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A Gap Analysis of Confined Field Trial Application Forms for Genetically Modified Crops in East Africa: Evaluating the Potential for Harmonization

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ABSTRACT

The regulatory approval of genetically modified crops in the field initially requires small, restricted experimental trials known as confined field trials. These small scale experiments provide researchers with important information on environmental interactions and agronomic performance of the crop in a safe and contained manner. To authorize confined field trials regulatory review is required, with formats for obtaining relevant information differing from country to country. In this paper, a Gap Analysis is used to identify informational gaps and potential for harmonization of confined field trial application processes in three East African countries – Tanzania, Kenya, and Uganda. The basic principle behind gap analysis is a comparison of the status quo to an ideal with the identification of the differences or gaps and the difficulty involved in removing the gaps. The resulting similarity of the application forms provides a potential basis for harmonization of confined field trial application processes between countries leading to potential efficiency gains.

Key words: biotechnology, biosafety, bioconfinement, confined field trials, gap analysis, harmonization

TABLE OF CONTENTS

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Nicholas A. Linacre[1] and Joel I. Cohen[2]

1. INTRODUCTION

Modern biotechnology has potential for the promotion of human well-being, through the development of technologies that can be used to assist with meeting critical food needs, improving agricultural production, addressing environmental problems and providing health care products (CBP 1999). However, to obtain potential benefits from biotechnology, biosafety laws are required to ensure human and environmental safety (Jaffe 2004; Cohen and Paarlberg 2004).

Currently one of the primary driving forces behind the development of biosafety systems is the Convention on Biological Diversity through the Cartagena Protocol on Biosafety (CPB) which governs the transboundary movement, transit, handling and use of GMOs. National biosafety[3] laws govern research, development, and commercialisation of all transgenic organisms including genetically modified (GM) crops and in many developing countries, these laws are based on the CPB. However, there are regulatory differences between national regulatory systems, even when common guidelines are available.

One comparative method (Paarlberg 2001) ranks national biosafety systems on a qualitative scale from promotional to preventative. Promotional systems are designed to

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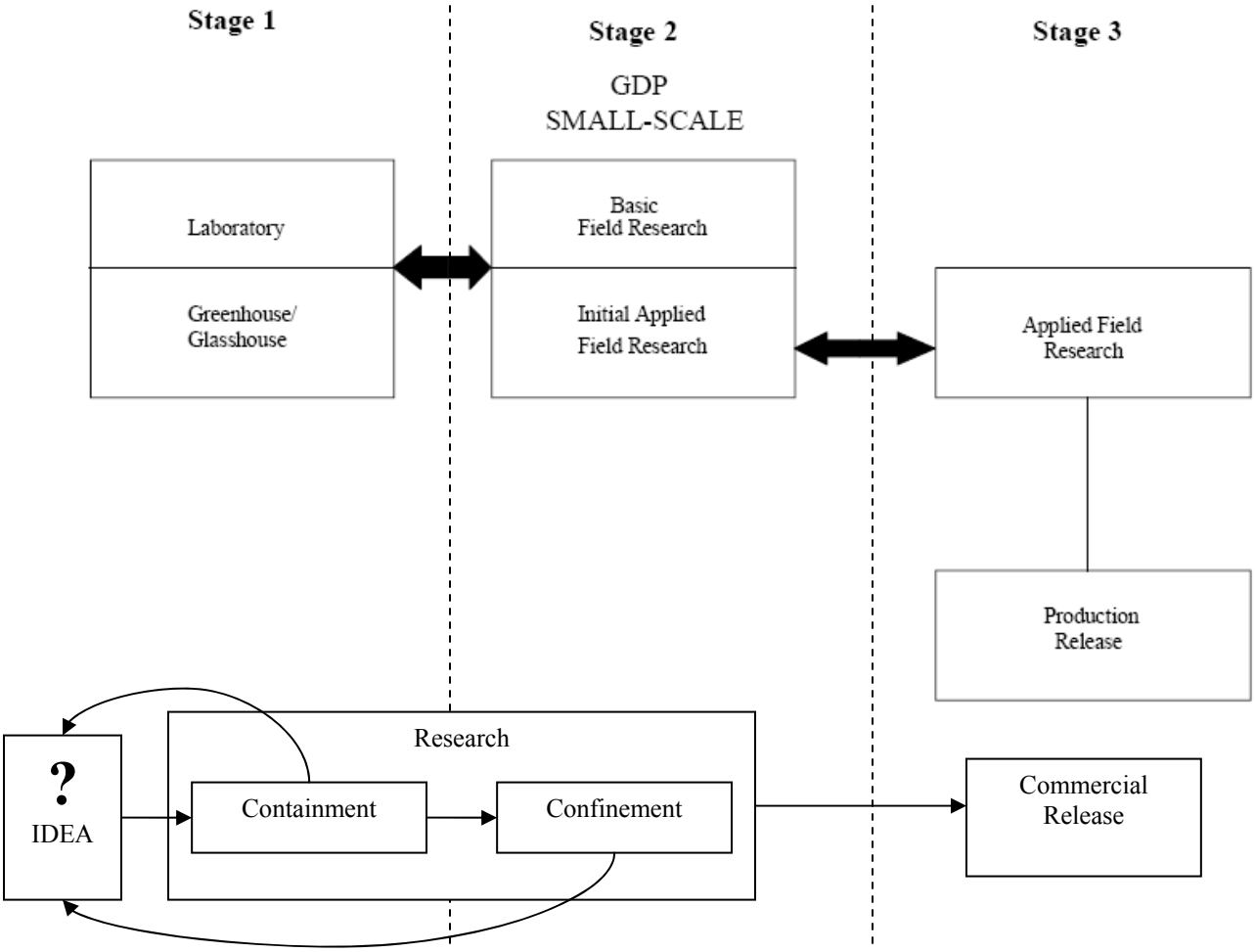
[3] Biosafety may be defined as the regulatory system and its associated risk analysis measures designed to ensure that applications of modern biotechnology (in particular Genetically Modified Organisms) are safe for human health, agriculture, and the environment.

accelerate the adoption of genetically modified organisms within a country. Permissive systems attempt to be neutral towards the technology, neither slowing nor increasing the rate of adoption of the technology. Precautionary systems slow the rate of adoption of the new technology. Preventative systems restrict the legal adoption of biotechnology. Achieving a permissive system that has a neutral approach towards the technology requires an integrated series of regulatory stages to ensure innovation through delineation of research and commercialization activities (Cohen 2005).

An example of the interrelationship between components of a biosafety system is shown in Figure 1.

Figure 1--The delineation between: containment, confinement, and commercial releases. The figure is adapted from OECD (1992: p 20) - Good Development Practice in the context of field research.



Understanding the delineation between research activities and commercial releases is important from a regulatory standpoint. This is illustrated by the dotted line between Stage 3 and the other two stages. Further separation of research activities is also recognized, having both contained and confined activities. Stage 1 generally represents contained activities, stage 2 confined actives, and stage 3 commercial releases.

For transgenic plants or GM crops, “contained activities” refer to research done within laboratories, growth chambers, and greenhouses that are completely separated from the open environment. . From a safety perspective, the purpose of containment is to ensure that genetic material does not escape into the environment; at the same time it provides the means for testing methodologies for transformation and determination of the expression of specific genetic constructs (Robinson et al., 1998). Such activities are done at the earliest stages of development, often following review by an Institutional Biosafety Committee.

Following the containment stage, small scale field experiments, called confined field trials (CFT), are conducted that provide important agronomic performance data. Confined field trials also allow regulators and government scientists to obtain important environmental, human and animal safety information on the crop. Confined field trials provide risk assessment data that is essential for any regulatory system (NRC 2004). This information is used for fuller safety assessments required for commercial release approval of GM crops. In contrast to contained and confined experiments, commercial releases of GM crops usually represent uncontrolled environmental release. Generally, commercial releases can be distinguished from confined trails by the size and scale of planting and the absence of restrictions to limit the movement of genetic materials.

As mentioned above, understanding these differences between research and commercialization is extremely important for testing transgenic crops. Regulatory requirements for GM crops vary depending upon the stage of development (as shown above) and between different countries, but most countries require submission of an application prior to approval for a confined field trial or for commercial release.

The remainder of this paper focuses on the regulation of the confined field phase of GM crop development. A Gap Analysis is used to identify informational gaps and potential for harmonization of confined field trial application processes in three East African countries – Tanzania, Kenya, and Uganda. Section 2.0 explains the Gap Analysis method and develops the rationale for the key informational requirements needed for the safe conduct of confined field trials. Section 3.0 presents the results of the analysis and Section 4.0 discusses the potential areas of harmonization identified by the Gap Analysis.

2. METHODS - GAP ANALYSIS

An extensive banking and finance, strategic management, and marketing literature exists on gap analysis, for example see: Goodstien et al. (1993), Porter (1998), Fleisher and Bensoussan (2002). The basic principle behind gap analysis is a comparison of the status quo to an ideal with the identification of the differences or gaps and the difficulty involved in removing the gaps. In this context, the International Food Policy Research Institute[4] (IFPRI) held a Gap Analysis workshop in July 2005 on Confined Field Trials. An expert group was convened to analyze the CFT application forms from Tanzania, Uganda, and Kenya. This workshop was part of a wider initiative supported with funding from the United States Agency for International Development (USAID). This initiative, Program for Biosafety Systems (PBS), is managed by IFPRI, working through a consortium of partners including Michigan State University, the Donald Danforth Plant Science Center, and Western Michigan State University, to identify and review strategic gaps in the formulation and development of Biosafety Systems

[4] IFPRI is part of the Consultative Group on International Agricultural Research www.cgiar.org and www.ifpri.org.

in East Africa. Other activities included a three country legal gap analysis; for details see Jaffe (2006).

The first step in the Gap Analysis was the agreement on, and preparation of, a uniform CFT application used in comparison with national application forms. There appears to be few systematic attempts within the scientific literature to define the informational requirements for confined field trials. However, a number of companies, countries, scientific and international organizations offer guidance on the safe conduct of confined field trails. Generally, the approval process for a confined field trial is based on information supplied in a form. Typically, all confined field trial forms contain:

- general administrative information;
- biological information on the unmodified and modified plant;
- biophysical information about the trial site including geospatial information;
- information on genetic and material confinement measures; and
- contingency plans.

This information is designed to ensure the safe conduct of an experiment. It identifies measures to limit the movement of biological materials within the trial site and to ensure that only genetically modified plants suitable for confined field trials are approved. This is achieved by obtaining information on the similarity of the GM crop to existing commercial varieties using the principle of 'familiarity[5]' (van Dommelen 1999) and growing the crop under highly restricted conditions (confinement measures) to limit the movement of any genetic material (NRC 2004). Information is provided in an application on the performance of the

[5] "Familiarity is not synonymous with safety; rather, it means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks." (OECD 1995).

unmodified and modified plant as it relates to confinement, such as the plants ability to escape, establish and persist in the environment into which it is being introduced. Information on the modified plant is obtained to assess relationships of the intended phenotypic changes to appropriate confinement measures.

Information is also required on the biophysical environment into which the experimental plants are being introduced. This would include a description of the purpose of the field trial, the experimental design and the nature and type of data to be collected. This information should include the nature of the habitat at the site, and a list of organisms of conservation concern located within the general area of the site. The aim of obtaining this information is to understand how the biophysical environment might affect the genetic and material confinement measures. Broadly, there is consensus on approaches for genetic confinement[6] which include: spatial separation; removal of reproductive structures; temporal separation; removal of floral parts; and, harvesting time, for example see OECD (1992). Finally, information is required on contingency plans, which specify how accidental releases of genetically modified plant material will be dealt with including.

These various considerations are summarized in a detailed sample application form developed by the expert group during the gap analysis workshop. This appears in Appendix A. The sample form is used as the basis for a comparative analysis between Kenya, Uganda, and Tanzania. However, some caveats must be applied. The application form summarizes current knowledge contained from a number of sources (e.g. OECD 1992, PRR 2005) and is therefore based solely on publicly available information. The sample form only deals with experimental trials for GM crop plants. The form indicates basic information needed for a confined field trial. However, each country has a unique set of circumstances driving the application process.

[6] For example see OECD (1992), Angle and Linacre 2005, Halsey (2005).

Some requests for information may be present because of societal considerations rather than scientific considerations.

The sample form used for the country comparisons (Appendix A, B), has its informational requirements divided into seven categories as follows:

1. Administrative information: basic application contact details, name of crop and proposed locations
2. Unmodified plant information: information on performance of the unmodified plant as related to confinement
3. Modified plant information: description of modified crop as related to confinement
4. Trial description: full description of field trial, purpose, design and other relevant information
5. Genetic confinement: explaining how confinement of the GM crop will be maintained
6. Material confinement: plans for keeping the GM crop out of human or animal food chain
7. Contingency plans: explain how accidental releases of GM crop/products would be handled.

These same categories are used in Table 1for the gap analysis.

3. RESULTS - GAP ANALYSIS

The Gap Analysis of Tanzania, Kenya, and Uganda using the analytical framework developed in the previous section are shown in Table 1. The sample application form was compared to relevant sections in the country applications. The analysis provides a 'snap shot' of the information currently requested by each country. Below are highlights observed from the gap analysis. While information addressing the seven categories above is in differing locations on each country form, there is broad agreement with the sample form. This shows a

common perspective emerging among countries for managing applications for confined field trials versus those for full commercial, open release or use.

Table 1-Gap analysis of confined field trial application forms comparing sample form to those from Kenya, Tanzania, and Uganda.

		Relevant sections from national regulatory forms		
Benchmark (Sample form; Appendix A)	**Explanations from sample form**	**Tanzania**	**Kenya**	**Uganda**
National Regulatory Authority for confined field trials		TPRI[♣]	National Council for Science and Technology	UNCST[♦]
1. Application Information				
Purpose of the application	This is an application for a confined field trial for (name of crop species).	√	√	√
Application history in all jurisdictions	Provides information on the status of previous or current applications for this event including field tests and unconfined (commercial release). Applications could be pending, approved, or not approved in multiple jurisdictions	F5, F7	A4, B11, B11, B12	III B.e
Applicant	Name of applying institution, ancillary information may also include the name of the principal investigator and confined field trial manager.	C, D	A2, A3	I
Contact information	Applicant contact details	C, D	A2	I
Proposed size, location and duration of the trial	Name, address, email, phone, and facsimile of the Trial Manager as well as GPS information on the exact location.	G1, G2	A2, A5	IV A.a[f]

[♣] Tropical Pesticide Research Institute

[♦] Uganda National Council for Science and Technology.

[f] Information on the trial site manager does not appear to be required.

2. Unmodified Plant Information				
Plant species name	Common and scientific names	A1, A2	B1	III A.a
Reproductive mechanism of the plant	Information on the biology of the plant. Some information may be obtained from Organization for Economic Co-operation and Development (**OECD**) biology consensus documents	A3	B2	III A.b
Tendency to weediness	Is the unmodified plant regarded by agricultural experts as a weed in regions where it is cultivated? If so, are control methods available that effectively limit the dispersal and establishment of the unmodified plant.	A4	B4	III A.d.ϒ
Center of Origin:	What is the center of origin of the unmodified plant?	A7	B3	III A.c
Toxicity	Is the unmodified plant known to contain toxins or allergens of concern to humans or animals? Toxicity information could be a factor in determining appropriate handling procedures. It could also be important for evaluating worker exposure. The applicant should describe whether local fauna, not usually exposed to the toxins introduced due to the trial, could be adversely affected by the trial. This information might be needed to evaluate effects on non-target organisms, if not currently exposed to any toxins introduced by the trial.	A14, A15	B5	II∞

Benchmark	**Explanations from sample form**	**Tanzania**	**Kenya**	**Uganda**
3. Modified Plant Information				
Intend phenotypic changes	What are the intended phenotypic changes to the plant?	F13	B6ϒ	
Intended reproductive affects	Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes affect strategies for confinement?	F13.1 – F13.6ℑ	B7	III B.b
Source of genetic material	What is the source of the genetic material and does this affect the safe conduct of a confined field trial? Provides information on the potential introduction of infectious agents, plant, animal or human pathogens or allergens or toxins.	F9	B8, B9, B10	III B.c, III B.d

ϒ No allowance is made on the form for explanation.
∞ Extremely detailed and may not get at risk information.
ϒ Wording asks for a description of the genetic modification presumably this is intended to cover any phenotypic effects.
ℑ Several specific issues are identified as opposed to provide flexibility to describe the phenotypic changes.

4. Trial description	Information on the purpose of the field trial, the experimental design and the nature and type of data to be collected, including any pesticide or herbicide use.	H1, H2, H3	---	---
5. Genetic confinement				
Geographical information affecting genetic confinement	Provide information on trial size including a map of the trial site(s) and surrounding fields and geographic features.	G2, G4	C1	IV.A.a
Compatible species	Are there sexually compatible wild plant species that could result in viable offspring near the trial site? Do confinement mechanisms provide effective barriers against potential gene flow via pollen, tissues and/or seed? Are sexually compatible wild relatives likely to be present in the confinement area of the trial? Are these wild relatives of conservation concern?	G5, G4	C2	IV.A.b
Genetic confinement measures	Mechanisms to contain gene flow. Measures include, but should not be limited to: physical isolation, temporal isolation including termination of trial before flowering, and other measures may be appropriate depending on the biology of the unmodified plant, the nature by which pollen and seeds are dispersed and the intended genetic modification (the intended phenotype).	H4	C3	IV.A.c
Volunteer control	Information on post-trial plans to control volunteers on the trial site.	G6	C4	IV.A.e
6. Material confinement				
Packaging/transport	How will the genetically modified plant material will be packaged for transport to the trial site; how the packaging material will be cleaned and/or disposed of after use and; how the packaging material containing genetically modified plant material will be marked or identified during transport to the trial site.	H5	D1, D2	IV.B
Planting, harvesting, monitoring, transport and storage	How will material be harvested; how harvested retained material is will stored and/or transported off site.	H5, H8	D3	IV.B
Disposal and clean up	How will surplus planting material will be disposed of at the trial site; how any equipment used during planting and other farm operations will be cleaned; and how harvested materials and crop residues be disposed of.	H6	D7	IV.B
Site Security and training	Measures that could be needed to prevent unauthorized removal of material from the trial site and include: fencing, security patrols, and locked gates.	H9	D5	IV.B

7. Contingency plans				
Notification of Authorities	If a breach of the license for the CFT occurs then authorities must be notified	H10	E	C
Recovery of materials	Materials should be recovered to the extent possible.	H10	E	C
Confinement of materials	Materials should be confined to the spillage area or local site of accidental release	H10	E	C
Other	Any other measure deemed necessary to ensure the safe conduct of the CFT	H10	E	C
8. Declaration	Certification of the correctness and completeness of information	√	√	√

Category 2. Unmodified plant information. As seen from Table 1 there is broad agreement between each countries application with information appearing in different sections of the form.

Category 3. Modified plant information. As seen in Table 1 each form requires a description of the genetic modification made to the crop. However, the Tanzanian form (part F 1 – 13) requests more details than the Kenya and Uganda forms, which are less specific, but still require significant amounts of molecular information. In the Ugandan form, Section III B focuses on this, with the last questions calling for an annex that would essentially match what the Tanzanian form has formatted in detail. A similar approach is taken in B.6 of the Kenyan form.

Category 4. Trial description. Detailed instructions for information are presented in the sample form for this category. They include the following: full description of the purpose of the field trial; experimental design data to be collected; nature of habitat at site, and a list of organisms of conservation concern. Furthermore, a field history is requested, including crops planted in the last 3 years and pesticides applied. This type of detail is not seen in the current Kenyan form. While the Tanzanian form covers this in Section H, it is a general approach, without detail of elements listed above. The Ugandan form focuses on type of data to be collected; however, it does so without a summary of the trial objectives, or answers to many of the suggested information needs shown above.

Category 5. Genetic confinement. Each country has devoted specific questions to address the four items under this category in Table 2. One issue that comes up in the Ugandan and Kenyan form is the frequency of monitoring of volunteer plants for pulling up. However, broader or long term monitoring is not considered for the confined field trials. The Tanzanian form

captures this in Section H.9, but in a more general way, not specifically tied to pulling volunteer plants.

Category 6. Material confinement. Here, the Tanzanian form asks information on planting; to know if it is mechanical or by hand, while all three forms focusing directly on packaging and transport. Use of pesticides or herbicides in the trial is asked specifically in the Tanzanian form. Agrochemical use is mentioned in the sample form, in Section 4, trial description. However, additional details may be needed if forms are lacking this information.

4. DISCUSSION

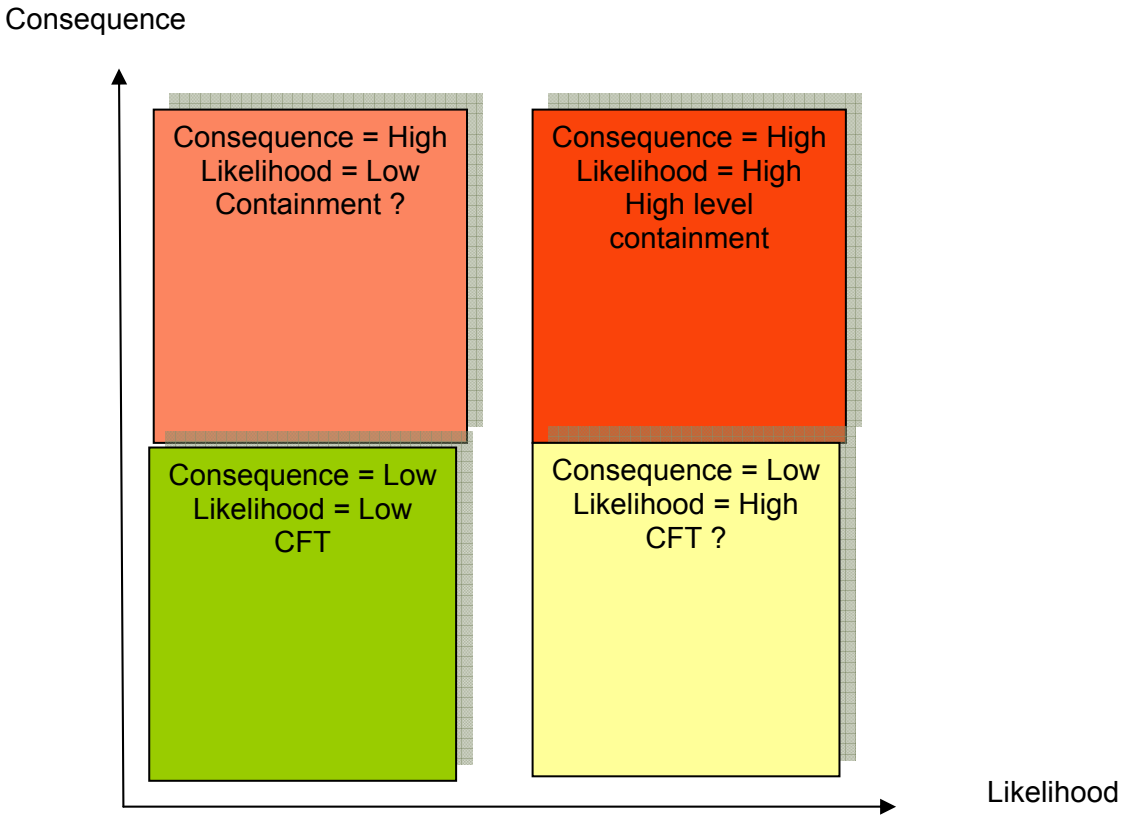
This section discusses potential limitations of the research, confined field trials and risk analysis issues, and the possibility of moving towards a harmonized confined field trial application process in East Africa.

An important caveat on the Gap Analysis approach is the identification of the sample application form. It is possible the selection of experts biased the selection of questions on the form. For consistency purposes, the sample form was compared to the Canadian CFT application form and OECD documents. IFPRI's own experts reviewed the form. However, while every reasonable step has been taken to ensure the completeness and accuracy of the form (Appendix A) it remains possible that a different group of experts might produce a different form and to this extent, the analysis is potentially limited. Therefore, countries interested in using these research results would normally also consult with their own domestic experts on the appropriateness or otherwise of the research for the individual circumstances of the particular country applying the results of this analysis.

Regulators in developing countries should also recognize that small scale confined field trials have their limitations. This is why it is important to move towards larger scale trials, or scale up to production. Providing efficient management and review of confined trials is essential for this progression, as the confined trials illuminate the majority of potential effects on appearance and behavior of GM plants. However, some effects are more likely detected in larger scale trials, which give an additional round of testing for safety (OECD 1993).

It is also important to recognize that the confined field trial application forms represent a risk screening step. Generally, only genetically modified crops that are unlikely to cause severe damage are approved for confined field trials; however, opinions differ on the perceived degree of damage which could potentially occur. When combined with stringent confinement measures to produce a low likelihood of exposure, the resulting risk (combination of the consequence and likelihood of exposure) is thought to be extremely low (Figure 2) (NRC 2004).

Figure 2--Combining likelihood and consequences for confined field trials. The risk screening provided by the CFT application and associated material confinement measures helps to identify low risk scenarios.



The similarity of the country applications under scores the potential for regional harmonization in confined field trial application processes and the potential for a single regional approach, which would allow developers to collect risk assessment and agronomic data within the region without having to go through multiple application processes. Potential efficiency gains include better use of human resources, streamlined application processes, reduced environmental risk, and the development of strong regional cooperation. Regional biosafety approaches are negotiated between interested countries. Details of such agreements may include common specific approval documents, reciprocity of regulatory testing

data/information, and policies outlining relation of national to regional decision. Of course, many other opportunities exist for further collaboration as confidence begins to build.

In the simplest case, harmonization could occur by each country's application form being standardized with similar expectations of informational requirements. This would make it easier for applicants to fill out the forms and would standardize the expectations of developers about what is required of them from neighboring countries (for example see Jaffe 2006). A more integrated approach could involve a single regional approval body using a regionally developed confined field application form and data expectations. Decisions by the regional body would be non-binding on the countries involved and would allow domestic regulators the right to either accept or not implement the recommendation. This way national sovereignty would be assured. A number of benefits might be derived from such a regional approach including the more efficient use of human resources, efficient application processes, and enhanced environmental safety.

A regional system could potentially more efficiently utilize the limited biosafety capacity in the region by using scientists from all three countries to assess a single application that could then be used in all countries. Standardizing data requirements could provide greater certainty for developers and regulators and, given the porous nature of borders in East Africa (Minde 2005), it is likely that the development of regional environmental risk analyses will provide greater environmental security. Fundamental to this is the use of confined field trials to collect environmental data to inform regulatory commercial release decisions. Potentially, the greatest challenge lies in the development of a coordinated regional approach that is not mired in endless rounds of analysis.

The essential importance of confined field trials for research in developing countries is now being realized. Regulators understand that products are not introduced into the open environment immediately. Instead, they go through regulatory stages appropriate to the GM crop seeking testing approval. However, confined field trials, while essential, do not fully approximate farmer's fields or broader use. Thus, confined field trials are a midway point in determine the eventual safety, success or failure of a given GM crop. Vast differences in information requirements for field tests or information requirements that belong elsewhere in the regulatory approval process can cause considerable confusion. Therefore, the more harmonized are the national forms, the easier it becomes to use other's data, and to make approval decisions as per common understanding of confined field trials.

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APPENDIX A

Sample Application Form∏.

Section 1. Administrative information

1.1 Purpose of the application: This is an application for a confined field trial for (name of crop species).
1.2 Application history in all jurisdictions: Provide information on the status of previous or current applications for this event including field tests and unconfined (commercial release). Applications could be pending, approved, or not approved. If this is a new application or a renewal this information will appear here. If the event is under consideration in multiple markets this information also appears here. Information related to successful or unsuccessful applications should appear here, accompanied by an appropriate explanation.
1.3 Applicant: Name of applying institution, ancillary information may also include the name of the principal investigator and confined field trial manager.
1.4 Contact details: Address, email, phone, and facsimile.
1.5 Proposed location(s) of the trial: Provide the name, address, email, phone, and facsimile of the Trial Manager as well as GPS information on the exact location. **1.6 Proposed duration of the trial.** **1.7 Proposed size of the trial.**

Section 2. Unmodified Plant Information

Comment: The purpose of this section is to elicit information on the performance of the unmodified plant as it relates to confinement. Typically information is obtained on the plants ability to escape, establish and persist in the environment into which it is being introduced.

∏ This is intended as a guide only and should not be applied with out consider and consultation with biosafety experts.

2.1 Plant species name (common and scientific):
2.2 Reproductive mechanism of the plant: Provide information on the biology of the plant. This information may be obtained from Organization for Economic Co-operation and Development (**OECD**) biology consensus documents when available and, where applicable, should include: • A description of inter and intra specific breeding • Pollen production and dispersal mechanisms • Seed production and dispersal mechanisms • Seed dormancy • Vegetative reproduction.
2.3 Tendency to weediness: Is the unmodified plant regarded by agricultural experts as a weed in regions where it is cultivated? If so, are control methods available that effectively limit the dispersal and establishment of the unmodified plant. (NOTE: the information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this form.)
2.4 Center of Origin: What is the center of origin of the unmodified plant?
2.5 Toxicity Is the unmodified plant known to contain toxins or allergens of concern to humans or animals? If it does identify the toxin(s) or allergen(s) then provide information on the affected species and dose-response information. Toxicity information could be a factor in determining appropriate handling procedures. It could also be important for evaluating worker exposure. The applicant should describe whether local fauna, not usually exposed to the toxins introduced due to the trial, could be adversely affected by the trial. This information might be needed to evaluate effects on non-target organisms, if not currently exposed to any toxins introduced by the trial.

Section 3. Modified Plant Information

Comment: this section seeks information on intended affects that pertain to issues that affect confinement measures.
3.1 Describe the intended phenotypic changes to the plant.

3.2 Intended reproductive affects Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes affect strategies for confinement? Explain.
3.3 What is the source of the genetic material and does this affect the safe conduct of a confined field trial? If so how? Provide information on the potential introduction of infectious agents, plant, animal or human pathogens or allergens or toxins.
3.4 Provide a brief description for each genetic element (or feature) of the construct including coding sequences, promoters, enhancers, termination, and polyadenylation signal sequences. Attach a genetic map and information on the method of modification in an annex.

Section 4. Trial description

Provide a full description of the purpose of the field trial, the experimental design and the nature and type of data to be collected, including any pesticide or herbicide use. This information should include the nature of the habitat at the site, and a list of organisms of conservation concern located within the general area of the site. Furthermore, a field history should be given including crops planted in the last 3 years and pesticides applied.

Section 5. Genetic Confinement

Comment: this section outlines the approach taken to ensure confinement of the genetically modified test material. It is based on knowledge of the unmodified crop and the intended genetic modification.
5.1 Provide information on trial size including a map of the trial site(s) and surrounding fields and geographic features.
5.2 Are there sexually compatible wild plant species that could result in viable offspring near the trial site? Do confinement mechanisms provide effective barriers against potential gene flow via pollen, tissues and/or seed? Are sexually compatible wild relatives likely to be present in the confinement area of the trial? Are these wild relatives of conservation concern?
5.3 Describe mechanisms to contain gene flow. Measures include, but should not be limited to: Isolation distances (justify proposed distances based on existing information from the unmodified crop and the intended genetic modification), detasseling or removal of floral parts, bagging of flowering parts, temporal isolation, termination of trial before flowering, guard rows / pollen trap rows /

wind breaks, and measures to prevent seed dispersal from test area. Other measures may be appropriate depending on the biology of the unmodified plant, the nature by which pollen and seeds are dispersed and the intended genetic modification (the intended phenotype). Documentation and record keeping is required to provide field inspectors with the necessary and essential information to ensure compliance with the application approval.

5.4 Volunteer control.
Provide a description of post-trial plans to control volunteers on the trial site. Issues that need to be considered include: cropping patterns on the site including the location of modified and unmodified plants, duration of monitoring for volunteers, frequency of monitoring, disposal of any identified volunteers, and any other measures needed to ensure the safe conduct of the confined field trial. Documentation and record keeping is required to provide field inspectors with the necessary and essential information to ensure compliance with the application approval. This may include information on the use of herbicide control.

Section 6. Material Confinement

Comment: describe the mechanisms by which modified plant material is kept out of the human or animal food chain, and to ensure exposure to the environment through accidental release is effectively zero.

6.1 Packaging
Describe how the genetically modified plant material will be packaged for transport to the trial site; how the packaging material will be cleaned and/or disposed of after use and; how the packaging material containing genetically modified plant material will be marked or identified during transport to the trial site. Typically the applicant will describe how the chain of custody will be ensured and the type of records that will be maintained. Chain of custody information serves as important evidence ensuring the proper pre- and post-trial containment of the regulated materials used.

6.2 Harvesting, transport and storage
Describes how material will be harvested; how harvested retained material be will stored and/or transported off site.

6.3 Disposal and clean up
Describes how surplus planting material will be disposed of at the trial site; how any equipment used during planting and other farm operations will be cleaned; and how harvested materials and crop residues be disposed of. Maintenance of good records ensures that environmental release was limited to the CFT site.

6.4 Site Security and training
Detail measures that could be needed to prevent unauthorized removal of material from the trial site and include: fencing, security patrols, and locked gates. This section also includes information that may be needed to prevent fauna from removing material from

the trial site.

Section 7: Contingency Plans

Provide information on how accidental releases of genetically modified plant material will be dealt with. The information included in this section covers: notification of authorities and other applicants, recovery of materials, confinement of materials, and any other measures deemed necessary to ensure fast and efficient confinement of materials and mitigation of potential adverse environmental effects.

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