Round Table on Government Actions And Advisory Options Related Human Genome Editing (before and after 2015)

S.R.Rao
Senior Advisor
Department of Biotechnology,
Ministry of Science and Technology
Government of India

Second International Summit on Human Genome Editing
The University of Hong Kong
November 27-29 2018

Rules 1989 0f Environmental Protection Act 1986
Legal provisions Regulating Genome Editing And Genetic Engineering In Organisms

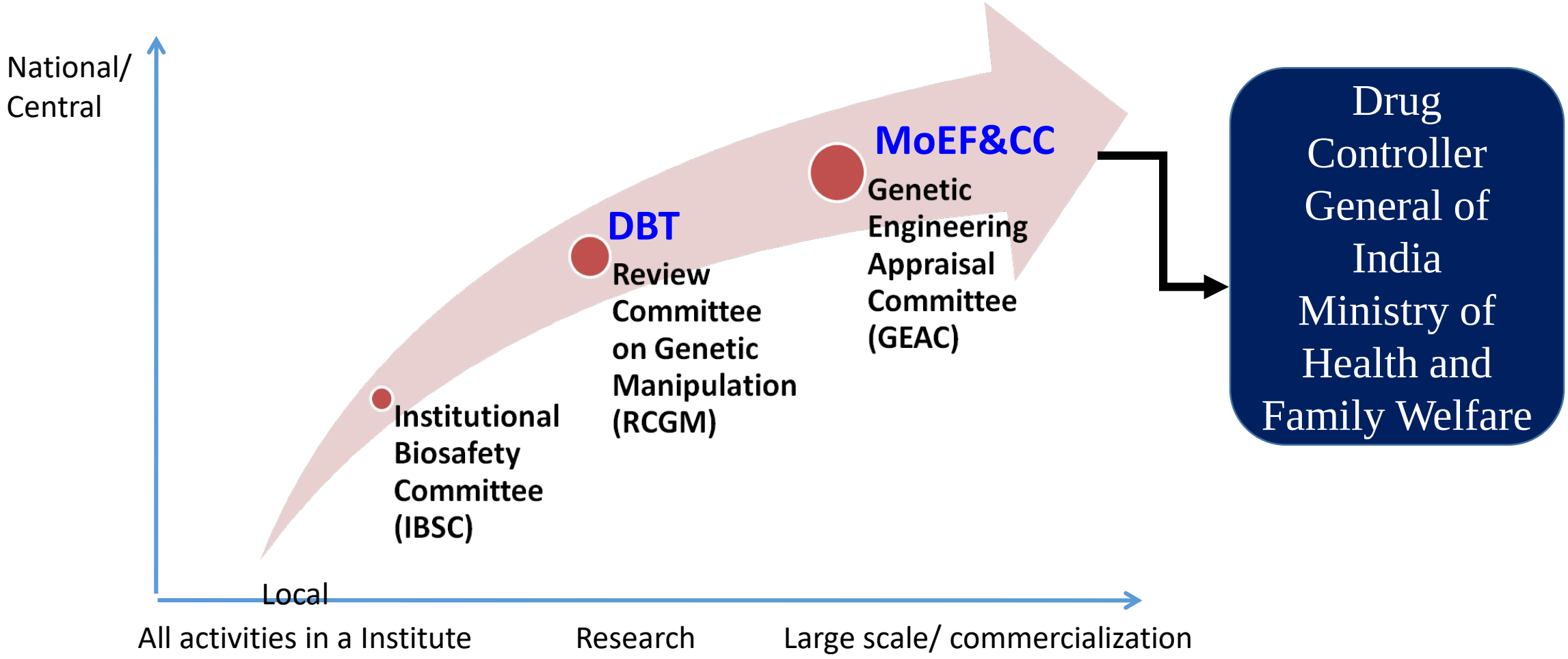
Indian laws regulating process and products of genetic engineering also have legal provisions and definitions include specific references to effects of Genome Editing process.

The clauses (ii) and (iv) of rule 3 of Rules 1989 of E(P)A 1986 "Genetic engineering" is defined as 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.**

Further rules 1989 also state that "These rules shall also apply to **new gene technologies** apart from those in clauses (ii) and (iv) of rule 3 (referred above) and these rules shall apply to organisms /micro-organisms and cells generated by the utilisation of such **other gene-technologies and to substances and products of which such organisms and cells form part."**

Genome editing regulated in India as process and product as it involves deletion or insertion of a nucleotide or a DNA sequence coding for a gene or regulatory element and may result in the development of a trait that may or may not existed in nature and the products

Implementing Ministries And Statutory Authorities Under Rules 1989, EPA 1986 And Drugs And Cosmetics Act, 1940



DBT: Department of Biotechnology
Ministry of Science And Technology

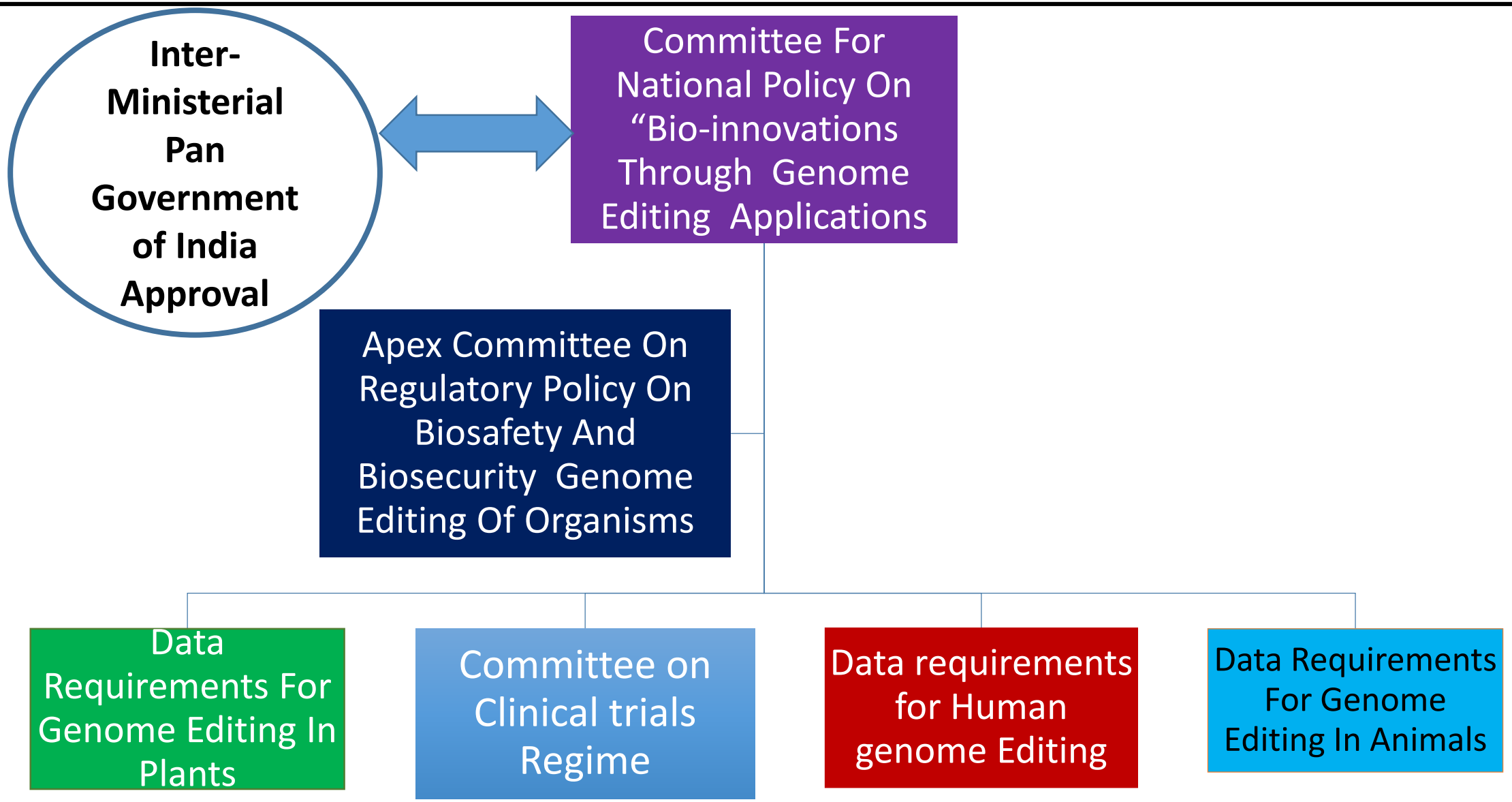
MOEF&CC :
Ministry of Environment , Forests and Climate Change

Department of Biotechnology
Ministry of Science and Technology
Government of India
Initiates

Key points deliberated currently in developing Policy Framework for Regulation and principles of Risk assessment of Genome Edited (GEd) Products/Organisms

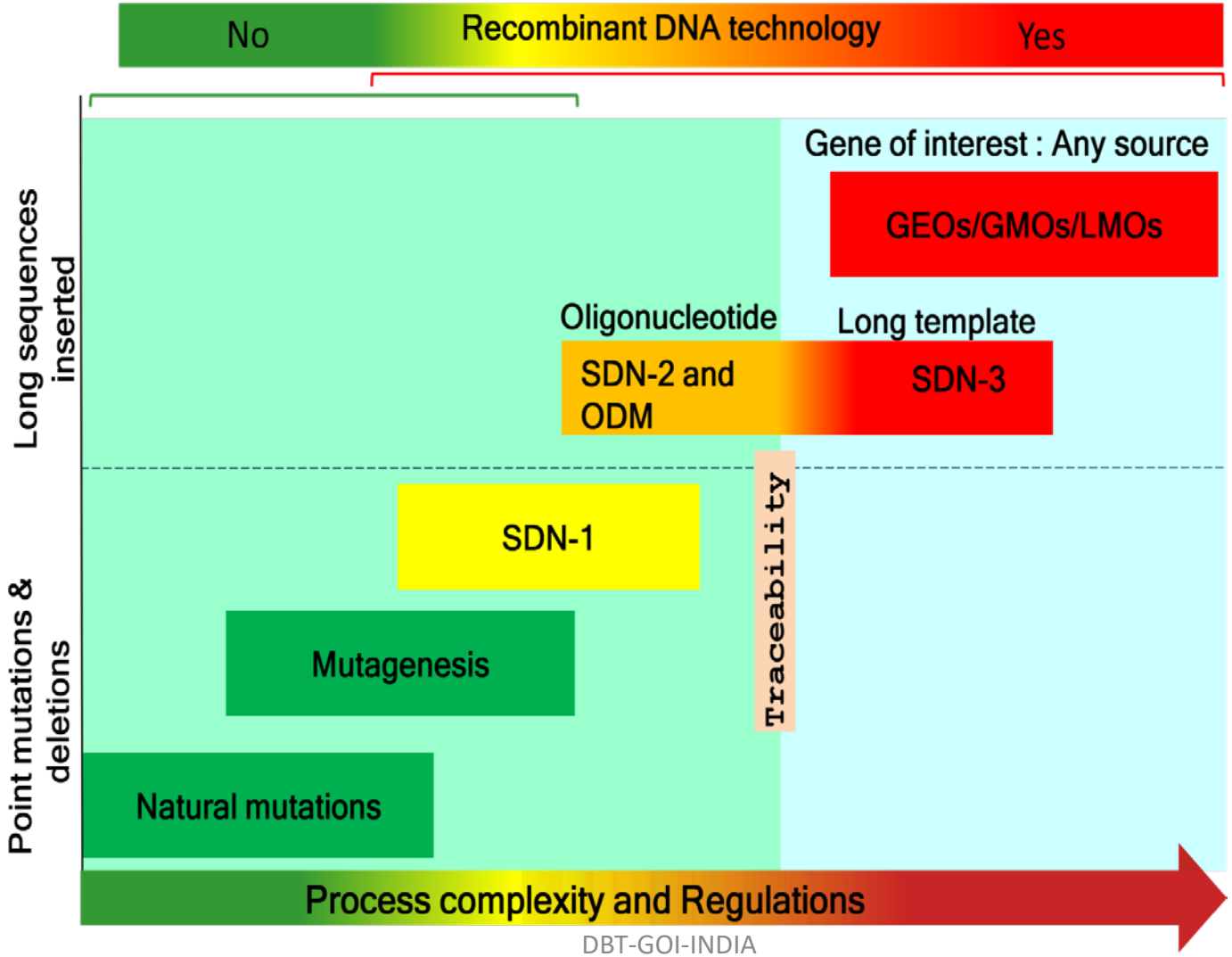
Through consultations
Experts, inter-ministerial opinion and otherstakeholders

Government Actions And Advisory Options On A Developing Policy Related Genome Editing Of Organisms And Applications

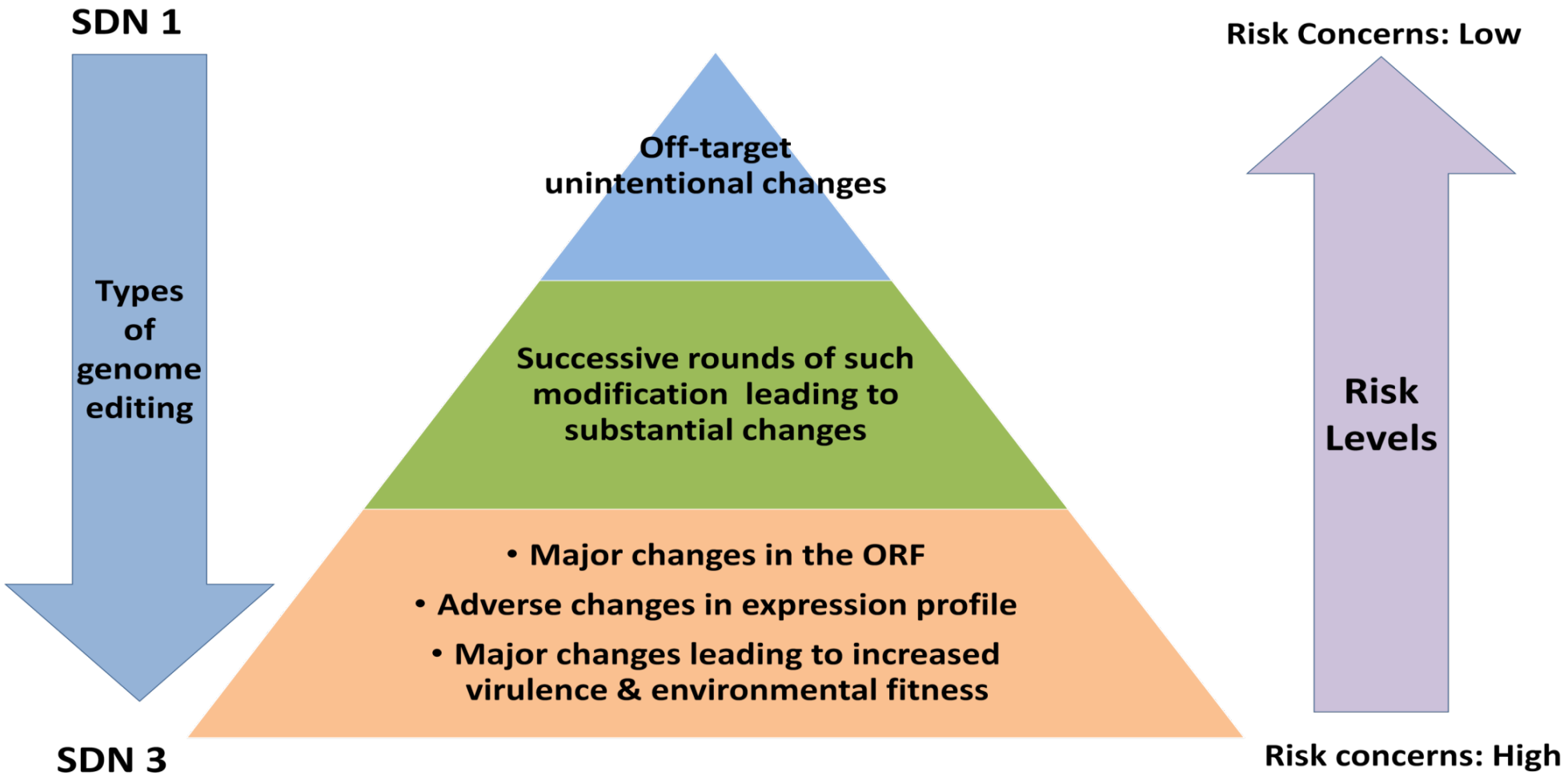


Evolving Policy Framework for Regulation …….

1.0 Understanding Process complexity, product features and traceability of Genome editing techniques relative to unregulated techniques



2.0. Risk scenarios in genome editing.



Evolving Policy Framework for Regulation .....

Intensity of Risk levels of site-directed nuclease technologies to the Categories of genome editing for risk assessment

	Category		
	Category I	Category II	Category III
Method	Transient expression of PN	Stable introduction of rDNA with subsequent removal from the genome to generate rDNA-free null segregants	Stable plant genome integration of rDNA
SDN I Targeted DSB repairs involving NHEJ	Low/ Negligible	Low to Moderate	NA
SDN 2 & ODM Targeted DSB repairs involving by HR involving one or very few Nucleotides	Low	Low to Moderate	Moderate
SDN3 Targeted DSB repairs With insertion of large DNA	NA	Moderate	High

The Generic regulatory policy proposed was presented in various National and international meetings. with wider acceptance

1. International Conference On New Plant Breeding Molecular Technologies –Technology Development And Regulation" held on October 9, 2014 and October 10, 2014 in Hotel Le Meriden, Jaipur.

2. DBT sponsored panel panel on "Panel for Genome Editing " at Indian Science Congress at Tirupati on 6th January 2016

3. 20th ADNAT Convention: International Symposium on Genome Editing Technologies and their Applications in Biology, Medicine and Agriculture with a talk on "Evolving Indian regulatory Policy on Biosafety Assessment for Products Using Genome Editing Technologies" 16th to 18th February 2017

4. ICMR-INSERM-DBT Symposium On " Ethical And Scientific Issues Of Gene Editing Using Crispr-cas9 Technology on April 27th, 2017 at NII, New Delhi

The Generic regulatory policy proposed was presented in various National and international meetings. with wider acceptance

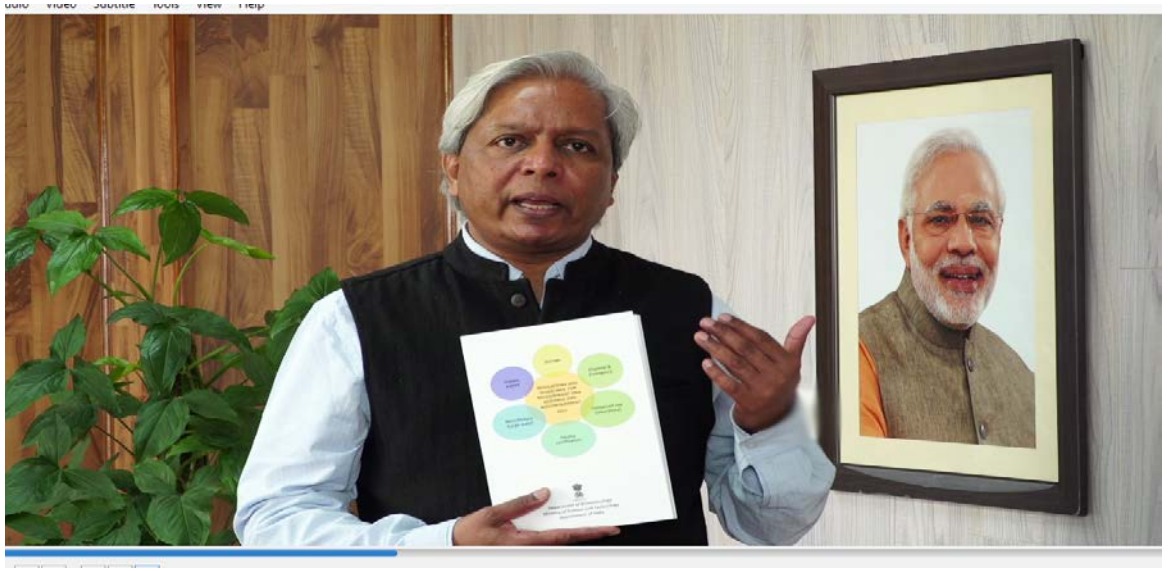
5. Third International Workshop for Regulation of Animal Biotechnology Hosted by the U.S. Department of Agriculture – Foreign Agriculture Service and Virginia Tech University Charlottesville, Virginia, USA, June 26-30, 2017

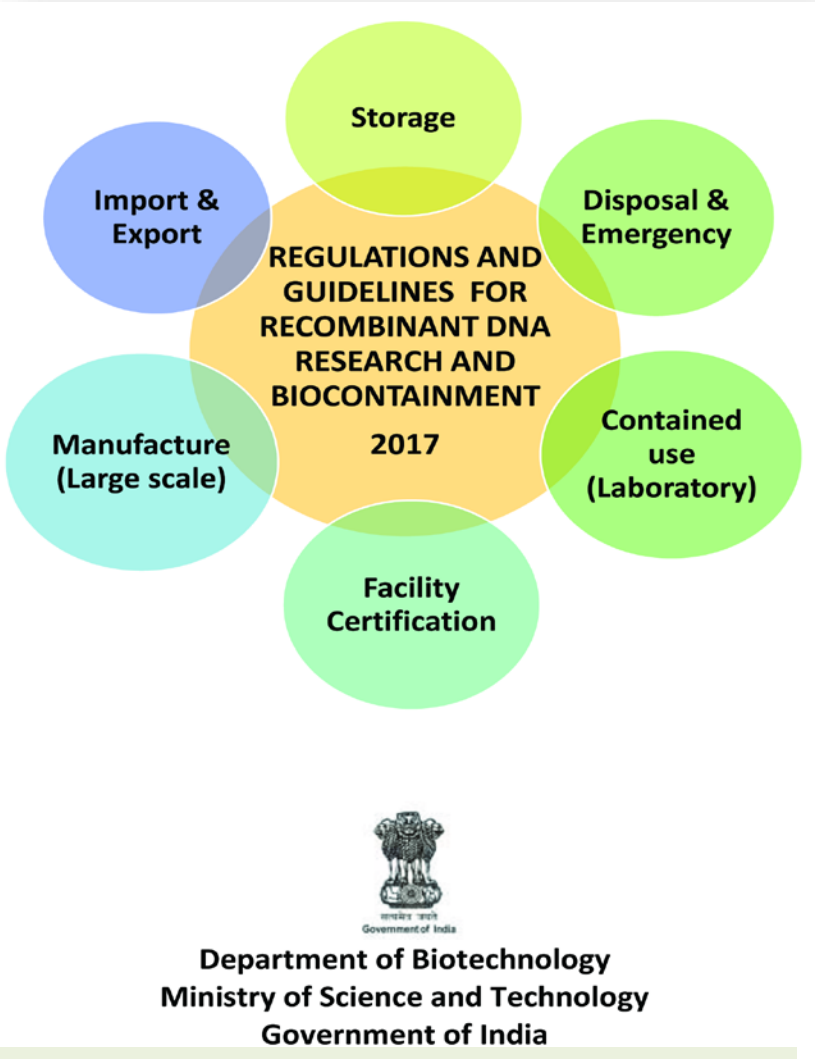
6. International Workshop "Assessing the Security Implications of Genome Editing Technology" October 11 - 13, 2017, Herrenhausen Palace, Hanover, Germany

7. Products of genome editing technologies and biosafety regulatory challenges In IN VITRO BIOLOGY 2018 MEETING. June 2 to 6, 2018 in Saint-Louis, Missouri.

5. Evolving Legal, Regulatory And Policy Strategies For Genome Engineering In General in *Workshop Genome Engineering , IISc Bengaluru 24-29th June 2018*

Notified. : Guidelines for R&D of genome editing organisms including human cells under Rules 1989 of EPA, 1986





- **IBSCs are empowered in decision making process for**
- **Inform IBSC for Genome editing Lab experiments of SDN1-type mutations.**
- **Apply for authorisation by IBSC for Genome editing experiments of SDN2 and 3 -type modifications.**

Released at the Meeting of States Parties of the Biological Weapons Convention (BWC) at Geneva, Switzerland on 5th December, 2017

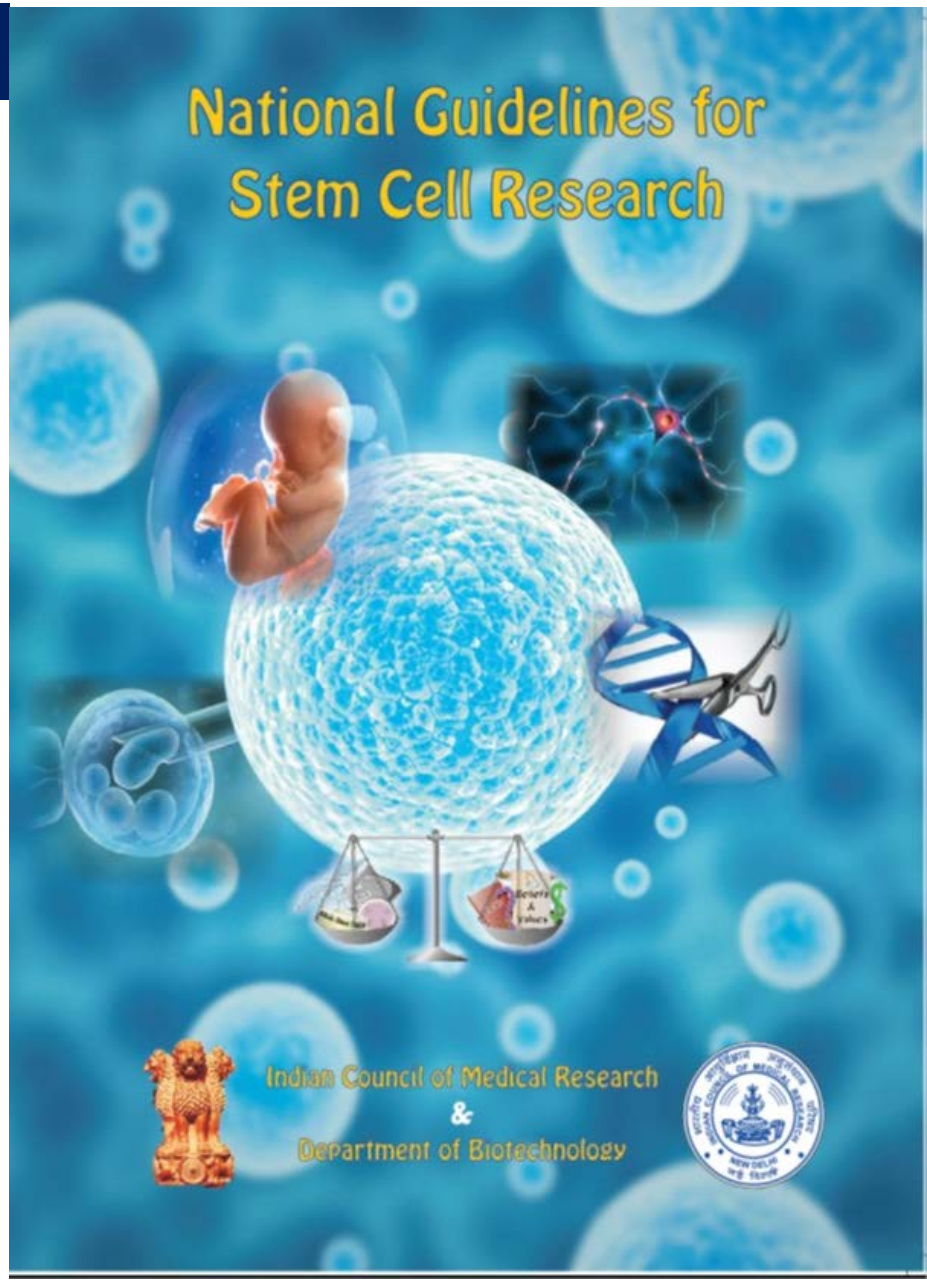
Notified : National Guidelines For Stem Cell Research 2017

Indian Council for Medical Research Ethical guidelines 2006

Prohibited Areas of Research for human's research is

"Any research related to germ line genetic engineering or reproductive cloning".

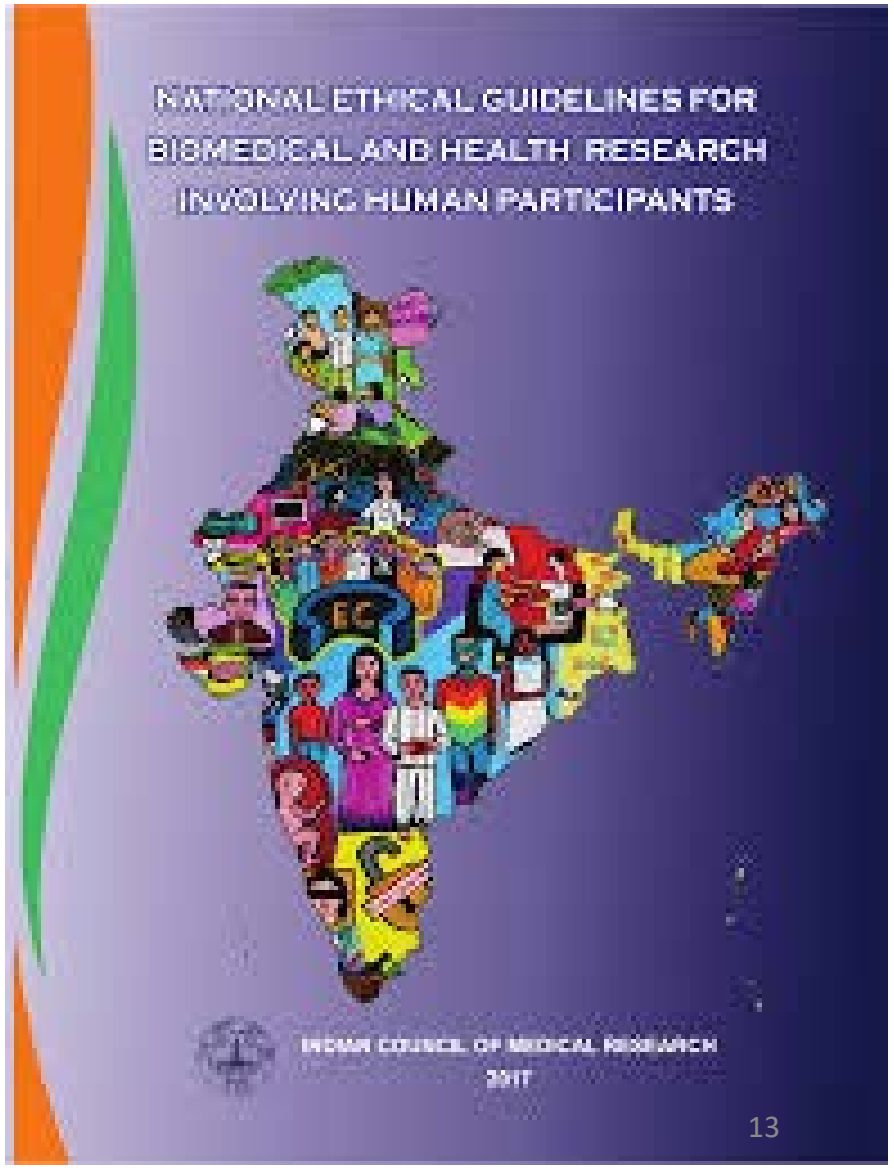
New Guidelines (2017)
notified allows use of somatic cells for therapy and gene therapy with some conditions subject to Rules 1989 of EPA 1986



Notified : National Ethical Guidelines for Biomedical and health Research involving Humans notified

The new guidelines have a total of 12 sections including Responsible Conduct of Research, Informed Consent Process, Vulnerability, Public Health Research, Social and Behavioural Sciences Research for Health, Biological materials, Biobanking and Datasets and Research during Humanitarian Emergencies and Disasters.

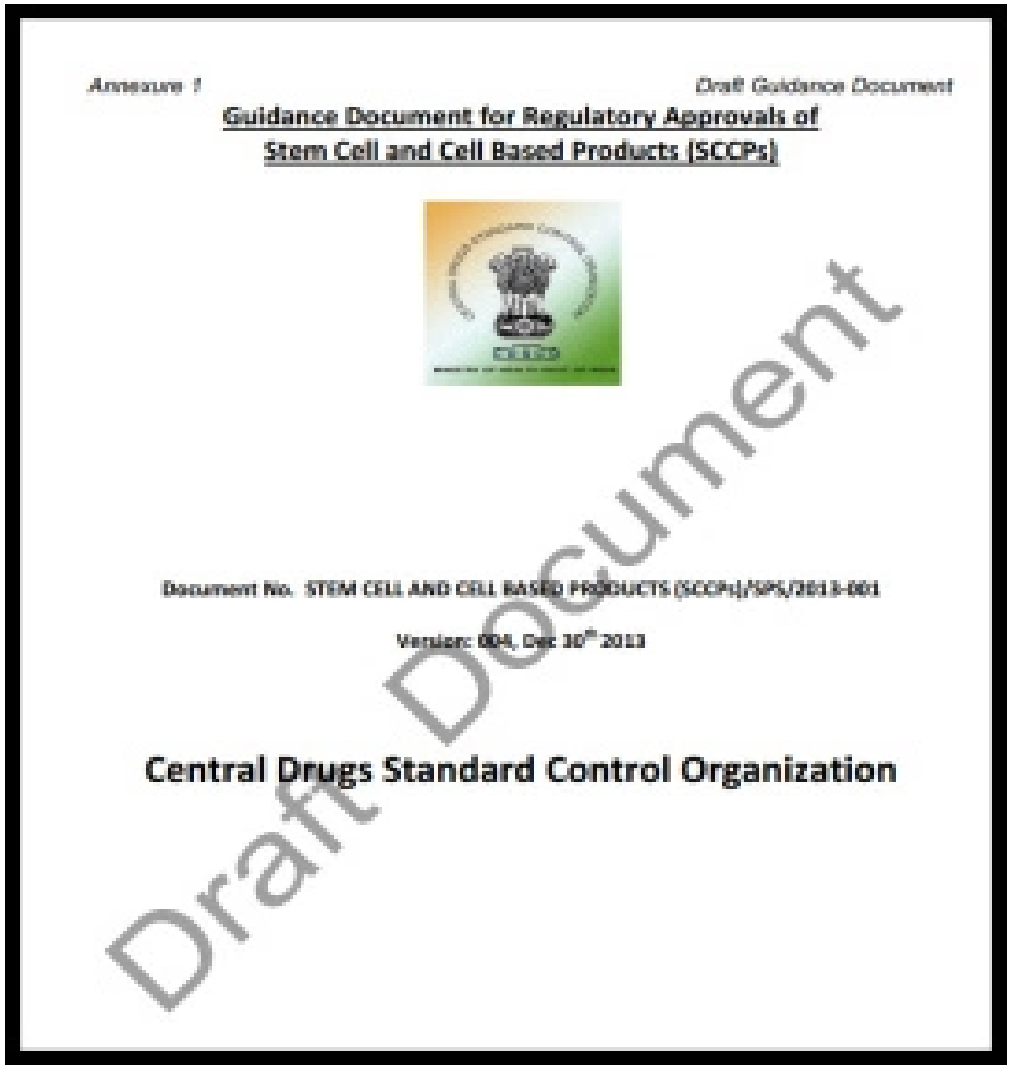
The section on ethics review process has been elaborated to help the many ethics committees who have doubt about the various procedures to be followed.



सत्यमेव जयते

Notification pending : Drug Controller General of India (DCGI) Ministry has clinical trials regimes for Somatic cell therapy include genome editing 2017

Stem Cell and Cell based Product means a drug which has been derived from processed cells including cell or tissue which has been processed by means of substantial or more than minimal manipulation with the objective of propagation and / or differentiation of a cell or tissue,' cell activation, and production of a cell-line, which includes pharmaceutical or chemical or enzymatic treatment, altering a biological characteristic, combining with a non-cellular component, manipulation by genetic engineering including gene editing & gene modification.


Annexure I

Draft Guidance Document

Guidance Document for Regulatory Approvals of Stem Cell and Cell Based Products (SCCPs)

Document No. STEM CELL AND CELL BASED PRODUCTS (SCCPs)/SPS/2013-001

Version: 004, Dec 30th 2013

Central Drugs Standard Control Organization

Draft Document

The Regulatory pathway for genome editing from for gene therapy – R&D to Clinical trials-India

Guidelines for R&D of genome editing organisms including human cells under Rules 1989 of EPA, 1986

Stem cell research Guidelines

Ethical clearance

- ***Safety***
- IBSC
- Rules 1989,EPA 1986

Laboratory

Preclinical

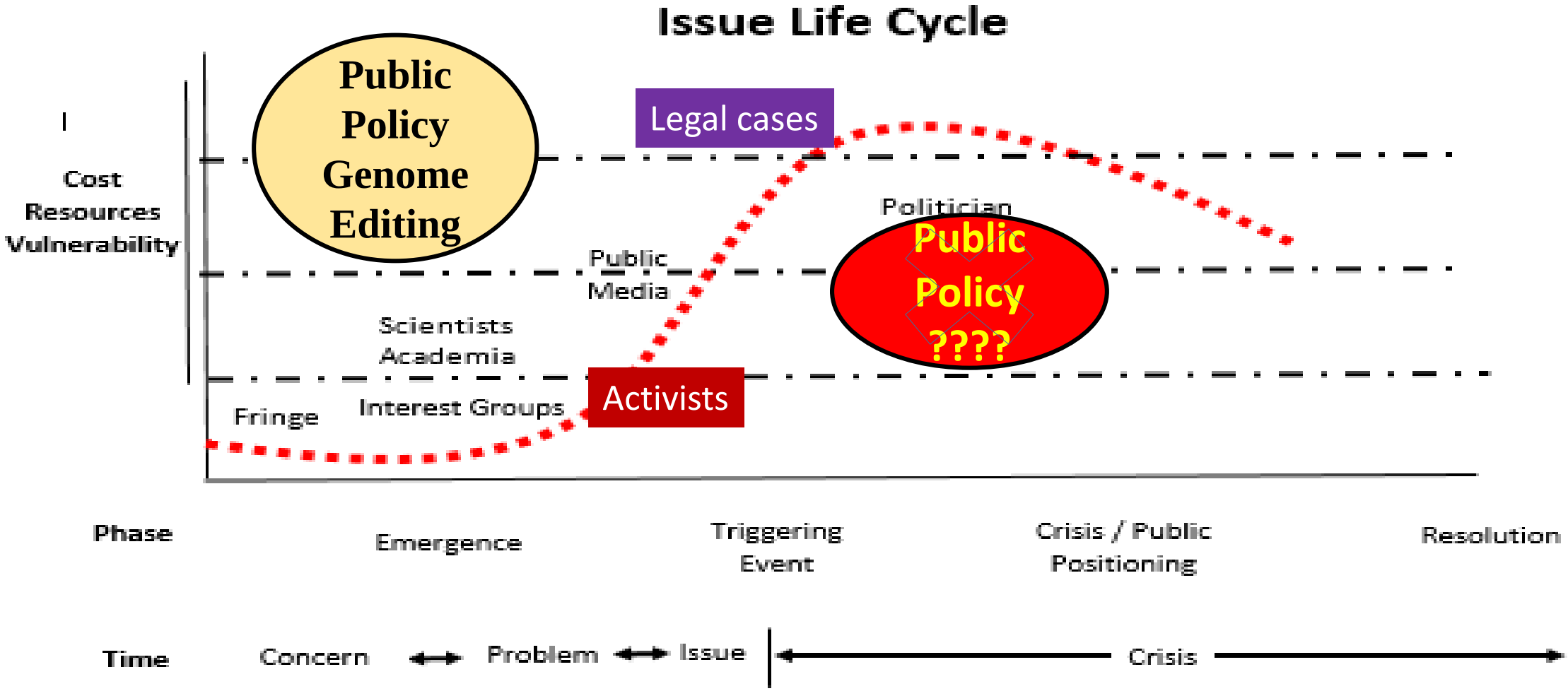
- ***Safety and efficacy***
- Statutory bodies
- (RCGM/GEAC at federal govt level
- Rules 1989,EPA 1986

- ***Safety and efficacy and unintentional changes***
- DCGI/Drugs and cosmetic Act

Ethical clearance

Human Clinical

Public Policy proposed upfront on Genome Editing of organisms by the Government As technology is evolving - 2017



Source : Corporate Environmental Strategy; Autumn 1997; Deborah Anderson; Procter & Gamble

Public Policy proposed upfront on Genome Editing of organisms by the Government As technology is evolving - 2017

- **Vision**
- **Mission**
- **Priorities Of Research And Applications**
  - Health Care,
  - Agriculture ,
  - Environment
  - Industry
- **Capacity Building**
  - Human Resource With Skill Development
  - Research Resources And Infrastructure
  - Accelerated Genomics Research
  - Bioinformatics And Computation Biology
- **International Cooperation**
- **Public -Private Partnerships**
- **Regulatory And Risk Assessment Policy And Pathway**
- **Approach To Address Biosecurity Issues**
- **Public Engagement**
- **Pan- Government Oversight Agency**
- **Outcomes And Outputs Relevant To Development**

सत्यमेव जयते

Acknowledgements :

Indian Council for Medical Research

Drug Controller General of India

Experts in various Scientific committee

Thanks