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South Asia Biosafety Program

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The Safety Assessment of Foods Derived from Genetically Engineered Plants Phase I Workshop

On May 19-23, 2014, the "Safety Assessment of Foods Derived from Genetically Engineered Plants" workshop was held at the Vivanta by Taj-Ambassador Hotel in New Delhi, India. The workshop was organized by the Center for Safety Assessment of Food and Feed (CSAFF), ILSI Research Foundation, with support from Biotech Consortium India Limited; DuPont Pioneer; Estel Consulting Ltd.; the Food Allergy Research and Resource Program, Department of Food Science and Technology, University of Nebraska-Lincoln; and the University of the Philippines, Diliman.

This workshop was part of a strategic program of capacity building that focuses primarily on the technical training of three critical stakeholder groups: (1) regulators and scientists from the public sector who are called upon to conduct safety assessments of foods derived from genetically engineered (GE) plants on behalf of national biosafety committees; (2) public sector scientists engaged in product development; and (3) scientists from public institutions that are functioning as contract research organizations to provide testing services for public sector product developers. Nine of the fifteen participants were from the South Asia Biosafety Program countries of Bangladesh, India and Pakistan.

During this workshop, participants worked on gaining a baseline understanding of the concepts and principles of GE food safety assessment, with an emphasis on how to identify appropriate risk hypotheses, consider the applicability of data developed for other jurisdictions, and determine what additional studies may be appropriate to the safety assessment.

Participants were surveyed after the completion of the workshop in order to evaluate the content and structure of the event. This edition of the South Asia Biosafety Program Newsletter is dedicated to sharing lessons learned from those who attended the event.

SNAPSHOT OF THE WORKSHOP

15 participants attended the 5 day workshop in New Delhi, India.

Participants traveled from **7 different countries**, including Bangladesh, India, Pakistan, Ghana, Nigeria, Kenya and Paraguay.

Attendees who responded to the workshop evaluation survey ranked the **relevance of the content** of the workshop as a **4.5 out of a 5.0** scale.

The **extranet website** that has presentations, resources and materials was rated a **4.5** out of 5.0.

The **usefulness** of the workshop workbook received a rating of **4.4** out of 5.0.

The **workshop exercises** were rated **4.2** out of 5.0

92% of responders would recommend this workshop to a colleague.

Participants shared that their **knowledge and understanding** of safety assessments of foods derived from GE plants **increased** from a rating of "fair" prior to the workshop to a rating of "very good" after attending the workshop.

Key Findings of the Workshop

MOST VALUABLE ASPECT: Participants were surveyed after the workshop on the most valuable aspect of the workshop and why. Here are the results:

"Overall the whole workshop was very valuable. As a developer, I had some knowledge on the studies to be undertaken for safety assessment of GM crops but not much about the type of data to be generated from these studies and was under the impression that all the studies have to be undertaken for every GM crop. All this will help me in developing a road map for our transgenic event."

"Group exercises with real life scenarios and use of extra-net links and database for GM food safety evaluation."

"Allergenicity and toxicity evaluation aspects. These are two vital issues of GM foods required for safety evaluation."

"Elaborate presentations coupled with exercises not forgetting the interactive sessions."

"A developer of GE crops needs to know the biosafety requirements of GE crops. The course was well organized and provided us hands on experience on biosafety of GE food crops. I have learnt a lot from the course. Besides the lessons learnt from this workshop, it will also help me in teaching students on biosafety."

THE FACULTY: When asked for feedback on the individual faculty members and corresponding presentations, participants responded:

"Monica Garcia-Alonso did marvelous. Her paper supplied to us prior to the workshop helped people to get oriented."

"Flerida Cariño simplified her presentation and made it easy to understand. I really liked her engagement with her audience using the fruit examples."

"Mike Wach's presentation provided vital resources for information on BCH, assessing risk assessment documents, information about events, commercialized GE crops, consensus documents, among others. We couldn't ask for more."

"Rick Goodman's topic of presentation was quite advanced for me but he was able to simplify it and made it easy for us to understand and follow along. He is a very good speaker and presenter."

"Bryan Delaney's talks were to the point. Good toxicologist."

OVERALL: When asked for their overall thoughts on the workshop, participants shared:

"I work as a regulator and our institution has been in place for a few years. This training has been conducted at the right time for us. It greatly enhanced our expertise and skills as we continue to carry out our mandate in the regulation and supervision of all GMO activities. I am pleased that there will be continued mentorship throughout the phase of this workshop and I look forward to sharing what I have learned with my colleagues."

"Very useful and informative."

"Articulate speakers and very knowledgeable."

"The websites are really useful, especially the links and applications for evaluation of nutritional aspects, toxicity and allergenicity."

"I really enjoyed the group exercise as it gave us the opportunity to draft the decision document and apply what we had learnt. His guidance and discussion during the presentations made us understand it even better."

"Nice arrangement, excellent organization with warmest hospitality."

"It will be great if we continue our interaction and sharing information. I am glad that the extranet website has been set up and information is being shared. That was a brilliant idea. I couldn't suggest more."

"I enjoyed every bit from the presentations by speakers to the accommodations."

"The workshop was professionally organized. Everyone enjoyed the workshop."

"The workshop has been very useful and well managed. Thanks for a very comprehensive program. I look forward to some hands on toxicity assays as well."

New Knowledge Paving the Way

MONZUR MORSHED AHMED, PRINCIPAL SCIENTIFIC OFFICER, BANGLADESH COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH (BCSIR) AND MEMBER OF THE BIOSAFETY CORE COMMITTEE (BCC), DHAKA

The "Safety Assessment of Foods Derived from Genetically Engineered Plants" workshop aimed at capacity building and human resources development for GM stakeholder groups such as regulators and scientists responsible for GM food safety assessment, public sector scientists engaged in product development and scientists from public institutions that are providing testing services for public sector product developers. The workshop covered a wide range of topics for safety assessment of food/feed derived from GE plants, including problem formulation, frameworks for safety assessment, access to information and useful resources, accessing crop compositional data, characterization of genetic modification, allergenicity assessment and use of bioinformatics, assessing potential toxicity, transportability of data for risk assessment, safety of nutritionally enhanced crops and risk communication. All the theoretical lectures were followed by group exercises with case studies.

The problem formulation methodology for food and feed safety assessment was presented elaborately. It mainly focused on protection goals, gathering relevant information, conducting initial risk characterization, and identifying missing information. It actually provides a good way to target the assessment to answer key questions and to organize the assessment in a logical way to facilitate decision making. In the lecture "Accessing Information and Useful Resources for GM Food /Feed Safety Assessment", a number of helpful information sources, links, and databases such as the Biosafety Clearing House (BCH) Database, the Risk Assessment Search Mechanism of ICGEB, the CERA GM Crop Composition Database, the OECD Bio Track Product Database and the OECD Consensus Documents links were provided which are very useful for problem formulation and decision making for the safety assessment of food/feed derived from GE plants. The lectures that focused on the allergenicity assessment of GMOs were very detailed and comprehensive which I believe improved participants understanding. The demonstration of the bioinformatics database and use for amino acid sequence comparison provided new knowledge and are extremely useful for the allergenicity assessment of GM foods.

Being a food safety scientist and regulator for GMO activities in the country, I was expecting to gain comprehensive knowledge for the safety assessment of food and feed derived from GM plants. The five day long workshop has developed and harmonized a baseline understanding of concepts, principles and protocols of safety assessment. Moreover, the understanding of problem formulation and use of databases and bioinformatics have fulfilled my expectations for the workshop. This new knowledge will pave the way during GMO dossier evaluations and decision making for the safety assessment of food/feed derived from GM plants in Bangladesh.

Bringing Scientists Together to Build Technical Capacity

DR. EMDADUL HAQUE CHOWDHURY, PROFESSOR, DEPARTMENT OF PATHOLOGY, BANGLADESH AGRICULTURAL UNIVERSITY, MYMENSINGH, BANGLADESH & FORMER NATIONAL CONSULTANT FOR THE DEVELOPMENT OF NBF OF BANGLADESH AND BIOSAFETY EXPERT OF FAO

I was invited along with two other participants from Bangladesh by the conference organizers to attend the Safety Assessment of Foods Derived from Genetically Engineered Plants Phase I workshop. The participants of Bangladesh were selected from the Bangladesh Agricultural University who were previously involved with the toxicological risk assessment of genetically modified maize Bt11 as foods and feeds in animal models in Japan; the formulation of the National Biosafety Framework of Bangladesh as a consultant; the Bangladesh Council for Scientific and the Biosafety core committee as a participant; or the Bangladesh Standard and Testing Institute in Dhaka, Bangladesh who is supposed to be involved with setting standards for genetically engineered (GE) foods in Bangladesh.

The main objective of this workshop was to bring scientists working on biotechnology and risk assessment of foods and feeds of GE plants from the region and abroad to build technical capacity in assessments of food safety risks from the GE plants and as well as to share experiences and knowledge of the science and practice on different aspects of the toxicological and allergenicity evaluation of genetically engineered crops in the region and abroad. The workshop included several sessions with theory lectures and group exercise. The workshop was very much useful for the participants as we were divided into several groups to exercise what we had learned from the sessions.

In Bangladesh, quite a number of laboratories are involved with biotechnological research that includes development of GE crops, organisms or products. Bangladesh has approved a few GE crops for either contained, confined or field testing or commercial releases. However, the scientists of the country are still far behind the technical know-how of food safety evaluation tools of GE crops. It was under this background that the workshop was very much useful for the participants. The experience gained through this workshop could be effectively utilized by the participants in their respective countries in implementing risk assessment strategies for transgenic crops developed in their own countries and abroad.

UTILIZE THE ONLINE RESOURCES FOR GE FOOD/FEED SAFETY ASSESSMENT SHARED DURING THIS WORKSHOP

- Biosafety Clearing House Database — https://bch.cbd.int/
- CERA GM Crop Composition Database — http://cera-gmc.org/index.php?action=gm_crop_database
- OECD BioTrack Product Database — http://www2.oecd.org/biotech/byOrganism.aspx
- OECD Consensus Documents — http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnology.htm
- Risk Assessment Search Mechanism — http://rasm.icgeb.org

PAKISTAN

Informative Program Increases Awareness

ZAHID ALI, ASSISTANT PROFESSOR, DEPARTMENT OF BIOSCIENCES, COMSATS INSTITUTE OF INFORMATION TECHNOLOGY, ISLAMABAD

The advanced biotechnology applications for genetic improvement of crop plants by introducing desirable traits through genetic engineering and food production (GM foods) open new avenues and potential benefits for humanity. Science-based safety evaluation and risk assessment is essential that could determine the benefits and risks of the food. The Center for Safety Assessment of Food and Feed (CSAFF), ILSI Research Foundation has published the detailed database on the basis of very comprehensive and extensive study of GM/non GM plants and the products derived from, which can help researchers and regulatory scientists in many areas such as plant biology, food science, and animal nutrition worldwide, to analyze the following parameters prior to release of GM products in market: if the GM food has a traditional counterpart that has a history of safe use; if there any changes in concentration of any naturally occurring toxins or allergens in the food; how the levels of key nutrients changed and up to what extent; what are the food's digestibility affects; was the food produced using accepted, established procedures/methods; ff any new substance produced, do the new substances in the GM food have a HOSU.

To address these questions and potential use of GM crop/food data base for safe release of GM foods, recently in May 2014, the CSAFF organized an international training workshop titled "Safety Assessment of Foods Derived from Genetically Engineered Plants" in New Delhi India, which, indeed was a step forward, providing an informative training program. The utilization of the Risk Assessment Search Mechanism, CERA GM Crop Database, OECD BioTrack Product Database, Characterization of Genetic Modification and Proteins, and Allergenicity Assessment of GMOs database can open new avenues in transgenic technologies and acceptability of GM products by the public.

Now, there is intense need of awareness through seminars/lectures and scientific conferences and efficient utilization of such databases so that environment friendly and safe GM products may get marketed smoothly. Although there are several other steps prior to approval, the developers must analyze the developed GM products using such databases for efficient regularization and safe commercialization of foods.

INDIA

Relevant Learning Opportunities Help Move Things Forward

VIBHA GUPTA, PRINCIPAL SCIENTIST, CENTRE FOR GENETIC MANIPULATION OF CROP PLANTS (CGMCP), UNIVERSITY OF DELHI SOUTH CAMPUS, NEW DELHI

The workshop on "Safety Assessment of Foods Derived from Genetically Engineered Plants" was a good learning experience for me. The timings of this workshop could not have been better as we are in the process of getting food safety studies conducted by some contract research organizations in India for one of our transgenic events. We knew what studies were to be undertaken but were not very clear on the parameters to be studied, appropriateness of the experimental design and interpretation of the data generated from these studies.

After the workshop, it is now clear that all the food safety studies should be done on a case by case basis and should be formulated in a manner that will facilitate decision making by the regulator. Some of the results will be statistically different in the transgenic event versus its non-transgenic counterpart, but then these have to be looked at from the perspective of their biological relevance. There is no absolutely safe plant but one should look at the results to see whether the transgenic food is as safe as its non-transgenic counterpart. All these fundamentals became very clear which will now help us in collating all the results and putting the dossiers together in a systematic manner.

Starting from the concept of problem formulation to the history of safe use, protein safety assessment, toxicity studies and how to assess the already available database were very useful sessions. This will now help us in taking our product forward to the regulatory approval process and achieve our objective of commercializing it for the benefit of the farmers and the society.

Useful Exercises Increase Understanding

POOJA BHATNAGAR MATHUR, SENIOR SCIENTIST, CELL AND MOLECULAR BIOLOGY, INTERNATIONAL CROPS RESEARCH INSTITUTE FOR SEMI-ARID TROPICS (ICRISAT), HYDERABAD

It was a pleasure to be able to attend the "Safety Assessment of Foods Derived from Genetically Engineered Plants" workshop. The workshop very beautifully dealt with issues of food and feed safety assessment of GM crops, in light of existing safety concerns. Attending the workshop has been very useful for a technology developer like me, especially because the course modules were very focused with a mix of lectures, exercises and case studies dealing with critical topics starting from problem formulation and risk assessment, information on crop composition databases to very applied topics like compositional analysis and characterization of the recombinant proteins particularly for assessing its allergenicity and toxicity. The detailed information on using tools such as Allergen online, Expasy etc. have been particularly useful for researchers to conduct preliminary bioinformatics searches based on the molecular data. These tools are very useful for a thorough protein characterization before going for enzymatic procedures.

I also enjoyed all the exercises including the ones on the preparation of decision documents based on case studies. This helped me have a better understanding on what kind of data is looked for by the regulators. These exercises also helped us learn not only how to present the research findings but also how to identify the gaps and the associated significance of these studies.

I am grateful to CSAFF, ILSI, BCIL and all the faculty members for sharing this knowledge with us and giving us an opportunity to interact with researchers and regulators from other regions, sharing information and experiences which immensely helped to understand both perspectives.

Hands-On Experience Enforce Principles on Food Safety Evaluation

DR. D. SUDHAKAR, PROFESSOR, DEPARTMENT OF PLANT BIOTECHNOLOGY, CENTRE FOR PLANT MOLECULAR BIOLOGY & BIOTECHNOLOGY, TAMIL NADU AGRICULTURAL UNIVERSITY, COIMBATORE

My area of research is in the development of genetically engineered (GE) plants in major crops such as rice and cotton for biotic stress resistance and nutritional quality. GE crops are regulated in all countries and undergo biosafety testing. A developer is expected to be aware of biosafety evaluation of GE crops.

The workshop organized by CSAFF in New Delhi on "Safety Risk Assessment of Foods Derived from Genetically Engineered Plants" provided me an opportunity to learn safety assessment of GE food. I wanted to learn principles of risk and safety analysis as well as how safety data are generated and interpreted.

The faculty of the workshop were experts in the field of safety evaluation and they provided us hands-on experience on different aspects of GE food safety evaluation such as problem formulation, characterization of genetic modification, assessment of potential allergenicity and toxicity and risk communication. In this workshop, I learned alot about the safety assessment of food safety, particularly the assessment of potential toxicity and allergenicity.

The expertise I gained during the workshop will be very useful to me as I work on developing GE crops and teaching biosafety of GE crops to students. The workshop also gave me an opportunity to interact with participants from other countries and learn regulations in their countries and listen to their experiences. I cherish every moment I spent at the workshop and I am thankful to the faculty and CSAFF for the opportunity.

Expectations Were Met During Well Planned Workshop

SRIKANTA KUMAR RATH, PRINCIPAL SCIENTIST, GENOTOXICITY LABORATORY, TOXICOLOGY DIVISION, CENTRAL DRUG RESEARCH INSTITUTE, LUCKNOW

As a toxicologist at the Central Drug Research Institute, I have sixteen years of experience in regulatory toxicity of new drug entities. I was involved in developing transgenic fish at CSIR-CCMB Hyderabad before joining CSIR-CDRI. However, I had very little knowledge about the safety evaluation of GM food and feed. Therefore, I had expectations for the workshop to help me know the differences between the two types of safety evaluations, although I knew that the NDEs are mostly small molecules while proteins are a major concern in GM food.

I am very happy to share that the workshop completely satisfied my expectations. The course work was well planned and organized in a systematic way, from brief descriptions with scientific backgrounds to indepth individual evaluations with essential internet resources. I should also emphasize that the resource persons were very good and thorough in the subject they were presenting.

The knowledge gained by this training will help me immensely as a member of statutory body of RCGM in India. It will also help me as a scientist in the laboratory while evaluating recombinant proteins. This workshop also helped me plan for setting up a new facility for safety evaluation at CSIR-CDRI for GM food and feed and to help any other institute in India.

Messages from the Workshops on Genetically Modified Crops at Regional Agriculture Stations

In India, State Agriculture Universities (SAUs) are actively engaged in developing and conducting confined field trials of genetically modified (GM) crops. The scientists from SAUs also provide support to central and state level agencies in monitoring such activities at a state level. Confined field trials of GM crops are conducted at various research stations of these SAUs.

In view of the active role of technical staff and scientists from these research stations at these SAUs, Biotech Consortium India Limited (BCIL) had organized two workshops at the Regional Agricultural Research Stations (RARS) of Acharya N.G. Ranga Agricultural University (ANGRAU) at Warangal and Tirupati on March 29 and April 26, 2014, respectively. These workshops were attended by more than 200 participants including scientists, researchers, faculty and students of these research stations, associated Krishi Vigyan Kendaras, representatives of state agriculture departments and progressive farmers in these districts. The deliberations of the meetings were in Telugu.

The objective of the workshops was to share information about procedures adopted during the safety assessment and conduct of confined trials of GM crops. Presentations were made by faculty of ANGRAU, Hyderabad, National Institute of Nutrition, Directorate of Rice Research and BCIL. The Director of Research, ANGRAU chaired the workshop at Tirupati while the workshop at Warangal was chaired by the Director of the Institute of Agriculture Biotechnology of the University.

An e-learning module on confined field trials of GE crops prepared under the aegis of South Asia Biosafety Program (SABP) was introduced to the participants. Interactive question and answer sessions, in the local language, followed the presentations to facilitate participation by farmers. The workshops helped in clarifying several issues related to safety assessment and confined field trials. A booklet on "Facts about GM crops" translated in the Telugu language was also circulated to participants. The information about the workshops was published extensively in the local newspapers thereby helping in wider dissemination at a grassroots level.

South Asian Regional Workshop on Biosafety: An Initiative Towards Regional Cooperation

The South Asian Regional Workshop on Biosafety was organized by Bhutan Agricultural and Food Regulatory Authority (BAFRA) at Paro, Bhutan from May 27-29, 2014. The workshop was inaugurated by the Minister of Agriculture and Forests, Royal Government of Bhutan.

The objective of the workshop was to bring regional experts from South Asian Association for Regional Cooperation (SAARC) member countries to provide regional perspectives, discourse and potential directions towards building a legal instrument that will benefit the regional/global experiences in biosafety. The theme of the workshop was ensuring biosafety through legal and regulatory instruments: through South Asian perspectives. Representatives from Bangladesh, Bhutan, Nepal, India and Pakistan participated in the workshop and spoke about the biosafety regulations and systems in their countries. In addition, there were presentations by representatives of FAO, SAARC Agriculture Centre and UNEP on cross-cutting issues related to regional harmonization of biosafety regulatory framework.

Dr. Vibha Ahuja, Country Coordinator, South Asia Biosafety Program (SABP)-India, apprised the participants about the activities under SABP. She informed that SABP has been active in India and Bangladesh since 2005 and in Pakistan since 2012. Among several activities, participants noted with interest how SABP played a key note in the harmonization of guidelines for conducting confined field trails of genetically engineered (GE) plants in India and Bangladesh. Representatives from Bangladesh also appreciated the role of SABP in biosafety capacity building.

SAVE THE DATE

2ND ANNUAL SOUTH ASIA BIOSAFETY CONFERENCE AND WORKSHOP

SEPTEMBER 15-17, 2014

COLOMBO, SRI LANKA

Registration information to follow.

SOUTH ASIA
BIOSAFETY PROGRAM

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
National Conference on Pre-/Post-Harvest Losses and Value Addition in Vegetables	Association for Promotion of Innovations in Vegetables (APIV) in collaboration with Indian Institute of Vegetable Research (IIVR), Varanasi	July 12-13, 2014 Varanasi	http://www.apiv.in/conference
New Frontiers in Hybrid Seed Production and Genetic Purity Testing Summer School	Anand Agricultural University	August 5-25, 2014 Anand, Gujarat	http://aau.in/sites/default/files/summer_school_baca_aau_anand_may_2014.pdf
Advanced Course on Novel Approaches in Pest and Pesticide Management in Agro-Ecosystem	CCS Haryana Agricultural University	August 19 - September 8, 2014 Hisar, Haryana	http://www.hau.ernet.in/ento1529.pdf
INTERNATIONAL			
Risk Assessment: The Role of Science in GMO Decision-Making	ICGEB Biosafety Unit, Trieste, Italy	June 30-July 4, 2014 Trieste, Italy	http://www.icgeb.org/meetings-2014.html
Theoretical and Practical Course "Plant Tissue Culture: Tool for Genetic Engineering of Plants"	ICGEB and National Biotechnology Development Agency, Abuja, Nigeria	August 10-23, 2014 Abuja, Nigeria	http://www.icgeb.org/meetings-2014.html
13th IUPAC International Congress of Pesticide Chemistry	IUPAC and ACS-AGRO	August 10-14, 2014 San Francisco, California United States	http://www.iupac2014.org/
South Asia Biosafety Conference	South Asia Biosafety Program	September 15-17, 2014 Colombo, Sri Lanka	http://cera-gmc.org/index.php?action=upcoming_meetings
12th Asian Conference and Expert Consultation on Maize for Food, Feed, Nutrition and Environmental Security	Asia-Pacific Association of Agricultural Research Institutions (APAARI), International Maize and Wheat Improvement Center (CIMMYT) and Vietnam Academy of Agricultural Sciences (VAAS)	October 27-29, 2014 Hanoi, Vietnam	http://www.apaari.org/events/12th-conference-on-maize.html
13th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO13)	International Society for Biosafety Research (ISBR)	November 9-13, 2014 Cape Town, South Africa	http://isbr.info/ISBGMO13

SOUTH ASIA BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international developmental program implemented in India, Bangladesh and Pakistan with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.

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