

Editorial

Effective and stringent biosafety and biosecurity to safeguard Indian Agriculture

Biosafety is usually defined as the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The practices of safe handling of pathogenic microorganisms and their toxins in the biological laboratory are accomplished through the application of containment principles and the risk assessment. Thus, biosafety is the application of safety precautions that reduce a laboratorian's risk of exposure to a potentially infectious microbe, limit contamination of the work environment and the community. Therefore, biosafety is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. World Health Organization (WHO) issued a practical guide line on techniques to be used in laboratories and they are considered as biosafety for containment principles, technologies and practices that are executed to prevent unintended exposure to pathogens and toxins, or their accidental release. WHO encouraging all the countries to have cooperation between Food and Agricultural Organization which contributes to the development of pertinent guidance and considerations for plant health sectors. The international Cartagena Protocol on Biosafety, deals primarily with policies and procedures implemented to ensure the environmentally safe application of modern biotechnology in Agriculture with special reference to living modified organisms (LMOs).

Biosafety concepts include biohazardous materials, virulence, route of entry, viability, infectious dose, concentration, immune status and Biosafety Containment Levels (BSL 1-4 & ABSL 1-4) and infectious agent Risk Groups (RG1-4). The principles related to containment, technologies and practices that are used to avoid unintentional exposure to pathogens and toxins or their accidental release should be adopted for biosafety are described in the Laboratories Biosafety Manual (LBM) of WHO. The national regulatory policies should be developed considering the concepts described in LBM should be considered while developing and enhancing national regulatory policies. Necessary safety precautions should be taken during various activities to protect population and the environment while adopting various international convention as obligatory to Biosafety. The concept of biosafety needs to be rationalized under changing risk conditions, particularly if new working methods are accepted, new organisms are handled, new equipment which are pertinent to biological safety are introduced and existing facilities replaced / changed. Biosafety also has different scenario under laboratory concentrating infectious diseases of human and environment on the introduction of genetically modified organisms (GMOs). Biosafety-relevant risk management approaches are presently addressed in legal instruments like international treaties and national laws as well as in legally non-binding international and national guidelines. Thus, the concepts of biosafety are guided by international regulations to be best fitted into national scenario.

The Environment Protection Act (EPA), 1986 provides guidelines on the handling, research, application and technology transfer of GMOs. India is the first to have a department of biotechnology to deal such kind of regulations and implementations, even than our biosafety framework has the restrictions due to lack of robust domestic biotechnology policies on majority of the areas. The Indian regulatory structure comprises of six different committees to regulate GMOs which are as follows: Recombinant DNA Advisory Committee (RDAC), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committee (IBSC), Genetic Engineering Approval Committee (GEAC), State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC).

National biosafety framework (NBF) has been developed with a combination of policy, legal and technical tools to address safety issues related to environment and human health in the context of development and application of modern biotechnology or other biohazardous biological agents. An effective NBF should have the fundamentals to confirm implementation and compliance as consisting of legally binding regulations and non-binding guidelines including procedures for GMOs release, biosafety review system, risk assessment and management and feedback mechanisms based on scientific knowledge. Institutional components of national biosafety framework (NBF) are as National Biosafety Decision Making Body (National Biosafety Committee, NBC), National Biosafety Administrative Office, Science Advisory Committee, Institutional Biosafety Committee (IBC), Pool of Scientist for Reviewing Applications of Releasing GMOs, Public Consultation Process and Appeal Process, Inspection Monitoring Body.

Biosecurity has been defined and interpreted differently by various stakeholders. Food and Agriculture Organization defined as Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) for analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment. Biosecurity deals with food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (e.g. genetically modified organisms or GMOs), and the introduction and management of invasive alien species. World Health Organization defined biosecurity as institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins. The biosecurity means the protection of countries against alien pests (insects, vertebrates, etc.) and diseases. Biosecurity has also been used to describe procedures taken to reduce the risk of spread of animal disease on farms and defence against biological weapons like deliberate introduction of smallpox or anthrax into human populations. The overarching goal of biosecurity is to prevent, control and/or manage risks to life and health as appropriate to the particular biosecurity sector. Therefore, biosecurity is considered as a holistic concept of direct relevance to the sustainability of agriculture, and wide-ranging aspects of public health and protection of the environment, including biological diversity.

Plant Biosecurity is of paramount importance to any country especially India to safeguard food-security, sustainability of agricultural/horticultural production and also in protecting livelihood of people. The recent concern in the national agriculture scenario is to manage many types of invasive alien pests (insects / mites / nematodes / diseases/weeds etc.) species that cross over from across the globe. To save the agriculture/ plant biodiversity from the ravages of introduced exotic pests and diseases, almost all countries in the world have plant quarantine measures in place. They are a government endeavour enforced through legislative measures to regulate the introduction of planting materials, plant products, soil and living organisms, etc. in order to prevent inadvertent introduction of pests (including fungi, bacteria, viruses, nematodes, insects and weeds) harmful to the agriculture of a country/ state/ region, and if introduced, prevent their establishment and further spread. In India, Destructive Insect Pests Act, 1914 and the Plant Quarantine (Regulation of import into India) Order 2003 and its various amendments are well placed to take care of introduction and further spread of pests harmful to agriculture. The Plant Quarantine (Regulation of Import into India) Order, 2003 has been legislated and came into force from April 1, 2004, under which import of commodities, additional declarations for freedom from quarantine pests is based on a standardized pest risk analysis (PRA). The potential damage of the introduced pest depends on it getting introduced in to new areas, finding suitable environmental conditions as well as susceptible hosts to survive and complete their life cycles. These pests vary considerably in vitality, some being short lived and resistant to desiccation and extremes of temperature, while others are susceptible to these factors and are delicate and short lived. Hence, basically plant quarantine measures act as filters against the entry of exotic species and check or delay the introduction of unwanted organisms. India suffers from several introductions of exotic pests causing severe economic and environmental losses. The noxious *Lantana camara*, fluted scale, bunchy top disease of banana, Golden nematode and wart of potato are some of the examples. In spite of quarantine regulations well placed, during recent years country faced several exotic introductions namely, chilli thrip, cassava mealybug, fall armyworm, *Meloidogyne enterolobii*, rugose spiralling whitefly and South American tomato pinworm and they are causing huge losses.

Several challenges namely, transboundary animal and plant diseases; migratory birds, fishes and insects; poor infrastructure in respect to biosafety and quarantine laboratories; lack of diagnostics to be used at field level; lack of containment facility; non-compliance of regulations; weak capacity of some neighboring countries to identify and respond to biosafety and biosecurity risk; limited understanding and knowledge about biosafety and biosecurity; inconsistent approaches and system; fragmented accountabilities; insufficient use of available trained human resources; poor risk assessment; weak monitoring and evaluation; lack of robust data base including alert list of pests and budgetary constraints have to be addressed properly for efficient biosafety and biosecurity at National level.

Scientifically sound and transparent PRA prior to import is an important tool, so that, our agricultural production is not jeopardized. Also, the Agricultural Biosecurity Bill 2013 being drafted by the Ministry is an attempt at a holistic approach towards biosecurity in India. The Government of India initiated a regulatory mechanism for research on microorganisms through National Portal for Biological Research as Biological Research Regulatory Approval Portal (BioRRAP) going to facilitate approvals and clearances of microorganisms through Department of Biotechnology. International Collaborative Life Science Research Review Committee (IC-LSR) is being proposed for nongovernmental organization/institutions which will be Co-chaired by Secretary DBT and Secretary, Health.

Proper awareness and strict adoption of National regulations in harmonization with international regulations along with strengthening of the plant quarantine system in the country both in the terms of manpower and facilities are required for safeguarding Indian Agriculture. Integrated biosecurity approach involving all the sectors responsible at National levels are required to harness the potential benefits to improve public health, enhanced international trade, improved agricultural production and protection of the environment.

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