



**Food and Agriculture Organization
of the United Nations**

Technical summary report
**Training on Genetically Modified (GM) food safety assessment,
risk communication and advocacies programme**

23–27 July 2018
Thimphu, Bhutan



Technical summary report
**Training on Genetically Modified (GM) food safety assessment,
risk communication and advocacies programme**

23–27 July 2018
Thimphu, Bhutan

Regional Office for Asia and the Pacific
Food and Agriculture Organization of the United Nations
Bangkok, 2018

Required citation:

FAO. 2018. *Technical summary report - Training on Genetically Modified (GM) food safety assessment, risk communication and advocacies programme*. Bangkok, 26 pp. License: CC BY-NC-SA 3.0 IGO.

The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations (FAO) concerning the legal or development status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by FAO in preference to others of a similar nature that are not mentioned.

The views expressed in this information product are those of the author(s) and do not necessarily reflect the views or policies of FAO.

© FAO, 2018



Some rights reserved. This work is made available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO license (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this license, this work may be copied, redistributed and adapted for non-commercial purposes, provided that the work is appropriately cited. In any use of this work, there should be no suggestion that FAO endorses any specific organization, products or services. The use of the FAO logo is not permitted. If the work is adapted, then it must be licensed under the same or equivalent Creative Commons license. If a translation of this work is created, it must include the following disclaimer along with the required citation: "This translation was not created by the Food and Agriculture Organization of the United Nations (FAO). FAO is not responsible for the content or accuracy of this translation. The original English edition shall be the authoritative edition.

Any mediation relating to disputes arising under the license shall be conducted in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law (UNCITRAL) as at present in force.

Third-party materials. Users wishing to reuse material from this work that is attributed to a third party, such as tables, figures or images, are responsible for determining whether permission is needed for that reuse and for obtaining permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

Sales, rights and licensing. FAO information products are available on the FAO website (www.fao.org/publications) and can be purchased through publications-sales@fao.org. Requests for commercial use should be submitted via: www.fao.org/contact-us/licence-request. Queries regarding rights and licensing should be submitted to: copyright@fao.org.

Abstract

Upon the official request of the Royal Government of the Kingdom of Bhutan, a national training workshop entitled “training on genetically modified (GM) food safety assessment, risk communication and advocacies programme” was co-organized by the Bhutan Agriculture and Food Regulatory Authority (BAFRA) and the Food and Agriculture Organization of the United Nations (FAO) on 23 – 27 July 2018 in Thimphu, Bhutan. Eight-nine participants comprising members of the Bhutan Biosafety Technical Working Group (TWG), BAFRA officers and inspectors from various stations in Bhutan, relevant stakeholders, and resource people attended the workshop. The objectives of the workshop were to provide: 1) an understanding of the relevant rules and regulations concerning GMOs and GM products in Bhutan; 2) an understanding of the internationally accepted principles of GM food safety assessment, risk management and risk communication and information on challenges involved in enacting these principles; 3) an understanding of the required expertise and types of experts for undertaking GM food safety assessments so that possible shortcomings in assessment capacity/resources in Bhutan could be identified; 4) hands-on experience in extracting relevant safety information from condensed GM food case studies and presenting the information in a simple and concise way; 5) general information about biosafety and biotechnology in the international arena with particular emphasis on communication; and 6) a way forward for BAFRA to conduct any suggested follow up activities.

The training involved presentations and case studies, interspersed with facilitated discussion, to introduce participants to the concept of a GM food safety assessment and the principles underlying the communication of information on GM organisms and their products. A number of areas were identified for improvement in the areas of risk analysis around GM foods and particularly focused on expertise for safety assessment, detection strategy, and communication. It was acknowledged that lack of practice in assessing a GM food application presented a significant barrier to being able to test the rules, regulations and documents that have been developed. While some initiative needs to be taken by the local authority to address these gaps, FAO will assist for the remainder of 2018 with the development of a biosafety communication strategy document, the development of an incident management plan and the procurement of a suitable GM food dossier that could be used by the TWG for producing a practice safety assessment.

Contents

Abstract	iii
Contents	v
Acknowledgements	vi
Abbreviations and acronyms	vii
Executive Summary	viii
1. Introduction	1
1.1. Overview	1
1.2. Background.....	2
2. Highlights of the training.....	2
2.1. Day 1	2
2.2. Day 2.....	3
2.3. Day 3.....	4
2.4. Day 4.....	5
2.5. Day 5.....	6
3. Conclusions and recommendations	6
4. Evaluation	8
Annex 1. List of participants	10
Annex 2. Final workshop agenda	13

Acknowledgements

Food and Agriculture Organization of the United Nations (FAO) would like to express its appreciation to the many people who contributed to the report. This report was prepared for FAO and the development process was coordinated by Masami Takeuchi (FAO). The first draft was prepared by Janet Gorst, FAO consultant from Food Standards Australia New Zealand (FSANZ, Australia) with inputs from Jambay Dorji, Bhutan Agriculture and Food Regulatory Authority (BAFRA) and finalized with review comments and feedback received from the participants and relevant government officials of Bhutan. Overall guidance from Somsak Pipoppinyo, FAO Representative to Bhutan/Nepal and contributions from several FAO Bhutan colleagues are also herewith acknowledged.

Abbreviations and acronyms

BAFRA	Bhutan Agriculture and Food Regulatory Authority
Bt	<i>Bacillus thuringiensis</i>
FAO	Food and Agriculture Organization of the United Nations
FSANZ	Food Standards Australia New Zealand
GM	genetically modified
GMO	genetically modified organism
IRRI	International Rice Research Institute
NFTL	National Food Testing Laboratory, BAFRA
TWG	Bhutan Biosafety Technical Working Group

Executive Summary

While the Bhutan Agriculture and Food Regulatory Authority (BAFRA) now has a basic enabling institutional framework that includes a legal framework, aligned protocols and standard operating procedures, it has yet to receive an application for a genetically modified (GM) food safety assessment. Given the current legal restriction on the environmental release of viable GM organisms in Bhutan, ensuring the safety of GM food in the market is the main priority for BAFRA, especially given Bhutan's reliance on significant imports to satisfy food needs. It was therefore considered timely to provide a workshop on risk analysis that would benefit those officers tasked with undertaking the safety assessment of any applications for GM foods, as well as providing some basic understanding on genetic modification to those BAFRA officials and stakeholders who may be directly or indirectly impacted by the presence of GM food in Bhutan and who, especially, may be required to communicate information on genetic modification, how a GM food is assessed for safety, and the rules and regulations underpinning the GM regulatory framework in Bhutan.

A national training workshop entitled “training on genetically modified (GM) food safety assessment, risk communication and advocacies programme” was co-organized by BAFRA and the Food and Agriculture Organization of the United Nations (FAO) on 23–27 July 2018 in Thimphu, Bhutan. Eighty-nine participants comprising members of the Bhutan Biosafety Technical Working Group, BAFRA officers and inspectors from various stations in Bhutan, relevant stakeholders, and resource people attended the workshop. The objectives of the workshop were to provide: 1) an understanding of the relevant rules and regulations concerning GMOs and GM products in Bhutan; 2) an understanding of the internationally accepted principles of GM food safety assessment, risk management and risk communication and information on challenges involved in enacting these principles; 3) an understanding of the required expertise and types of experts for undertaking GM food safety assessments so that possible shortcomings in assessment capacity/resources in Bhutan can be identified; 4) hands-on experience in extracting relevant safety information from condensed GM food case studies and presenting the information in a simple and concise way; 5) general information about biosafety and biotechnology in the international arena with particular emphasis on communication; and 6) a way forward for BAFRA to conduct any suggested follow up activities.

Over the five days of the workshop, participants received a number of presentations that introduced them to basic concepts of risk analysis as applied to GM foods. They were then able to use these concepts to undertake group work on selected case studies. Communication was one of the key themes of the workshop and participants were encouraged to contribute to discussion and to make suggestions about how BAFRA can move forward in its role of overseeing the introduction of genetically modified foods. Through these discussions a number of challenges/gaps were identified and possible approaches for solutions were discussed.

1. Introduction

1.1. Overview

Upon the official request of the Royal Government of the Kingdom of Bhutan, a national training workshop entitled “training on genetically modified (GM) food safety assessment, risk communication and advocacies programme” was co-organized by Bhutan Agriculture and Food Regulatory Authority (BAFRA) and the Food and Agriculture Organization of the United Nations (FAO) on 23 – 27 July 2018 in Thimphu, Bhutan. Eighty-nine participants comprising six Bhutan Biosafety Technical Working Group (TWG) members, four BAFRA headquarters officers, 57 field inspectors from Bumthang, Dagana, Dagapela, Gasa, Gedu, Gelephu, Gomtu, Haa, Jomotshangkha, Lhamoiyzyingkha, Lhuentse, Mongar, National Food Testing Laboratory (NFTL), Yusipang, Nganglam, Phuntsholing, Panbang, Paro, Pemagatshel, Punakha, Samdrupjongkhar, Samrupcholing, Samtse, Tashigang, Thimphu, Trashiyangtse, Trongsa, Tsimasham, Tsirang, Wangdue and Zhemgang, 22 relevant stakeholders from Department of Trade, National Organic Program, National Seed Centre, Regional National Seed Centre, Food Corporation of Bhutan Ltd., Mountain Hazelnut Venture, SHABAH Bhutan, Office of the Consumer Protection, National Plant Protection Centre, Bhutan Agro Industries Limited, Department of Public Health, National Environment Commission, Royal Centre for Disease Control, Fruit Processing Unit, Dralha Flour Mill, Tashi Beverage, Karma Feed, Zimdra Food, Bhutan Fruits Products Pvt. Ltd, Ice Beverages Private Ltd, Army Welfare Project and Pema Feed Processing, Masami Takeuchi, FAO Food Safety Officer and Janet Gorst, FAO consultant, Food Standards Australia New Zealand (FSANZ) attended the workshop. The list of participants is attached as Annex 1.

The objectives of the workshop were to provide: 1) an understanding of the relevant rules and regulations concerning GM organisms (GMOs) and GM products in Bhutan; 2) an understanding of the internationally accepted principles of GM food safety assessment, risk management and risk communication and information on challenges involved in enacting these principles; 3) an understanding of the required expertise and types of experts for undertaking GM food safety assessments so that possible shortcomings in assessment capacity/resources in Bhutan can be identified; 4) hands-on experience in extracting relevant safety information from condensed GM food case studies and presenting the information in a simple and concise way; 5) general information about biosafety and biotechnology in the international arena with particular emphasis on communication; and 6) a way forward for BAFRA to conduct the follow up activities.

Over the five days of the workshop, participants received a number of presentations that introduced them to basic concepts of risk analysis as applied to GM foods. They were then able to use these concepts to undertake group work on selected case studies. Communication was one of the key themes of the workshop and participants were encouraged to contribute to discussion and to make suggestions about how BAFRA could move forward in its role of overseeing the introduction of genetically modified foods. Through these discussions a number of challenges/gaps were identified and possible approaches for solutions were discussed. The final agenda of the workshop is attached as Annex 2.

1.2. Background

BAFRA, an authority within the Royal Government of Bhutan Ministry of Agriculture and Forests is the designated national competent authority for the implementation and enforcement of biosafety-related activities as provided by Chapter II, section 14 of the *Biosafety Act of Bhutan 2015*. Following the endorsement of *Biosafety Rules and Regulations of Bhutan 2018*, BAFRA has a role in carrying out risk assessment (environment, food and feed), risk management and risk communication associated with biosafety. Specifically, in relation to GMOs and GM products, it is tasked with handling applications for release, inspection and monitoring, and laboratory detection. One of the main mandates of BAFRA is to protect biological diversity, the environment, and the health of humans and animals.

While BAFRA now has a basic enabling structure that includes a legal framework, aligned protocols and standard operating procedures (SOPs) it has yet to receive an application for a GM food safety assessment. Given the current legal ban on the environmental release of viable GMOs in Bhutan, ensuring the safety of GM food in the market is the main priority for BAFRA, especially given Bhutan's reliance on significant imports to satisfy food needs. It was therefore considered timely to provide training on risk analysis that would benefit those officers tasked with undertaking the safety assessment of any applications for GM foods, as well as providing some basic understanding on genetic modification to those BAFRA officials and stakeholders who may be directly or indirectly impacted by the presence of GM food in Bhutan and who, especially, may be required to communicate information on genetic modification, how a GM food is assessed for safety, and the rules and regulations underpinning the GM regulatory framework in Bhutan.

2. Highlights of the training

2.1. Day 1

The opening session was held with the presence of key people at the top table including Mr Namgay Wangchuk (Director General of BAFRA), Mr Jamyang Phuntsho (Chief of Analytical and Certification Division), Chadho Tenzin (FAO Assistant Representative to Bhutan), Masami Takeuchi (FAO Food Safety Officer), and Janet Gorst, (FAO Consultant and expert from FSANZ). In his welcoming remarks to the workshop participants, Mr. Wangchuk set the scene by emphasising the reliance of the Bhutan food supply on a significant amount of imports from neighbouring countries and the role of BAFRA in ensuring the safety of this food. He stressed the policy of the Government in supporting primarily organic-based food production systems internally, while acknowledging that the need for imports would likely result in the presence of GM foods in the future food supply. He suggested that this could be addressed by BAFRA using a science-based approach to monitor the presence of these foods, to ensure a safe food supply by developing the capacity to undertake GM food safety assessments, and to communicate information on GMOs and their products to the public. However, he also asked participants to consider pragmatically whether this should be a priority for resource allocation in Bhutan and whether there were more pressing food-related concerns to address.

The FAO Food Safety Officer also provided an opening remark on behalf of FAO, stating that while FAO recognizes biotechnology potentially provides powerful tools for the sustainable development of agriculture, fisheries and forestry, as well as the food industry, FAO is also aware of the concern about the potential risks posed by certain aspects of modern biotechnology. She

assured participants that FAO continues to assist its member countries, particularly developing countries, to reap the benefits derived from the application of biotechnologies in agriculture, forestry and fisheries and assists countries to develop capacity in relevant risk assessment, management and communication.



©FAO/Masami Takeuchi

The first day of the workshop focused on the basic principles underlying risk analysis and sought to contextualize the issue of GM food safety by referring to examples of breaches of food safety that are caused by a number of factors (e.g. contaminants, microorganisms, under-nutrition) unrelated to genetic modification. Reference was made to relevant Codex Alimentarius documents that underpin global regulatory approaches to GM food safety assessment while emphasising the difficulty in assessing a whole food (as opposed to a single substance), and the reality that 100% safety of any food, whether GM or derived from conventional breeding, cannot be assured. The general food authorisation process already in place in Australia/New Zealand and proposed for Bhutan were compared and acknowledged to be similar. The day concluded with an introduction to the FAO GM Foods Platform as a resource for accessing safety assessments for a large number of approved GM foods.

2.2. Day 2

On the second day, some key terminology in safety assessment (comparative approach, substantial equivalence, unintended effects) was discussed before participants were provided with one of three case studies prepared by the FAO for the purpose of GM safety assessment training. After hearing from the expert about the type of information required and its significance, participants were asked to break into groups (three groups per case study) and extract information from the case studies

relevant to the component of a safety assessment concerned with identifying the recombinant DNA plant, the host plant, the organism donating the genes and the description of the genetic modification. Each group was then asked to present its findings in a simple but scientifically accurate way. The final session for the day was a presentation on other key components of the safety assessment (protein toxicity/allergenicity, compositional analysis), using information taken from the Golden Rice application submitted by the International Rice Research Institute (IRRI) to FSANZ and approved in February 2018.

2.3. Day 3

During the morning sessions of the third day, participants again broke into discussion groups and, using their assigned case studies, extracted information relevant to the safety assessment of protein toxicity/allergenicity and compositional data. It was obvious from the enthusiastic buzz generated around the hall that the groups were actively engaged in their work. During the presentation of their findings, feedback was provided by the Resource People. Given the lack of relevant scientific background of most of the participants, the groups did a surprisingly good job of sifting through the information in the case studies and identifying the key points.



©FAO/Masami Takeuchi



©Janet Gorst, 2018

The theme for the afternoon of the third day switched from risk assessment to risk communication and more general communication. The FAO Officer provided some insights on the Codex considerations on risk communication within the risk analysis framework and stressed the multi-directional, interactive nature of communication exchange. She noted that GM food, while scientifically regarded as low risk is perceived by some to be high risk and this makes for a complex communication strategy. Mr Tenzin from the National Centre for Animal Health within the Department of Livestock gave an example of a risk communication strategy, already deployed in Bhutan, for Avian Human Influenza containment program. While this example has notable differences from one that would be used for GM food, it provided some relevant pointers for determining who should be involved in preparing a strategy, what phases/messages/activities need to be considered, who the target audience is, what communication channels are available and what follow-up evaluation should be done. The FSANZ expert then gave a presentation on general communication of genetic modification topics and provided some results from a 2017 survey conducted in Australia of consumer attitudes to GM food. The opinions of participants were sought regarding the approach BAFRA should take with communicating information on GMOs and the

discussion ventured into such diverse areas as labelling, detection and the safety of GM in general. Before finishing for the day the participant groups were tasked with preparing a brief communication message aimed at summarising their case study and providing information to the general public.

2.4. Day 4

The first session of the fourth day was devoted to hearing the communication messages prepared by each of the groups. In particular, the groups put much thought into choosing a vehicle for communication and considered very relevant points around using the national language and targeting the many farmers in Bhutan – national television was the clear winner, followed by national radio. It was also pleasing that there was a good understanding of the need to emphasize that the food had been assessed by the competent authority and had been found to be safe for consumption; these are very key messages in any country for reassuring the public and indicating that the competent authority is working on behalf of the public. The Resource People facilitated a lively discussion that raised a number of questions to consider: what should be proactively communicated and what should be prepared for “back pocket” information in case it may be needed?; what target audiences – farmers, schools, community groups?; are brochures/pamphlets of use?; and what can be done to circumvent adverse publicity that may arise from a misinformed but influential member of society?

After morning tea, the main topic again changed and focussed on the current capacity to detect GMOs in Bhutan. Ms Dechen Wangmo, Officer In-Charge from NFTL outlined the procedures for detection and raised the question of what should be done if the results are positive for a GMO. Under the Biosafety Act of Bhutan, it is illegal to have any activities involving a GMO in viable form, including research and development. This highlighted the urgent need for the development of an incident management protocol. Mr Jambay Dorji, Focal Officer for Biosafety, BAFRA Headquarters described a recent, limited surveillance project designed to detect the presence of GMO in feed samples and GM Bt brinjal¹ in four official entry points and one major town and vegetable markets respectively. A total of 280 brinjal samples were tested using a simple rapid test kit. While the projects indicated there was no evidence of GMO in feed samples and Bt brinjal being present, it served to highlight a) the complexity, time and expense involved in even a simple detection and b) the fact the result may often not be definitive. This raised the question of whether it may be appropriate for Bhutan to consider outsourcing the event-specific detection and quantification until in-country capacity is developed.

Another change of topic saw a presentation by the FSANZ expert on the expertise required by a safety assessment team and the various approaches used in other countries to meet this expertise. From the ensuing discussion, it was apparent that Bhutan wishes to be able to have the capacity to undertake in-country safety assessments rather than to rely on using the safety assessment of another country i.e. mutual recognition is not a desired option. While BAFRA may not currently have all of the expertise (in particular expertise in the areas of toxicology, allergenicity and

¹Another common name for brinjal is eggplant. Bt brinjal has been genetically modified to contain a gene, from the soil microorganism *Bacillus thuringiensis* (Bt) that confers protection against a number of insect pests, particularly brinjal fruit and shoot borer. Bt brinjal was developed in India, where brinjal is an important food crop, and was initially approved for commercialization there in 2009 but a moratorium on growing it was later imposed. It was approved for commercial release in Bangladesh in 2013. It is possible that Bt brinjal could enter Bhutan through informal trade across the border.

nutrition were identified as lacking), it is likely to be available within Bhutan (e.g. in universities, health sectors and colleges) or could be sourced via collaboration with other countries if need be.

The final session of day four was again a group exercise that asked participants to identify at least five significant gaps that they perceived in Bhutan's ability to undertake GM food safety assessments and to suggest immediate actions that could help address the gaps. The predominant gaps identified were:

- Need for a communication strategy
- Low level of awareness of GM topics – amongst both the general public and higher officials/policy makers
- Insufficient level of awareness of what BAFRA does on Biosafety
- Insufficient capacity in developing detection and monitoring system
- Need for an incident management response plan
- Underutilisation of expertise within the country
- Need of real experience in undertaking GM food safety assessments
- Low level of knowledge by the general public on what GM products might be entering the country (this knowledge would help to target testing)
- Insufficient amount of available information on the benefits of GM
- Need for collaboration with international agencies/organisations

As the session was concluding for the day, large numbers of plastic posters providing basic information about GMO regulation in Bhutan were distributed to all the BAFRA staff. These posters represented the first communication efforts on GMOs undertaken by BAFRA and provide a clear and simple message. While intended for display in BAFRA offices, these posters could just as appropriately be displayed in public places or schools. The BAFRA staff are to be congratulated for their initiative.

2.5. Day 5

The final day of the workshop took advantage of the presence of BAFRA officers from all over Bhutan to provide an update on the Revised Rules and Regulations from three areas – Livestock, Plant and Food sections of BAFRA. These updates were presented by BAFRA Focal Officers, namely Mr Kinley Penjor, Mr Sonam Yonten and Ms Gyem Bidha respectively. With the presence of the Director General of BAFRA, FAO Resource person presented the conclusions and recommendations which have been summarized in Section 3. Following the distribution of certificates to participants, the workshop was closed, mid-afternoon, with remarks from FAO Resource People (Janet Gorst and Masami Takeuchi), Mr Namgay Wangchuk, Director General and Mr Jambay Dorji, Planning Officer/Focal for Biosafety. In particular, Mr Wangchuk acknowledged that the decision to hold the workshop was perfectly justified and expectations had been exceeded.

3. Conclusions and recommendations

The two key areas for consideration at this workshop were a) science-based safety assessment of GM foods and b) the communication of safety assessment outcomes specifically and genetic modification (as used in food production), in general. It was also hoped that participants at the

workshop, in considering these areas, would be able to discuss any relevant thoughts on how BAFRA could proceed more effectively in its role as the designated national competent authority for the implementation and enforcement of biosafety-related activities.

The baseline knowledge of the participants at the workshop varied considerably and the pre-workshop questionnaire (see Section 4) indicated that most had not been exposed to the topic in any depth. It was therefore not surprising that, for these people, the scientific detail was somewhat excessive. Nonetheless as indicated by the post-workshop questionnaire, the participants felt they had gained an appreciation not only of the legislative context surrounding GM food but also of the scientific basis for the approach to GM food safety assessment. This was an important positive outcome since most of the participants deal directly with the public and are in a position of being able to pass on the knowledge gained from the workshop to those for whom genetic modification and its regulation is a totally new concept (because Bhutan has not yet needed to embrace the technology) and/or is a negative concept (because it falls outside the principles of organic farming). To assist the participants in any revision or communication work, they were provided with a USB containing all of the resource material used in the workshop and were also given a training exercise (using their own mobile phones) on how to navigate the FAO GM Foods Platform, a valuable resource for accessing safety assessments and information on a large number of GM foods approved in other countries.

Discussions held, and opinions sought, during the workshop questioned the current preparedness of Bhutan to deal with the influx of GM products into the food supply. While a number of key enablers have been finalised, notably the legislative texts, relevant regulations, safety assessment guidelines, administrative forms and the formation of a TWG to consider GM food applications, there remain several areas that require development. At the heart of the problem is the fact that Bhutan has not yet received an application for a GM food. Consequently, the ability and expertise of the TWG has not been tested, no communication strategy has been developed, and resources have not been allocated for developing a realistic monitoring strategy and putting in place an incident response plan in the event of a non-compliant detection.

Technical expertise for dealing with two aspects of GM safety was highlighted for consideration. Firstly, it was believed that while the level of knowledge of the TWG members, required for undertaking GM food safety assessments, appears to be sufficiently high in general, some additional expertise needs to be made available. Suggestions to address this included a) mobilization of expertise from within Bhutan, a strategy that would benefit from firstly undertaking a stock-taking exercise of available and required expertise within the government system and b) actively developing linkages with regulatory authorities in other countries with experience in GM food safety assessment. Secondly, it was recognized that a sound detection and quantification capacity, involving both equipment and expertise, needs to be available at NFTL. Currently, the focus is on use of rapid test kits for detecting the presence of a specific genetic modification and qPCR in element screening in a specific target fresh food. This approach cannot be used for general screening of processed foods that contain multiple ingredients. The laboratory also needs to invest resources to train laboratory personnel in order to be able to undertake event-specific identification and quantification. It was recognized that it would be impossible for the laboratory to monitor all areas of the food supply and *ad hoc* surveillance studies would help to inform the likely extent of presence of GM food which, in turn, would help to rationalize a strategy

for monitoring the food supply in the longer term. Strengthened collaboration with neighboring countries (trade partners) in discussing biosafety issues, particularly involving potential low level and adventitious presence in the food supply, would also help to focus monitoring capacity.

The development of a communication strategy remains a high priority. In discussing the area of communication, it was acknowledged this encompasses a broad field and is important not only for the open channel that needs to be maintained between safety assessors, risk managers and decision-makers but also for reaching a diverse audience that includes the general public, farmers, high level officials, the media, industry and shop-keepers. In particular it was felt that policy makers and senior officials are not currently as well-informed as they could be about genetic modification and would benefit from an awareness programme. The importance of BAFRA needing to prepare official and consistent communication material, for both active communication (e.g. education modules for schools) and for contingency should questions arise on (future) GM approvals, was seen as an important component of the communication strategy. The conduct of a survey by BAFRA on opinions and beliefs amongst the public about genetic modification was suggested as a useful exercise for identifying specific communication topics that could then be tailored for delivery through a variety of fora (e.g. schools, community groups, websites, radio/TV, and social media). The new poster prepared by BAFRA and released for distribution by workshop participants represents an excellent start to the job of communication.

While some initiative needs to be taken by BAFRA to address those areas identified as requiring attention, FAO will assist, for the remainder of 2018, with the development of a biosafety communication strategy document, the development of an incident management plan and the procurement of a suitable GM food dossier that could be used by the TWG for producing a practice safety assessment.

4. Evaluation

Pre- and post-workshop questionnaires were administered to measure the knowledge gained by participants. The questionnaires included commentary parts on participants' expectations (pre-workshop) and recommendations (post-workshop). Many participants wrote that their expectations for the workshop were to: 1) gain more knowledge and understand the principles of risk analysis, GM food safety assessment and risk communication; 2) understand science on gene modification and be able to explain what GM foods are; 3) gain confidence in testing for GMOs and understand GMO monitoring; 4) learn more about internationally accepted principles for GM food safety assessment; 5) understand both advantages (benefits) and disadvantages (possible risks) of GM products; 6) learn the status of GMO in Bhutan; 7) obtain various case studies, experiences and lessons learned from other countries; and 4) have confidence in providing training on the same subject in the future.

As to the knowledge gain assessment, pre-workshop questionnaire scores (PRE) and post-workshop questionnaire (POST) scores were analysed by the paired t-test. Those who did not return either of the questionnaires were excluded from the analysis (N=80). With the highest score of 11 and the lowest of 1, the means of PRE and POST were 3.90 (SD 1.73) and 7.43 (SD 2.28), respectively. Thus, a 95% confidence interval of this difference ranges from -4.14 to -2.91, and the t-value was calculated to be 11.4219 with the degree of freedom of 79. The result showed that with the P value of < 0.0001, the knowledge gained by participants was statistically significant.

Post-workshop comments from participants showed that their expectations were fulfilled. Many participants emphasized that the workshop was very informative, educative, useful, and helpful especially for those who have been newly introduced to this topic. Many felt the subject matter has been overly scientific but lectures were well presented in a simple way. Additional comments included the need for a follow-up to engage public to raise more awareness. Some participants wrote that they wanted to see some case studies with rejected (unsafe) GMOs, but there is no such rejected applications in the world thus it is not feasible. Some suggested to have less participants in the follow-up workshops to provide more intensive sessions to those who are directly involved in GM food safety assessment (e.g. TWG members). The specific additional objectives determined before the workshop (equipped with a full resource package for further training, enhanced understanding on the FAO GM Foods Platform with various GM food safety assessment results shared, and full understanding on the need of effective communication on the topic for different types of audience) have been also successfully achieved.

Annex 1. List of participants

A. Participants from Bhutan Agriculture and Food Regulatory Authority (BAFRA)

#	Name	BAFRA Offices	Area
1	Tshewang Dorjee	Zhemgang	Agriculture
2	Tshering Dorji	Gasa	Agriculture
3	Gembo Dorji	Lhamoyzingkha	Agriculture
4	Sangay Darjay	Lhamoyzingkha	Agriculture
5	Dzeko Dukpa	Dagana	Agriculture
6	Lalit Kumar Orari	Punakha	Agriculture
7	RinzinNorbu	Gomtu	Agriculture
8	Suraj Tamang	Samtse	Agriculture
9	Karma Dorji	Paro	Agriculture
10	Karma Choden	Trongsa	Agriculture
11	Sangay Wangmo	SamdrupJongkhar	Agriculture
12	Sangay Tshering Lepcha	Samrupcholing	Agriculture
13	Pancha Man Rai	Mongar Gyelpozhing	Agriculture
14	Maha Prasad Homagai	Gelephu	Agriculture
15	Pema Namgay	Gelephu	Agriculture
16	Om Prakash Ghalley	P/ling	Agriculture
17	Yeshe Wangchuk	P/ling	Agriculture
18	Sonam Yonten	Headquarters	Agriculture
19	Jambay Dorji	Headquarters	Food
20	Pema Jamtsho	Trashigang	Food
21	Rinzin Wangdi Sherpa	Tsirang	Food
22	Kuenzang Choden	Thimphu	Food
23	Tenzin	Thimphu	Food
24	Tshering Yangzom	Thimphu	Food
25	Karma Yangzom	Thimphu	Food
26	Pasang Wangdi	Thimphu	Food
27	Phuntsho	P/ling	Food
28	Gyem Bidha	Headquarters	Food
29	Damcho Norbu	Mongar	Food
30	Yeshe Nidup	Lhuentse	Food
31	Sonam Tshering	Samtse	Food
32	Karma	Trashiyangtse	Food
33	Lham Dorji	Gelephu	Food
34	Kinzang Chhodon	Samtse	Lab
35	Tashi Dorji	NFTL	Lab
36	Leki Zangmo	NFTL	Lab

37	Dechen Wangmo	NFTL	Lab
38	Kelzang Dorji	Pemagatshel	Livestock
39	Khandu Wangchuk	Nganglam	Livestock
40	Dechen Dema	Nganglam	Livestock
41	Tashi	Tashigang	Livestock
42	Sonam Dorji	Panbang, Zhemgang	Livestock
43	Durga Subba	Paro	Livestock
44	Manda Dari Dungana	Dagapela	Livestock
45	Bijay Kumar	SamdrupJongkhar	Livestock
46	Sonam Gyeltshen	SamdrupJongkhar	Livestock
47	Chenga Tshering	Jomotshangkha	Livestock
48	Ugyen Dorji	Tsirang	Livestock
49	Pendenla	Bumthang	Livestock
50	Jigme Choden	Thimphu	Livestock
51	Sonam Choki	Thimphu	Livestock
52	Kaling Dorji	Thimphu	Livestock
53	Kezang Trashi	Wangdue	Livestock
54	Mahesh Chhetri	Gedu	Livestock
55	Karma Tobgye	Tsimasham	Livestock
56	Kinley Rabgay	Gelephu	Livestock
57	Sonam Dendup	Sarpang	Livestock
58	Rinzin Wangchuk	P/ling	Livestock
59	NK Rimal	P/ling	Livestock
60	Jigme	Haa	Livestock
61	Prakash Tamang	Headquarters	Livestock

B. Bhutan Biosafety Technical Working Group members

#	Name	Affiliation
1	Karma C. Nyedrup	Environment Specialist, National Environment Commission
2	Kezang Tshering	Specialist, RDC, Yusipang, DoA, MoAF
3	N.B. Tamang	Specialist, Department of Livestock, MoAF, Yusipang
4	Chimmi Dorji	Dy. Chief Laboratory Officer, RCDC, DoPH, MoH, Serbithang
5	Penjor	Associate Lecturer, College of Natural Resources, Royal University of Bhutan, Lobeysa
6	Lhab Tshering	Biodiversity Officer, National Biodiversity Center, Ministry of Agriculture & Forests, Serbithang

C. Stakeholders

#	Name	Affiliation
1	Phub Dorji	Dept. of Trade
2	Dawa Dem	National Organic Program
3	Dorji Wangda	National Seed Center, DoA, Paro
4	Kinzang Cheda	Regional National Seed Center, DoA, Tashiyangtse
5	Ugyen Tenzin	Food Corporation of Bhutan Ltd
6	Phuntsho Chejay	Mountain Hazelnut Venture
7	Dechen Wangmo	SAARC Business Association of Home Based Workers, Bhutan
8	Tshering Wangchuk	Office of the Consumer Protection
9	Sonam Dorji	National Plant Protection Center
10	Jigme Wangmo	Bhutan Agro Industries Limited, Thimphu
11	Loday Zangpo	Dept. of Public Health
12	Drodhel Zangpo	National Environment Commission
13	Sonam Dendup	Fruit Processing Unit, Bumthang
14	Khandu Wangmo	Dralha Flour Mill, P/ling
15	Pushpa Tirwa	Tashi Beverage, P/ling
16	Thinley Pemo	Karma Feed, P/ling
17	Rinchen Chedup	Zimdra Food, P/ling
18	Karma Sonam	Bhutan Fruits Products Pvt. Ltd, Samtse
19	Mani Kumar Darjee	Ice Beverages Private Ltd, Samtse
20	Namgay Wangchuk	AWP, Samtse
21	Tenzin Yangki	Pema Feed Processing, T/yangtshi
22	Tshering Dorji	RCDC, DoPH, MoH, Serbithang

D. Resource people

#	Name	Affiliation
1	Janet Gorst	Food Standards Australia New Zealand (FSANZ)
2	Masami Takeuchi	Food and Agriculture Organization of the United Nations (FAO)

Annex 2. Final workshop agenda

Monday 23 July 2018

Time	Item
08.30 – 09.00	Registration
09.00 – 09.30	Opening session Welcome remarks by Jambay Dorji, BAFRA, MoAF Opening remarks by Director General, BAFRA, MoAF Opening remarks by Masami Takeuchi, FAO
09.30 – 09.45	Round-call: Introduction of the participants and resource people
09.45 – 10.00	Objectives of the training workshop Jambay Dorji, BAFRA, MoAF
10.00 – 10.30	Group photo Tea/coffee break
10.30 – 11.00	Introduction to food safety and biosafety Masami Takeuchi, FAO
11.00 – 12.00	General principles on risk analysis and its application in the area of GM food safety assessment Masami Takeuchi, FAO
12.00 – 13.30	Lunch
13.30 – 14.00	GM authorization process in Australia Janet Gorst, FSANZ, Australia
14.00 – 14.30	GM approval process in Bhutan Jambay Dorji, BAFRA, MoAF
14.30 – 15.00	Essentials in GM food safety assessment and relevant Codex documents Masami Takeuchi, FAO
15.00 – 15.30	Tea/coffee break
15.30 – 16.30	Discussions facilitated by: Janet Gorst, FSANZ, Australia Masami Takeuchi, FAO
16.30 – 17.00	Introduction to the FAO training tool and FAO GM Foods Platform Masami Takeuchi, FAO

Tuesday 24 July 2018

Time	Item
09.00 – 09.10	Housekeeping
09.10 – 10.00	The approach and framework for the GM food safety assessment Janet Gorst, FSANZ, Australia
10.00 – 10.30	Tea/coffee break
10.30 – 11.30	Step-by-step procedures of GM food safety assessment conducted by FSANZ Janet Gorst, FSANZ, Australia
11.30 – 12.00	Working individual session: using the case studies, identify: <ul style="list-style-type: none"> • Description of the r-DNA plant • Description of the host plant and its use as food

	<ul style="list-style-type: none"> • Description of the donor organism(s) • Description of the genetic modification(s)
12.00 – 13.30	Lunch
13.30 – 14.30	Working group session: Prepare a group presentation on the individual assignment
14.30 – 15.00	Plenary reporting: facilitated by: Masami Takeuchi, FAO Janet Gorst, FSANZ, Australia
15.00 – 15.30	Tea/coffee break
15.30 – 17.00	Characterization of GM, toxicity and allergenicity assessment and compositional analysis Janet Gorst, FSANZ, Australia

Wednesday 25 July 2018

Time	Item
09.00 – 09.10	Housekeeping
09.10 – 10.00	Working group session: using case studies, identify: <ul style="list-style-type: none"> • The toxicity studies and evaluate the possible toxicity • The allergenicity studies, and then evaluate the possible allergenicity • The description of compositional analysis and then evaluate the analysis
10.00 – 10.30	Tea/coffee break
10.30 – 11.00	Working individual session: taking the result of the working group session, formulate simple paragraphs to conclude your risk assessment results to inform risk managers / decision makers
11.00 – 12.00	Plenary reporting: facilitated by: Janet Gorst, FSANZ, Australia
12.00 – 13.30	Lunch
13.30 – 14.00	Principles of risk communication Masami Takeuchi, FAO
14.00 – 14.30	Risk communication strategy in Bhutan: an example of the Avian Human Influenza Risk Communication Strategy Tenzin, National Centre for Animal Health, DoL, MoAF
14.30 – 15.00	Discussion facilitated by Janet Gorst, FSANZ, Australia
15.00 – 15.30	Tea/coffee break
15.30 – 17.00	Working group session: Formulation of risk communication message

Thursday 26 July 2018

Time	Item
09.00 – 10.00	Plenary reporting: Facilitated by Masami Takeuchi, FAO
10.00 – 10.30	Tea/coffee break

10.30 – 11.00	Discussion on detection of GMO and development of relevant incident management guidelines/SOPs Dechen Wangmo/Jambay Dorji, BAFRA, MoAF
11.00 – 11.30	Surveillance study on GMO and Available expertise for GM food safety assessment in Bhutan Jambay Dorji, BAFRA, MoAF
11.30 – 12.00	Case study in Australia on required expertise for GM food safety assessment Janet Gorst, FSANZ, Australia
12.00 – 13.30	Lunch
13.30 – 15.30	Group session: Needs and challenges identification and immediate actions; presentations from groups Discussion facilitated by Masami Takeuchi, FAO Janet Gorst, FSANZ, Australia
15.30	Tea/coffee break; close

Friday 27 July 2018

Time	Item
08.30 – 09.30	Evaluation questionnaire
09.30 – 10.30	Revised Livestock Rules and Regulations 2017 with emphasis on quarantine systems Kinley Penjor, BAFRA, MoAF
10.30 – 11.00	Tea/coffee break
11.00 – 11.45	Revised Plant Quarantine Rules and Regulations 2018 Sonam Yonten, BAFRA, MoAF
11.45 – 12.30	Revised Food Rules and Regulations 2018 with emphasis on Food import control systems (Part 1) Gyem Bidha, BAFRA, MoAF
12.30 – 13.30	Lunch
13.30 – 14.00	Revised Food Rules and Regulations 2018 with emphasis on Food import control systems (Part 2) Gyem Bidha, BAFRA, MoAF
14.00 – 14.30	Provision of certificates to participants
14.30 – 14.45	Technical Recommendations Janet Gorst, FSANZ, Australia
14.45 – 15.15	Conclusions and a way forward Masami Takeuchi, FAO
15.15 – 15.45	Closing remarks by Director General, BAFRA, MoAF Vote of Thanks Jambay Dorji, BAFRA, MoAF
15.45 – 16.15	Close of workshop; Tea/coffee break
16.15 -	Address to BAFRA staff by Director General, BAFRA, MoAF

