Session 3 :Regulatory Approaches in different countries

Indian Regulatory Frame Work In India for Risk Assessment , Public Engagement And Post Release Management

S.R.Rao and A.K.Rawat

Department of Biotechnology (DBT) Minister of Science & Technology
Government of India

Workshop
3rd International Workshop for Regulation of Animal Biotechnology

Biosafety is regulated in India is under Rules 1989 of Environment (Protection) Act 1986

Rules are applicable to:

- **The import, export, transport, manufacture, process, use or sale of GMOs and use of GMOs for research**
- **Authorization for production of genetically modified microorganisms, plants and animals**
- **Approval for deliberate or intentional release of GMOs into the open environment**
- **Approval for production, sale and import of foodstuff, ingredients in foodstuff including processing aid which may contain GMOs or cells**

Indian Regulatory framework - Scope

DEFINITIONS Rules 1989

In these rules unless the context requires.

"Gene Technology" means the application of the gene technique called genetic engineering, include self cloning and deletion as well as cell hybridisation;

"Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism.

It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

Regulatory framework- Statutory Bodies- functions

NATIONAL LEVEL		
Genetic Engineering Appraisal Committee (GEAC)	**Final Approval for environmental release including confined field trials**	**M/o of Environment and Forests and climate change**
r DNA Advisory Committee	**Advise on biosafey of emerging technologies**	**M/o S&T D/o Biotechnology**
Review Committee For Genetic Manipulation (RCGM)	**Scientific risk assessment of plants, animals, biopharma, microbes and Guidelines**	
INSTITUTE /UNIVERSITY/COMPANY LEVEL		
Institutional Biosafety Committee (IBSC) with Nominee of RCGM (600 +)	**R&D and Contained Experiments**	
STATE LEVEL		
State Biotechnology Coordination committee for monitoring and supervision		**State Governments**

Biosafety Support Unit funded by DBT

Internal Scientific food and environmental safety assessment

Risk Assessment Unit (GE Biopharma) Chief Scientist

- Pharmacology
- Toxicology
- Biochemistry
- Microbiology
- Veterinary pharmacology
- Molecular biology and genetics
- Bio-processing
- Bio-analysis
- Drug regulatory affairs
- Analytical chemistry

Chief Scientific Officer

Scrutiny & Evaluation of Dossier and Application and preparation of Risk assessment and Risk management Report

Risk Assessment Unit (Agri-biotech) Chief Scientist

- Agronomy
- Genetics and plant breeder
- Entomology
- Plant physiology
- Plant pathology
- Plant molecular biology
- GM food toxicologist
- Biostatistics
- Soil microbiology
- Environmental biology

GMOs applications assessed by statutory bodies

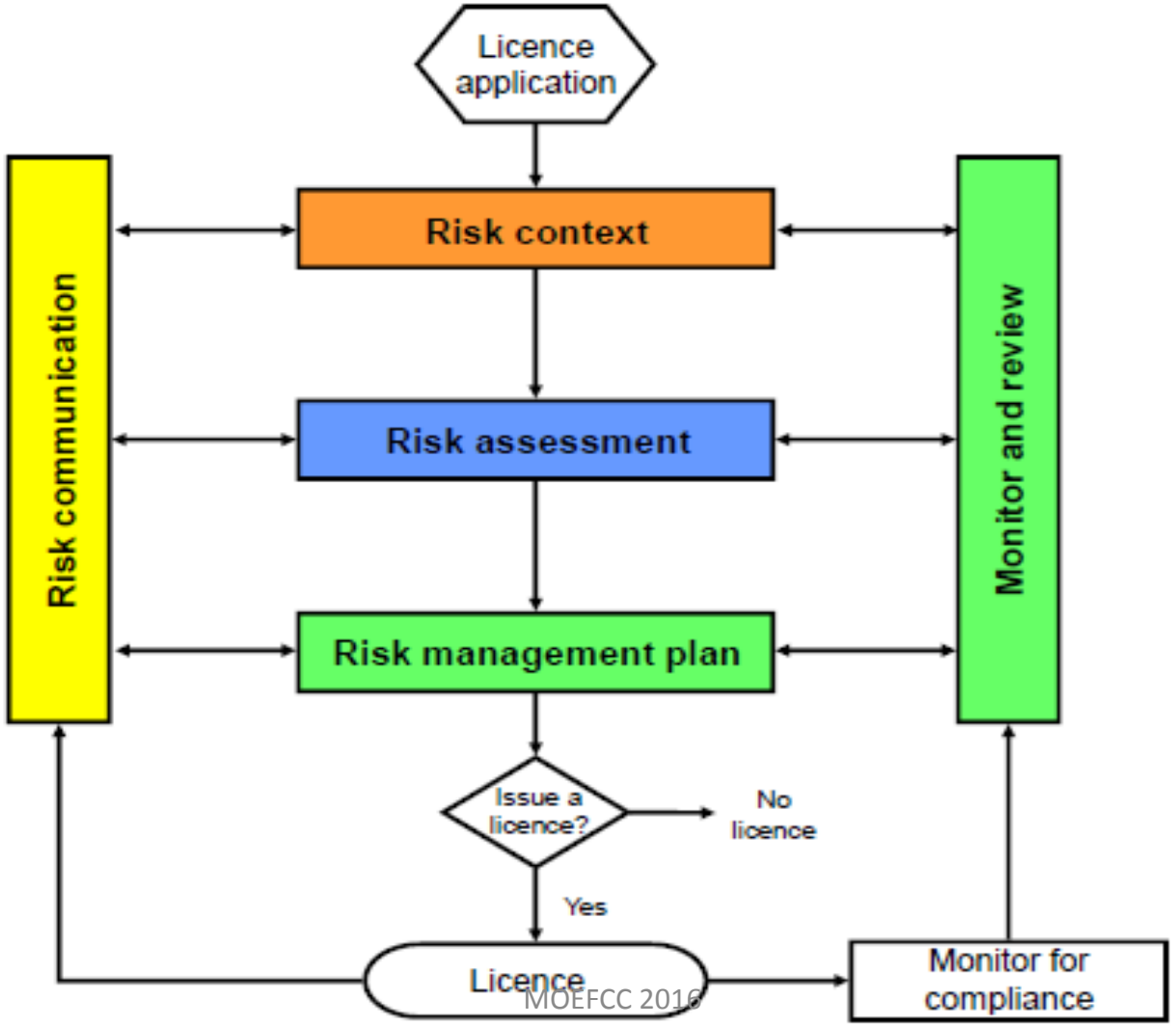
- 340. Applications in agriculture per year
- 20 for Animal biotechnology
  - 10 for transgenic mouse an
  - 7 for recombinant vaccines
  - 1 transgenic silk worm
  - 1 transgenic mosquito
  - 1 transgenic rohu fish

Indian has imported so far >200 transgenic model mice mostly from USA

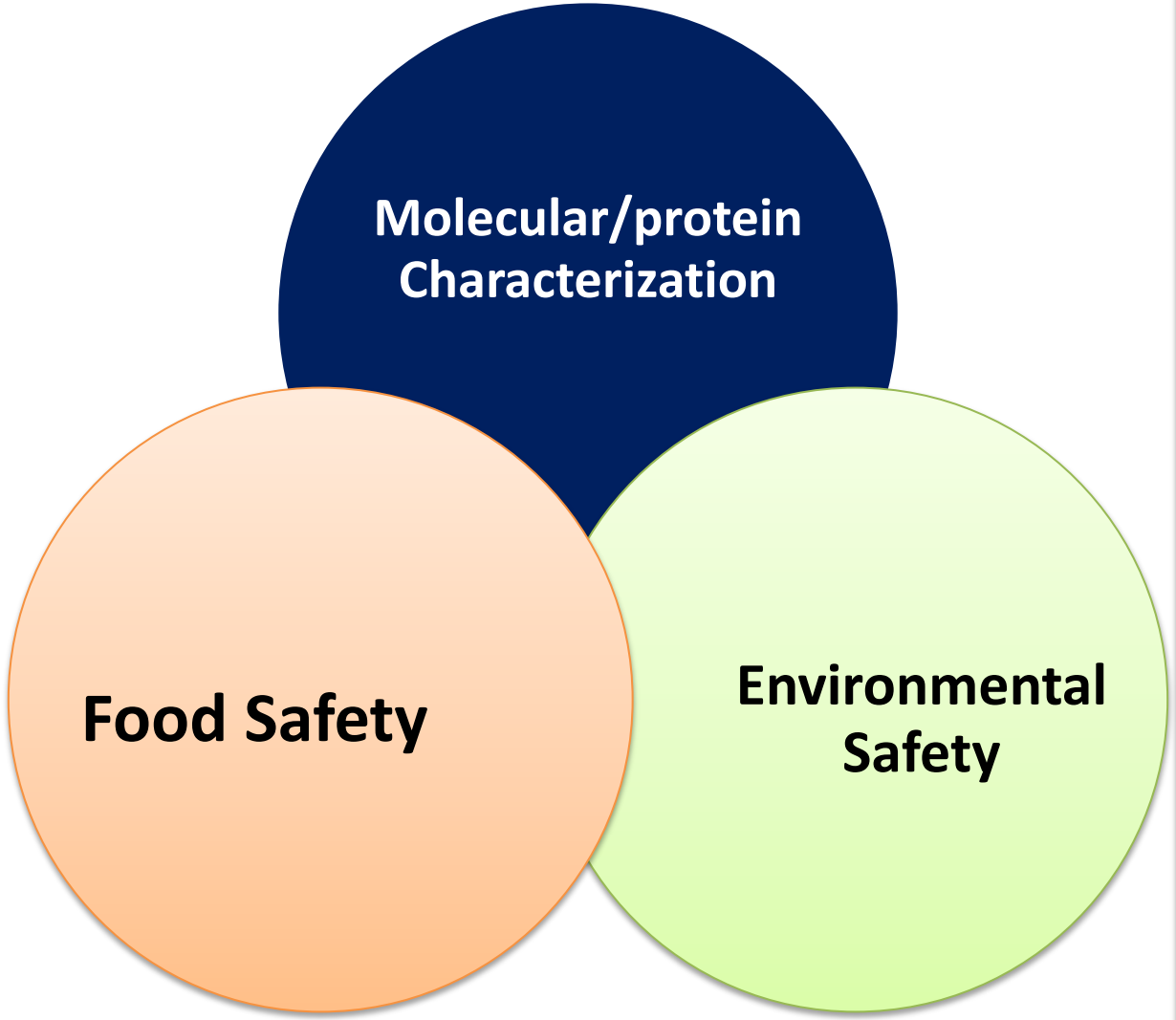
Application reviewed 2007-2016

Year	Health care	Agriculture
2007	202	668
2008	348	617
2009	355	367
2010	388	390
2011	511	452
2012	394	450
2013	374	277
2014	324	312
2015	300	350
2016	205	400
TOTAL	3401	4283

Risk analysis – Doing it the ISO way (ISO 31000:2009)

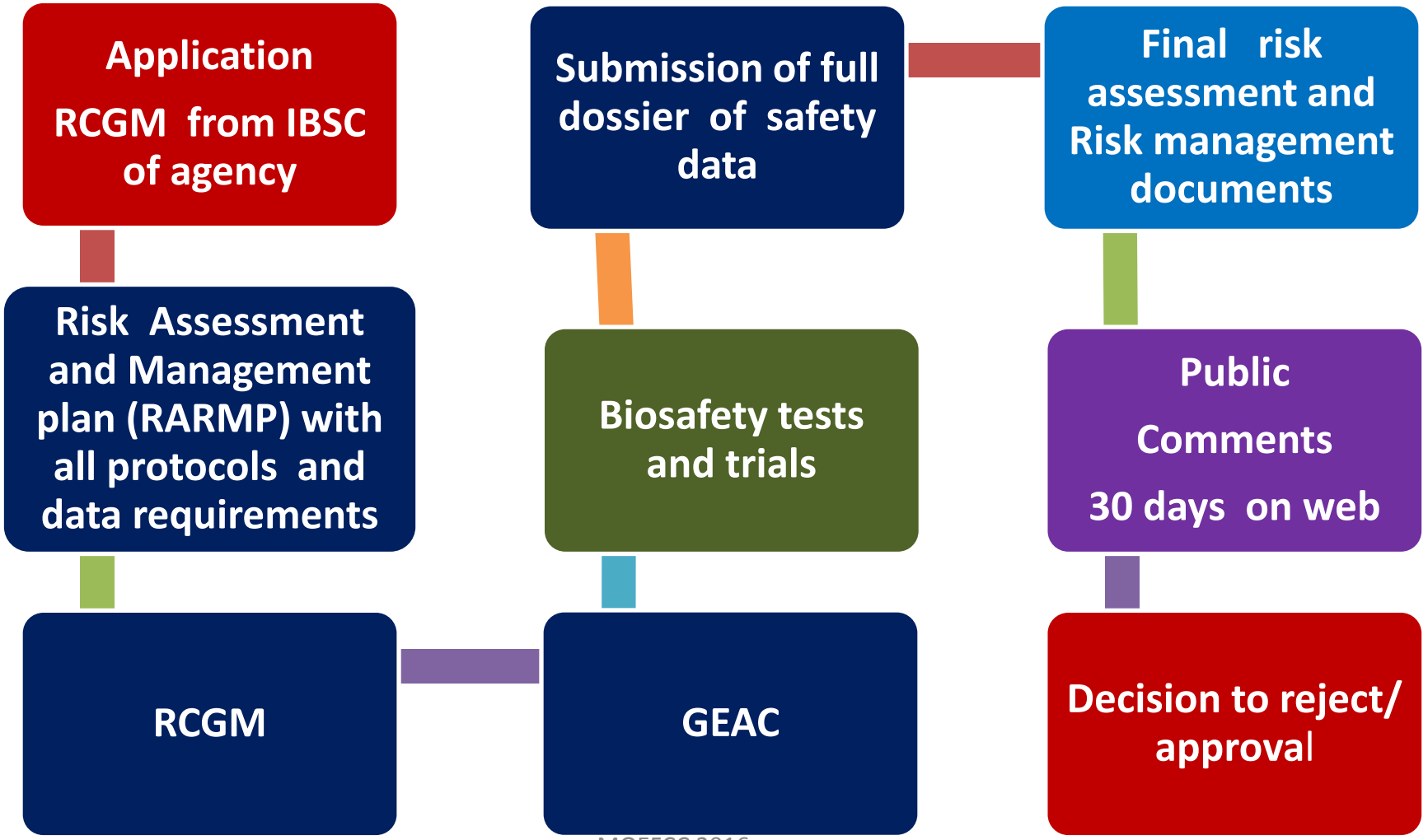


3. Principles of scientific risk assessment



Food and feed safety assessment and the **environmental risk assessment** are **separate and distinct evaluations** and share some common elements of information through the **molecular characterization** of the GM organism and characterization of expressed, transgenic proteins.

GM crop approval / rejection pathway- process



HIGHLIGHTS OF EVOLVING INDIAN GUIDELINES FOR BIOSAFETY ASSESSMENT OF TRANSGENIC ANIMALS WITH IN THE EXISTING LAW

Based on the intended purpose of genetic modification, the current efforts in transgenesis in livestock

- Production of pharmaceuticals expressed in milk, serum or urine (referred to as "**biopharm**" animals) in the course of gene pharming
- Production of animals as organ donors for xeno-transplants
- Creation of models for study of human disease
- Development of livestock suitable for use in agriculture

SCOPE

✓Cover areas of research involving genetically engineered animals containing heritable rDNA construct

✓Provides guidance for assessing potential effects of GE animals on animal and human health and the environment and the rationales for data requirements for a comprehensive environmental risk assessment.

This document does not cover

X Genetically engineered animals with non-heritable rDNA construct (e.g. those modifications intended to be used as gene therapy)

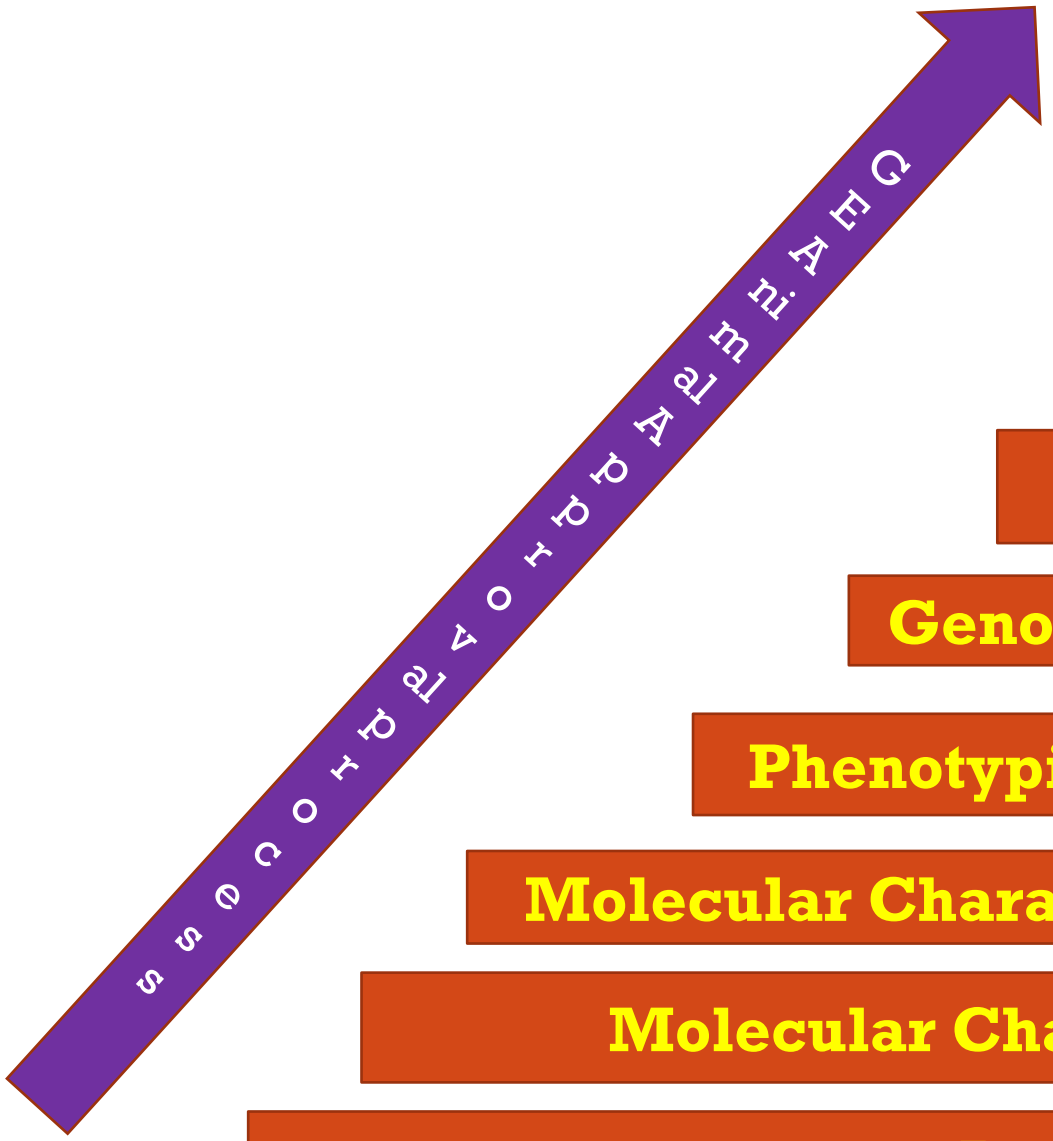
X GE insects being developed for plant pest control or animal and human health protection

XGE animals of non-food species that are raised and used in contained and controlled conditions such as GE laboratory animals used in research institutions.

ADOPTED GUIDELINES

- Recombinant DNA safety Guidelines and Regulations. (DBT, 1990)
- Revised Guidelines for Research in Transgenic plants & Guidelines (DBT, 1998)
- The Singapore biosafety guidelines for research on genetically modified organisms (GMOs) prepared by GMAC, Singapore in 2006
- Application for licence for dealings with a GMO involving intentional release of the GMO into the environment (DIR) http://www.ogtr.gov.au/ by OGTR, Australia
- Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, June 2015 (FDA #187)
- Guideline for the conduct of food safety assessment of foods derived from recombinant DNA animals- Codex Alimentarius Commission, 2008 (CAC/GL 68-2008)
- Guidance on the environmental risk assessment of genetically modified animals by European Food Safety Authority (EFSA), 2013
- NIH guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines), April 2016

APPROVAL PROCESS FOR GE ANIMALS



Post-Approval Reporting

Decision

Claim Validation

Environmental food/feed Safety

Genotypic and phenotypic Durability plan

Phenotypic Characterization of the GE animal

Molecular Characterization of the GE animal lineage

Molecular Characterization of the Construct

Product Definition

Evolving Indian regulatory Policy on Biosafety Assessment for Products Using Genome Editing Technologies

Scope of Policy

Only for recombinant DNA products coming out of the new technologies using genome editing with engineered nucleases like Zn Finger Nucleases, TALENs, CRISPR-CAS etc.

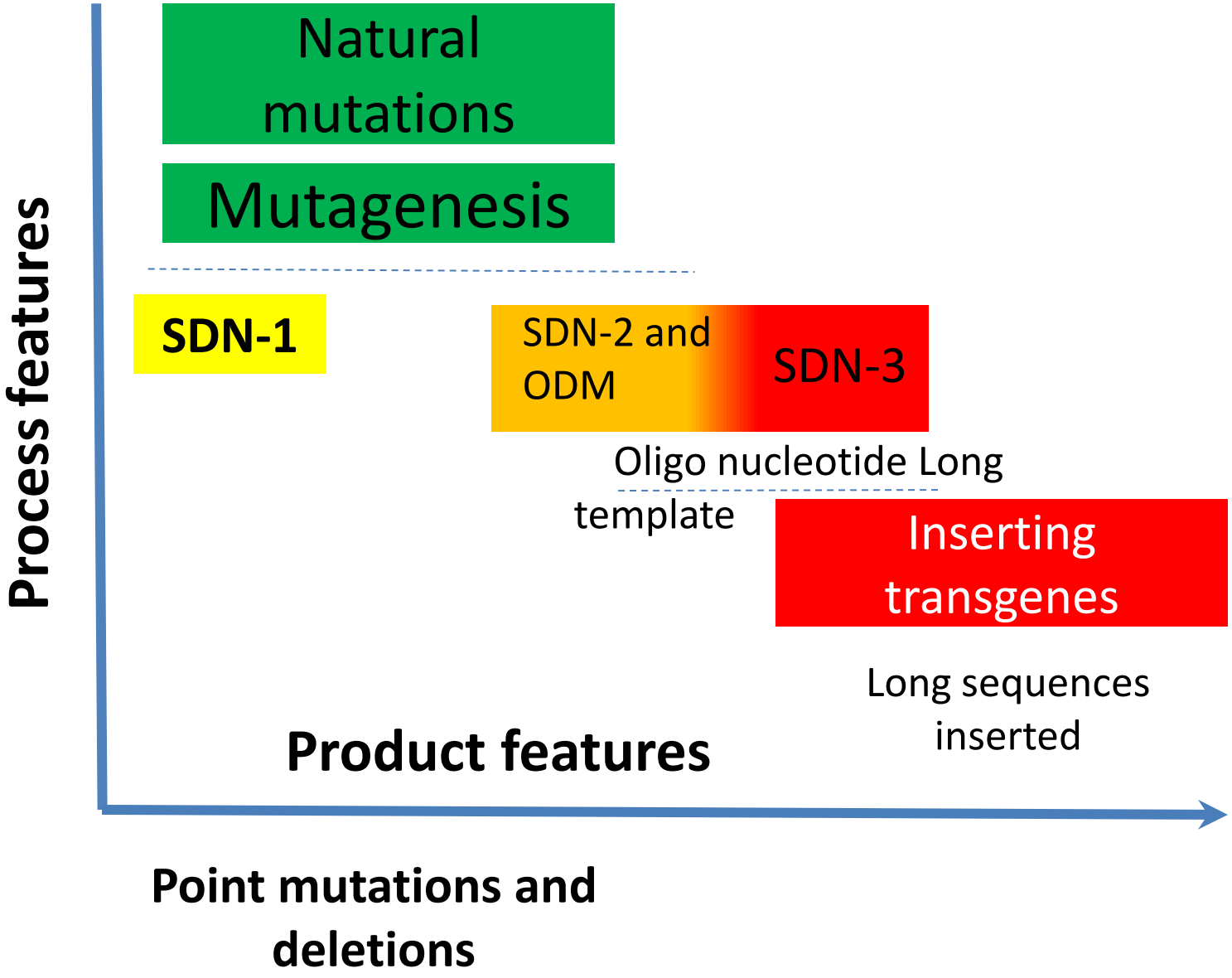
Does not include:

Genetically engineered organisms (GMOs/LMOs) that are developed using technologies other than genome editing technologies do not come under the purview of this policy.

For example:

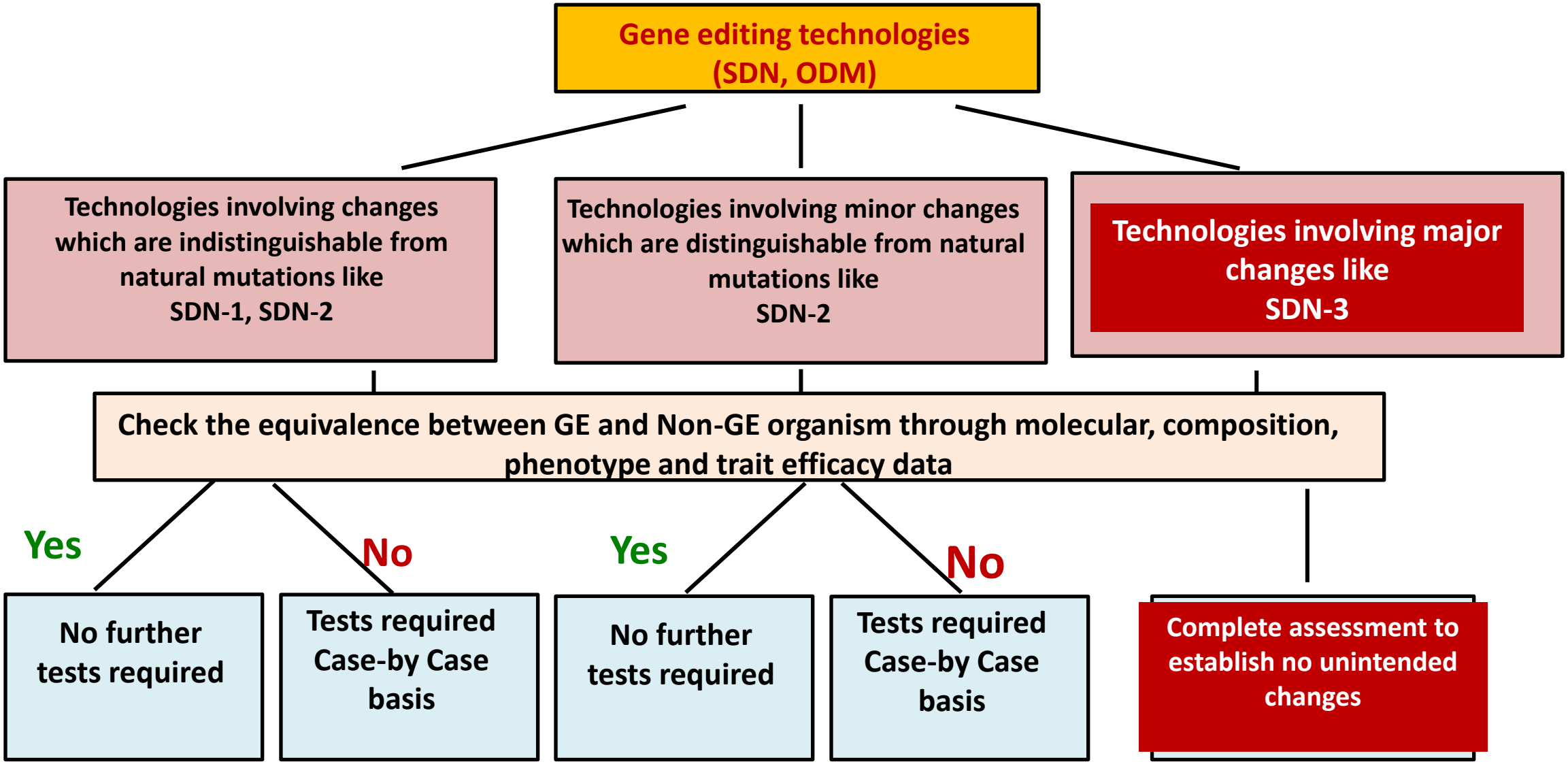
- **Recombinant DNA products expressing foreign proteins**
- **Products arising out of natural mutations, chemical or radiation mutagenesis**

Comparison of process and product features of some new technologies



Site-Directed Nuclease (SDN) techniques and Oligo-Directed Mutagenesis (ODM) are represented according to their process and product features, relative to unregulated techniques (natural mutations, chemical mutagenesis and radiation mutagenesis) and regulated techniques (inserting transgenes)

Process of Risk Assessment



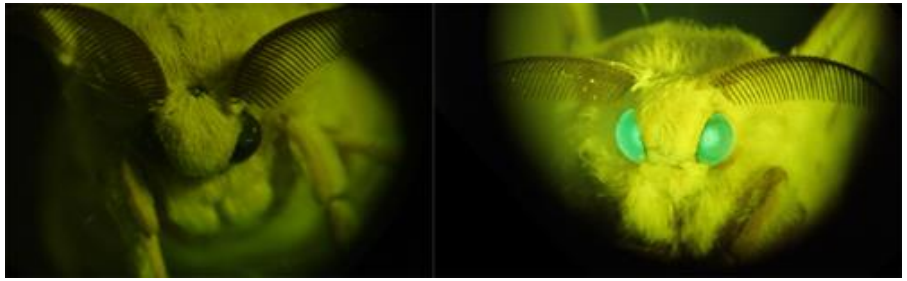
Conclusion

Regulatory requirements for transgenic livestock are not yet definitive but clearly have the potential to affect existing regulatory and industry practices in such important areas as animal health and diagnosis of disease, trade certifications, recording of animals' identification and ancestry, genetic evaluations, and product identity and traceability.

Biosafety Support Unit

GM 'surrogate hens' could lay eggs of rare chicken breeds,

Transgenic silkworm strains



Transgenic mosquito


THANK YOU
THANK YOU VERY MUCH
WELALIN
GRAZIE
CHOKRANE
RAIBH MAITH AGAT
MULTUMESC
NIRRINGRAZZJAK
MOCHCHAKKERAM
MATUR NUWUN
MERCI
OBRIGADO
ASANTE
SPASIBO
VINAKA
ZIKOMO
SUWUN
MATONDO
EIO
MAAKE
SAAGHA XALDA HWA
どうも
СПАСИБО
БАЯРЛАЛАА
МНОГО ВИ БЛАГОДАРЯ
KHUBLEI
QUYANAQ
MULTUMESC