Situational Analysis

1. Cartagena protocol
   Thirteen countries in the CARICOM community are party to the Cartagena protocol on biosafety of the Convention of Biological Diversity. Biosafety refers to policies and procedures that are implemented to reduce or eliminate the potential risks resulting from products of modern biotechnology (e.g. genetically modified organisms) to human health, biodiversity and the environment. One hundred and sixty nine countries are signatory to the Cartagena protocol, which provides an agreed basis to develop and implement biosafety policies.

2. Modern Biotechnology (and their products, genetically modified organisms) like any other new technology faced early skepticism and was mired in controversies. The Cartagena protocol of the Convention of Biodiversity was developed to ensure that policies and procedure were put in place to eliminate or reduce the potential risks associated with Living Modified Organisms (LMOs) to human health, and the environment, using scientific risk analysis but with the option of using a precautionary approach to decision making when scientific uncertainty exists.

3. During the 18 years of commercialization of LMOs and LMO-FFPs the potential risks associated with LMOs and LMO-FFPs have not actualized as feared, resulting in modern biotechnology being seen in a slightly more favorable light. The confidence in the biosafety measures implemented has also improved, further reducing public fear. These will continue to improve into the future, which will see regulatory measures coming in line with the actual risk rather than being pegged at a higher level of perceived risk. This will invariably reduce the regulatory burden on countries.

4. Simultaneously in response to the concerns raised by the public and NGO groups, the technology has undergone considerable improvement over the years and is likely to continue in this trend making it more precise and safe, thus reducing the public concerns of the technology. For example, RNAi mediated technologies have reduced the risk associated with the presence of a foreign protein in plants and site directed mutagenesis techniques are now allowing modification of traits without having to transfer genes from another species (transgenesis). The technology will continue to improve over the coming decades.

5. On the other hand Modern biotechnology has become more complex with LMOs containing a variety of stacked events or a variety of regulatory sequences making the products more challenging to detect but offering greater value to the farmers. The technology has given the early adopters of the technology a comparative advantage
compared to the non-adopters in the cultivation of a number of commodity crops (corn, cotton, canola, soy). This advantage may soon extend to other crops including vegetables and orchard crops as the technology use becomes more widespread. Hence the risk of not adopting the technology has to be factored into the socio-economic evaluation along with the potential negative risks associated with loss of markets by adopting the technology.

6. The comparative advantage of small island developing states in the Caribbean is continuously being eroded due to the smaller scale of production and reduced technology adoption in agriculture. The reduced cost of imports compared to cost of local production of food is resulting in the mass abandonment of Agriculture, with the threat of food security more and more becoming a reality. In light of the looming threat of food security many countries are looking to greater technology adaptation in Agriculture, climbing the value chain and exploring niche marketing options. Biotechnology is one of few scale neutral technologies that can have a profound effect on improving the profitability and competitiveness of food crops and it is important that the region has a policy that keeps this option open.

7. Living modified organisms (LMOs) are not cultivated within the CARICOM, at present, except in Belize. However, research on the development of LMOs is on-going in Jamaica and Trinidad and may expand to other countries in the region.

8. Regulation of LMOs
LMOs for purposes of regulation are categorized based on the intended use, as follows, in the Cartagena protocol.

(a) LMOs (intended for deliberate introduction into the environment) are subjected to an ‘Advanced Informed Agreement (AIA)’ procedure. This allows countries to determine through a scientific risk assessment process whether the country wishes to allow imports for purposes of growing in the environment. There is some allowance in the protocol for countries to take a precautionary approach to decision making when there is scientific uncertainty. The country can also use ‘socio-economic evaluation’ in addition to the ‘scientific risk assessment’ in decision making.

(b) The Food and Feed derived from LMOs are referred to as LMO-FFP (LMOs intended for Food, Feed or processing). Based on the Cartagena protocol these are exempt from the ‘AIA’ procedure but will instead be governed by local legislation. Given the fact that many of the CARICOM countries are signatory to Codex Alimentarius (FAO/WHO) it is important that the harmonized policy for food safety and labelling adheres to the recommendations of this commission. Codex Alimentarius uses the principle of ‘substantial equivalence’ as the basis in decision making.

(c) LMOs in containment refer to LMOs being evaluated in a contained setting either within a laboratory, greenhouse or confined field trials. These would require permits or guidelines, with monitoring to ensure guidelines are followed.
(d) LMOs in transit refer to LMOs not intended for the country but is being transshipped through the country. This will require strict adherence to packaging and labelling requirements of the country.

9. CARICOM Trade and LMOs
As much as 90% of the imports of food and feed into CARICOM countries, particularly those that are derived from commodity crops such as corn, soy, canola and cotton are imported from the Americas, and are predominantly LMO-FFP. The importing countries in the Caribbean have therefore enjoyed lower food prices due to the higher yields and lower cost of production in the origin countries. Furthermore many of these commodities are imported and converted into a range of manufactured products in Caribbean countries and traded within the CARICOM region. Changing the country of import or administrating traceability systems (to ensure GMOs are avoided in the food and feed supply chain) will greatly increase the cost of food and feed. A more pragmatic system of dealing with LMO-FFP both in terms of managing their importation and exportation is important. Similarly a more pragmatic approach to food labelling that will keep the cost of food low and at the same time allow choice to the consumer is important.

10. The 13 CARICOM countries that are party to the Cartagena protocol have received funding from UNEP/GEF in the past to support the development of a National Biosafety Policy and a National Biosafety Framework for the implementation of the framework. These however were executed in isolation of one another. This has resulted in policies and frameworks being widely different among the countries.

11. The CARICOM initiative
Recognizing the disparate initiatives (UNEP/GEF funded projects) by various CARICOM countries to develop biosafety policies and National Biosafety Frameworks and taking into account the potential disruption to trade that this can create, the CARICOM appointed a committee chaired by CARDI to develop a harmonized regional policy for biosafety and biotechnology. Although a harmonization policy was developed it has not been considered and adopted by COTED to date.

12. The Regional Biosafety Project
The Regional Biosafety Project, the most recent of the UNEP/GEF funded projects on Biosafety was approved in 2012 and is being executed by UWI. It aims to develop and implement a harmonized biosafety system in the 12 participating CARICOM countries, based on the Cartagena Biosafety Protocol. The project is providing support to countries to (a) establish biosafety legislation & regulations based on a harmonized policy (b) establish a harmonized administrative system, (c) develop jointly public education strategy, objects and modules to create greater transparency in the Biosafety implementation process that will bring great cost/effort efficiency, (c) set up a regional website with national nodes to share biosafety information (d) to improve biosafety capacity through short-term theoretical and practical training workshops, an MSc level
training programme in Biosafety and by establishing and operationalising national biosafety laboratories for testing of genetically modified organism and (e) develop guidelines, protocols and standards for risk assessment, decision making, administration and information sharing. The project also hopes to put in a sustainability mechanism to ensure that the biosafety systems developed can be sustained post project.

13. Lack of harmonization of biosafety in the region will not only affect trade but also create an uneven innovation and investment climate within the region.

14. The objective
The objective of this policy is to achieve an effective, efficient, pragmatic and balanced biosafety regime in the CARICOM region that is in line with the actual risks (not perceived risks) and enjoys the public confidence. It will ensure safety while not unduly hampering innovation, investment and economic growth.

15. The way forward
For the regional project to be effective with regard to biosafety implementation, it is imperative that the regional biosafety policy be approved by COTED. The biosafety policy brief presented herein is a document that has been discussed at many regional fora within the region (including the Regional Project Steering Committee meeting) as well as with external consultants and approved by the national coordinators from the 12 participating CARICOM countries.

Policy Imperatives
A harmonized CARICOM biosafety policy is important for the following reasons.

1. Disparate biosafety policies within CARICOM nations could potentially affect trade of agricultural produce and products, thus compromising the spirit of the Treaty of Chaguaramas establishing the Caribbean Community and Common Market (CARICOM).

2. Disparate biosafety policies may not be pragmatic due to the close proximity of countries of the region and the considerable legal and illegal traffic that exists between the nations.

3. A harmonized biosafety policy within CARICOM nations could allow for the sharing of human and other resources, often limiting in the small territories of the Caribbean; and allow for the development of a model legislative and regulatory framework that can be adopted in countries.

4. Harmonisation among CARICOM nations would result in greater efficiencies in capacity building, scientific risk assessment, and development of common guidelines, protocols,
standards; thereby achieving greater efficiencies and thus a smaller regulatory burden on small countries in the region.

5. The common standards, guidelines and methods under a harmonized policy environment will allow greater networking and mutual sharing of experiences among CARICOM countries.

6. A number of existing CARICOM institutions can play an integral role with regard to biosafety including UWI, CARDI, CAHFSA and CROSQ.

7. Biotechnology and biosafety are interlinked processes and a balanced approach to biosafety is required to ensure that biotechnology development is not unduly hampered. Lack of harmonization of biosafety in the region will not only affect trade but also create an uneven innovation and investment climate within the region. This will accentuate the differences in investment, technology adaptation, and economic welfare within the region thus relegating some countries to the backwaters of development.

Principles of Policy Harmonisation

1. The Regional Biosafety Policy will take into account the sovereign rights of CARICOM countries as well as the human rights of the individual.

2. The policy will adhere to the principles and the spirit espoused by the nations in the Treaty of Chaguaramas that established the CARICOM as well as the revised treaty.

3. The policy will be dynamic and take into account best practices and lessons learnt by countries around the world and give consideration to the growing body of shared global information systems and knowledge systems, thus creating an evolving and nimble biosafety system (risk assessment, decision making and regulatory systems), by ensuring that it is reviewed and modified from time to time.

4. The policy will allow the development of a model legislative and regulatory framework adapted to the needs of each country.

5. The policy will utilize the collective wisdom and knowledge of the regional scientific community for scientific risk analysis; or for the optional step of socio-economic analysis bringing greater efficiency.

6. The risk assessment for LMOs will be science-based using the best science available and using the best scientists available within the CARICOM, with the option of co-opting experts from outside the region, where necessary to reduce cost and improve efficiency (Regional Scientific Risk Assessment).

7. The policy will allow countries the option of having a socio-economic evaluation in addition to the scientific risk assessment of LMOs, where necessary. (National or Subregional).
8. Risk assessment and decision making for LMO-FFPs will be only science-based and grounded in the principle of substantial equivalence as espoused by Codex Alimentarius (FAO/WHO). This will be at the regional level.

9. Decision making for LMOs (intended for intentional introduction into the environment) and LMOs in contained use will be at the country level and will be on a case-by-case basis and on a stage-by-stage. In the case of LMO-FFP the decision making will be at the regional level possibly coordinated by a regional regulatory organization such as CAHFSA (CARICOM Agriculture, Health and Food Safety Agency).

10. The policy will ensure transparency in decision making through clear communication as well as the publication of the decision documents on the biosafety clearing house.

11. The policy will support an effective and regionally coordinated public education programme aimed at reducing the potential risk associated with LMOs and LMO-FFPs to the actual levels of risk thus ensuring that the regulatory burden is in line with the level of risk.

12. The regulatory system for biosafety will be country-based (national) and will at least involve the following agencies; food safety, plant quarantine and the environmental management authority.

13. Regulation of LMOs (each event) will be based on a one-time permit and will be based on the AIA procedure at the country level. Regulation of LMO-FFP will be based on a common permitted list on the Regional node of the Biosafety Clearing House. Regulation of LMOs in contained use will be based on a stage-by-stage permit (country level). Regulation of research institutions working on modern biotechnology would be based on a system of guidelines and oversight.

14. The policy will establish three tiers of laboratories to support the regulatory agencies – national laboratories, reference laboratories and accredited international laboratories performing the functions of surveillance, monitoring and routine testing; reference testing and capacity building; and validation functions, respectively.

15. Biosafety information management would be through an internet based biosafety clearing house, with a regional hub and national nodes, ensuring communication and harmonisation between the national biosafety systems and the regional hub.

16. The policy will harmonise and streamline the administrative system by building in a gatekeeper function to the Regional node of the Biosafety Clearing House. Using the website to receive applications on a common agreed application format allows the application to be shunted to all the nodes and manage the entire application processing process electronically. An applicant could apply to the regional node indicating which countries that they wish to seek approval for.
17. The policy will allow for a **pragmatic approach** to biosafety that takes into account the reality of trade relations within CARICOM and between CARICOM and the world.

18. The food labelling policy will be based on a system of **voluntary negative labelling**. The critical level for negative labelling will be at the **level of 5% LMO content**.

19. The policy should be **balanced** ensuring the safety of products of modern biotechnology while at the same time not unduly restricting biotechnology, investment, food security and economic prosperity into the future.

20. The Biosafety Centre of the University of the West Indies should **provide sustainability** by supporting capacity building programmes, public education programmes, maintaining the regional node of the Biosafety Clearing House and by commissioning scientific risk assessment on behalf of CARICOM countries and sending the recommendations to individual countries for decision making with regard to LMOs and submitting to **CAHFS** for consideration for LMO-FFPs.

**Proposed Mechanism of Regional Harmonization of biosafety Implementation in the CARICOM**

**A. Regional harmonization of LMOs intended for intentional introduction into the environment**

Fig. 1 provides an outline of the proposed biosafety framework at the national and regional levels and how harmonization can be achieved in the operations. The follow account describes the Harmonised Regional Biosafety System and outlines the roles of the various institutions.

The Administrative system

The administration system provides the central coordinating role for biosafety. It supports the processing of applications (e.g. AIA procedure for LMO) for import into the country, within the stipulated timeframes as specified in the Cartagena protocol, maintains a roster of experts from various disciplines, commissions scientific risk assessment and socio-economic risk assessment (optional), supports the decision making body, communicates the decision to the interested parties, make available the decision documents and maintain a list of approved LMOs and LMO-FFP events in the biosafety clearing house, communicates and coordinates between the regulatory agencies with regard to implementation; commissions the development of guidelines, standards, dossiers and coordinates the public education and engagement programmes to ensure transparency of the system.

The Regional Biosafety Centre (RBC) will form the administrative hub at the regional level which will house the regional node of the biosafety clearing house. The regional node of the Biosafety Clearing House (R-BCH) will be administered from this administrative hub. The R-
BCH will assume a gatekeeper function, receiving notifications with respect to LMOs intended for intentional Introduction into the Environment on an agreed application format on behalf of the region, and shunting it to the national BCH nodes and managing the entire application processing process electronically. It will also maintain the timeline with prompts to the National Biosafety Authorities to ensure that decisions are made in the stipulated timeframe. The RBC will commission a Scientific Risk Assessment and the Risk Assessment Report along with an opinion that will be sent to the National Competent Authority within the stipulated time. The Regional Biosafety Centre will also be responsible for maintaining a regional roster of experts as well as providing capacity building programmes as well as commissioning biosafety research on behalf of the region, where necessary. It will also support public education programmes as well as document all decisions made in the CARICOM with regards to biosafety.

The National Competent Authorities will house the national administrative hub and will be responsible for maintaining the national node of the biosafety clearing house. Upon receiving the scientific risk assessment and opinion from the Regional Biosafety Centre through the R-BCH it has the option of commissioning an optional socio-economic evaluation to determine the socioeconomic cost vs benefit, and commissioning meeting/s of the decision making body. It is possible that such socio-economic evaluation can be performed also at a subregional level (for instance the OECS countries). The biosafety secretariat of the National Competent Authority will support the decision making process by provision of all pertinent information and will be responsible for decision communication to all parties including the applicant (for AIA) (within the stipulated time frames as outlined in the Cartagena Biosafety Protocol) and the national regulatory agencies for implementation of the decisions. The national administrative hub will also be responsible for maintaining an up-to-date register of institutional biosafety committees (IBCs), supporting the smooth functioning of the designated National Biosafety Laboratory, rolling out a public education programme to ensure that the public upraised with new technological developments, capacity building and maintaining the linkages with all biosafety stakeholders.

The National Regulatory Agencies, Food and Drugs Division or its equivalent, Environmental Authority or its equivalent and the Agricultural Quarantine will be responsible for implementing the decisions. In some countries the regulatory agencies are coordinated under an umbrella organization (e.g. NAHFS). The role of the regulatory agencies is to maintain surveillance at the border (border control) as well as in the environment to ensure that unapproved LMO event are not introduced or have not be introduced unintentionally. The agencies will also provide permits, guidelines and monitoring to ensure that the laws are upheld. The food and drugs or equivalent agency will ensure that labeling is in line with legislation.
Fig 1. Regional Harmonisation of Biosafety of LMO intended for Intentional Introduction into the Environment
Harmonisation is achieved in (a) the administrative process (application format, timelines with regard to processing of applications) (b) scientific risk assessment and opinion generation (c) socio-economic assessment (if done subregionally) (d) decision making process (particularly for LMO-FFPs) (e) standards, guidelines and methods used (f) capacity building programmes (g) public education as well as (i) biosafety research support thus reducing the regulatory burden of individual countries and fostering an environment of mutual support. Nevertheless, the approach allows sovereign countries to make their own decisions with regards to LMOs. The standards, guidelines, methods and approaches can be jointly developed at the regional level and from time to time reviewed by CAHFSA and/or CROSQ, regional organisations set up by the CARICOM as regulatory and standard setting organisations, respectively.

**B. Regional harmonization of biosafety systems for LMO-FFP**

LMO-FFP represents LMOs intended for food, feed or processing. Since these are not introduced into the environment, the environmental and agricultural risks are not important or low and hence the Cartagena protocol recommends that countries regulate these through their local food safety regulations. Since most of the countries in the CARICOM are signatory to the Codex Alimentarius Commission of the FAO/WHO, the Regional Biosafety Policy will adhere to the principles and practices recommended by this commission with regards to LMO-FFPs. According to Codex Alimentarius Commission risks are assessed solely based on scientific risk assessment and the decisions made based on the principle of ‘substantial equivalence’. In light of this it is recommended that scientific risk assessment, the decision making process and the maintenance of an updated list of approved events on the regional biosafety clearing house could and should be carried out at the regional level. While the scientific risk assessment could be carried out by the RBC as previously described the decision making function could reside in CAHFSA a regional regulatory agency. CAHFSA could commission a decision making body to make decisions on its behalf and provide the decisions to RBC to transmit to countries. This will ensure that decisions based on the same scientific body of knowledge are not disharmonious thus affecting trade between trading partners and within the region. Fig-2 illustrates the proposed regional harmonization of risk assessment and decision making of LMO-FFPs in the CARICOM.

**C. Regional harmonisation of labelling of LMO-FFP**

Rationale for approach
Different countries in the world have adopted different systems of labelling. Whichever method is used, the labeling should be truthful and provide consumers choice. Mandatory labelling systems given the geospatial position of the Caribbean and our trading relationships and practices will not be pragmatic. It would require that the suppliers of produce (corn, rice, canola, soy, cotton etc) grow their crops separately from other LMO crops (under an agreement
with the buyer) and with traceability systems in place to preclude the probability of admixture occurring during processing, storage and shipping. This will greatly increase the price of the basic staple goods to the average consumer by at least 20%. On the other hand voluntary negative labeling systems are more pragmatic and easier to implement. In this approach buyers could import product that have been certified as uncontaminated and be able to label them as such. This will allow them to differentiate their product from all other non-labeled products and hence be able to sell it at a higher price to those who prefer products not contaminated with LMOs. It offers the consumers who wish to have non-LMO food products a choice, while keeping the price low for the majority of the consumers who do not care about it. It must be mentioned that in all cases the LMO-FFPs imported would have been verified as substantially equivalent to the non-LMO counterparts; and therefore would not pose a health risk to the citizenry.

Given the errors associated with sampling the lower the LMO contamination level required to verify the accuracy of labeling the higher the cost associated with detection. Hence, to be pragmatic, the Regional Biosafety Harmonisation policy will set a 5% LMO level as the limit for certification processes. This is the practice in many metropolitan countries including Japan. Once labeling legislation is approved the regulatory agency responsible for food safety would have to do routine surveillance to ensure that the labels are truthful.

The Policy:
The regional biosafety policy brief advocates a system of voluntary negative labeling, with the truthfulness of the labeling verified at limit of 5%.

D. Regional harmonization of Biosafety Framework for LMOs in contained use

Rationale
The Biosafety Framework and legislation is important to deal with application for contained or confined use of LMOs for the following purposes:
(a) Support a research and development agenda of an institution or a company by allowing the development of LMOs in the laboratory and testing them in a contained setting in the greenhouse or in confined setting in restricted field trials before an application for commercial release is made.
(b) Testing of a LMO in a confined setting before commercial release by a company into the environment or
(c) For allowing the production of LMO seeds or products for export within a confined setting with no intention of general introduction into the environment.

Policy guidelines
The countries Biosafety administration system must register each of the institutions or companies (Institutional Biosafety Committees, IBCs) that wish to work with LMOs in a contained or confined setting. The application process and fee can be harmonized. The IBCs will be authorized to carry on LMO work based on a harmonized signed agreement (with
conditionalities) and regionally developed guidelines. A regulatory agency will be authorized by law to conduct routine monitoring to ensure that institutions or companies are adhering to the guidelines. Applications for evaluation of LMOs in contained and confined settings before commercial release will be based on a stage-by-stage basis.

Although risk assessment and decision making would be at the national level, regional harmonization of the process is important to allow for the joint development of common guidelines, sharing of best practices, regional support for risk assessment and for providing an even biotechnology development climate throughout the region. Note: There was a joint document developed in a workshop based on discussions with a number of countries in a workshop setting. This has to be adopted.

E. Regional harmonization of Biosafety Framework for LMOs in transit

It is foreseeable that LMOs even if not intended for introduction into the environment from time to time may be transited through one country to the destination country. This may not be a problem for island nations as much as for mainland countries. If proper packaging and labeling standards are not followed then there is a chance that this may lead to unintended introduction into the non-destined environment. Developing a common standard and guidelines for regulatory agencies would ensure that transiting will not pose a problem. The Cartagena protocol provides guidance on this.

F. Liability and redress

The region must develop agreed common methods for Liability and Redress based on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.
Decisions lodged in the R-BCH

Regional Biosafety Clearing House

BIOSAFETY CENTRE

CAHFS

Decision Making Body

Scientific Risk Assessment

Decision

National biosafety Node

Admin Secretariat

Regulatory Agencies

F&D

1

2

3

4

Fig 2. Regional Harmonisation of Biosafety of LMO-FFP
Conclusion

The Cartagena protocol on Biosafety provides the basic guidelines for harmonization but leaves other decisions to individual countries. A regional harmonized policy is necessary to ensure that the countries in the CARICOM are able to develop a harmonized legislative framework that will allow the implementation of the protocol in an effective, efficient and pragmatic manner, while reducing the regulatory burden on individual countries and ensuring more importantly that the spirit of the Treaty of Chaguaramas is upheld.

Prepared by: Path Umaharan (March, 2015)