



SOUTH ASIA
BIOSAFETY PROGRAM

Report on a Series of Four Technical Training Workshops on Safety Assessment of Foods Derived from Genetically Modified Crops

Hyderabad, Lucknow, Pune and Kolkata

Organised by
Indian Council of Medical Research (ICMR)



In association with

agbios



REPORT ON A SERIES OF FOUR TECHNICAL TRAINING WORKSHOPS ON SAFETY ASSESSMENT OF FOODS DERIVED FROM GENETICALLY MODIFIED CROPS

INTRODUCTION

The Indian Council of Medical Research (ICMR), in association with AGBIOS Inc., Canada and Biotech Consortium India Limited (BCIL), New Delhi organised a series of four workshops on the “Safety Assessment of Genetically Modified (GM) Foods” at Hyderabad, Lucknow, Pune and Kolkata between September 2006 and January 2007 under the South Asia Biosafety Program (SABP).

These technical workshops were designed to provide in-depth, hands-on training about key requirements for the safety assessment of foods derived from genetically modified plants, including methodologies used to evaluate the potential toxicity and allergenicity of novel proteins, and the nutritional analysis of GM foods.

Well known international experts from the United States, Canada and the Philippines, who are highly experienced in GM food safety assessments, conducted these workshops in the week-long programmes. Presentations were coupled with discussions and practical exercises where the participants were tasked with taking on the role of a risk assessor to evaluate information and data for a number of experimental and commercialized GM foods. The workshops focused on the interdisciplinary nature of GM food safety assessment and the participants worked in teams that included toxicologists, allergists, plant breeders and nutritionists. Over 80 participants attended this series of workshops.

OBJECTIVE

The objective of the workshops was to introduce the concepts and principles of GM food safety assessment and to provide practical hands-on training to scientists and regulators as potential risk assessors/science advisors.

LOCATIONS

Locations and dates of the workshops were as follows:

City	Venue	Dates
Hyderabad	National Institute of Nutrition (NIN)	September 18 to 22, 2006
Lucknow	Industrial Toxicology Research Centre (ITRC)	September 25 to 29, 2006
Pune	Yeshwantrao Chavan Academy of Development Administration (YASHADA)	January 22 to 26, 2007
Kolkata	Bose Institute	January 29 to February 2, 2007

DOCUMENTS

The documents circulated to participants included:

1. Codex Alimentarius Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants.
2. Case Study of Safety Assessment of GM Corn (MON 863), which provided summary of an original submission to the regulatory authorities along with an assessment worksheet to be filled in by participants.
3. Presentations and workbook exercises on:
 - Framing the safety assessment of foods derived from GM crops;
 - Assessing the potential allergenicity of GM foods;
 - Assessing the potential toxicity of GM foods;
 - Nutritional and compositional assessment of GM foods; and
 - Safety assessment and decision making.
4. Selected references on allergenicity, toxicity and nutritional assessment.

In addition, detailed submissions of an approved GM crop were circulated to participants as a case study for their review during the workshop only.

PROGRAMME

At each venue the workshop was inaugurated by the Director of the respective Institute. Talks on the need for and the objectives of the workshops were delivered in the opening session by experts who included Dr. Vasantha Muthuswamy, Senior Deputy Director General, ICMR; Dr. Morven A. McLean and Dr. Donald J. MacKenzie of AGBIOS Inc.; and Dr. O.P. Agarwal, Emeritus Scientist, CSIR.

The day-by-day workshop programme was as follows:

Day	Topics
1	Concepts and principles of GM food safety assessment, Codex principles and guidelines, host and donor organism, molecular characterization.
2	Assessment of potential allergenicity, introduction of bioinformatics tools and databases, human serum testing and animal models.
3	Assessment of potential toxicity, bioinformatics analysis, <i>in vitro</i> digestibility assays, heat stability and animal toxicity testing.
4	Compositional analysis and livestock feeding trials for nutritional assessment.
5	Case study review and decision preparation.

Participants were introduced to the case study following the introduction of basic concepts and principles on the first day. The three subsequent days were devoted to the three components of safety assessment *viz.* toxicity, allergenicity and nutritional assessment and were conducted by international experts in the relevant subjects. An online search using bioinformatics tools and a review of MON 863 as a case study provided insight into safety assessment and a practical example for the participants.

The case study documents were reviewed by participants in groups and a decision document was prepared. Each group defended its decision through a presentation and there were in-depth discussions on various points.

PARTICIPANTS

Three months before the workshop information about the workshop was widely circulated to concerned Ministries/Departments, research institutions and members of regulatory committees. Information was also placed at ICMR's website and in the SABP newsletter. There was an encouraging response from scientists, members of regulatory committees and research students. Taking into consideration their expertise, the applicants were then short-listed by ICMR and BCIL.

Workshop participants were scientists from public sector institutions and members of regulatory bodies.

FEEDBACK

A detailed workshop evaluation form was circulated on the fifth and final day of each workshop. Out of the 61 respondents who submitted feedback forms, about 60 per cent of participants rated the workshop as excellent and remaining 40 per cent as good. The participants expressed great satisfaction with gaining hands-on experience through the case studies. Some of the participants indicated that they were exposed to systematic safety assessment procedures for GM foods for the first time in a comprehensive manner. The coverage of topics, presentations and discussions were rated as excellent by most of the participants. It was commented that more such workshops should be conducted on a regular basis in future and guidance manuals should also be prepared and widely circulated.