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REPORT ON THE TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS FOR SOUTH, SOUTHEAST AND PACIFIC ASIA, MANILA, 7 TO 11 NOVEMBER 2022

INTRODUCTION

1. At its eighth meeting, in decision CP-VIII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to support, subject to the availability of resources, regional and subregional capacity-building activities on risk assessment of living modified organisms.

2. Likewise, in decision CP-VIII/3 on capacity-building, the Parties to the Protocol also requested the Executive Secretary to facilitate the priority capacity-building activities for supporting the implementation of the Cartagena Protocol.

3. With support from the Government of the Republic of Korea, through the Korea Biosafety Capacity-Building Initiative, and in collaboration with the ASEAN Centre for Biodiversity, the Secretariat of the Convention on Biological Diversity organized the training course on risk assessment of living modified organisms for South, Southeast and Pacific Asia, which was held in Manila 7 to 11 November 2022.

4. The objectives of the workshop were to provide theoretical and practical training for participants on:

(a) The risk assessment process (concepts, steps, methodology, key issues to consider);

(b) Hands-on training in the evaluation of case studies of living modified organisms for environmental release, identifying protection goals and applying the risk assessment methodology to develop risk scenarios to assess.

5. Twenty participants from twelve countries and one organization from South, Southeast and Pacific Asia attended the workshop (see annex I).

ITEM 1. OPENING OF THE WORKSHOP

6. The workshop was opened at 9 a.m. on Monday, 7 November 2022, by Mr. Zakir Jafry from the Secretariat of the Convention on Biological Diversity (SCBD). In his opening, he thanked the Government of the Republic of Korea for its generous financial support and the ASEAN Centre for Biodiversity (ACB) for its kind contributions to the organization of the workshop. Further, he thanked the International Centre for Genetic Engineering and Biotechnology (ICGEB) for its facilitation with the workshop. He invited participants to take advantage of the opportunity to put the knowledge gained during the workshop to the benefit of their respective countries and for the effective implementation of the Cartagena Protocol on Biosafety.

7. Next, Ms. Clarissa Arida provided opening remarks on behalf of Ms. Theresa Mundita S. Lim, executive director of ACB. In her statement, she welcomed the participants, the resource team and the SCBD staff to the workshop. She reminded the participants of the partnership between ACB and SCBD, while also explaining the role of ACB in the South, Southeastern and Pacific Asian region. Following this, she drew attention to the need to assess the risks of modern biotechnology, such that there would be no

adverse impacts on biodiversity. Further, she mentioned that through capacity-building initiatives such as this workshop, participants would be better prepared to assess the potential risks resulting from newly developed organisms and to support the global biodiversity framework, particularly its proposed target on biotechnology.

8. Following the opening remarks, a pre-recorded video statement from the Executive Secretary of the Convention on Biological Diversity, Ms. Elizabeth Maruma Mrema, was played. In the video statement, Ms. Maruma Mrema underlined the importance of the Cartagena Protocol, while specifically highlighting the importance of risk assessment of living modified organisms. She highlighted the continued need to reinforce capacities, such that Parties could follow the rapid development within the field of biotechnology. Moreover, she noted that the ability for Parties to assess risks would allow them to respond to global problems and support the post-2020 global biodiversity framework.

9. After the video, participants in the workshop were invited to introduce themselves and provide a short summary of their experience and current activities related to risk assessment of living modified organisms as well as their expectations of the workshop.

10. After the introductions by the participants, Mr. Jafry explained the workshop objectives and organization of work for the meeting.[1] He also invited the participants to examine the provisional agenda[2] for details related to the programme and organization of work for the workshop.

11. Following the organization of work, a video presentation of the ASEAN Centre for Biodiversity was played. The video highlighted the work of ACB in the field of biodiversity and how its initiatives align with the work under the Convention on Biological Diversity and its Protocols. The video was followed by a short presentation by Ms. Corazon de Jesus on the various programmes and projects conducted by ACB.

ITEM 2. OVERVIEW OF BIOSAFETY AND THE CARTAGENA PROTOCOL ON BIOSAFETY

2.1. History of the Protocol and main provisions

12. Under this agenda item, Ms. Marianela Araya Quesada from SCBD gave a virtual presentation on general concepts in biosafety and the Cartagena Protocol on Biosafety, including the history of the Protocol and its main provisions; as well as on relevant decisions of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

2.2. The Biosafety Clearing-House

13. After, Mr. Zakir Jafry and Mr. Austein McLoughlin from SCBD presented on the new Biosafety Clearing-House (BCH) platform and its functions and new features. During the presentation, the importance of the scientific records of the BCH and their link to risk assessment of living modified organisms was emphasized. The participants learned how to navigate on the BCH and use the various filters and sub-filters to find relevant information within it.

2.3. Techniques used in modern biotechnology

14. Following the presentation on the BCH, Ms. Boet Glandorf, Senior Environmental Risk Assessor from the Netherlands, presented an overview of modern biotechnology, including common techniques, history and new developments, such as new genomic techniques.

[1] CBD/CP/RARM/OM/2022/3/1/Add.1, annex.

[2] CBD/CP/RARM/OM/2022/3/1.

ITEM 3. NATIONAL BIOSAFETY FRAMEWORKS

3.1. Competent national authorities, practices and principles

15. Under this agenda item, Ms. Wendy Craig presented an overview of the structure and role of national biosafety frameworks, including a definition of national competent authorities and examples of biosafety frameworks from various countries.

3.2. Expert advice and the role of the risk assessors

16. Next, Ms. Boet Glandorf presented on the role of regulators and scientific advisory bodies, including such issues as the responsibilities of risk assessors, the roster of biosafety experts, and public participation. Examples of scientific advisory bodies in different nations were also provided.

3.3. Biosafety in the Philippines

17. Following the resource team presentations, Mr. Enrykie Fortajada and Mr. Leocris Batucan Jr. from the National Committee on Biosafety of the Philippines shared information on the Philippines' experience in biosafety. They provided details on the development of national biosafety regulations, including the current process for contained use, field trials and direct use of living modified organisms for food, feed or for processing. Lessons learned and future project plans were also mentioned.

ITEM 4. OVERVIEW OF THE RISK ASSESSMENT

4.1. Methodology

18. To begin agenda item 4, Ms. Boet Glandorf provided an overview of the risk assessment methodology, including such issues as national protection goals, assessment endpoints, practices and principles, and definition of terms, such as adverse effects, exposure and characterization.

4.2. Overarching issues (quality and relevance of information, uncertainty)

19. Further, Ms. Boet Glandorf presented on quality of evidence in terms of appropriateness, reliability, transparency, expertise, strength and robustness. Relevance of sources of information, and the identification and consideration of uncertainty, were also explored.

4.3. The planning phase (context and scope, assessment endpoints, choice of comparators)

20. Next, Mr. Phil Macdonald explained the context and scope, selecting relevant assessment endpoints or representative species, establishing the baseline for risk assessment, how to choose suitable comparators and how to develop risk hypotheses.

4.4. Conducting the risk assessment (identification of novel characteristics, evaluation of livelihood and consequences, estimation of the overall risk, acceptability of risk)

21. Ms. Wendy Craig provided information key for conducting the risk assessment. The identification of the novel characteristics of living modified organisms, how to evaluate the likelihood or occurrence of adverse effects and the possible consequences, as well as the overall estimation of the risk were detailed. Further, concepts such as gene flow, allergenicity and receiving environment were also mentioned.

4.5. Preparing a risk assessment report and recommendation

22. Mr. Phil Macdonald presented on the important aspects to consider when drafting risk assessment reports. In his presentation he highlighted that a report presented in a well-structured form will not only facilitate the deliberations of decision makers but will also allow for an easier exchange of information and experience. The presentation also included information on the background and scope of the risk assessment, characterization and estimation of risk, and a description of risk management and monitoring strategies.

4.6. What are engineered gene drives and some proposed applications

23. Mr. Dan Tompkins, Science Director of Predator Free 2050 Limited, joined virtually to provide a lecture on the technical aspect of engineered gene drives to support the understanding of the case study (see agenda item 5 below). In his presentation, Mr. Tompkins introduced the participants to what an engineered gene drive is and how such a technology could potentially be applied for managing invasive alien species. Mathematical models were used to illustrate the population dynamics of living modified organisms containing engineered gene drives and with a consideration for resistance formation. To end his presentation, some potential benefits and adverse effects were presented, as well as a brief mention of the state of the technology in terms of deployment. Following his presentation, participants were given an opportunity to ask technical questions.

ITEM 5. CASE STUDIES

24. A hypothetical modified mouse containing an engineered gene drive for release on a South Pacific island to control invasive mice populations was developed for the participants to assess. To introduce the case study, Ms. Boet Glandorf presented an overview of the case study and the biology document for mice (*Mus musculus*).

25. Following the introduction of the case study, participants were divided into small groups and tasked with applying the theory and concepts from the previous agenda items to assess the environmental release of the modified mice containing engineered gene drives. The resource team members guided the participants in developing their harms, protection goals, pathways to harm, evaluations of risk and mock dossiers. Participants were given opportunities to present their group work as they worked through the risk assessment process.

ITEM 6. RESOURCE MOBILIZATION

6.1. Resource mobilization opportunities

26. Ms. Marianela Araya Quesada, presenting virtually, summarized the current work under risk assessment under the Cartagena Protocol, as well as the main issues to be discussed at the upcoming meeting of the Parties. In addition, information on resource mobilization opportunities, including information on how to access funding from the Global Environmental Facility for projects on biosafety, was also provided in her presentation.

ITEM 7. CONCLUSIONS AND RECOMMENDATIONS

7.1. Evaluation of the workshop and feedback

27. An evaluation form was given to participants to collect their opinions on the workshop. Participants were also given an opportunity to discuss their feedback. The results of the workshop evaluation are presented in annex II.

28. Overall, the participants found the practical exercise to be the most useful element of the workshop as it solidified the theoretical portion of the training workshop. In their feedback, they also appreciated the facilitation of the workshop. One participant suggested that an additional session on the ongoing work programmes of the Cartagena Protocol could benefit future workshops. Others suggested that risk communication, risk management and monitoring could also be added to the agenda for future workshops.

7.2. Closure of the workshop

29. The workshop closed at 12.30 p.m. on Friday, 11 November 2022.

Annex I

LIST OF PARTICIPANTS

PARTIES

Bangladesh

1. **Mr. Md. Hasan Hasibur Rahman**
Deputy Director
Department of Environment
Ministry of Environment, Forests and Climate Change
E-16 Agargaon, Sher-E-Bangla Nogor, Dhaka-1207, Bangladesh Dhaka 1207
Bangladesh
Tel.: +8802-01712-304-222
Fax: +88-02-8181-772
Email: m.h.h.rahman@gmail.com, hasanhasibur@doe.gov.bd

Bhutan

2. **Mr. Norbu Jamtsho**
Assistant Laboratory Officer
National Food Testing Laboratory
Ministry of Agriculture and Forests P.O. Box 1071
Thimphu, Bhutan
Email: nortsho77@gmail.com

Cambodia

3. **Mr. Monyrak Meng**
Deputy Director General
General Directorate of Policy and Strategy Ministry of Environment
Phnom Penh Cambodia
Tel.: + 855 78800816
Fax: +855 23 72 10 73
Email: mmonyrak@gmail.com

India

4. **Dr. Abhilasha Singh Mathuriya**
Scientist D of Conservation and Survey-III Division
Ministry of Environment, Forests and Climate Change
Indira Paryavaran Bhavan, Jor Bagh Road
New Delhi 110003
India
Email: abhilasha.mathuriya@gov.in

Indonesia

5. **Ms. Ilmi Kurniawati**
Junior Policy Analyst
Directorate of Biodiversity Species and Genetic Conservation
Ministry of Environment and Forestry
7th Floor, Block VII, Manggala Wanabakti Building, Jalan Gatot Subroto
Jakarta 10270
Indonesia
Email: ilmikurniawati73@gmail.com, subditkonvensi.kkh@gmail.com

Kiribati

6. **Mr. Morrison Tabokai**
Biosafety Project Officer
Ministry of Environment, Lands and Agricultural Development P.O. Box 234
Bikenibeu Tarawa Kiribati
Email: m.tabokai@melad.gov.ki

Lao People's Democratic Republic

7. **Mr. Panya Bouphasiri**
Deputy Director, Biosafety Management Division
Department of Science
Ministry of Education and Sports
Lanexang Avenue, Box: 067
Vientiane Capital
Lao People's Democratic Republic
Email: panyabouphasiri@gmail.com

Malaysia

8. **Dr. Mohana Anita Anthonysamy**
Principal Assistant Director
Evaluation and Research Section
Department of Biosafety
Level 4, Block F11, Complex F, Lebuh Perhana Timur, Precinct 1 Putraya 62000
Malaysia
Email: anita@biosafety.gov.my

Maldives

9. **Ms. Eenas Mohamed**
Senior Environment Analyst
Environmental Research & Conservation Section
Environmental Protection Agency
Green Building, 3rd floor,
Handhuvaree Hingun, Maafannu
Malé 20392
Maldives
Email: enas.mohamed@epa.gov.mv

Philippines

10. **Mr. Leocris Batucan, Jr.**
S&T fellow
Office of the Undersecretary for Research and Development
National Committee on Biosafety of the Philippines
Department of Science and Technology (DOST), 2nd Floor, General Santos Avenue, Bicutan, Tagig
Metro Manila 1630
Philippines
Email: leocrisjr@gmail.com

11. **Mr. Enrykie Fortajada**
S&T fellow
Office of the Undersecretary for Research and Development
National Committee on Biosafety of the Philippines
Department of Science and Technology (DOST), 2nd Floor, General Santos Avenue, Bicutan, Tagig
Metro Manila 1630
Philippines
Email: ebfortajada1@up.edu.ph

12. **Ms. Louise Veronica D. Jose**
Science Research Specialist I
Environmental Management Bureau
Department of Environment and Natural Resources Visayas Avenue, 1100 Diliman
Quezon City Philippines
Email: louise_jose@emb.gov.ph

Solomon Islands

13. **Mr. Trevor Maeda**
Principal Conservation Officer
Environment and Conservation Division
Ministry of Environment, Climate Change, Disaster Management and Meteorology
P.O. Box 21
Honiara, Solomon Islands
Email: tmaeda@mecdm.gov.sb, trevor.maeeda@gmail.com

Thailand

14. **Pr. Weerasak Pitaksaringkarn**
Agricultural Research Scientist Biotechnology Research and Development Office
Department of Agriculture
50 Phahonyothin Road, Chatuchak Bangkok 10900
Thailand
Email: weraouddy@hotmail.com

INDIGENOUS PEOPLES AND LOCAL COMMUNITIES

Society for Wetland Biodiversity Conservation – Nepal (SWBCN)

15. **Mr. Kamal Kumar Rai**
IPs Chair for Indigeneity Research and Conservation Advocacy
Indigenous Knowledge and Peoples Networks for Indigeneity
Society for Wetland Biodiversity Conservation - Nepal
PO Box 12476
Kathmandu, Nepal
Tel.: +9779841322054
Email: ipskirantsampang@gmail.com, swbc_rai@yahoo.com, biodiv_rai@hotmail.com

ORGANIZATIONS

ASEAN Centre for Biodiversity

16. **Ms. Clarissa C. Arida**
Director
Programme Development and Implementation
ASEAN Centre for Biodiversity
Domingo M. Lantican Avenue
University of the Philippines Los Banos
4031 Laguna, Philippines
Tel.: +63495362865
Fax: +63495362865
Email: ccarida@aseanbiodiversity.org, gsrodulfo@aseanbiodiversity.org

17. **Ms. Corazon A. de Jesus, Jr.**
Programme Specialist
Programme Development and Implementation ASEAN Centre for Biodiversity
Domingo M. Lantican Avenue
University of the Philippines Los Banos
4031 Laguna, Philippines
Tel.: +63 49 536 2865
Email: cadejesus@aseanbiodiversity.org, gsrodulfo@aseanbiodiversity.org

18. **Ms. Rhia Galsim**
Programme Officer
Programme Development and Implementation ASEAN Centre for Biodiversity
Domingo M. Lantican Avenue
University of the Philippines Los Banos
4031 Laguna, Philippines
Tel.: +63 49 536 2865
Fax: +63 49 536 2865
Email: rcgalsim@aseanbiodiversity.org

19. **Ms. Jahn Zylke Ong**
Knowledge Management Associate
Biodiversity Information Management
ASEAN Centre for Biodiversity
Domingo M. Lantican Avenue
University of the Philippines Los Banos
4031 Laguna, Philippines
Email: jazztorresong@gmail.com

20. **Ms. Grace Anne S. Rodulfo**
Technical Officer
Programme Development and Implementation
ASEAN Centre for Biodiversity
Domingo M. Lantican Avenue
University of the Philippines Los Banos
4031 Laguna, Philippines
Tel.: +63495362865
Fax: +63495362865
Email: gsrodulfo@aseanbiodiversity.org

RESOURCE TEAM

International Centre for Genetic Engineering and Biotechnology (ICGEB)

21. Ms. Wendy Craig
Group Leader Regulatory Science Group
International Centre for Genetic Engineering and Biotechnology
AREA Science Park, Padriciano 99
Trieste 34149 Italy
Email: craig@icgeb.org

22. Ms. Boet Glandorf
Senior Environmental Risk Assessor
Dutch National Institute for Public Health and the Environment
International Centre for Genetic Engineering and Biotechnology
AREA Science Park, Padriciano 99
Trieste 34149 Italy
Email: boetglandorf0@gmail.com

23. Mr. Philip Macdonald
Former National Manager
Plant and Biotechnology Risk Assessment Unit Canadian Food Inspection Agency
International Centre for Genetic Engineering and Biotechnology
AREA Science Park, Padriciano 99
Trieste 34149 Italy
Tel.: +1 613 773 5288; +613 221 7002
Fax: +1 613 773 5391; +613 228 7298
Email: philip.macdonald@inspection.gc.ca

STAFF

Secretariat of the Convention on Biological Diversity (SCBD)

24. Mr. Zakir Jafry
BCH Programme Officer
Biosafety Protocol Unit
Secretariat of the Convention on Biological Diversity
413, Saint-Jacques Street W., Suite 800
Montreal, Quebec, H2Y 1N9
Canada
Email: zakir.jafry@un.org, zakir.jafry@cbd.int

25. Mr. Austein McLoughlin
Associate Programme Management Officer
Biosafety Protocol Unit
Secretariat of the Convention on Biological Diversity
413, Saint-Jacques Street W., Suite 800
Montreal, Quebec, H2Y 1N9
Canada
Email: austein.mcloughlin@un.org, austein.mcloughlin@cbd.int

Annex II

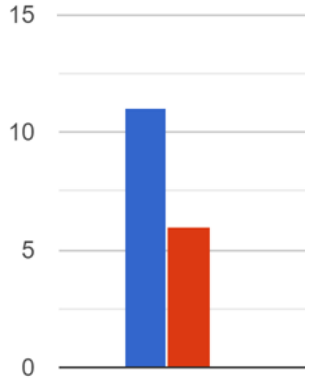
RESULTS OF THE WORKSHOP EVALUATION QUESTIONNAIRE

At the end of the training course, a survey was distributed to gather feedback from participants. Graphical representations of the 17 responses are illustrated below.

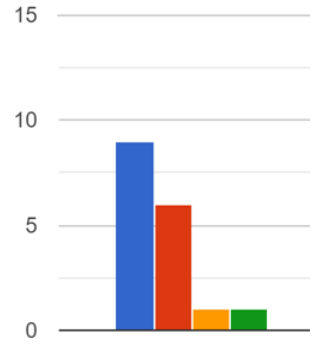
1) During the workshop, how much did you learn regarding the following:

Rate on a scale from 5 – 1, where 5 is "a significant amount" and 1 is "None"..

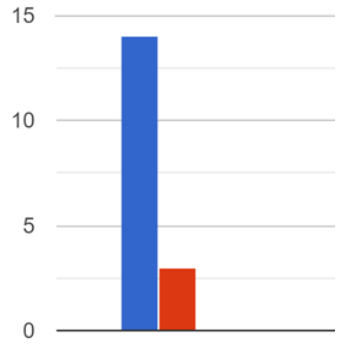
a. *The Cartagena Protocol and its approach to risk assessment*



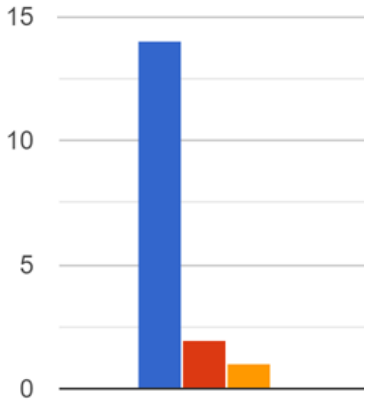
b. *The Biosafety Clearing-House (BCH)*



c. *The various steps to conduct risk assessment*

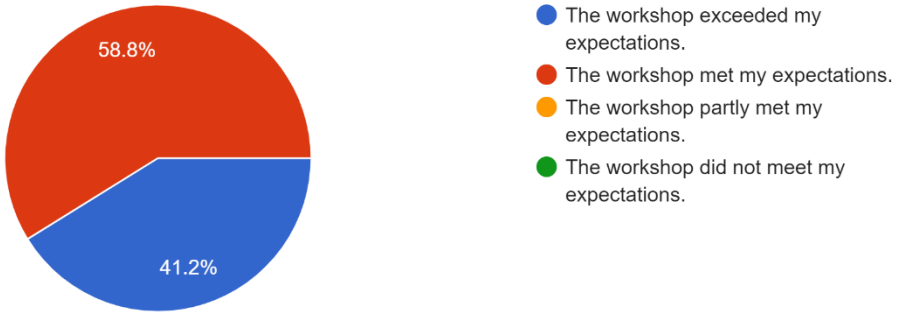


d. *Practical (hands-on) experience in assessing mock dossiers*



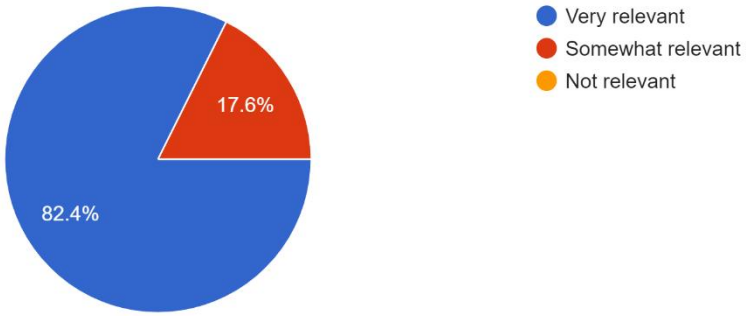
2) To what extent were your expectations regarding the workshop met?

17 responses



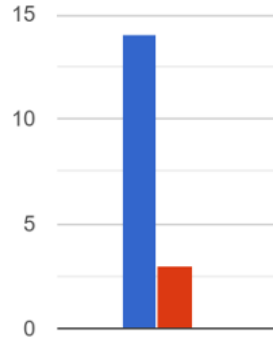
3) How relevant was the subject matter of the course to your job activities?

17 responses

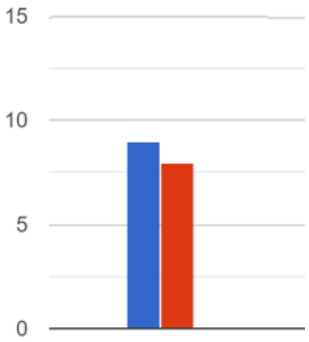


Content and facilitation of the workshop

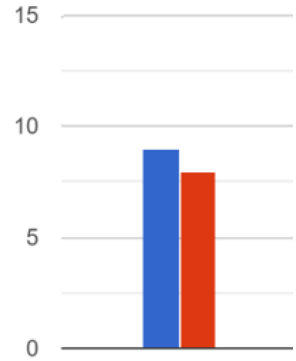
4) The workshop objectives were clear



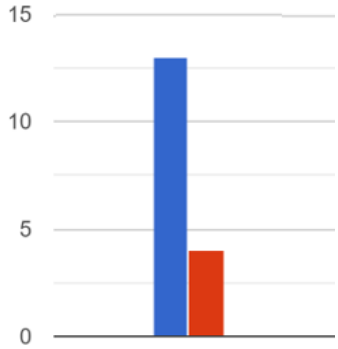
5) Quality of training materials



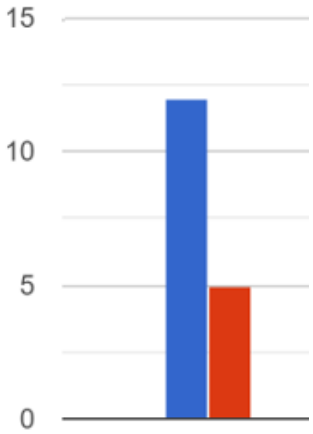
6) Organization of sessions



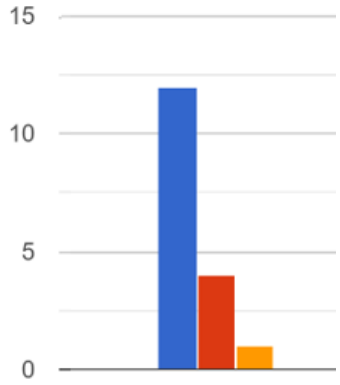
7) Balance and relevance of topics



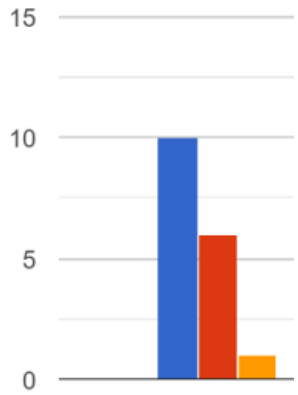
8) Overall assessment of trainers/facilitators



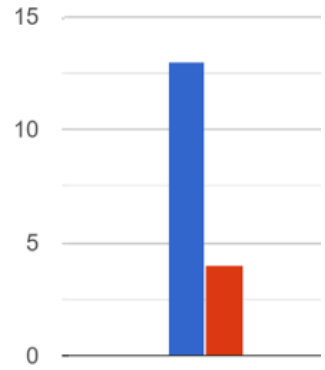
9) Usefulness of each session/topic: *Overview of biosafety and the Cartagena Protocol on Biosafety*



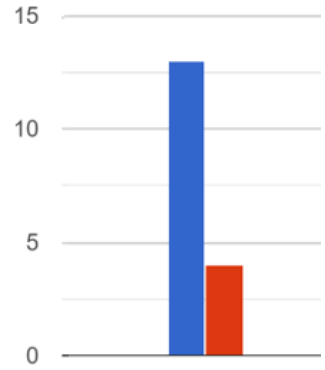
9.2) Usefulness of each session/topic: *National biosafety frameworks*



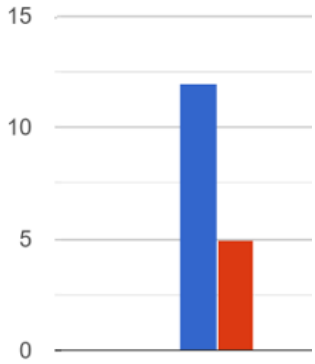
9.3) Usefulness of each session/topic: *Overview of the risk assessment*



9.4) Usefulness of each session/topic: Case studies



9.5) Usefulness of each session/topic: *Current risk assessment discussions and resource mobilization*



10) Overall assessment of the workshop