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
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.
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.
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Thank You for your attention!