can be considerable. In practice, however, it may be difficult to confirm the presence of a particular GMO event in small trace quantities when the sequence of the related GMO construct is not fully known. Current methods are likely to encounter difficulties in distinguishing the LLP GMO from background noise, and the signal may be too low to perform subsequent DNA sequence analysis to confirm the identity of the (unauthorized) GMO. Especially in those cases in which elements have been used in the GMO construct that may also end up in the product under scrutiny by other routes, the outcomes of the analyses should be considered very carefully because the likelihood of drawing the wrong conclusions is considerable.
- **A policy with a low threshold for LLP:** This is a policy under which LLP levels above a certain percentage threshold will lead to action by the inspection authorities. There will be difficulties with confirming the presence of, and in quantifying, LLP GMO varieties at around the very low threshold level. This will be even more difficult when the exact sequence of the LLP GMO variety is not known, because in this case the method is likely to be less specific. Given that LLP GMO varieties often result from mixing of seed batches comprising different GMO events during plant breeding programmes, it is possible that the number of LLP incidents will increase as such plant breeding programmes advance in the future. These aspects should be taken into account when considering a policy of setting a threshold for LLP in food and feed sectors.
- **Case-by-case LLP policy:** All available information concerning the LLP GMO variety could be considered when determining the required action when a LLP has been detected. The information may provide details on the genetic elements that have been detected, as well as sequence information that is directly available or may be obtained in subsequent experiments. Based on the data provided, a first assessment can be performed on the

possibility that the LLP GMO variety may have an adverse effect on the health of humans, other animals and/or the environment. If it can be determined that exposure of humans and other animals to the levels at which the LLP of the GMO variety was detected does not pose a risk, no further action may be required. If this cannot be determined, risk management actions are required to prevent the LLP GMO variety from penetrating further into the country's food and feed supply chains. This approach is science based, and would work in concert with an international mechanism to share available data on identified and/or quantified LLP GMO varieties.

Some of the above considerations for the various policy options are compared and elaborated further in Table 1.

Table 1: Options for LLP-related policies

Option	***Does it require risk assessment as a basis for GM crop-specific policy decisions?***	***Does it require access to information from the exporting country's safety assessment and/or detection methods?***	***Does it require detection, quantification and analytical capacity with high sensitivity and reliability?***	***Relative frequency of border detentions, refusals, recalls, etc. based on positive detection (LLPs)***	***Anticipated administrative burden of policy development and implementation***
Zero-tolerance policy	No	Yes, information on detection methods	Yes	High	Low
Policy with a low threshold for LLP GMO varieties	Yes and no, depending on the rationale behind the preset threshold (technical–analytical or risk-based)	Yes, information on detection methods for enforcement, as well as on safety assessment (if risk-based)	Yes, while sensitivity should be compliant with threshold	Moderate–High (depending on thresholds set)	Low–Moderate
Case-by-case LLP policy	Yes	Information on both safety and detection	Yes and no, depending on outcomes (i.e. if and what kind of detection is needed for enforcement)	Low–High (depending on outcomes)	Moderate–High
No policy – all pass	Not applicable	No	No	Low	Low

The issue of trust in another country's regulations and authorization process, including safety assessment, is a sensitive but important one. An option not featured in Table 1 is cooperation among countries in the area of food safety assessment. Depending on the level at which this cooperation were brought into effect (e.g. in legislation or at the level of case-by-case risk assessment and risk management), LLP would cease to be an issue or could be efficiently handled internationally.

Vietnam offers a unique policy. Vietnam's legislation foresees an expedited approval procedure for GM crops that have already been approved and positively assessed according to the Codex guidelines in five developed countries, while it still requires other new GM crops to go through a full approval procedure (Gruere, 2011).

7. Needs and concerns of developing countries

Given that sufficiently comprehensive and detailed data are unavailable, it is difficult to determine exactly how often LLP/AP incidents occur in developing countries. However there is no reason to assume that they occur less often in developing countries than in developed countries. According to international overviews of development with relation to the production of GMOs (ISAAA, 2013), the number of developing countries producing GM crops is rapidly increasing. In addition, the scientific literature shows that an increasing number of countries are involved in the development of new varieties of GMO. As a consequence, developing countries may be confronted with LLP/AP incidents via importation from other GMO-producing countries or national production of GM crops.

It may be very challenging for developing countries to formulate adequate LLP/AP-related regulations and enforce these regulations. Available laboratory facilities may not be equipped to conduct effective GMO monitoring programmes. Such countries may also be in need of adequately educated staff to set up informative monitoring, as well as to conduct safety assessments for their respective countries. There may also be practical hurdles to overcome when segregating production systems incorporating different types of GMOs and/or non-GM crops within the country. In specific cases, such as conditions of food insecurity and/or food aid, it may be difficult for national authorities to control and manage LLP/AP incidents, because such situations require rapid decision-making despite any rigorous regulations that may be put in place. In these cases, capacity should be made available to implement appropriate control programmes, where desired. Major challenges for developing countries in the identification of LLP/AP incidents are described in Table 2.

Table 2: Challenges for policies on prevention, mitigation and control of LLP/AP incidents

Challenge	***Options to address the challenge***	***Cost implication for implementation***	***Difficulty level for implementing the options***
Lack of clear LLP policy and regulations	Develop relevant policy and regulations	Moderate	Moderate–High, requiring clear political insights
Limited detection capacity, including laboratory facilities and skilled staff	Improve laboratory infrastructure and train skilled technicians (capacity development)	High	Moderate, with assistance from international organizations, NGOs, etc.
Limited capacity to conduct safety assessment of GM crops domestically	Improve food control system as a whole (fundamental capacity development)	High	High
Limited access to information on DNA sequences, safety assessment and detection protocols	Improve and strengthen international databases (e.g. FAO GM Foods Platform)	Low for developing countries, high for database managers/ owners	High
Limited capacity to segregate production systems (limited capacity to clean properly and implement good practices, prohibitive associated costs, etc.)	Raise awareness, and improve or develop systems incorporating good practices	Moderate–High	Moderate–High

8. Analysis of future trends

Several ongoing developments may have an effect on the future occurrence of LLP/AP incidents in international trade (Table 3).

Table 3: Factors potentially influencing future occurrence of LLP/AP incidents

Factor	***Possible impact on future LLP/AP incidents***	***Possible management options***
Increasing volume of GM crops produced	High	Implement good practices, measures and procedures
Increasing volume of GM crops traded (movement)	High	Implement good practices, measures and procedures International collaborations Improved and optimized practice on segregations
Increasing diversity of traits that are used for new GM crops	Moderate–High	Information sharing (database) International collaborations Improved and optimized practice on segregations
Unintentional (accidental) mixing (production, processing, storage, transportation, etc.)	Moderate–High	Implement good practices, measures and procedures Improved and optimized practice on segregations
Different timing of approvals (asynchronous approvals [AA])	Moderate–High (particularly for LLP)	International collaboration Cooperation during safety assessment for approval Information sharing (database)
Situations where approval is not being sought outside the producing country (asymmetrical approval)	Moderate–High (particularly for LLP)	International collaboration Information sharing (database)
Diverse LLP policies	Moderate–High	International collaboration Information sharing (policies)
Diverse levels of implementation and enforcement of the relevant regulations	Moderate–High	International collaboration Implement good practices, measures and procedures
Diverse labelling requirements	Low	International collaboration Information sharing (labelling)
Increasing use of advanced molecular biological techniques	Moderate–High	Information sharing (database) International collaboration
Increasing sensitivity of detection methods	Moderate–High	Information sharing (database) International collaboration
Improved capacity for detection (i.e. developing countries)	Low–Moderate	Capacity building
Advances in plant breeding programmes	Moderate–High	Information sharing (database) International collaboration
Advances in "-OMICS" technologies (e.g. next-generation sequencing) for detection	Low–Moderate	Information sharing Capacity building

With regard to the occurrence of LLP incidents, important factors are the asynchronicity of approval systems and the fact that producers may not apply for market approval for a particular GM crop variety in all countries. Increasing volume and types of a GM commodity will also be major contributing factors for LLP incidents in the future. With regard to the occurrence of AP incidents, these are more often directly related to the nature of GMO plant breeding programmes, in which many similar GMO events are generated, and subsequently undergo stringent selection, when developing the final GM crop variety for which market approval will be sought. Several AP incidents relate to GMOs that were removed from a plant breeding programme, but somehow occurred in low quantities in final seed batches that were marketed.

One of the most important developments in this respect is the increasing use of advanced molecular biological techniques in many countries around the world. As a result, not only will more GM crop varieties move onto the world market but they may, by carry-over in international supply chain networks, end up in small amounts in batches in countries where they have not (yet) received approval.

Another effect may result from the set-up of plant breeding programmes. Plant breeders often use a genetic construct that comprises the genetic elements for new and advantageous traits to be transferred to elite crop varieties, in order to transform not just one plant cell in the initial stages of the plant breeding programme, but many plant cells simultaneously. Many individual plant cells will be used to generate GM plant cells with copies of the foreign DNA integrated into the plant's DNA. In the subsequent steps, the GM cells will be selected on the basis of the integrity and functionality of the DNA that has been incorporated, and on its expected performance. The selected cells will then be grown into full plants. The GM plants subsequently will undergo a series of steps to select the best-performing plants. Finally, in most cases, a number of selected plants will also be tested in a series of field trials of increasing scale, before final decisions are made on the exact cultivar, containing one or a few GMO events, for which market approval will be sought.

Many more GM crop varieties will be produced that will not be selected to become commercial varieties, but that may accidently end up in seed batches for commercial production, for example as a result of gene flow in the field, carry-over processes occurring during transport of the plants or seeds, and/or human error during complex breeding trials. In these cases of AP, the GM varieties are likely to be similar to varieties that may be selected for commercial production, but their specific food/feed and environmental safety characteristics will not have been assessed in regular regulatory approval procedures.

Moreover, it can be observed that some of the current major GM crop-producing countries, such as China and India, have such large internal markets that the incentive to obtain regulatory approval in other countries for the respective GM crops is likely to be limited. As a result, GM crops that have been assessed only in these countries but may nevertheless find their way into international supply networks to other parts of the world, e.g. by carry-over, may increasingly lead to LLP occurrences in batches from these countries in particular (i.e. asymmetrical approval).

Also of relevance to the LLP/AP discussion is the development of divergent views on whether certain new plant breeding techniques[2] that are at the border between conventional breeding and recombinant DNA techniques are to be regulated in the same way as GMOs or not (EMBO, 2012). As a result, it is unclear whether, in the future, the presence of novel crops obtained through these techniques and present in conventional batches should be regarded as LLP/AP. A number of reports have been published that aim to aid in the categorization of these new breeding techniques as

[2] Techniques that fall in this "grey area" include the application of different zinc finger nuclease technologies, cisgenesis/intragenesis and oligo-directed mutagenesis.

producing either GMO or non-GMO plants, but only a few countries have formulated explicit guidance on this. Even if the presence of such novel crops were regarded as LLP/AP, it still may be impossible to verify their presence on the basis of the detection of DNA that may show great similarity to DNA already present in the host plant but with the insertion of DNA in a predefined location in the plant genome.

In addition, the diversity of traits that are being used for new GM crops is increasing. Whereas, to date, most GM crops have incorporated either herbicide tolerance or insect resistance traits, the number of GM crops with other traits, such as virus resistance, abiotic stress resistance, but also improved nutritional or sensory characteristics, is slowly rising (Ruane, 2013). This increasing diversity may result in the need for constant development and updating of appropriate methods for detection and identification of all newly developed GM crops. The chances of new GM crops being detected are linked to the likelihood of inclusion of the GM elements in their genetic constructs in the screening protocols of different laboratories around the world.

Various international initiatives are aimed at developing more sensitive detection of unauthorized GM crop varieties. One approach in this respect is the use of the "-OMICS" technologies, in particular next-generation sequencing (NGS), to detect and identify unauthorized GM crops. This involves a combination of targeted assessment for the presence of unknown or unapproved combinations of GMO-related elements and the elucidation of adjacent genomic regions or more profound whole-genome sequencing approaches linked to extended NGS data analysis. These approaches are still in an early stage of development, but the applications should be developed in the near future and most experts agree that the potential is high. This approach could become even more targeted and powerful when linked to advanced data- or text-mining tools that can screen the Internet and relevant databases for indications of newly developed GMOs that may have a concern for food/feed and/or environmental safety.

9. Conclusions

The global development and production of GMO in recent years have led to various LLP/AP incidents in a range of different countries. Major contributing factors are the increase of GMO manufacture and the increased diversity of GMOs produced in a growing number of countries, both developing and developed.

At the same time, advanced technologies have become available for the detection, identification and quantification of both approved and unapproved GMOs. The application of these technologies requires, however, dedicated equipment and skilled laboratory staff. As a result, some countries have greater capacity to detect LLP/AP incidents than other countries.

In most countries, there are no generally applicable LLP/AP policies, legislation or regulations yet in place. Different options have been used when setting LLP or AP policy, including a zero-tolerance policy, a low threshold policy and a case-by-case policy. In the latter scenario, further exchange of data/information on the safety of the respective GMOs as well as their detection methods would be a prerequisite for future global harmonization.

In addition, further capacity building to strengthen national food control systems is key to enabling developing countries to manage LLP/AP issues. Such capacity-building activities could include implementing good practices in agricultural production systems, improving laboratory capacity for GMO detection and identification, and scientific capacity to perform food safety assessments according to the Codex guidelines, as well as risk assessment for environmental impacts. This will further support equal opportunities for safe and controlled food and feed supplies for all countries.

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Annex 1. LLP/AP Incidents as reported in the FAO survey

Reporting country	*Year*	*Commodity*	*Amount (tonne; unless stated)*	*Imported from*	*How situation was discovered*	*How situation was managed*
Argentina	2008	Canola	100	Canada	Farmer complaint	Converted to biofuel
Brazil	2009	Flax	ND	Canada	Detection at the port	Consignment rejected
	2012	Maize	ND	United States	Detection at the port	Consignment rejected
Bulgaria	2007	Unauthorized GM soy protein	Two lots, of 2.7 and 6.2 tons	Brazil	Rejected by the Bulgarian authorities	Notification reference "2007.CBB" was issued by Bulgaria via RASFF
Canada	2005	Corn (Bt10)	86 acres worth of the event	United States	Proponent informed the government	Proponent destroyed crop
	2006	Rice (LLRice601)	None in Canada, trace amount in the United States of America	United States	Proponent informed the government	Proponent removed crop from commercial seed production
Croatia		Food supplements			Official control (inspection and sampling)	Consignment held for testing
		Soy			Official control (inspection and sampling)	Consignment held while information was sought and then released (under 0.9%)
		Feed			Official control (inspection and sampling)	If it unauthorized GMO it would be destroyed or returned to country of origin
Cuba	2002	Rice		United States	Review	
Cyprus	2007	Rice protein	100	China via the Netherlands	Control on the market	Returned to the dispatcher
	2007	Pet food	19.5	United States	Control on the market	Returned to the dispatcher
	2007	Pet food	2.16	United States/ Greece	Control on the market	Returned to the dispatcher
	2009	Pet food	19.7	United States	Sampling	Seized, destroyed
	2009	Pet food	19.6	United States	Sampling	Seized, destroyed
	2010	Maize	0.74	Italy	After laboratory testing	Consignment was sent back to the country of origin

Denmark	2009	Linseed (feed use)	1.5	Presumably originating from Canada (bought via supplier in Germany)	A sample of linseeds showing a low level of Flax CDC Triffid (FP967) was identified in the official control of feed	Affected batches were destroyed
	2009	Linseed (food use)	Different lots	Canada via other EU Member States	Via the EU rapid alert system	Affected batches were withdrawn from the market
France	2004	Maize GA21		United States	RASFF of member	Market withdrawal
	2005	Maize Bt10		United States	Information from US authorities	EU emergency measures
	2006	Rice LL601		United States	Information from US Authorities	EU emergency measures
	2006	Rice LL62		United States	Official control	Market withdrawal
	2006	Rice Bt63		China	Greenpeace	EU emergency measures
	2009	Lin FP967		Canada	RASFF of member	Market withdrawal
	2009	Maize MON88017		United States	RASFF of member	Blocked, pending EU approval
	2009	Maize MIR604		United States	RASFF of member	Blocked, pending EU approval
	2012	Rice Kefeng6 and KMD		China	Official control	Market withdrawal and consumer recall
	2012	Rice OGM		Pakistan/ India	Operator auto control	Market withdrawal and consumer recall
	2012	Papaya		Thailand	Official control	Market withdrawal and consumer recall
Germany (*numbers of incidents in parentheses*)	2003 to 2013	Rice (24), Rice noodles and crackers (30), Linseed (45), Maize and maize flour (2), Papaya (16), Pet food (4)		China (41), United States (24), Colombia (2), Canada (36), Thailand (3), Pakistan (2), India (1), Philippines (1), Germany (7), Italy (3), Belgium (3)		Recall, withdrawal, destruction
Hungary	2007	Maize seed	0.21			Fined
	2010	Maize seed	21	Argentina	Check sampling	Fined

	2011	Maize and soybean seed	376	Canada, United States, Romania, Croatia, France, Chile	Check sampling	Destroyed
	2012	Maize seed	≥134	United States, Romania, Chile, France, South Africa, Serbia, the Netherlands	Check sampling	Destroyed
Iran	2005 to 2012	Maize and soy	Millions of tonnes	Argentina and Brazil	Research by graduate students and random check by public research institutes	Not managed
Ireland	2007	Maize (Herculex-RW) -Feed	12 000	United States	Laboratory tests	Product was stored until EU authorization of Herculex was approved and then released. There is ongoing disruption to trade due to asychronous authorizations between EU and third countries. The current "tolerance" of < 0.1% under Reg 619/2011 is inadequate to facilitate trade between third countries and the EU. Trade problems are likely to increase in future, as more GM events enter the pipeline, giving rise to more frequent incidents of asynchronous authorizations and rejection of consignments
Italy	2007	Maize in pet food	–	United States	Official control at import	Consignment redispatched
	2009	Maize in dried pet food	–	United States	Official control at import	Consignment rejected
	2010	Maize for popcorn	25	Argentina	Official control at import	Consignment redispatched
	2013	Maize grains (popcorn)	2.5	Argentina	Market control	Withdrawal from the market
Japan	2005	Maize (Bt10)	42000	United States	(Detected in Japan) Notification by the exporting country	After the notification, consignments already imported into Japan were tested and those found positive were shipped back. After the above phase, import became acceptable only when consignments for Japan were tested and certified to be free of Bt10. Without such certification, consignments were tested in Japan, and if Bt10 was detected, those consignments were rejected

	2006	Rice (powder, noodle)	138	China	Testing at the time of importation	Consignment rejected
	2007	Rice (powder, noodle)	362	China	Testing at the time of importation	Consignment rejected
	2008	Rice (powder, noodle)	69	China	Testing at the time of importation	Consignment rejected
	2008	Maize (DAS59132)	N/A	United States	Notification by the exporting country	After the notification, consignments already imported into Japan were tested and found to be free of DAS59132. After the above phase, import became acceptable only when consignments for Japan were tested and certified to be free of DAS59132. Without such certification, consignments were tested in Japan, and if DAS59132 was detected, those consignments were rejected
	2009	Flax (FP967)	N/A	Canada	Notification by the industry involved	After the notification, consignments already imported into Japan were tested and found to be free of or < 1% FP967. If FP967 was detected at < 1%, the consignment could be used as feed but only for processing under appropriate measures to limit the contact with the environment. After the above phase, import became acceptable only when consignments for Japan were tested and certified as under the threshold. Without such certification, consignments are tested in Japan, and if FP967 is detected: at < 1%, the consignment can be imported but only for processing under appropriate measures to limit the contact with the environment; at > 1%, the consignment will be rejected
	2009	Rice (powder, noodle)	26	China	Testing at the time of importation	Consignment rejected

	2009	Flax seed (fresh, roasted)	31	Canada	Testing at the time of importation	Consignment rejected
	2010	Flax seed (roasted)	5.6	Canada	Testing at the time of importation	Consignment rejected
	2011	Papaya	N/A	Chinese Taipei	By testing conducted in response to information from a researcher	Recalled unplanted seeds from their distributors Destroyed all plants germinated from the seeds of concern
	2011	Flax seed (granola)	0.04	Canada	Testing at the time of importation	Consignment rejected
	2011	Rice (powder, noodle)	1.1	China	Testing at the time of importation	Consignment rejected
	2011	Rice noodle	14	Vietnam	Testing at the time of importation	Consignment rejected
	2012	Rice noodle	3.6	Vietnam	Testing at the time of importation	Consignment rejected
Latvia	2011	Soybean meal	5451.5	Argentina	Manufacturing enterprise attested GMO certificate Monsanto Roundup 40-3-2	Consignment was released for free circulation in EU
	2012	Hipro soybean meal and soybean expeller (feed materials)	5700	United States	Manufacturing enterprise attested GMO certificate Monsanto Roundup 40-3-2 (1 from all consignments was selected for sampling and tested for quality and quantity of	Consignment was released for free circulation

					Monsanto 40-3-2)	
	2012	Soybean meal	7615.23	Argentina	Manufacturing enterprise attested GMO certificate Monsanto Roundup 40-3-2	Consignment was released for free circulation in EU
Luxembourg	2009	Linseed	55	Germany/ Canada	EU RAFF	After confirming the AP by testing, the linseed was withdrawn from the market
Madagascar	2007	Maize		France	Environmental impact study	Demolition
Namibia	2013	Maize	Not disclosed	South Africa	The enterprise trust sent samples of maize for testing in South Africa and found that these products contained genetically modified maize	The Namibian Agronomic Board (NAB) has reprimanded those responsible for producing and marketing maize products that a consumer lobby alleged contain so-called genetically modified maize
Netherlands	2005	Bt10 maize in feed		United States	Announcement by company	Consignments held for testing and later released on basis of negative results; EU emergency measure put in place (19 April 2005)
	2006	Chinese rice (Bt63) in food		China	Greenpeace/ Friends of the Earth	EU emergency measure (9 April 2008)
	2006	LLRICE601 in food		United States	Announcement by company	Blocking of US rice consignments by Dutch companies until negative test results were obtained, risk assessment by Dutch Food safety authority (NVWA-front office); EU emergency measure (23 August 2006)
	2007	Maize in maize gluten, brewers grain Herculex RW 59122		United States	Greenpeace	Consignments traced and held for testing by Dutch food safety authority, tests negative, no need for further measures. Action plan put in place by US company for voluntary testing of consignments to EU and certification
	2009	FP967 linseed (CDC Triffid) in food		Canada	Detection by third country authorities	Consignments traced and held for testing by Dutch food safety authority, recalls performed, risk assessment done by the Netherlands Food and Consumer Product Safety Authority-front office, action plan by Canadian government

New Zealand	2001	Maize seed		United States	In-house testing of growing crop by company	Crops 'held' while information was sought and then released
	2002	Maize seed	1400 seeds	United States	In-house testing of finished crop by company	Seed testing; field management
	2003	Sweetcorn product		United States	Testing of sweet corn product in Japan	Residual seed tested
	2004	Maize		United States	Re-testing seed consignments from earlier season	Stored grain used for feed rather than food
	2006	Sweetcorn seed	1.8	United States	Ministry of Primary Industry's quality system	Retesting arranged by seed supplier. Unplanted seed and young plants destroyed.
Norway	2008	JiangXi rice vermicelli		China	Compulsory testing by authorities according to national legislation	Consignment held for testing and rejected after testing
	2010	Rice Mix		United States (origin Thailand)	Testing according to national surveillance programme	The product was not allowed to sell and the finding was notified in the European RASFF-system
	2012	Dongguan Rice Vermicelli	7.9	China	Compulsory testing by authorities according to national legislation	Consignment held for testing and rejected after testing, notified in the European RASFF-system
	2012	Oriental rice cracker mix	6.2	China	Compulsory testing by authorities according to national legislation	Consignment held for testing and rejected after testing, notified in the European RASFF system
Philippines	2006	Liberty Link rice			Report of alleged presence in the	All commercial rice alleged to contain LL601 was recalled by

		LL601 (for food use)			local market by Greenpeace	the National Food Authority; Further shipments from the source were required for testing (negative) by Philippine authorities (Department of Agriculture-Bureau of Plant Industry)
	2008	TC 1508 (for propagation)			Declaration by technology developer	Whole shipment was quarantined and destroyed
Poland	2011	RR oilseed rape				Withdrawn from the market
Spain	2009	Maize, soy cake		United States		Border rejection

*N/A, not applicable; ND, not determined