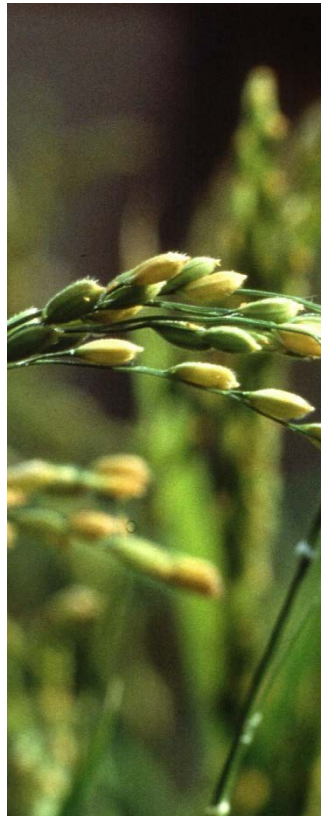


Regional Harmonisation: Contribution by SABP

Dr. Vibha Ahuja, Chief General Manager, BCIL





Harmonization of regulatory requirements

Pursued in multiple sectors in order to

- To optimize resources by the developers as the cost of bringing new products to the market is high and increasing
- To facilitate mutual recognition of data by regulatory agencies
- To improve access to technologies and products
- Challenges with asynchronous approvals
Such as Low-level presence ,Trade disruptions





Regulatory Harmonization of Technical requirements

Focussed on

- Conceptual approaches
- Information and data requirements
- Test protocols





Example – Medicinal Products

- All countries have laws, regulations and guidelines for reporting and evaluating the data on quality, safety and efficacy of new medicinal products.,
- Continuous efforts underway to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner by OECD,WHO etc.
- **The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)** brings together regulatory authorities and pharmaceutical industry of Europe,Japan ,USA etc. to discuss scientific and technical aspects of drug registration.
- Guidelines,Consensus documents prepared on regular basis and available for use by regulatory authorities in various countries
- Mutual recognition of data helps in expeditious approvals



Benefits of Technical harmonization and Mutual Recognition

- More efficient resource utilization by regulatory agencies
- Greater consistency in dossier submissions
 - One core dossier can be used for multiple jurisdictions, which benefits applicants
- Promotes greater synchrony in submission timing between jurisdictions, and possibly decision-making
- Is the only practical solution to addressing issues related to low-level presence



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Key International Forums for GE Food/Feed Discussions

- Codex Alimentarius
- Organization of Economic Cooperation and Development (OECD)





Key Points

- Internationally-accepted guidance, like the Codex 2003 Plant Guideline and the OECD's resources, provide the necessary scientific (technical) foundation for a common approach to GE food and feed safety assessment
- This is foundational to achieving regulatory harmonization between countries
- It promotes science-based decision-making
- It helps in reducing costs and time
- Regulatory harmonization does not compromise national autonomy



Examples of GE Food Safety Harmonization Efforts

- Vietnam
- Common Market for Eastern and Southern Africa (COMESA)
- Health Canada & Food Standards Australia New Zealand





South Asia Biosafety Program: A capacity building initiative

- A program that works to facilitate implementation of transparent, efficient and responsive biosafety regulatory frameworks.
- Active in India and Bangladesh since 2005,
- Funded by United States Agency for International Development (USAID) and implemented by International Life Sciences Institute (ILSI- RF) and International Food Policy Research Institute based in Washington with support from in-country partners.
- Partners with many other international and national organizations in both countries



Partners and activities

- SABP has worked cooperatively with many partners in India and Bangladesh, concerned ministries, scientific bodies, research institutions etc.
- Activities include preparation of resource documents, support for preparation of guidance documents, training workshops etc.
- Assistance in setting up biosafety websites, circulation of a monthly newsletter, organizing an annual conference since 6 years.

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South Asia Biosafety Program

NEWSLETTER for greater circulation only - not for sale

Guidelines for the Environmental Risk Assessment of GE Plants in Bangladesh PAGE 2	New paper on Data Transportability now available PAGE 2	Programme and speaker lineup announced for ISBGM013 PAGE 3	FAO email conference on the Impact Assessment of Agricultural Research begins this month PAGE 3
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PAKISTAN

Spotlight on the Biosafety Research in Pakistan Grants Program

The Biosafety Research in Pakistan Grants Program (BRPGP) supports laboratory, field, and literature research that will significantly advance knowledge relevant to the environmental risk assessment of genetically engineered plants in Pakistan.

This month, we are introducing Dr. Muhammad Saleem Arif and the work he is doing on Bt cotton in Punjab.

2013 GRANTEE: Dr. Muhammad Saleem Arif

JOB TITLE: Assistant Professor, Department of Environmental Sciences

ORGANIZATION: Government College University Faisalabad

PROJECT TITLE: "Linking Cry protein persistence with microbial diversity, enzymatic activity, nutrient cycling and gaseous emissions in soils under Bt cotton in Punjab"

PROJECT DESCRIPTION: Persistence of Bt protein in soil over a certain period of time is very crucial to impart any significant impact of Bt crop plants on soil ecological functioning. Through this project, we will be assessing the impact of repeated Bt cotton cultivation on soil properties. We are targeting the chromosome of Bt cotton introduction in the cotton belt area of Punjab and their subsequent impact on soil properties. Five Bt cotton cultivation areas of known chronosequence will be selected along with one pristine non-Bt cotton area. Soil will be analyzed for different soil properties and correlated with the prevailing agro ecology of the area.

All grantees work to:

- Address the effects of genetically engineered (transgenic) crops on the environment.
- Be relevant to Pakistan and take place in Pakistan.
- Demonstrate applicability to environmental risk assessment of transgenic plants and regulatory decision-making in Pakistan.

TO VIEW ALL GRANT PROJECTS, VISIT THE CERAs WEBSITE AT:
<http://bit.ly/1hVizAM>

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ACTIVITIES UNDER SABP



Cover various aspects, confined field trials, food safety assessment, environmental safety assessment and biosafety compliance



Regional Harmonisation in Biosafety in the South Asian Region

- Discussion initiated at 2nd SABC-2014 (Colombo, Sri Lanka), 3rd SABC in 2015 (Dhaka, Bangladesh), 4th SABC, 2016 (Hyderabad, India) and 5th SABC, 2017, Colombo
- Regional Harmonisation workshop by BAFRA under the UNEP Biosafety project Bhutan in 2012 in Bhutan
- Regional workshop under Phase II UNEP/GEF Biosafety Capacity Building Project in India
- A paper prepared comparing guidelines for safety assessments for foods derived from GE plants of India and Bangladesh with the Codex Guidance
- Letter sent to SARSO for considering a regional standard on food safety assessments for GE plants
- Proposal to adopt a common standard on GM food safety guidance under consideration in SARSO Technical Committee.



Acknowledgements

- Dr Morven Mclean, Executive Director, ILSI Research Foundation
- Dr Andrew Roberts, Deputy Director, ILSI Research Foundation



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Thank You for your attention!