Implementing National Biosafety Frameworks in the Caribbean Sub-Region

GUIDELINES FOR THE RISK ASSESSMENT OF COMMONLY REGULATED GM CROP EVENTS

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EXECUTIVE SUMMARY

Many GM crops have been evaluated for environmental and food safety by several national regulatory authorities and are now traded and used internationally by many countries worldwide. There now exists a substantial history of safe use for these crops, supported by numerous regulatory decision documents and published peer-reviewed literature. This existing body of data is of sufficient substance and quality to inform determinations of safety for the use of these GM crops in (country). Using the approach described herein, the Government of (country) intends to draw upon all this information to efficiently and proactively determine environmental and food safety of individual GM crops.

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1. INTRODUCTION

These Guidelines present an approach that the Government of (country) uses to simplify and expedite the assessment of environmental and human health safety of genetically modified (GM) crops that have a long history of safe use in other countries. This approach is based on the collection and evaluation of a variety of high-quality, relevant data and other evidence. This information may appear in the regulatory decisions of other countries, in peer-reviewed scientific literature, or in international consensus documents, as well as in other appropriate sources. The goal of this approach is to evaluate whether there is sufficient evidence available of environmental or human health safety for the Government to determine that a particular GM crop is safe, when grown as a commercial crop or when used in food and feed. This approach is science-based and grounded in well-established, internationally accepted concepts of risk assessment, including the consideration of the weight of available evidence and the comparative approach.

2. WEIGHT OF EVIDENCE APPROACH

All governments assess the safety of GM crops before they are used within the country. The assessment may focus on environmental safety, in the case of GM crop seeds intended for planting, or on food safety, in the case of GM crop material that will be used in the food supply. In either case, government regulators consider data from an application proposing a use for the GM crop in the country, but they also consider relevant data from other appropriate sources. The types of data to be collected, evaluated, and weighed differ, depending on whether the risks are related to the release of the GM crop into the environment, or the use of the GM crop in the food supply. For a GM crop that has been placed on the international market for several years, there is a large body of available data regarding its safe use. A fundamental step in the approach described in these Guidelines is for the Government to determine whether the body of scientific evidence is in agreement regarding the risks posed by a particular crop and regarding the significance of the risks. When there is disagreement, that is, if there is some evidence of a significant risk associated with the crop, regulators must determine the weight this evidence in comparison to the weight of evidence indicating the GM crop is safe. Factors considered by the regulators will include the amount of data published on each side of the question, the quality of the experimental studies, the source of the data, and other factors.

Weighing the evidence in this manner is a fundamental part of all governmental decision-making, both in (country) and internationally and is a key part of the approach laid out in these guidelines.

3. THE COMPARATIVE APPROACH

Another fundamental feature of the risk assessments for GM crops performed by governments worldwide is that the assessments use a comparative approach. That is, any environmental or

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food safety risks posed by the GM crop are compared to the risks posed by an appropriate non-GM counterpart. The goal of this comparison is to identify characteristics that the GM and non-GM versions of the crop both share, that is, the ways in which the two crops are substantially equivalent. The focus of the risk assessment then becomes those specific differences between the GM and non-GM versions that could result in new or increased risks. The comparative approach is based on the common understanding that many traditionally bred crops have adverse impacts, either on the environment or on the food supply. For example, cassava roots contain toxic cyanogenic substances, soya beans contain allergenic proteins, and oilseed rape possesses weedy characteristics. Therefore, any risks posed by a GM crop must be compared against the baseline of a non-GM counterpart to determine if either: 1) the risk posed by the GM is a new risk not posed by the non-GM version, or; 2) if the risk posed by the GM crop is significantly greater than that posed by the non-GM version. These new or increased risks then become the focus of the risk assessment.

Using the comparative approach in this way, to identify similarities between the GM and non-GM version of the crop and to focus on any differences posing increased risk, is another key component of the approach described in these guidelines.

4. ORGAGANISATION OF THE RISK ASSESSMENT

Although these guidelines describe an expedited approach to assessing risks of GM crops with a long history of safe use, the organisation of the assessment document should reflect that of a full risk assessment, when the subject of the assessment is a new GM crop. The assessment document should contain the following sections:

- **Introduction**
- **Scope of the assessment**
- **Potential food safety risks**
- **Potential environmental risks**
- **Conclusion**
- **References**

It is advisable to use a consistent organisation with each subsequent assessment decision document, to make the consistency of the decision-making process evident to stakeholders.

4.1 INTRODUCTION

4.1.1 CROP BIOLOGY AND GENETIC MODIFICATION

The introduction should consist of two sub-sections. In the first sub-section, the biology of the non-GM crop should be described. Although this section should give a general description of the crop biology, regardless of the type of risk assessment, the focus of this section should reflect the assessment decision in question, namely either a food safety assessment or an environmental risk assessment:

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Focus for a food safety assessment:

- Existing food uses of the crops, emphasising domestic uses*;
- Existing processing methods used, emphasising domestic methods*;
- Domestic subpopulations with special uses for the food*;
- Known toxins present in the food;
- Known allergens present in the food;
- Typical nutritional composition of the food.

Focus for an environmental risk assessment:

- Common domestic agronomic production methods*;
- Methods of plant reproduction (sexual or asexual);
- Methods of pollination, including known pollinators;
- Known wild relatives* and likelihood of outcrossing;
- Known adverse impacts to the environment (weediness, invasiveness, adverse impacts on other organisms, etc.)

For most crops grown and traded internationally, the above information can be found in consensus documents developed by the Organisation for Economic Co-operation and Development. These consensus documents have been developed specifically to assist in food safety[1] and environmental risk[2] assessments and provide data that has been reviewed and approved by multinational panels of experts. Details regarding domestic crop production and use (marked with an asterisk in the lists above) will need to be developed by the Government.
Next, the document should provide a description of the specific GM crop in question. This should include a brief description, in plain language, of the trait or traits that have been engineered into the crop, including the genetic material that has been inserted and how it functions in the plant. A brief discussion of the expression of the novel traits and locations in the plant where expression occurs should be included as well. This section should also discuss any unexpected agronomic characteristics of the GM crop that have been observed. Again, excellent online sources of this information are available, and each can be searched by the name of the GM crop under consideration:

- United States Food and Drug Administration (https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon)
- United States Animal and Plant Health Inspection Service (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status)
- Canadian Food Inspection Agency (http://inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236)
- Health Canada (https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html)
- Australian Office of the Gene Technology Regulator (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cr-1)

1 http://www.oecd.org/chemicalsafety/biotrack/consensus-document-for-work-on-safety-novel-and-foods-feeds-plants.htm
2 http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnologybiologyofcrops.htm

- FSANZ (http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx)
- EFSA (http://www.efsa.europa.eu/en/science/gmo)

4.1.2 GLOBAL REGULATORY STSTUS OF THE GM CROP

The second subsection of the Introduction should summarise the global regulatory status of the GM crop, specifically the list of countries where either food use or environmental release has been authorised. When available, the regulatory decision documents released by each country should be downloaded. Be advised that many countries do not publish their risk assessments.

- ISAAA (http://www.isaaa.org/gmapprovaldatabase/default.asp) - To obtain country list and regulatory documents
- FAO GM Foods Platform (http://www.fao.org/food/food-safety-quality/gm-foods-platform/browse-information-by/oecd-unique-identifier) - To obtain country list and regulatory documents

4.2 POTENTIAL TOXICITY, ALLERGENICITY, AND SIGNIFICANT NUTRITIONAL DIFFERENCES

If the subject of the assessment document is food safety, then the document should provide a summary of data or regulatory findings regarding the potential for the GM crop to be more toxic or allergenic than its non-GM counterpart. In addition, data or regulatory findings regarding any nutritionally significant changes to the composition of food made from the GM crop should be discussed. Section 4.1.1 above provides the list of likely sources of regulatory decisions. At the end of this discussion, the Government should indicate its own decision regarding food safety.

4.3 POTENTIAL ADVERSE ENVIRONMENTAL IMPACTS

If the subject of the assessment document is environmental safety, then the document should provide a summary of data or regulatory findings regarding the potential for the GM crop to become an agricultural weed or an invasive species, or whether the crop could have significant adverse impacts on environmental or agricultural resources, biodiversity, or valued species. Again the sources provided above in Section 4.1.1 should supply a wealth of information regarding these issues. At the end of this discussion, the Government should indicate its own decision regarding environmental safety.

4.4 USING PEER-REVIEWED LITERATURE IN THE DECISION-MAKING PROCESS

Most of the regulatory documents available through the sources listed in Section 4.1.1 will also provide references to peer-reviewed literature and other sources of information. To further explore the peer-reviewed literature, use Google Scholar (https://scholar.google.com), as it provides full-text journal articles, when available. Keep searches simple to ensure good coverage of the topic, using the name of the GM crop variety, the name of the gene of interest, or the name of the novel protein encoded by the gene. For example, variety MIR604 is an insect-resistant GM maize variety bearing the cry3A gene, which produces the Cry3A protein. Good

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search strings to use with Google Scholar to locate additional peer-reviewed literature for the food and feed safety of MIR604 are suggested below as examples to emulate:

- "MIR604 food feed safety"
- "MIR604 toxicity"
- "Cry3A food feed safety"
- "Cry3A toxicity"

Use similarly structured searches to locate articles regarding allergenicity, composition, animal feed, weediness, invasiveness, non-target species impacts, biodiversity impacts, etc. Remember, Google typically provides a large number of irrelevant "hits," so each search result will need to be evaluated to ensure that it provides relevant, high-quality information, before a particular article is used to inform the decision-making process.

4.5 FINAL SAFETY DETERMINATION

At the conclusion of the document, the Government should state its determination regarding safety, whether food safety or environmental safety. This assessment document must reflect the Government's independent findings, so the determination should be characterised primarily as the outcome of a thorough review of data and regulatory decisions relevant to the safety of the GM crop in question, rather than merely an agreement with other regulatory authorities. For example, a statement such as

> *The Government has determined that there is no evidence that the GM crop is more toxic than its non-GM counterpart*

indicates an independent finding, based on a review of available data.

4.6 REFERENCES

To foster transparency, all documents reviewed by the Government should be cited, including regulatory decision documents, published literature, and consensus documents, such as OECD publications. When possible, URLs linking to the original documents should be included, but all links provided should be tested, in the event that the URL has changed. If full-text versions of the document are available, with no copyright limitations, the Government should make electronic versions of these documents available to interested stakeholders through the Government webpage or some other means, rather than including them as a part of the assessment document.

5. CONCLUSION

For those GM crops whose safety is supported by a substantial body of evidence, including numerous regulatory decisions and peer-reviewed literature, in addition to a long history of safe use in the environment and in the food supply, there is no science-based justification to re-assess their safety de novo. Instead, the Government can issue authorisations for the domestic use of such crops using an expedited approach, including a detailed review of available information, following a process as described in these guidelines. This process makes efficient use of limited Government resources, supports internationally harmonised decision-making, and reduces uncertainty in a trade environment where large volumes of GM crops and products derived from them move continuously between countries.

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