UWI/ICGEB Workshop on "Biosafety Legislation"
The University Inn and Conference Centre
The University of the West Indies,
St. Augustine, Trinidad
11 – 15 May 2015

This interactive workshop aims to provide participants with practical knowledge and tools to understand the government and parliamentary processes involved in designing, development, drafting and implementation of a biosafety regulatory framework. The workshop will involve: (a) presentations that will provide background materials, and; (b) hands-on exercises about particular subject matters in specified modules to develop practical and relevant materials by individual groups of participants. This workshop is designed to provide background knowledge and hands-on experience in the drafting of legislation and is not intended to provide model legislation endorsed by the presenters.

Day 01 – Monday 11 May 2015

08:30 – 08:45	*Registration*	
08:45 - 09:00	Welcome and Introduction	**Michelle John & Pathmanathan Umaharan** *University of West Indies (TTO)*
09:00 - 10:30	Introduction to ICGEB & Biosafety Unit, Workshop overview, and self-introductions of participants	**Wendy Craig** *ICGEB (ITA)*
10:30 – 11:00	*Tea break*	
11:00 – 12:00	Discussion and Update on the status of the proposed legislative framework on biosafety for each country	
Module 1	**The process of turning government policy into an Act of Parliament (referred to as primary legislation)**	
12:00 – 12:30	**Presentation 1** – *Triggers and the need to create new laws, processes of turning policy into law, policy approval process and consultation requirements, Constitutional powers to make law, passage of laws in Parliament, Scrutiny of Bills, Assent and Commencement, and the making of delegated legislation created under Acts of Parliament.*	**Marlene Keese** *Therapeutic Goods Administration (AUS)*
12:30 – 13:30	*Lunch*	
13:30 – 13:45	Short presentation in relation to the parliamentary processes involving passage of Bill in Belize, St Vincent and the Grenadines, and Trinidad and Tobago	**Randall Sheppard, Carol Williams & Parvin Sookhai**
13:45 – 14:30	**Group Practice Exercises**	All participants
14:30 – 15:10	Report back to plenary and discussion	All participants
Module 2	**What are Bills or Acts of Parliament and the drafting of Bills of Parliament**	
15:10– 15:45	**Presentation 2** – *Background and basic features of Bills and Acts, format content and specified provisions required, general principles to be taken into consideration in the drafting of Bills, consistency with other laws, adherence to government policy, required accompanying documentation for introduction in Parliament and their relevance to statutory interpretation of provisions.* **Presentation 3(a)** - What are genetically modified organisms? The science and the law.	**Marlene Keese**
16:00 – 16:30	Discussion in plenary	All participants

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Day 02 – Tuesday 12 May 2015		
Module 3	**Scoping, designing, and creating a regulatory framework on biosafety**	
08:00 – 08:30	**Presentation 3(b)** - *International obligations, state practice and its implementation in national regulatory framework on biosafety.*	**Marlene Keese**
08:30 - 09:10	**Group Exercise**	All participants
09:10 – 09:50	Report back to plenary and discussion	All participants
09:50 – 10:30	**Presentation 3(c)** – *Process of designing and creating a regulatory framework, what should be the elements of an appropriate biosafety regulatory framework on genetically modified organisms (GMOs) and products derived from such organisms, what activities and processes involving such organisms and products should be regulated, should all GMOs be regulated, are there instances in which they should not be the subject of regulation, who should be the decision-maker, which government agency should be involved in the regulation, how should a regulator make decisions, should there be one regulator, or should there be several regulators and schemes, what are the powers and functions of a regulator, what are the criteria to be used in granting an approval for a dealing of GMOs and products derived from them.*	**Marlene Keese**
10:30 – 10:40	Introduction to the scoping exercise	
10:40 - 11:10	*Tea break*	
11:10 - 12:30	**Group Scoping Exercise**	All participants
12:30 - 13:30	*Lunch*	
13:30 - 15:30	**Continuation of Group Scoping Exercise**	All participants
15:30 – 17:00	Report back to plenary and discussion	All participants

Day 03 – Wednesday 13 May 2015		
Module 4	**Drafting of instructions to carry out the essential elements of the proposed regulatory framework**	
08:30 – 09:10	**Presentation 4(a)** – *How to issue drafting instructions in relation to essential legal elements and supporting administrative systems for the drafting of provisions of the Bills of Parliament, using the results of the scoping exercise.*	**Marlene Keese**
09:10 - 09:30	Introduction to the drafting exercise	
09:30 – 10:30	**Group Drafting Exercise**	All participants
10:30 – 11:00	*Tea break*	
11:00 – 12:30	**Group Drafting Exercise**	All participants
12:30 - 13:30	*Lunch*	
13:30 - 14:00	**Continuation of Group Exercise**	All participants
14:00 – 15:30	Report back to plenary and discussion	All participants
15:30 – 16:10	**Presentation 4(b)** – *Statutory Interpretation of provisions in the Act and legislative instruments.*	**Marlene Keese**
16:10 – 17:00	**Group Exercise**	All participants

Day 04 – Thursday 14 May 2015		
09:00 - 09:40	Report back to Plenary and Discussion	All participants
Module 5	**Drafting of Model provisions on each of the essential elements of the proposed regulatory framework**	
09:40 - 10:20	**Presentation 5** – *Drafting and Examples of model provisions, what should be in these provisions, what are enabling provisions, and what details should be left in the delegated legislation.*	**Marlene Keese**
10:20 - 10:30	Introduction to the drafting exercise and the drafting of model provisions	
10:30 – 11:00	*Tea break*	
11:00 – 12:30	**Group Exercises** - *Drafting of specified model provisions – (a) what is the scope and operation of the regulatory framework; (b) definitions of key terms*	All participants

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	in the legislation; (c) what types of organisms, products derived from GMOs, and activities are to be regulated; (d) types of approval of specified dealings/activities in relation to GMOs, and GMO-derived products; (e) what GMOs, products and activities are not going to be regulated; (f) how should such exemptions and exclusions be implemented; (g) who is the regulator and what are the functions of the regulator?	
12:30 – 13:30	*Lunch break*	
13:30 - 14:30	**Continuation of Group exercises**	All participants
14:30 – 15:30	Report back to plenary and discussion	All participants
15:30 – 17:30	**Group Exercises** - *The drafting of provisions relating to the following: (a) assessment of applications and criteria for decision-making; (b) how should applications be made and what is required to be included in the application; (c) who makes the decision and administrative procedures associated with decision-making (cc) role of advisory committees, if any, and composition; (d) the risk assessment component in decision-making and what are the risks that are required to be taken into account; (e) review of decisions; (f) monitoring and investigations; (g) enforcement of requirements and conditions, and sanctions for non-compliance; (h) governance arrangements, and; (i) regulation-making power etc.*	All participants

Day 05 – Friday 15 May 2015

09:00 - 09:40	Report Back to Plenary and discussion	All participants
09:40 – 10:30	**Group Exercise -** *Drafting of a Bill of Parliament incorporating what attendees learnt in Module 1 and the draft provisions incorporating essential elements.*	All participants
10:30 - 11:00	*Tea break*	
11:00 – 12:30	**Continuation of Group Exercise**	All participants
12:30 - 13:30	*Lunch*	
13:30 - 15:30	Group Presentation and Discussion	All participants
15:30 - 16:30	Questions and Review of the course and workshops and Follow-up activities	
16:30	*Evaluation and End*	

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