



**Committee on Sanitary and Phytosanitary Measures**

**REPORT  
WORKSHOP ON RISK ANALYSIS  
MONDAY, 13 OCTOBER – TUESDAY, 14 OCTOBER 2014  
WTO, CENTRE WILLIAM RAPPARD, GENEVA**

**NOTE BY THE SECRETARIAT<sup>1</sup>**

The Secretariat of the World Trade Organization held a workshop on risk analysis in Geneva, Switzerland, on 13 and 14 October 2014.

The WTO funded, through assistance from the Doha Development Agenda Global Trust Fund (DDAGTF), the participation of 48 governmental officials from developing country Members and Observers in the workshop as well as in the SPS Committee meetings. The WTO, in partnership with the Inter-American Institute for Cooperation on Agriculture (IICA), co-funded the participation of nine participants from the Caribbean region. Sponsored participants were selected from approximately 600 applications.

In addition, the WTO Global Trust Fund made it possible to cover the costs of travel for several of the speakers in the workshop. Total attendance was close to 200, and included Geneva- and capital-based delegates, as well as participants from intergovernmental organizations and academia.

The presentations from this workshop and audio recordings are available via the SPS Gateway at [http://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/wkshop\\_oct14\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/wkshop_oct14_e.htm). The final programme for the workshop is contained in G/SPS/GEN/1358.

**1 BACKGROUND OF THE WORKSHOP**

1.1. The SPS Committee agreed, at its March 2014 meeting, to use the occasion of the SPS Thematic Workshop in October 2014 to focus on risk analysis, based on a proposal submitted by the United States, in the context of the Fourth Review.<sup>2</sup> The United States proposed that the Committee should organize a workshop on decision making and communication during the risk analysis process to build upon the previous workshop held in 2000.<sup>3</sup>

1.2. The Committee also agreed to address South Africa's proposal<sup>4</sup>, which consisted of two questions related to the implementation of Article 5.4 of the SPS Agreement, in the workshop.

1.3. Members were invited at several stages to make comments on the programme and also to put forward names of speakers, and their proposals and suggestions were taken into account in preparing the programme.

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<sup>1</sup> This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights or obligations under the WTO.

<sup>2</sup> See G/SPS/W/275.

<sup>3</sup> Programme and presentations from the Workshop on Risk Analysis held in 2000, are available via the following link: [http://www.wto.org/english/tratop\\_e/sps\\_e/risk00\\_e/risk00\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/risk00_e/risk00_e.htm).

<sup>4</sup> See G/SPS/GEN/1307.

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## 2 OBJECTIVE OF THE WORKSHOP

2.1. The objective of the workshop was to bring together officials responsible for participation in and implementation of the SPS Agreement for an in-depth discussion, at a technical level, on decision making and communication during the risk analysis process. More specifically, the workshop aimed to:

- Review relevant developments in SPS-related risk analysis since the SPS workshop in 2000, including information from the Codex, IPPC and OIE (the "Three Sisters") on their respective work, as well as a review of the outcome of WTO dispute settlement cases as they relate to the risk assessment provisions of the SPS Agreement;
- Discuss the link between risk assessment outcomes and risk management decisions, including sharing of experiences in using risk assessment as a basis for SPS-related risk management decisions, and experiences in co-operation between the public and private sectors;
- Discuss experiences in SPS-related risk communication; and
- Explore ways to leverage resources to more effectively perform risk assessments, as well as emerging issues and challenges in risk analysis.

## 3 OVERVIEW OF WORKSHOP

3.1. Overall, the workshop focused on Members' experiences in various areas of the risk analysis process, such as undertaking risk assessments, making risk management decisions and conveying risk communication messages. Focus was also placed on leveraging resources for risk assessments. Presentations were made by Members from developed and developing countries, as well as by several organizations such as IPPC, WHO (on behalf of Codex), IICA and the International Livestock Research Institute (ILRI). The workshop provided an open platform for discussion and experience sharing, as well as best practices concerning SPS-related risk analysis. A summary of the various sessions of the workshop is provided below.

## 4 WORKSHOP SESSIONS

### 4.1 Introductory session<sup>5</sup>

4.1. In order to provide some context for the workshop, an introductory session briefly reflected on the previous workshop held by the Committee in 2000 and identified some of the main points of focus that merited exploration 14 years later.

4.2. **Mr Robert Griffin**<sup>6</sup>, National Coordinator for Agricultural Quarantine Inspection of the USDA Animal and Plant Health Inspection Service, highlighted that the 2000 workshop had primarily focused on the key concepts introduced by the SPS Agreement, such as the appropriate level of protection, sufficient scientific evidence and risk assessment. Mr Griffin outlined that there were relatively few international standards that were in concert with the Agreement at that time, which resulted in a very strong focus by Members on risk assessment and the associated concepts, terms and methods. He also highlighted the role of standard-setting organizations in developing harmonized frameworks for risk assessment.

4.3. In reflecting on where discussions are today, Mr Griffin highlighted the extensive guidance that has been developed for risk assessment by the Three Sisters as well as the wealth of insight available on risk analysis and its relationship to the SPS Agreement. In particular, Mr Griffin identified the available legal interpretations of the SPS Agreement from several disputes, and the various risk assessments established by national agencies. Key points that were still of relevance today included: the role and relationship of uncertainty to SPS measures, and the rational relationship between risk assessments and SPS measures.

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<sup>5</sup> The audio recording of the Introductory session is available at:  
[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session1.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session1.mp3).

<sup>6</sup> Speaker's presentation and summary are available at:  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Opening\\_PPT\\_Robert\\_GRIFFIN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Opening_PPT_Robert_GRIFFIN.pdf) and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Opening\\_Summary\\_Robert\\_GRIFFIN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Opening_Summary_Robert_GRIFFIN.pdf).

4.4. In going forward, Mr Griffin highlighted several challenges which would need to be addressed, such as questions surrounding the quality and reliability of information used as evidence in risk analyses given the increasing availability of information e.g. through the internet. In addition, other areas of focus for WTO Members included: more holistic and sophisticated views of risk assessment; incorporating modelling and economic analyses; and looking at risk management from a systems standpoint.

## 4.2 THE SPS AGREEMENT AND RISK ANALYSIS (Session 1)<sup>7</sup>

4.5. **Session 1** set the framework for the subsequent presentations, focusing on Members' obligations arising from the risk assessment provisions (Article 5) of the SPS Agreement and important interpretations from the outcomes of WTO dispute settlement cases. Two officials from the WTO Secretariat, Ms Gretchen Stanton and Ms Christiane Wolff presented during this session.

4.6. **Ms Gretchen Stanton**<sup>8</sup> outlined the scientific justification principle in the SPS Agreement, highlighting that SPS measures must either be based on an international standard (Article 3) or on a risk assessment (Article 5). Ms Stanton outlined a series of questions often used in SPS-related disputes to guide the determination of whether a SPS measure follows the scientific justification principle of the SPS Agreement:

1. Is the measure an SPS measure? (Article 1.1);
2. Does a relevant international standard exist? (Article 3);
3. Is the measure based on an international standard? (Article 3);
4. Is the measure a provisional measure? (Article 5.7);
5. Does a risk assessment exist which complies with the SPS Agreement? (Articles 5.1 – 5.3);
6. Is the measure based on a risk assessment? (Article 5.1);
7. Is the appropriate level of protection consistent? (Article 5.5); and
8. Is the measure the least trade-restrictive? (Article 5.6).

4.7. Ms Stanton identified the SPS-related disputes where legal rulings have been made and those that were pending. She further highlighted that questions of scientific justification and risk assessment were a critical aspect of almost every SPS dispute and that there have been substantive legal rulings made in several of these cases.

4.8. **Ms Christiane Wolff**<sup>9</sup> provided an overview of the risk assessment provisions, particularly, highlighting the obligation under Article 5.1 for Members to ensure that their SPS measures are based on a risk assessment, as appropriate, and that they take into account risk assessment techniques developed by the relevant international organizations. Ms Wolff drew participants' attention to the definitions of risk assessment as outlined in Annex A.4 of the SPS Agreement, highlighting the differences in the definition for food safety risks and the definition for pest or disease risks. Ms Wolff elaborated on the guidance provided by Article 5.2 on the factors to take into account in undertaking risk assessments, highlighting among others scientific evidence, and the link between Articles 5 and Article 2.<sup>10</sup> Ms Wolff emphasized that this link has also been established by panels and the Appellate Body.

4.9. In presenting the lessons learnt from dispute cases, Ms Wolff first examined the question of whether a risk assessment exists within the context of the SPS Agreement. She highlighted that, based on legal interpretation, the requirements for food safety assessments were different from

<sup>7</sup> The audio recording of Session 1 is available at:

[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session1p2.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session1p2.mp3).

<sup>8</sup> The Secretariat's presentation is available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session1\\_PPT\\_SPS\\_Secretariat.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session1_PPT_SPS_Secretariat.pdf).

<sup>9</sup> See previous footnote.

<sup>10</sup> In particular, the text of Article 2.2 of the SPS Agreement indicates that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

those for assessments of pest or disease risks. Other legal findings of interest included: that the non-use of an international standard, as a basis for a measure, requires a risk assessment; that there is no need for each Member to carry out its own risk assessment, but that SPS measures can be based on an appropriate risk assessment carried out by another party; that a risk assessment does not need to be quantitative; and that risk assessments can consider divergent or minority scientific views.

4.10. In relation to the question of how to analyze whether a measure is based on a risk assessment, Ms Wolff explained that, according to the Appellate Body, the term "based on" required a rational relationship between the measure and the risk assessment. In addition, the risk assessment must reasonably support the measure, although the measure must not necessarily conform to every aspect of the risk assessment. Ms Wolff also referred to the economic factors, as outlined in Article 5.3, which should be considered in assessing pest or disease risks and presented the three-pronged test developed by the Appellate Body for analyzing whether plant and animal health risk assessments were in conformity with the SPS Agreement.

4.11. In examining Article 5.4, Ms Stanton outlined that once Members have determined the level of risk that they will accept, the objective of minimizing negative trade effects should be taken into account. It was further highlighted that this article had not yet been interpreted through dispute cases and that unlike Article 5.1, Article 5.4 used the term "should".

4.12. Ms Stanton provided an overview of Article 5.5, highlighting that the objective of the provision was to avoid arbitrary distinctions in the level of risk considered to be acceptable, if that distinction results in disguised restriction to trade. She made reference to the SPS Committee Guidelines on Consistency (G/SPS/15), developed to assist Members in implementing this provision. In addition, Ms Stanton outlined the three cumulative elements identified by the Appellate Body for a measure to be found in violation of Article 5.5. She further explained that previous legal rulings also indicated that if the ALOP was not clearly stated by a government, it could be derived from the level of protection embodied in the measure being challenged.

4.13. In relation to Article 5.6, an explanation was provided of the requirement to select the least trade restrictive measure, highlighting the three cumulative elements used by the Appellate Body to consider whether a measure is the least trade restrictive. Specifically, the complainant must establish that there is an alternative measure which: (i) is reasonably available, taking into account technical and economic feasibility; (ii) achieves the importing Member's ALOP; and (iii) is significantly less trade restrictive to trade than the existing measure.

4.14. In providing an overview of Article 5.7, Ms Stanton explained that this article was the only exception in the SPS Agreement to the requirement that SPS measures must be based on a scientific justification. She underscored that precaution "finds reflection in Article 5.7" as ruled by the Appellate Body, but that this does not override the obligations of Articles 5.1 and 5.2, and presented the four elements that Members must be able to demonstrate in order to legally justify a measure in the context of Article 5.7. Other rulings from the Appellate Body were highlighted such as that scientific uncertainty is not the same as insufficient scientific evidence, and that determination of sufficiency of evidence to undertake a risk assessment may depend on the importer's ALOP.

### 4.3 SPS RISK ANALYSIS IN THE CURRENT AGE (Session 2)<sup>11</sup>

4.15. Speakers in **Session 2** dealt with the current and evolving practices in undertaking risk assessments, as well as some of the challenges in dealing with uncertainty, data availability and qualitative vs. quantitative risk assessments. In addition, speakers discussed risk management using specific examples across various sectors.

#### 4.3.1 Part 1: Risk Assessment

4.16. **Dr Djien Liem**<sup>12</sup>, Lead Expert in International Scientific Cooperation at the European Food Safety Authority (EFSA) presented on risk assessment methodologies in various sectors and how

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<sup>11</sup> The audio recording of Session 2 is available at:  
[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session2p1.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session2p1.mp3).

to respond to challenges ahead. Dr Liem provided an overview of the role and functions of EFSA, highlighting that in the European food safety system, risk assessment is done independently from risk management. Integral to EFSA's work is its collaboration with external experts and other organizations, both within and outside Europe, such as national food safety agencies and research organizations, as well as international organizations.

4.17. Dr Liem outlined the various ways in which the nature of EFSA work is changing, identifying among others, that a growing part of EFSA's work relates to the safety assessment of regulated products, substances and claims submitted for authorization in the European Union. Given the growing and varied demand, as well as the changing nature of the questions that have to be addressed, EFSA has diversified into new areas such as evaluation of the safety and environmental impact of new products, development of new risk evaluation methods and the evaluation of efficacy/benefits.

4.18. One of the key objectives of EFSA's science strategy is its focus on introducing best practices in risk assessment, while ensuring that the best available information is obtained for the risk assessment, whether sourced worldwide or within the European Union. Dr Liem outlined the emergence of several new risks and challenges for risk assessment related to: chemical mixtures and combined toxicity; antimicrobial resistance; and hazards linked to globalization, including food-borne disease outbreaks.

4.19. In looking at the various stages of the risk assessment process, several global challenges were identified, such as the need for greater clarity on the questions to be addressed, as well as the impartial consideration of these questions and the type of methodology to be used. The importance of relevant and reliable data was also highlighted, as well as how to deal with uncertainty and knowledge gaps, among others. Further information was provided on the guidance that has been developed or is being developed by EFSA, in collaboration with other organizations, on several areas such as handling of uncertainties and weight of evidence, to name a few.

4.20. **Dr Amelia Tejada**<sup>13</sup>, Pesticide Residue Expert, Fertilizer and Pesticide Authority (FPA), from the Philippines' Department of Agriculture presented information on the Philippine's experience in assessing and managing risk in relation to pesticides for food safety. In her presentation, Dr Tejada underscored the importance of the standards development process of Codex and the role of JMPR, JECFA and JEMRA. Using the example of pesticides, Dr Tejada outlined the steps and associated analysis embodied in the estimation of dietary risk and its comparison with an established acceptable daily intake, in determining whether any potential health risk is posed to consumers by pesticide levels. Additional factors were indicated as necessary to further assess the hazards to non-target organisms, such as effects on honeybees and soil micro and macro organisms, among others. Several issues were raised in relation to the interpretation of results and the use of quantitative vs. qualitative risk assessments.

4.21. Dr Tejada also highlighted the role of the Philippine National Codex Sub-Committee in collating proposed MRLs and other pesticide issues, as well as submitting position papers to Codex. Reference was made to the 2013 Philippine Food Safety Act and its complementary elements in relation to the existing Codex procedures. Dr Tejada concluded by underscoring that the Philippines' Department of Agriculture and Department of Health used a risk analysis approach in setting mandatory food safety standards.

### 4.3.2 Part 2: Risk Management

4.22. **Mr Robert Griffin**<sup>14</sup>, National Coordinator for Agricultural Quarantine Inspection of the USDA Animal and Plant Health Inspection Service, provided some examples from the United States

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<sup>12</sup> Speaker's presentation and summary are available at:  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part1\\_PPT\\_Djien\\_LIEM.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part1_PPT_Djien_LIEM.pdf) and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part1\\_Summary\\_Djien\\_LIEM.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part1_Summary_Djien_LIEM.pdf).

<sup>13</sup> Speaker's presentation and summary are available at:  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part1\\_PPT\\_Amelia\\_TEJADA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part1_PPT_Amelia_TEJADA.pdf) and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part1\\_Summary\\_Amelia\\_TEJADA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part1_Summary_Amelia_TEJADA.pdf).

<sup>14</sup> Speaker's presentation and summary are available at:  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part2\\_PPT\\_Robert\\_GRIFFIN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part2_PPT_Robert_GRIFFIN.pdf) and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part2\\_Summary\\_Robert\\_GRIFFIN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part2_Summary_Robert_GRIFFIN.pdf)

on risk management. Mr Griffin highlighted that risk assessment may seem academic until there is the need to make decisions and to apply those decisions in practice. Mr Griffin outlined that one of the main challenges with risk management is the scope of its interpretation. In addition, potential benefits and difficulties were identified in the structural framework used by countries in the risk analysis process and the roles assigned, particularly in relation to whether risk assessment and risk management roles should be combined in SPS-related regulatory bodies. Mr Griffin highlighted that various structures are used within and across agencies in the United States. In some cases, risk assessment and risk management units may work together on a risk analysis, but the actual decision is taken elsewhere. However, in relation to risk analysis undertaken for decisions related to SPS measures, most of the structures in the United States separate policy making and the analysis process, in order to avoid policy exerting pressure on analysis.

4.23. Mr Griffin outlined the challenge of aligning past (pre-SPS Agreement) and current decisions within the regulatory framework, to be consistent with the SPS Agreement, as well as with an overall risk-based approach. Other challenges related to analysis were highlighted such as evaluating the role and type of economic analysis, and the role of a systems approach among others. Mr Griffin highlighted the role of inspection as a risk management tool, but underscored the need for the use of risk analysis principles in its application, in order to ensure consistency with the SPS Agreement. Issues related to transparency, adoption of processes outlined by the international standards and the statistical basis of sampling were identified.

4.24. Treatment strategies were also outlined as an area which has evolved, but required additional focus in relation to risk-based justification, level of efficiency, historical decisions and use of alternative options (i.e. equivalence). The use of systems approaches was further highlighted as a holistic tool to consider all events and conditions in the risk analysis process. In concluding, Mr Griffin raised additional issues for consideration such as how to manage uncertainty and assessing pathway specificity.

4.25. **Mr Peter May**<sup>15</sup>, General Manager of Food Standards Australia New Zealand presented Australia's experience in the use of HACCP in a risk-based food safety management system. Following an outbreak of *enterohaemorrhagic* E. coli O11 in 1995, in a particular food brand, the development of national food standards for food businesses was prioritized and particular focus was placed on having a preventative and coordinated approach in food safety risk management. The development of three standards for food businesses<sup>16</sup>, on the basis of assessment advice to implement a HACCP approach, was described as central to this approach. However, the broad implementation of the food safety programme by food businesses proved to be challenging, given the associated costs and practicality for the industry. In addition, enforcement agencies required a policy framework to support their application. In explaining this issue, Mr May provided an overview of the structure and decision-making roles within the risk management framework for Australia.

4.26. Four high risk sectors were identified for the mandatory introduction of the food safety programme. However, it became apparent that the requirement for a food safety programme, even for higher risk sectors, was not the right tool for all businesses as they could not fully implement HACCP and this further underscored the need for a tailored approach. In this regard, Mr May explained Australia's current approach of using a food safety risk priority classification framework which allows food business sectors to be classified, so that risk management regimes are assigned in proportion to the risk, taking into account the nature and capacity of the business. In this way, HACCP was used as a risk based tool in food safety management.

4.27. In concluding, Mr May outlined that this experience demonstrated an example of risk management responding to the economic and political drivers of small business. Mr May further emphasized that risk management has to be flexible and that while risk assessment can sometimes give a clear outcome, a range of other considerations may need to be taken into consideration, such as the capacity of food businesses to implement the standards, which may depend on the scale and maturity of the business.

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<sup>15</sup> Speaker's presentation and summary are available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part2\\_PPT\\_Peter\\_MAY.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part2_PPT_Peter_MAY.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session2\\_Part2\\_Summary\\_Peter\\_MAY.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session2_Part2_Summary_Peter_MAY.pdf).

<sup>16</sup> Standard 3.2.1: Food Safety programs, Standard 3.2.2: Food Safety Practices and General Requirements, and Standard 3.2.3: Food Premises and Equipment.



#### 4.4 INTERNATIONAL STANDARDS AND GUIDELINES FOR PERFORMING RISK ANALYSIS (Session 3)<sup>17</sup>

4.28. In **Session 3**, the IPPC and the WHO on behalf of Codex presented on the procedures and guidelines used by those bodies in performing risk analysis.<sup>18</sup> Presenters highlighted changes in the relevant procedures and guidelines since 2000 and outlined the efforts to strengthen international standards and to overcome gaps. In addition, several challenges were highlighted, as well as the lessons learnt in the process of ensuring that guidelines are understood and followed by Members.

4.29. **Dr Philippe Verger**<sup>19</sup> from the Food Safety and Zoonoses Department of the WHO provided an overview of the three components of the risk analysis paradigm within the Codex system, highlighting the role of FAO, WHO, the Codex Alimentarius Commission and member States in the process. Dr Verger explained that historically, Codex had always been implementing risk analysis since its creation in the early 1960s. Subsequently, the SPS Agreement was established, including specific provisions on risk assessment and determination of the appropriate level of SPS protection. Dr Verger further highlighted that according to the Agreement, risk assessments are to take into account the techniques developed by relevant international organizations.

4.30. Dr Verger outlined the various ways that risk analysis has been integrated into the Codex process, highlighting new Codex documents that have been published since the risk analysis workshop in 2000.<sup>20</sup> In addition, specific documents on risk analysis principles or policies have been prepared in recent years by Codex Committees dealing with food additives and contaminants, residues of veterinary drugs in foods, pesticide residues, nutrition and hygiene. Dr Verger also drew attention to the 2007 Codex publication on "*Working Principles for Risk Analysis for Food Safety for Application by Governments*".<sup>21</sup>

4.31. Dr Verger outlined the trends in risk analysis, highlighting that in risk management, the focus has been on improving problem formulation, identifying how the advice is to be used and indicating the significance and urgency of the work, among others. In terms of risk assessment, Dr Verger identified the increased focus in several areas, such as ensuring that the best science is available, seeking independent advice, ensuring transparency in the assessment and comparing various options. Dr Verger further explained that the issue of precaution is an inherent element of risk analysis and emphasized that the degree of uncertainty and variability in the available scientific information should be explicitly considered and described in the risk assessment and risk management options. Other legitimate factors were presented; however, Dr Verger indicated that the advice of Codex is that these factors should not affect the scientific basis of the risk analysis.

4.32. Several benefits of risk analysis within the Codex framework were underscored, such as the focus on issues of international concern, the use of globally applicable information and tools, and the identification of areas where knowledge and data are lacking. Several challenges were also outlined in relation to identifying priorities at the international level, defining the possible scope of work and use to be given to results and harmonizing risk assessment methodologies based on the Codex principles, among others.

4.33. **Ms Ana Peralta**<sup>22</sup>, IPPC Capacity Building Officer reminded participants that the text of the IPPC had been revised in 1997 to incorporate the principles of the SPS Agreement. Ms Peralta highlighted that pest risk analysis (PRA) was more than a process; it was also a principle. She provided background on the development of the first ISPM '*Phytosanitary Principles for the Protection of Plants and the Application of Phytosanitary Measures in International Trade*' (ISPM No. 1) and its subsequent revision in 2006. Ms Peralta explained that since 2006, PRA had

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<sup>17</sup> The audio recording of Session 3 is available at:

[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session3.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session3.mp3).

<sup>18</sup> The OIE was not able to be present at the workshop.

<sup>19</sup> Speaker's presentation is available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session3\\_Part1\(Codex\)\\_PPT\\_Philippe\\_VERGER.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session3_Part1(Codex)_PPT_Philippe_VERGER.pdf).

<sup>20</sup> Criteria for the consideration of "other factors" (2001) and Working principles for risk analysis for application in the framework of the Codex Alimentarius (2003).

<sup>21</sup> The document is available at: <http://www.fao.org/3/a-a1550t.pdf>.

<sup>22</sup> Speaker's presentation is available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session3\\_Part2\(IPPC\)\\_PPT\\_Ana\\_PERALTA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session3_Part2(IPPC)_PPT_Ana_PERALTA.pdf).

been quoted in many of the IPPC principles and that PRA was the basis for other key operational principles, such as setting emergency measures and modifying current phytosanitary measures.

4.34. Ms Peralta provided an overview of the key IPPC standards involved with PRA, highlighting the specific standard for PRA<sup>23</sup>, as well as other PRA-related standards such as *ISPM 11: Pest Risk Analysis for Quarantine Pests* (2013) and *ISPM No. 21: Pest Risk Analysis For Regulated Non-Quarantine Pests* (2004). Ms Peralta described the evolution of ISPM 11, explaining that several revisions had been undertaken in order to respond to new PRA-related issues, such as dealing with risks for the environment and living modified organisms. Ms Peralta indicated that several other standards in relation to establishing phytosanitary measures on the basis of PRAs were available on the IPPC website.<sup>24</sup>

4.35. The importance of follow-up activities related to the implementation of standards, once the standards have been adopted, was highlighted. In this regard, IPPC had focused on this area of work through three main initiatives: (i) the Framework for Standards Task Force which conducts standards gap analysis; (ii) the Implementation Review and Support System (IRSS); and (iii) Capacity Development Committee (CDC). Ms Peralta highlighted the results of an IRSS study which showed that 24% of contracting parties reported low implementation of the main PRA standards, while 43% reported full implementation. Some of the reasons identified were related to inadequate quarantine facilities, lack of cooperation from other contracting parties and inadequate funding. Other results from CDC's work were also presented. Ms Peralta clarified that the IPPC does not require its Members to undertake quantitative PRAs.

4.36. Ms Peralta further outlined several actions taken by the IPPC to address various gaps, some of which had been funded by the STDF. Various IPPC PRA materials were also presented, which are available through the phytosanitary training website (<http://www.phytosanitary.info/training>). These include the IPPC PRA training course<sup>25</sup>, IPPC E-Learning Course on PRA (developed in cooperation with IICA)<sup>26</sup>, PRA Awareness raising materials<sup>27</sup>, and risk analysis reports on specific pests and products.

#### 4.5 MEMBERS DISCUSS THEIR RISK MANAGEMENT EXPERIENCES (Session 4)

4.37. Several practical experiences in making risk management decisions in the animal and plant health area were presented by developed and developing country speakers in **Session 4**.

##### 4.5.1 Part 1: Developing country experience<sup>28</sup>

4.38. **Dr Mpho Maja**<sup>29</sup>, Director of Animal Health in the Department of Agriculture, Forestry and Fisheries presented South Africa's experience in determining its risk management options when faced with the risk of the introduction of Porcine Reproductive and Respiratory Syndrome (PRRS) into the country, through imports of pig and pork products. Dr Maja explained that South Africa had historically been free of the virus, a status held by only a few countries worldwide, however PRRS was first introduced into the country in April 2004. Two other introductions of the virus occurred in 2005 and 2007. On each occasion the virus was successfully eradicated at considerable expense. Following the eradication initiatives, as well as a 2009 national surveillance effort on a number of pig diseases, South Africa was able to declare itself free of PRRS and several measures were put in place to prevent its reintroduction.

<sup>23</sup> ISPM 2: Framework for Pest Risk Analysis (2007). This document is available at: [https://www.ippc.int/static/media/files/publications/en/1323944382\\_ISPM\\_02\\_2007\\_En\\_2011-12-01\\_Refor.pdf](https://www.ippc.int/static/media/files/publications/en/1323944382_ISPM_02_2007_En_2011-12-01_Refor.pdf).

<sup>24</sup> All IPPC adopted standards are available at: <https://www.ippc.int/core-activities/standards-setting/ispms>.

<sup>25</sup> <http://www.phytosanitary.info/information/ippc-pest-risk-analysis-training-course>.

<sup>26</sup> <http://elearning.phytosanitary.info/>.

<sup>27</sup> <http://www.phytosanitary.info/prs>.

<sup>28</sup> The audio recording of Session 4 (Part 1) is available at: [https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session4.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session4.mp3).

<sup>29</sup> Speaker's presentation and summary are available at: [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part1\\_PPT\\_Mpho\\_MAJA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part1_PPT_Mpho_MAJA.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part1\\_Summary\\_Mpho\\_MAJA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part1_Summary_Mpho_MAJA.pdf).



4.39. Dr Maja highlighted that although the OIE does not have PRRS guidelines on the trade of pigs and products, South Africa's import requirements for live pigs and pig semen were stringent enough to mitigate the risk of introducing PRRS through trade in these products. However, import requirements for pork products were considered to be weak and findings from the investigation of the outbreak indicated that the use of legally imported swill as feed was the likely source of the outbreak. A review of existing risk assessments on PRRS which had been conducted by Australia and New Zealand, as well as the 2005 EFSA Scientific Opinion<sup>30</sup>, was subsequently undertaken. In particular, Dr Maja highlighted that the EFSA report concluded that "*infectious PRRS virus in fresh pig meat may constitute a hazard when exported from a country or region with PRRS to a country with a naive pig population*".<sup>31</sup> In this regard, South Africa had a completely naive population as it did not vaccinate against the virus, due to the absence of the disease in the country. Extensive information was provided on the EFSA findings including the possible avenues for infection and introduction of the virus, such as through swill feeding. Dr Maja explained that although swill feeding was prohibited in South Africa, there remained a high likelihood that scraps of pork would be ingested by pigs. With imports of over 40 tons of pork annually, the possibility of importing infected pork into South Africa was considered to be unacceptably high.

4.40. In considering the risk management options, Dr Maja highlighted that the safest measure would have been to prohibit all imports of raw pork, whether fresh or frozen, from all infected PRRS countries and only allow imports from PRRS-free countries. However, this would have been the most trade restrictive option, negatively affecting trade. In addition, this option would prove challenging as only a few trading partners could prove PRRS freedom. In order to allow consumers to continue to have a wide choice of safe pork products, as well as minimize the impact on trade, a balance was sought between the necessary risk mitigation actions and the risk associated with the products. In this regard, three alternatives were identified: (i) to import processed products – where the virus had been deactivated through processing; (ii) to import consumer ready cuts – products which required no further handling; or (iii) to import products for further processing in the country, post arrival, to make them safe.

4.41. In implementing these options, challenges had included the necessary changes required by the industry, consumers and trading partners, as well as inspection at the port of entry, within the context of limited resources. Lessons learnt included that risk management differs based on the circumstances and that a number of factors needed to be considered to ensure its practicality. In addition, the importance of ensuring that there are sufficient resources to check compliance was identified, as well as considerations related to the financial impact on the regulator and on trade.

4.42. **Mr Kenrick Witty**<sup>32</sup>, Plant Health Officer in the Plant Health Department of the Belize Agricultural Health Authority (BAHA)<sup>33</sup> focused on the risk management decision taken in relation to the importation of coconut seedlings and ungerminated coconut seed nuts from Mexico. Mr Witty highlighted that following an increased interest in coconut cultivation for the production of coconut water and coconut oil, both for the export and local market, investors were prompted to seek imported planting materials due to a shortage of local planting materials.

4.43. In one specific example, a request was submitted by an importer to import coconut seedlings from Mexico, in order to establish a coconut plantation in Belize for the purpose of exporting coconuts. A pest risk assessment (PRA) revealed the presence of fifteen pests of quarantine concern for Belize, most notably the red palm mite. This pest was of major concern due to its effects on several species of palms, including coconut palms, which were identified as important plant families in Belize. In addition, the red palm mite presented a threat to Belize's thriving banana production, one of the most important industries along with citrus and sugar. Based on the findings of the PRA, as well as taking into consideration that the planting material was needed to grow the fledgling coconut industry, the importer was given several options under which the material could be imported into Belize, instead of prohibiting importation.

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<sup>30</sup> The EFSA Journal (2005) 239, 1-85. *Scientific opinion on the probability of transmission of Porcine Reproductive and Respiratory Syndrome virus (PRRSv) to naive pigs via fresh meat*. Available online at: <http://www.efsa.europa.eu/en/efsajournal/doc/239.pdf>.

<sup>31</sup> *Ibid.* Specific quote referenced from page 41 of the document.

<sup>32</sup> Speaker's presentation and summary are available at: [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part1\\_PPT\\_Kenrick\\_WITTY.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part1_PPT_Kenrick_WITTY.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part1\\_Summary\\_Kenrick\\_WITTY.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part1_Summary_Kenrick_WITTY.pdf).

<sup>33</sup> The Belize Agriculture Health Authority is the national plant protection organization (NPPO).

4.44. One of the options included stringent requirements for the importation of coconut seedlings, as it posed a higher risk due to the presence of foliage. However, the importer was unable to meet these risk management measures. Instead, the importer was able to comply with the less stringent risk management measures for the ungerminated coconut seed, which posed a lesser risk due to the absence of foliage. BAHA also facilitated the importation of these products under an importation protocol. Mr Witty indicated that the planting material was subsequently imported into Belize and was currently being grown, while being monitored by the Plant Health Department.

4.45. Some of the main challenges from this experience included the actual undertaking of the PRA and gathering the necessary information for the assessment, especially as it related to information on pests. Mr Witty also emphasized the need for a dedicated PRA unit staffed with additional personnel. The importance of conducting PRAs in order to assess the extent of the risks and to justify the appropriate level of protection was also highlighted. In addition, Mr Witty underscored the importance of communication with the relevant parties throughout the process, in order to ensure that all stakeholders understood their role and the potential impact on the agricultural sector.

#### 4.5.2 Part 2: Developed country perspective<sup>34</sup>

4.46. **Dr Frans Verstraete**<sup>35</sup> from the European Commission, Directorate General for Health and Consumers outlined the approach taken in the risk management of contaminants in feed and food in the European Union, based on a risk analysis policy. Dr Verstraete identified some general principles related to the EU regulations on contaminants in feed and food, highlighting a fundamental principle which is that contaminant levels shall be kept as low as can be reasonably achieved by following good practice at all stages of the production chain.

4.47. Dr Verstraete explained that in order to achieve the general objective of the protection of animal and human health, the EU feed/food legislation is based on risk analysis. Risk management also takes into account the results of risk assessment and other factors legitimate to the matter under consideration and the precautionary principle, where appropriate. Maximum levels for specific contaminants are established where necessary and the consultation of a scientific body (EFSA) for all provisions which may have an effect upon animal and public health is mandatory.

4.48. Dr Verstraete highlighted that "prevention is better than cure" in relation to reducing the presence of contamination in the feed and food supply. He emphasized the importance of encouraging preventive actions such as good agricultural practices, good manufacturing practices, good storage conditions, and use of improved sorting procedures. Dr Verstraete indicated that maximum levels are established at a reasonably achievable level, stimulating feed and food business operators to apply preventive actions all along the feed and food chain in order to avoid contamination. In addition to setting maximum levels, various other risk management regulatory tools are applied at the EU level to prevent and/or reduce the contaminant levels in feed.

4.49. Three case studies illustrated how the abovementioned principles and tools have been applied in practice. The first case study focused on citrinin in food, the second on the regulation of certain mycotoxins in food, and the third on acrylamide in food.

4.50. **Dr Kerry Dearfield**<sup>36</sup>, Chief Scientist of the Food Safety & Inspection Service (FSIS), Department of Agriculture, Office of Public Health Service of the United States provided an overview of risk management from the perspective of the United States. He outlined the role of FSIS in ensuring that the commercial supply of meat, poultry, and egg products is safe, and the associated regulatory statutes. In emphasizing the science-based nature of the SPS Agreement as

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<sup>34</sup> The audio recording of Session 4 (Part 2) is available at:  
[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session4p2.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session4p2.mp3).

<sup>35</sup> Speaker's presentation and summary are available at:  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part2\\_PPT\\_Frans\\_VERSTRAETE.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part2_PPT_Frans_VERSTRAETE.pdf)  
and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part2\\_Summary\\_Frans\\_VERSTRAETE.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part2_Summary_Frans_VERSTRAETE.pdf).

<sup>36</sup> Speaker's presentation and summary are available at:  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part2\\_PPT\\_Kerry\\_DEARFIELD.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part2_PPT_Kerry_DEARFIELD.pdf) and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session4\\_Part2\\_Summary\\_Kerry\\_DEARFIELD.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session4_Part2_Summary_Kerry_DEARFIELD.pdf).

enshrined in Article 2.2, Dr Dearfield underscored the obligation for risk assessments to be based on science and highlighted the science-based approach taken by FSIS in its risk management decisions.

4.51. The risk assessment paradigm was presented, highlighting the importance of planning and scoping, in order to ensure that the risk assessment is successful and that the required information is obtained to make the necessary management decisions. Dr Dearfield emphasized the importance of risk assessments being aligned with risk management needs and that the best risk assessment is the one that "is fit for purpose", whether quantitative or qualitative, and the one that most directly informs the risk management issue. He also made reference to a publication by USDA/FSIS and the US Environmental Protection Agency on Microbial Risk Assessment Guideline.<sup>37</sup>

4.52. Dr Dearfield explained the FSIS decision-making framework, highlighting that while other factors are considered, the decision-making process is mainly informed by the risk assessment. Several important risk management considerations included having well defined risk management questions and understanding that risk assessments are not a "one size fits all". In addition, Dr Dearfield highlighted that the complexity of the risk assessment depends on the purpose for developing the risk assessment and that risk assessors and risk managers are independent, but interdependent.

4.53. Several options are available to risk managers once the risk assessment has been undertaken, such as: setting a regulatory level (e.g. MRLs); using international guidelines to establish national guidance; providing dietary advice; instituting mitigation strategies; and providing education and training opportunities. Two practical examples highlighted how risk assessments are used in setting regulatory levels and requirements. The first example dealt with a chemical-related issue of setting pesticide tolerances and the other dealt with a microbial-related issue dealing with the risk of Salmonella and Campylobacter in poultry.

#### 4.6 EXPERIENCE OF INTERNATIONAL AND REGIONAL ORGANIZATIONS (Session 5)<sup>38</sup>

4.54. In this session, the International Livestock Research Institute (ILRI) and the Inter-American Institute for Cooperation on Agriculture (IICA) presented information on research and capacity-building being undertaken in Africa and in the Americas respectively, as well as the tools available to assist in the risk analysis area.

4.55. **Dr Delia Grace**<sup>39</sup> from ILRI provided information from an international and research perspective on some of ILRI's experiences in risk assessment and management which has mainly been undertaken in Africa and Asia. ILRI's work has centred on two main areas: (i) capacity-building for risk analysis; and (ii) conducting risk assessments and piloting risk management options. Dr Grace highlighted the benefits of risk-based approaches, underscoring its emphasis on evidence and science, as well as its acceptability to most stakeholders. In this regard, ILRI has seen a large adoption of risk-based approaches in beneficiary countries, which complements the risk-based approach embodied in the SPS Agreement and international trade standards. However, Dr Grace pointed out that there has been little uptake and understanding at the level of implementation and especially at the level of the domestic market, where most of the food is traded. She highlighted several challenges in this regard, such as the need for change in attitudes and the lack of a clear distinction between risk and hazard, among others.

4.56. ILRI's experience in risk assessment has been two-fold: (i) assessing trade in livestock and livestock products, and (ii) assessing the risk of food in domestic markets. Dr Grace used the example of a risk assessment undertaken by ILRI in Ethiopia, at the request of the government, to highlight that the export of livestock and livestock products is less important to developing countries than originally thought and that SPS issues are not a major barrier. These findings, as

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<sup>37</sup> Document available at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments/microbial-risk-assessment-guideline/microbial-risk-assessment-guideline>.

<sup>38</sup> The audio recording of Session 5 is available at: [https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session5.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session5.mp3).

<sup>39</sup> Speaker's presentation and summary are available at: [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session5\\_Part1\\_PPT\\_Delia\\_GRACE.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session5_Part1_PPT_Delia_GRACE.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session5\\_Part1\\_Summary\\_Delia\\_GRACE.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session5_Part1_Summary_Delia_GRACE.pdf).

well as similar results from other research, have shifted ILRI's work away from the OIE import and export risk analysis towards food safety in domestic markets. In this regard, Dr Grace highlighted the participatory risk analysis approach used by ILRI for understanding and managing food safety in domestic markets. Several challenges were identified in the risk assessment process, such as huge information gaps and dealing with inadequate data.

4.57. Statistics were provided to highlight the major role of smallholder farmers in supplying food markets in developing countries. Dr Grace observed that the research showed that in most cases imported food was safer than locally produced food in the countries reviewed. In addition, informal markets played a huge role in food security and safety, and as such managing food safety in this context required tailored and targeted actions. Other findings from the studies showed that inappropriate regulation was associated with worse practices as it tended to push producers to cut corners and that compliance in the formal sector was often worse than in the informal sector.

4.58. **Dr Robert Ahern**<sup>40</sup> from the Inter-American Institute for Cooperation on Agriculture (IICA) provided information on regional initiatives related to risk analysis in the Americas. Dr Ahern outlined several risk analysis capacity assessment tools that have been developed by IICA, starting with the Common Vision, Evaluation and Action (CVEA) Tool in 2003. This tool was modified and further developed into the Performance, Vision and Strategy (PVS) Tools for: National Veterinary Services (OIE-IICA, 2004), National Plant Protection Organizations (2005); and National Food Safety Services (IICA-PAHO, 2005). Dr Ahern highlighted that in addition to assessing the three components of performance, vision and strategy, the tools also examined the interaction between the public sector and private sector, as well as assessed human and financial capital in order for countries to establish their capacity needs. The PVS tools have been widely applied in various countries.

4.59. Dr Ahern outlined that these tools assisted in the identification of gaps, allowing IICA to develop general and specific training courses to address the needs identified during PVS assessments. Some of these courses include: chemical and microbiological hazard risk assessment in food safety; risk assessment of animal diseases; online and on-site courses on risk communication; and updating and conducting an online course in pest risk analysis, in collaboration with IPPC.

4.60. Application of these tools has also helped to identify specific challenges related to capacity, compliance, funding, relevance, and sustainability of risk analysis units within the Americas. In addition, various opportunities were identified such as capacity building, especially through partnerships with academia, the private sector and institutions like the STDF. Dr Ahern also provided information on several STDF projects within the region and on IICA's collaborative work with Codex, IPPC and OIE to build technical capacity across the Americas. He also highlighted opportunities related to sustainability and funding; in particular, a SPS capacity-building project being financed through the 10<sup>th</sup> European Development Fund.

#### 4.7 LEVERAGING RESOURCES FOR RISK ASSESSMENTS – WAYS TO ADDRESS RESOURCE CONSTRAINTS (Session 6)<sup>41</sup>

4.61. The issue of resource constraints and finding resources to undertake risk assessments was covered in **Session 6** with some useful examples and suggestions on how to leverage resources for risk assessments, as well as experiences in using new ways to meet the WTO obligation in relation to risk assessment, such as the use of risk assessments drafted by parties other than the importing Member.

4.62. **Mr Sidney Suma**<sup>42</sup>, STDF developing country expert and consultant from Papua New Guinea, highlighted the resource constraints faced by Papua New Guinea, as well as by other

<sup>40</sup> Speaker's presentation and summary are available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session5\\_Part2\\_PPT\\_Robert\\_AHERN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session5_Part2_PPT_Robert_AHERN.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session5\\_Part2\\_Summary\\_Robert\\_AHERN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session5_Part2_Summary_Robert_AHERN.pdf).

<sup>41</sup> The audio recording of Session 6 is available at:

[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session6.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session6.mp3).

<sup>42</sup> Speaker's presentation and summary are available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session6\\_PPT\\_Sidney\\_SUMA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session6_PPT_Sidney_SUMA.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session6\\_Summary\\_Sidney\\_SUMA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session6_Summary_Sidney_SUMA.pdf).

Pacific Island Countries<sup>43</sup> in performing risk assessments. The main types of resource constraints associated with risk assessments were linked to: (i) funding; (ii) technical capacity, including availability of human resources; (iii) facilities, including access to utilities e.g. electricity, internet; and (iv) access to information.

4.63. Mr Suma provided several examples of the ways in which financial resources have been leveraged for risk assessments, such as through the implementation of cost recovery or the user-pay policy for risk assessments, as well as through donor funding. In order to address technical limitations, several approaches have been used, including the review of market access applications, which provides compiled information upfront through the submitted dossiers, thereby facilitating the risk assessment. In addition, PRA programmes and training opportunities under bilateral, regional or international projects were important in addressing technical constraints, as well as the use of PRA models developed by other technical bodies and the use of technical expertise from various sectors.

4.64. In relation to information resources, Mr Suma indicated that the use of risk assessment reports conducted by third parties as well as information made available through membership in professional societies or other technical sharing and information exchange networks was important. Mr Suma also emphasized the importance of information generated from regional projects and surveillance activities, particularly the work done by the Secretariat of the Pacific Community.

4.65. In examining the challenges, Mr Suma underscored the need for policy and regulatory support, especially where current laws do not support or do not provide a mechanism for third party risk assessments. Other challenges included the lack of inter-agency co-operation, limited consultation and participation of stakeholders, as well as inadequately documented procedures. In concluding, Mr Suma indicated that any form of risk assessment was better than none at all. Other lessons learnt included the importance of having prior approval or permission from the competent authority before undertaking or considering third party risk assessments and the value of using training opportunities to undertake real risk assessments.

4.66. **Mr Guilherme da Costa**<sup>44</sup>, Food Safety Expert in the Department of Sanitary and Phytosanitary Negotiations, Ministry of Agriculture, shared Brazil's experience in leveraging resources for risk assessment using the case of coffee. Mr da Costa provided an overview of the economic importance of coffee production in Brazil, highlighting Japan among its main importers. The issue related to the use of flutriafol, a fungicide used in cereal crops, and its associated MRL.

4.67. In 2009, Brazil had requested Japan to increase the import tolerance of flutriafol residue in coffee beans from 0.01 mg/kg to 0.05 mg/kg. Mr da Costa noted that no limits had been established by Codex at that time. However, several problems were experienced in some shipments to Japan as flutriafol residue was then detected at levels above 0.01 mg/kg. Mr da Costa highlighted that in 2009 and 2010 the private sector had undertaken several studies on the toxicology of flutriafol. In addition, Brazil had requested Japan to consider data produced by the European Union in 2011, indicating its amendment of MRL for flutriafol from 0.01 mg/kg to 0.05 mg/kg on the basis of EFSA findings. In 2012, Codex established the MRL for flutriafol in coffee beans at 0.15 mg/kg.

4.68. Mr da Costa highlighted that on the basis of several bilateral consultations and consideration of existing research, Japan consequently reviewed its maximum residue level and set it at 0.2 mg/kg. In concluding, Mr da Costa underscored some lessons learnt such as the importance of using studies undertaken by the private sector and other trading partners, as well as the work of JMPR. In addition, he highlighted the cooperation of Japan in the bilateral negotiations as a key factor, as well as the flexibility shown, as evidenced by the trade facilitating measure which was implemented.

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<sup>43</sup> Fiji, Samoa, Solomon Islands, Tonga and Vanuatu.

<sup>44</sup> Speaker's presentation and summary are available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session6\\_PPT\\_Guilherme\\_COSTA\\_JUNIOR.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session6_PPT_Guilherme_COSTA_JUNIOR.pdf)  
and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session6\\_Summary\\_Guilherme\\_COSTA\\_JUNIOR.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session6_Summary_Guilherme_COSTA_JUNIOR.pdf).



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#### 4.8 MEMBERS' DISCUSS THEIR RISK COMMUNICATION EXPERIENCES (Session 7)<sup>45</sup>

4.69. The challenges of communicating risk to various stakeholders were discussed in **Session 7**, where practical experiences highlighted the importance of targeting specific messages to various stakeholders, the timing of these messages, how to communicate uncertainty and the use of new communication tools, such as smartphone applications in disseminating information.

##### 4.8.1 Part 1: Internal Risk Communication

4.70. **Dr Mpho Maja**<sup>46</sup> from the Department of Agriculture, Forestry and Fisheries (DAFF) presented the South African experience in risk communication, focusing on animal health and animal disease-related issues. Dr Maja first provided an overview of South Africa's federal system, highlighting the SPS-related roles of the central competent authority (DAFF), as well as the nine provinces and related border control agencies. Dr Maja also highlighted the various monitoring efforts that South Africa had undertaken since it started trading in 1994, in order to prevent the introduction of animal health diseases and to ensure early detection and containment.

4.71. Dr Maja indicated that internal risk communication within South Africa was fairly easy at the central level, but highlighted some challenges in coordinating responses at the provincial level. This, however, was mitigated through regular structured engagements between risk assessors and risk managers at the provincial and national level. In providing an overview of South Africa's communication strategy, Dr Maja highlighted the various factors which impact the nature of its strategy, such as the type of risk, its source (whether of international and/or local origin) and the potential impact on the producer. The relevant communication procedures were explained in the case of diseases of an emergency nature. Specific reference was made to the OIE notification requirements and the internal processes to coordinate the submission of reports as well as informing relevant political authorities.

4.72. Dr Maja also explained the strategy used in cases where the identified risk emanated from outside the borders of the country, as well as risk arising internally. Key steps were further outlined to explain how the procedure works in practice. Key challenges included coordination issues, as well as differences in interests at the provincial and central level due to the difficulty in implementing strict measures to manage risk, as a result of local official's sense of loyalty to animal owners.

##### 4.8.2 Part 2: Translating risk assessment and risk management into communication messages

4.73. **Dr Antoon Opperhuizen**<sup>47</sup>, Director of the Office of Risk Assessment and Research of the Netherlands Food and Consumer Product Safety Authority (NVWA) presented new approaches to risk communication. Dr Opperhuizen explained the NVWA approach to understanding risk as being composed of 2 dimensions: the effect of the risk and the chance or probability that the effect will occur. While communication to the public is normally concerned about what will happen (i.e. effect), risk managers are normally concerned about limiting the chance of occurrence, so that the risk is limited.

4.74. The evolution of risk communication was outlined, highlighting that its initial goal was to educate the public, which then shifted to persuading the public and subsequently to engaging the public in a two-way communication. Experts were key to all of these stages in their main role of imparting knowledge to the public. However, the classical principles of good communication, such as openness, transparency, independence and responsiveness/timeliness were not very effective in

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<sup>45</sup> The audio recording of Session 7 is available at:

[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session7.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session7.mp3).

<sup>46</sup> Speaker's presentation and summary are available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session7\\_Part1\\_PPT\\_Mpho\\_MAJA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part1_PPT_Mpho_MAJA.pdf) and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session7\\_Part1\\_Summary\\_Mpho\\_MAJA.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part1_Summary_Mpho_MAJA.pdf).

<sup>47</sup> Speaker's presentation and summary are available at:

[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session7\\_Part2\\_PPT\\_Antoon\\_OPPERHUIZEN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part2_PPT_Antoon_OPPERHUIZEN.pdf)  
and  
[https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session7\\_Part2\\_Summary\\_Antoon\\_OPPERHUIZEN.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part2_Summary_Antoon_OPPERHUIZEN.pdf)



communicating risk. As such, Dr Opperhuizen underscored that future risk communication should focus on engaging other networks of stakeholders, in addition to the general public. This should be done in a cooperative manner where experts and non-experts contribute to what people want or need to know, using both cognitive and affective interaction. This was the approach currently being used in the Netherlands.

4.75. Dr Opperhuizen explained the role of perception in risk communication and how it can be influenced by disseminating information through various communication strategies. An example was provided on how to select risk communication strategies appropriate to different scenarios, using the subject of pesticides and marine biotoxins. Dr Opperhuizen explained that the public generally regards pesticides as a major risk, while experts see this as having minor importance for public health. However, the general population does not recognize marine biotoxins as a threat, while experts indicate this as an area for concern. In the case of pesticides, informing the public of the reality of the threat might be the main focus, incorporating mild risk communication strategies, whereas for marine toxins, awareness-raising might be a better alternative. Dr Opperhuizen presented an example of an awareness-raising campaign in the Netherlands in relation to the Ambrosia plant, which on contact, produces general discomfort. In particular, the Ambrosia Smartphone Application<sup>48</sup> was developed to help in identifying the plant and to report sightings of Ambrosia. This assisted in creating awareness about the plant and enabled authorities to have a better picture of the spread of Ambrosia in the Netherlands. In effect, this application was used both as an information and monitoring tool.

4.76. In concluding, Dr Opperhuizen outlined that different communication strategies can be used depending on the issue at hand, the target group and the type of risk. An awareness-raising strategy should focus on a target group where cognitive messages are used to educate, persuade, engage and stimulate emotions, but also incorporating the use of social media tools. Dr Opperhuizen underscored that this strategy required a great deal of work. On the other hand, trust-raising is suited to more formal ways of communicating. Dr Opperhuizen emphasized that these strategies should not be mixed, as when the communication strategy stimulates emotions, there is no longer control of the message along the network of risk communication stakeholders.

#### 4.8.3 Part 3: Targeting communication messages

4.77. **Mr Guilherme da Costa**<sup>49</sup>, Food Safety Expert from Brazil's Department of Sanitary and Phytosanitary Negotiations, Ministry of Agriculture, Livestock and Food Supply presented Brazil's experience in targeting risk communication messages. Mr da Costa used the example of an outbreak of Bovine Spongiform Encephalopathy (BSE) in Brazil in 2012, to highlight the steps used to tailor communication messages to a broad range of stakeholders, consumers and trading partners.

4.78. Mr da Costa provided an overview of the details surrounding the BSE outbreak in a native cow in Brazil, highlighting that based on the specifics of the case, the animal did not represent any risk of contamination to the food or feed chain. One of the key elements of Brazil's risk communication strategy was the establishment of a Crisis Office to handle the issue, which included the coordination of all risk communication actions at a national and international level. The Crisis Office, which encompassed various Ministries and SPS-related authorities, worked with the media in order to provide targeted and appropriate information to consumers. In addition, technical notes on the situation were provided to international organizations like the OIE.

4.79. Mr da Costa highlighted several other avenues which were targeted for the circulation of information, such as through the SPS Committee, where Brazil communicated the final report of the BSE case (G/SPS/GEN/1232) in June 2013. Various bilateral meetings were also held with trading partners and in addition, a plurilateral meeting was organized in Geneva at Brazil's Permanent Mission with various trading partners, SPS Secretariat and SPS Chairperson.

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<sup>48</sup> Ambrosia Smartphone Application is a free downloadable application at: <https://itunes.apple.com/nl/app/ambrosia-melder/id545430441?mt=8>

<sup>49</sup> Speaker's presentation and summary are available at: [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session7\\_Part3\\_PPT\\_Guilherme\\_COSTA\\_JUNIO\\_R.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part3_PPT_Guilherme_COSTA_JUNIO_R.pdf) and [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct14\\_e/Session7\\_Part3\\_Summary\\_Guilherme\\_COSTA\\_JUNIOR.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop_oct14_e/Session7_Part3_Summary_Guilherme_COSTA_JUNIOR.pdf).

4.80. Mr da Costa concluded that risk communication was key to addressing potential misunderstandings, deterring trade barriers, as well as keeping consumers and trading partners informed of the steps being taken to address the situation. In this regard, he highlighted that Brazil had around 142 beef export markets and that sanitary measures were established by only 17 countries. Furthermore, there was no decrease in national beef demand and Brazil also maintained its OIE status as negligible risk country for BSE.

#### 4.9 OUTCOMES AND NEXT STEPS (Session 8)<sup>50</sup>

4.81. In summarizing the key outcomes of the various workshop sessions in **Session 8**, speakers highlighted the rapidly evolving nature of the risk analysis area, indicating that while significant progress had been made, there still remained some challenges. In addition, a wide ranging discussion focused on several aspects of risk analysis in the SPS area, including a few suggestions for follow-up steps.

4.82. **Dr Amelia Tejada** outlined the increasing concern and need for food safety risk analysis in developing countries, in order to reduce hazards from food. In summarizing the outcomes of the discussion, Dr Tejada provided an overview of several key points raised during the various presentations. In addition, Dr Tejada recalled some of the risk management options outlined by various speakers, such as: establishing regulatory requirements/levels based on MRLs; utilizing international guidelines to establish national guidance; instituting mitigation strategies; providing education and training opportunities; establishing research needs; and pursuing data gaps. Dr Tejada concluded by underscoring two points made by previous speakers, that prevention is better than cure and that the decision-making framework should take into account several factors, key among which is science.

4.83. **Mr Robert Griffin** observed that risk analysis has an important role in the SPS Agreement, highlighting that risk analysis within the context of the SPS Agreement is specific and not transferrable from any other discipline. In this regard, the distinction between risk assessments for food safety risks and animal/plant health risks was emphasized. Mr Griffin further indicated that although there had been an evolution since the first workshop in 2000, there was still room for additional growth as identified by the various challenges and possibilities presented by several speakers. The use of case studies was highlighted as providing an excellent learning opportunity and the suggestion was made for this approach to be incorporated in future workshops. Mr Griffin underscored the need to share and discuss the work being done by academia and emphasized that the academic community had started to look at the work being done by the SPS Committee. Mr Griffin suggested that opportunities should be created to analyse the findings from SPS-related disputes in order to further disseminate information on these legal interpretations. In conclusion, Mr Griffin underscored the importance of sharing experiences in order to promote the evolution of risk analysis and the SPS Agreement.

4.84. Ensuing discussions in the workshop focused on a range of risk analysis-related themes and suggestions which are presented below.

##### 4.9.1 Separation of risk assessment and risk management roles

4.85. Discussions focused on the factors to consider in deciding whether a country should maintain risk assessment and risk management functions within the same institution. Various speakers indicated that the main issue was not whether risk assessment and risk management should be in the same or different institutions, but instead to ensure that the risk assessment was done independently from the risk management. As such, emphasis was placed on separating the functions and not necessarily the institutions. The importance of communication and interdependence between risk managers and risk assessors was also highlighted, while underscoring the need to ensure that the risk manager was not able to influence the outcome of the risk assessment.

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<sup>50</sup> The audio recording of Session 8 is available at:  
[https://www.wto.org/audio/2014\\_10\\_13\\_spsworkshop\\_session8.mp3](https://www.wto.org/audio/2014_10_13_spsworkshop_session8.mp3).

#### 4.9.2 Availability of risk assessments and resource constraints

4.86. The availability of risk assessments was another issue discussed, especially since Members do not need to undertake their own risk assessments as a basis for their SPS measures, but can rely on existing risk assessments. In particular, the query was raised whether the SPS Committee can develop guidance in order to advance access to risk assessments. In response, the Secretariat highlighted Members' obligation to establish an Enquiry Point responsible for responding to queries, which also included the provision of information on risk assessment procedures, the associated factors taken into consideration, as well as the determination of the ALOP. The Secretariat also reminded participants that in the past, the SPS Committee had decided to encourage Members to share information on relevant websites and sources of information regarding national measures, and suggested that perhaps Members should also be encouraged to share risk assessment outcomes. While acknowledging that some of this information was already available, the Secretariat also recognized that there probably existed information on risk assessments which was not being shared, both on those undertaken by developed countries, as well as by developing countries. Several speakers provided examples of how risk assessments, technical assessment advice and decisions have been shared either through existing websites or publications.

4.87. Resource difficulties in carrying out risk analysis were also highlighted and the suggestion was made that Members should provide the necessary resources to carry out the required risk assessments in a timely manner.

4.88. Intellectual property issues associated with the use of scientific literature in the risk analysis process were further identified as a challenge. Speakers highlighted the legal constraints in sharing confidential information with trading partners, highlighting that applicants are not always keen on information being shared across jurisdictions. The institutional approach in the United States was indicated as being transparent, both in terms of the approach, guidelines and the tools that are used, as emphasis was placed on ensuring that any tools or guidance that are used in the process are freely available online.

4.89. The suggestion was made that the Secretariat, in light of developing countries' difficulties in accessing information, establish a system to allow access to SPS-related information, similar to a process used for health-related information by the WHO. In response, the Secretariat indicated that it would be unlikely that Members would agree to finance such a system solely for the SPS area and that if the WTO were to create such a virtual library, it would more than likely be created more generally on trade and trade agreements, and not only on SPS.

#### 4.9.3 Risk communication

4.90. Rebuilding trust in the government in cases where consumers placed greater trust in stakeholders such as NGOs was also discussed. In this regard, Australia's experience through its stakeholder engagement policy was highlighted, where focus was placed on using social media to share information not only from the government, but also from other agencies and stakeholders working on the particular issue. This approach assisted in communicating that the message was not only coming from the government but also from various other stakeholders, including community groups. The query was also raised whether it would be possible for the Secretariat to develop an E-Learning Course on risk communication, as well as other programmes in this area. In response, the Secretariat indicated that it did not have the necessary expertise in risk communication and as such, would not be best placed to undertake this activity.

4.91. In highlighting the limited experience many developing countries had in undertaking risk assessments, a query was posed to speakers from developed countries on the common errors made in the risk assessment process. In response, insufficient risk communication and the need for more dialogue between risk assessors and risk managers during the planning and scoping phase, as well as after the completion of the risk assessment were identified. The issue of who is responsible for undertaking risk communication, whether the risk assessor or the risk manager was also raised.

#### **4.9.4 Role of Codex, IPPC and OIE in the risk analysis process**

4.92. In the discussion, the importance of the role of Codex, IPPC and OIE in developing and maintaining the techniques of risk analysis was emphasized. It was also highlighted that the Three Sisters are best placed to provide training to their members in applying those techniques and that without these standard-setting bodies, the implementation of the risk assessment provisions of the Agreement would not be possible.

#### **4.9.5 Importing Members' obligation to undertake a risk assessment**

4.93. A query was raised in relation to how to ensure the timely submission of information from exporting countries. The Secretariat clarified that the text of the SPS Agreement indicates that the importing Member has the legal obligation to ensure that a measure is based on a risk assessment. The Secretariat acknowledged that in some cases, the exporter may initially undertake a risk assessment given its commercial interest in getting the product to the other market, however, the legal obligation remained with the importer to base its measure on a risk assessment.

#### **4.9.6 Involvement of private sector in risk assessments**

4.94. The appropriateness of the involvement of the private sector in risk assessments, especially in the case where they may or may not benefit, was also discussed. In this regard, the experience of Papua New Guinea was highlighted in relation to the involvement of the private sector in the user pay policy. However, it was highlighted that difficulties were sometimes encountered as the private entities that funded the undertaking of risk assessment were not always the only entities benefitting once market access was granted.

#### **4.9.7 Addressing risks in imported vs. domestic food**

4.95. The issue of how to increase coordination between those involved in assessing the risk of products destined for export markets and the risk in relation to imports was discussed. It was highlighted that import and export risk analyses are fundamentally different, as in the case of import analysis, the judgement is made by the importing country, while for export analysis, the information is provided to the trading partner for them to make the judgement. Other speakers indicated that imported food was treated the same as food intended for export, and as such the same risk assessment and risk analysis was undertaken for both. Another speaker also highlighted that the obligation not to discriminate between food products, whether intended for exports or for domestic use, was explicitly laid down in national general food law.

#### **4.9.8 Other issues**

4.96. In order to ensure the proper implementation of Article 7 and Annex B, a recommendation was made that all Members share information on their legislation via the WTO website, in order to check compliance with the SPS Agreement and reduce the number of dispute cases. The Secretariat reminded Members of their obligation to notify their SPS measures in advance as a draft or where necessary, as emergency measures. The Secretariat further clarified that the Committee was not mandated to pass judgement on whether national measures comply or not with the SPS Agreement, highlighting that the Committee provided an avenue for discussions and not for a judgement.

4.97. In summarizing the presentations from the workshop, the Secretariat highlighted the need to ensure that another 14 years did not pass before the next workshop, especially given the rapid evolution in the risk analysis area. The Secretariat also indicated that it was clear that risk analysis was not as unfamiliar to Members, as compared with the situation in 2000, but that several challenges still persisted related to resource constraints, where to find the data, how to deal with communication and how to address the many demands.

4.98. In closing, the United States, who submitted the initial proposal for the workshop, as well as South Africa, who submitted a related proposal for consideration, expressed their satisfaction with the outcome of the workshop.

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