**Enhancing Biosecurity Oversight in Malaysia with Dual Use Case Studies**

**Workshop Facilitator’s Reference**

**Case study article:**

Song Y et al. (2017) Limits of variation, specific infectivity, and genome packaging of massively recoded poliovirus genomes.

This case study exercise was developed by Gryphon Scientific and the Science and Technology Research Institute For Defence (STRIDE), for the workshop titled “Workshop on Enhancing Biosecurity Oversight in Malaysia with Dual Use Case Studies”

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**Introduction**

**Goal**

The purpose of this case study is to train participants on the identification, assessment, management, and communication of biosecurity risk in life sciences research posing dual use potential.

**Objectives/Outcomes**

At the end of this exercise, participants should be able to explain the steps involved in the risk analysis framework: risk identification, risk assessment, risk management, and risk communication. Participants will learn how to apply the risk analysis framework to research by analyzing the experiments described in a published scientific article. After the activity, participants should be able to use the framework to evaluate their own research, research proposals, and the research of their peers. Participants also should develop an understanding of risk analysis concepts that will enable them to teach these concepts to others and to develop new educational materials as research changes.

**Overview of Selected Case Study**

Case-study based training promotes critical thinking skills about complex concepts using an interactive format and local, real-world examples. This case study is based on an article describing the creation and testing of poliovirus with modified sequences of codons and codon pairs. The viral genome was modified without changing the protein sequences. These modified genomes were designed using software before being synthetized from scratch (i.e., chemical synthesis). The synthesized viruses were examined for pathogenic properties, such as cytopathic effects and infectivity in cells *in vitro*.

You may choose this case study if you are interested in the following risks, which the case study addresses:

* Dual use life sciences research of concern
	+ Design and chemical synthesis of a virus
	*Note: “Synthesis of pathogenic microorganisms” is listed as a dual-use research of concern in a report on Malaysia’s 2015 biosecurity workshop[[1]](#footnote-1)*
	+ Potential for evasion of sequence-based detection and diagnosis, enhanced virulence, or altered host tropism because of changes in the genome sequence
	*Note: The researchers were not trying to achieve these dual-use endpoints. Rather, the resulting pathogens, methods, and information might enable another researcher to achieve these ends*
* Physical biosafety and biosecurity in handling poliovirus and management of informational risk

This case study is suitable for audiences educated in the life sciences. Participants may include research faculty, students, professionals in the medical, veterinary, or public health fields, and people responsible for reviewing research in some capacity. Participants need not be specialists in the subject area of the case study, though familiarity with the topic may yield better discussion.

*Please provide feedback and recommendations on the case study activity to* *gautham@gryphonscientific.com**.*

**Process**

The case study exercise works best as small group discussions (3-5 people). If working with a larger audience, divide the audience into smaller groups for discussions to ensure that all participants actively can engage in the exercise. Groups can share highlights of their discussions with the larger audience through the facilitated discussion. The final reflection, in which participants apply the risk analysis framework to their own work, can be conducted in a single large-group facilitated discussion format.

The facilitator begins by outlining the learning goals and objectives for the activity, so that all participants understand the scope, expectations, ground rules, and learning expectations of the case study. The facilitator leads a general discussion on risk in the context of life sciences research and describes the risk analysis framework and its use. Next, the facilitator leads a discussion reviewing the case study article. The facilitator should provide expertise to answer any clarifying questions. Participants will be asked to apply the risk analysis framework to the case study article and engage in small group discussion. Facilitators should engage participants in discussion, asking leading questions. Finally, participants will reflect on the risk analysis framework.

This interactive session is designed to last ~3-4 hours. Suggested timing is provided below, but the facilitator may adjust the pace of the workshop at his/her discretion.

* **Introduction and Risk Analysis Overview: 50-60 minutes**
	+ - For each discussion slide, allow 5 minutes for discussion in pairs or small groups as you prefer, followed by up to 10 minutes of full group discussion
* **Case Study Exercise**
	+ **[Optional] Time for participants to read case study article: 20 minutes**
		- Participants are advised to read the case study article prior to the workshop. If needed, additional time may be allotted for reading before the start of the case study exercise.
	+ **Discussion of Case Study Article (Research Objective, Background, and Methodology): 30 minutes**
		- Allow 15 minutes for discussion in small groups followed by 15 minutes of full group discussion
	+ **Risk Analysis Framework (Risk Identification, Risk Management, Risk Analysis): 45 minutes**
		- Allow 10 minutes for participants to record their answers in their participant packets, 20 minutes for small group discussion, and 15 minutes for full group discussion
	+ **Discussion of Case Study Article (Results and Conclusions): 10 minutes**
		- Allow 5 minutes for discussion in small groups followed by 5 minutes of full group discussion
	+ **Risk Analysis Framework (Risk Communication): 20 minutes**
		- Allow 5 minutes for participants to record their answers in their participant packets, 10 minutes for small group discussion, and 5 minutes for full group discussion
	+ **Reflection: 15 minutes**
		- For each reflection slide, allow 5-10 minutes of full group discussion

**Your Role**

Your role as facilitator is to ensure that workshop participants understand the risk analysis framework and the case study article, facilitate group discussion, and ensure that participants understand how to apply the framework to research conducted in their own institutions and laboratories. Emphasize the importance of high-quality research and selection of risk management strategies that will not compromise the utility and quality of the scientific research. You are responsible for clarifying questions about the overall and individual steps of the framework, and pertinent details of the article. You may use your own knowledge of the subject, guidance from WHO and Malaysian documents, and information in this facilitator’s guide to conduct the case study-based training.

You may use standard facilitation techniques, such as asking guiding questions, to encourage participants to think critically about the article details, associated risk, and possible risk mitigation strategies. Be sure that discussion focuses on risk analysis and not on critiquing the scientific approach in the selected article. You may intervene to keep all discussions focused on risk analysis rather than scientific merit. However, you can highlight the importance of a combined analysis of risk and scientific merit when evaluating research proposals, protocols, progress reports, conference abstracts and presentations, and manuscripts.

Finally, keep the conversation constructive. Trainees may disagree with others’ evaluations, but they should focus on the topic of the case study instead of critiquing fellow trainee contributions.

**Your Responsibilities**

*At least two weeks before the workshop*:

* Read the case study article and any supplementary information. Familiarize yourself with scientific concepts and methodologies in the article and be prepared to answer any clarifying questions about the methodologies or results of the article. Be familiar with the risks associated with this research.
* Review this Facilitator’s Reference document and the Case Study Slides.
* Familiarize yourself with the risk analysis framework including the overall process and individual steps, and risk concepts that apply to the case study article.
* For more information on relevant concepts, refer to the following suggested documents:
	+ Science & Technology Research Institute for Defence (STRIDE) Ministry of Defence Malaysia. (2015) Workshop on the *Development of a National Code of Conduct for BIOSECURITY in the Framework of Biological and Toxin Weapons Convention*. Kuala Lumpur: Academy of Sciences Malaysia. https://issuu.com/asmpub/docs/code\_of\_conduct\_for\_biosecurity\_wor
	+ World Health Organization (WHO). (2010) *Responsible Life Sciences Research for Global Health Security: A Guidance Document*.

*At least one week before the workshop*:

* Send to participants:
	1. The case study article and any supplementary information
	2. The learning goals and objectives for the workshop

*At least one day before the workshop*:

* Print out a copy of the **Participant Packet: Intro Section** and **Participant Packet: Case Study Exercise** for each participant. You may print the case study article for each participant if the article’s copyright permissions allow it.
* Make sure the room has a projector and screen to show slides, and a white board or flip chart to document participant answers. (Writing participant answers is important to show that participants’ contributions are being acknowledged.)

*The day of the workshop*

* Present and discuss the introductory material with the participants. The introductory discussion is to be completed prior to distributing the participant packets.
* Distribute the **Participant Packet: Intro Section**, which includes definitions of risk and mitigation concepts and the risk analysis framework for reference, and **Participant Packet: Case Study Exercise**, which has spaces to record responses to discussion questions.
* If participants have not read the case study article in advance, you may choose to allot time after the introductory session for this purpose.
* Have the participants work through the case study. Use the case study slide deck as a guide, but focus on participant interactions.

*After the case study*

*[Optional] Seek feedback from participants on the activity.*

1. Science & Technology Research Institute for Defence (STRIDE) Ministry of Defence Malaysia. (2015) Workshop on the Development of a National Code of Conduct for BIOSECURITY in the Framework of Biological and Toxin Weapons Convention. Kuala Lumpur: Academy of Sciences Malaysia. [↑](#footnote-ref-1)