UWI/ICGEB Workshop on "Biosafety Regulations & Administrative Systems"
Hilton Trinidad and Conference Centre,
Port of Spain, Trinidad
18 - 22 May 2015

This interactive workshop aims to provide participants with practical tools to understand and implement biosafety legislation. The primary mechanism of learning is through hands on exercises using break out groups and facilitators to develop practical and relevant materials through sharing knowledge and experiences. The workshop will explore legal, administrative and risk analysis frameworks and processes to achieve effective and efficient regulatory oversight of GMOs.

Day 01 – Monday 18 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*	
Module 1	**Delegated legislation – Regulations**	
11:00 – 11:30	**Presentation 1** – *Discussion on: what is delegated legislation, the need for regulations, who makes delegated legislation and legal basis for making delegated legislation; what provisions can be included in delegated legislation; and that provisions must be within the scope of the Act; how are they made?*	**Marlene Keese** *Therapeutic Goods Administration (AUS)*
11:30 – 13:00	**Practical exercise 1(a)** - Participants will be required to identify what provisions should be included in the Regulations, why are they appropriate to be in the Regulations, identify provisions in the draft Bill where regulations are required to be made, discuss how much scope and discretion does the decision-maker have in the making of regulations.	
13:00 – 14:00	*Lunch*	
14:00 – 15:00	Report back to plenary and discussion	All participants
15:00 – 16:30	**Practical exercise 1(b)** - Draft regulations provisions as required under the primary legislation	All participants
16:30 – 17:30	Report back to plenary and discussion	All participants

Day 02 – Tuesday 19 May 2015

Module 2	**Administrative systems to implement proposed regulatory framework**	
08:30 - 09:00	**Presentation 2(a)** - *Essential components of a functioning regulatory body.*	**Paul Keese** *Office of the Gene Technology Regulator (AUS)*
09:00 - 10:30	**Practical exercise 2(a)** - Design an administrative system to implement the legislation. Determine delegations or specified decisions to be made and consultation procedures.	All participants

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10:30 – 11:00	*Tea break*	
11:00 – 12:30	Report back to plenary and discussion	All participants
12:30 – 13:00	**Presentation 2(b)** - *Introduction to good decision-making*	**Marlene Keese**
13:00 – 14:00	*Lunch*	
14:00 - 16:00	**Practical exercise 2(b)** - Develop a decision tree for approval of: a) importing a GMO; b) a confined field trial of a GMO.	All participants
16:00 – 17:00	Report back to plenary and general discussion	All participants

Day 03 – Wednesday 20 May 2015

Module 3	**Administrative arrangements to support good decision-making**	
08:30 – 09:00	**Presentation 3(a)** – *Administrative processes for effective decision-making including drafting of guidelines, policy documents and standard operating procedures*	**Paul Keese**
09:00 - 10:30	**Practical exercise 3(a)** - Draft guidelines for transport, storage and disposal of a GMO.	All participants
10:30 – 11:00	*Tea break*	
11:00 – 12:30	Report back to plenary and discussion	All participants
12:30 - 13:00	**Presentation 3(b)** - *Essential administrative tools – forms, checklists*	**Paul Keese**
13:00 - 14:00	*Lunch*	
14:00 – 16:00	**Practical exercise 3(b)** - develop a form for approval: a) to import a GMO; b) to carry out a confined field trial of a GMO.	All participants
16:00 – 17:00	Report back to plenary and general discussion	All participants

Day 04 – Thursday 21 May 2015

Module 4	**Introduction to risk analysis**	
09:00 - 09:30	**Presentation 4(a)** – *Risk analysis is commonly used in the decision-making process. It provides a robust, evidence-based methodology for regulatory decision-making. The basic elements include risk assessment, risk management and risk communication. International approaches to risk assessment include work done by the OECD and the Cartagena Protocol for Biosafety.*	**Paul Keese**
09:30 – 11:00	**Practical exercise 4(a)** - Develop risk assessment guidelines according to Annex III of the Cartagena Protocol for Biosafety	All participants
11:00 – 11:30	*Tea break*	
11:30 – 12:30	Report back to plenary and general discussion	All participants
12:30 – 13:00	**Presentation 4(b)** – *Imposing conditions on the approval/licence. Why are they important? What are the types of conditions can you impose? Do you think conditions should be imposed at the time of approval or any time after approval? How do you ensure that conditions achieve objectives, are clear, lawful, understandable and capable of being complied with?*	**Paul Keese**
13:00 – 14:00	*Lunch*	
14:00 - 16:00	**Practical exercise 4(b)** - Draft approval conditions for: a) importing a GMO; b) a confined field trial of a GMO.	All participants
16:00 – 17:00	Report back to plenary and general discussion	All participants
Module 5	**Monitoring, audit, investigations and enforcement process**	
17:00 – 17:30	**Presentation 5(a)** – *Monitoring, audit and investigation suitable for the regulation of GMOs and dealings relating to GMOs*	**Marlene Keese**

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Day 05 – Friday 22 May 2015		
08:30 - 09:30	**Practical exercise 5(a)** - List the persons who will be tasked to enter premises for monitoring, audit, and investigation purposes. What should be their qualifications and skills? Draft a checklist of what should be monitored and investigated, and how to assess low level non-compliance and serious non-compliance? Draft procedures regarding entry, what information should be requested, the taking of samples, the handling of samples and taking of documents.	All participants
09:30 – 10:30	Report back to plenary and general discussion	All participants
10:30 - 11:00	*Tea break*	
11:00 – 12:00	**Presentation 5(b)** – *Designing and implementing Sanctions and Enforcement Measures*	**Marlene Keese**
12:00 - 13:30	**Practical exercise 5(b)** - Design a decision pyramid in relation to sanctions and when such sanctions should be imposed	All participants
13:30 – 14:30	*Lunch*	
14:30 - 15:30	Report back to plenary and general discussion	All participants
15:30 - 16:30	Questions and Review of the course and workshops and Follow-up activities	All participants
16:30	*Evaluation and End*	

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