

PARLIAMENT QUESTION: BIO-SAFETY LABORATORIES

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The regulation and oversight of gene-editing in crops in India are guided by a comprehensive biosafety framework established under the Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or Cells, 1989 (the “Rules, 1989”), which notified under the Environment (Protection) Act, 1986 (EPA). The Ministry of Environment, Forests and Climate Change (MoEF&CC) administer the EPA.

Development of gene-edited (GE) plants is conducted under strict contained-laboratory conditions until the plants are shown to be free of exogenously introduced DNA. During this phase, Institutional Biosafety Committees (IBSCs) exercise regulatory oversight, with information reported to the Review Committee on Genetic Manipulation (RCGM).

The regulatory oversight of GE plant R&D is guided by the following:

- 1). Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017
- 2). Handbook for Institutional Biosafety Committees (IBSC), 2020
- 3). The notification regarding the exemption of site-directed nuclease (SDN)-1 and SDN-2 categories of genome edited plants, which are free from exogenous introduced DNA, from the provisions of Rules 7 to 11 (both inclusive) of the Rules, 1989 of the Environment (Protection) Act, 1986 issued by the MoEF&CC vide O.M. F. No. C -12013/3/2020-CS-III dated 30 March 2022. Furthermore, the subsequent development, evaluation, and release of a genome-edited plant as a new variety or hybrid shall be governed in accordance with all other applicable laws, acts, and regulations.
- 4). Pursuant to the mentioned notification the Department of Biotechnology (DBT), Ministry of Science and Technology (MoST) notified following guidelines and Standard Operating Procedures (SOPs) for research and development of gene-edited plants in India.
 - i). Guidelines for the Safety Assessment of Genome Edited Plants, 2022
 - ii). Standard Operating Procedures (SOPs) for Regulatory Review of Genome Edited Plants under SDN-1 and SDN-2 Categories, 2022

In line with the regulation, investigators who have produced GE plants free of exogenous DNA and wish to move them out of containment must submit the lab-generated regulatory data to their IBSC seeking exemption from Rules 7-11 of the Rules, 1989. After satisfactory review by the IBSC and acceptance of the minutes of the meeting of the IBSC by the RCGM, the IBSC conveys the exemption decision to the applicant. This mechanism aligns with international practice by distinguishing gene-edited plants lacking foreign DNA from conventional genetically engineered plants while maintaining biosafety oversight.

Category wise numbers of Biosafety Laboratories (BSL) registered with DBT is placed below.

Level of Biosafety Facility	Number of Laboratories
BSL-1	Laboratories of this type are deemed to be at the lowest risk level. They are utilized for the study of non-pathogenic microorganisms that present only a minimal hazard to healthy adults. In such environments, standard microbiological practices together with basic personal protective equipment (including lab coats and, where necessary, gloves), hand-washing facilities, and easily cleanable work surfaces are required.
BSL-2	750 nos.
BSL-3	89 nos.
BSL-4	01 nos.

The crops currently being gene-edited in these laboratories include, a wide range of species such as cotton, rice, sorghum, mung bean, banana, gerbera, saffron, tea, stevia, potato, onion, mustard, maize, pearl millet, foxtail millet, finger millet, ginger, chilli, cucumber, muskmelon, wheat, eucalyptus, pigeon pea, rice bean, groundnut, chickpea, soybean, tobacco, cauliflower, yellow sarson, rubber, apple, brinjal, sesame, papaya, ashwagandha, *Artemisia annua*, *Coleus forskohlii*, tulasi, *Cannabis sativa*, sunflower, urad bean, castor, sugarcane, jute, flax, *Salvia officinalis*, *Ophiorrhiza*, citrus, grass pea, lentil, black pepper, okra, and tomato. Institution wise containment facilities and details of crops undergoing gene-editing is placed as **Annexure-1**.

During the period 2020-2025, one incidence of lab-acquired infection has been reported. A doctoral student of National Centre for Cell Sciences, Pune was exposed occupationally to vaccinia virus in a biosafety level 2 (BSL-2) laboratory. Complete details of this occupational incidence is available in a public domain at <https://nccs.sciencecentral.in/990/#:~:text=Atom%20RSS%201.0%20RSS%202.0,sciencecentral.in/cgi/oai2>

All organizations including private entities are required to constitute and register IBSC with DBT before commencing research and development activities involving genetic engineering including gene-editing.

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Annexure-1

Institution/Organization wise containment facility, and details of crops undergoing Gene-editing

S. N.	Institute/ Organisation	Containment facility	Crop
1.	AgriGenome Labs Pvt. Ltd, Kochi	BSL-1	Rice, Tomato

2.	Ahmedabad University, Ahmedabad	BSL-1 and BSL-2	Groundnut
3.	Ajeet Seeds Pvt. Ltd., Aurangabad	BSL-1 and BSL-2	Cotton, Okra, Brinjal, Soybean, Tomato, Tobacco
4.	Anand Agricultural University, Anand	BSL-1	Tomato
5.	Bhabha Atomic Research Centre, Mumbai	BSL-1 and BSL-2	Banana, Rice, Soybean, <i>Ophiorrhiza plant</i>
6.	Bharathiar University, Coimbatore	BSL-1 and BSL-2	<i>Salvia officinalis</i>
7.	Bioseed Research India, Hyderabad	BSL-1 and BSL-2	Cotton, Rice
8.	Birla Institute of Technology & Science, Pilani	BSL-1 and BSL-2	Sorghum
9.	BRIC-Institute of Life Sciences, Bhubaneswar	BSL-1 and BSL-2	Tomato
10.	BRIC-National Agri-Food Biotechnology Institute , Mohali	BSL-1 and BSL-2	Wheat, Pea, Pearl millet
11.	BRIC-National Institute of Plant Genome Research, New Delhi	BSL-1 and BSL-2	Rice, Mustard, Tomato, Chickpea, Groundnut, Cauliflower, Yellow Sarson, Ricebean
12.	<i>Central University of Haryana</i> , Mahendragarh	BSL-1 and BSL-2	Soybean
13.	Central University of Rajasthan, Ajmer	BSL-1 and BSL-2	Mungbean (<i>Vignaradiata</i>), Rice
14.	College of Agriculture, Kerala Agricultural University, Vellanikkara	BSL-1	Banana, Rice
15.	College of Agriculture, Kerala Agricultural University, Vellayani	BSL-1	Banana

16.	CSIR-Central Institute of Medicinal and Aromatic Plants, Lucknow	BSL-1	Tomato, Tobacco, <i>Withania somnifera</i> , <i>Artemisia annua</i> , <i>Coleus Forskohlii</i> , <i>Ocimum basilicum</i> , <i>Ocimum sanctum</i> , <i>Cannabis sativa</i>
17.	CSIR-Indian Institute of Integrative Medicine, Jammu	BSL-1 and BSL-2	<i>Nicotianatabacum</i> , <i>Cannabis sativa</i>
18.	CSIR-Institute of Himalayan Bioresource Technology, Palampur	BSL-1 and BSL-2	Gerbera (<i>Gerbera jamesonii</i> Bolus), Saffron, Tea, Stevia, Potato
19.	CSIR-National Botanical Research Institute, Lucknow	BSL-1 and BSL-2	Tomato
20.	CSIR-North East Institute of Science and Technology, Jorhat	BSL-1 and BSL-2	Rice
21.	E.I. Dupont India Pvt. Ltd., Hyderabad	BSL-1	Rice
22.	Gujarat Biotechnology Research Centre, Gandhinagar	BSL-1 and BSL-2	Potato
23.	Guru Gobind Singh Indraprastha University, New Delhi	BSL-1 and BSL-2	Rice
24.	ICAR - Indian Institute of Groundnut Research, Junagadh	BSL-1	Groundnut
25.	ICAR Indian Institute of Maize Research, New Delhi	BSL-1	Maize
26.	ICAR-Central Citrus Research Institute, Nagpur	BSL-1	<i>Citrus aurantifolia</i>
27.	ICAR-Central Institute For Cotton Research, Nagpur	BSL-1	Cotton
28.	ICAR-Central Potato Research Institute, Shimla	BSL-1	Potato

29.	ICAR-Central Research Institute for Jute and Allied Fibers, Kolkata	BSL-1	Jute, Flax
30.	ICAR-Central Soil Salinity Research Institute, Karnal	BSL-1	Wheat, Mustard, Rice
31.	ICAR-Directorate of Onion and Garlic Research, Pune	BSL-1	Onion
32.	<i>ICAR-Directorate of Rapeseed & Mustard Research, Bharatpur</i>	BSL-1	Mustard
33.	ICAR-Indian Agricultural Research Institute, New Delhi	BSL-1 and BSL-2	Rice, Maize, Pearl millet, Foxtail millet, Finger millet, Mustard, Tomato
34.	ICAR-Indian Institute of Agricultural Biotechnology, <i>Ranchi</i>	BSL-1	Soybean, Groundnut, Cotton, Sunflower, Urad bean, Rice, Maize
35.	ICAR-Indian Institute of Horticultural Research, Bangalore	BSL-1	Papaya, Chilli
36.	<i>ICAR-Indian Institute of Maize Research, Ludhiana</i>	BSL-1 and BSL-2	Maize
37.	<i>ICAR-Indian Institute of Millet Research, Hyderabad</i>	BSL-1	Pearl millet, Sorghum
38.	<i>ICAR-Indian Institute of Oilseeds Research, Hyderabad</i>	BSL-1	Castor, Sunflower, Sesame
39.	ICAR-Indian Institute of Pulses Research, Kanpur	BSL-1	Grasspea (<i>Lathyrussativus</i>), Pigeon pea, Urad bean, Chickpea, Lentil
40.	ICAR-Indian Institute of Rice Research, Hyderabad	BSL-1	Rice
41.	ICAR-Indian Institute of Soybean Research, Indore	BSL-1	Soybean

42.	ICAR-Indian Institute of Spices Research, Kozhikode	BSL-1 and BSL-2	Ginger, Black pepper
43.	<i>ICAR-Indian Institute of Sugarcane Research, Lucknow</i>	BSL-1	Sugarcane
44.	ICAR-Indian Institute of Vegetable Research, Varanasi	BSL-1 and BSL-2	Chilli, Cucumber, Muskmelon, Tomato
45.	ICAR-Indian Institute of Wheat and Barley Research, Karnal	BSL-1	Wheat
46.	<i>ICAR-National Bureau of Plant Genetic Resources New Delhi</i>	BSL-1 and BSL-2	Sesame, Linseed
47.	ICAR-National Institute of Abiotic Stress Management, Baramati	BSL-1 and BSL-2	Soybean
48.	ICAR-National Research Centre for Banana, Tiruchirappalli	BSL-1	Banana
49.	ICAR-National Rice Research Institute, Cuttack	BSL-1 and BSL-2	Rice
50.	ICAR-Sugarcane Breeding Institute, <i>Coimbatore</i>	BSL-1	Sugarcane
51.	<i>ICAR-Vivekananda ParvatiyaKrishiAnushandhanSansthan, Almora</i>	BSL-1	Maize
52.	Indian Institute of Science and Education and Research, Tirupati	BSL-1 and BSL-2	Rice, Tomato, Groundnut
53.	Indian Institute of Science Education & Research, Pune	BSL-1 and BSL-2	Potato
54.	Indian Institute of Science Education and Research, Thiruvananthapuram	BSL-1	Rice
55.	Indian Institute of Technology, Roorkee	BSL-1 and BSL-2	Pea, Wheat
56.	Institute of Forest genetics and Tree Breeding, Coimbatore	BSL-1	Eucalyptus

57.	International Center for Genetic Engineering and Biotechnology, New Delhi	BSL-1 and BSL-2	Saffron, Cotton, Pigeon Pea, Rice, Rice bean, Tomato
58.	International Crops Research Institute for the Semi-Arid Tropics, Patancheru	BSL-1 and BSL-2	Groundnut, Pearl millet, Pigeon pea, Chickpea, Sorghum, Foxtail millet
59.	ITC Life Sciences & Technology Centre, ITC Ltd., Bangalore	BSL-1	<i>Eucalyptus camaldulensis</i> , Soybean (<i>Glycine max</i>), Tobacco
60.	Jai Narain Vyas University, Jodhpur	BSL-1 and BSL-2	Tomato
61.	Jawaharlal Nehru University, New Delhi	BSL-1 and BSL-2	Tomato, Rice
62.	Mahyco Private Limited, Mumbai	BSL-1	Rice
63.	Metahelix Life Sciences Ltd., Bangalore	BSL-1 and BSL-2	Maize
64.	Micro CRISPR Private Limited, Valsad	BSL-1 and BSL-2	Tomato, Wheat, Mustard, Rice, Soybean
65.	National Centre for Biological Sciences, Bangalore	BSL-1 and BSL-2	Rice
66.	National Institute for Plant Biotechnology, New Delhi	BSL-1 and BSL-2	Wheat, Mustard, Rice, Pigeon pea, Finger millet, Chickpea
67.	Punjab Agricultural University, Ludhiana	BSL-1 and BSL-2	Sorghum, Foxtail Millet, Wheat
68.	Rajagiri College of Social Sciences, Ernakulam	BSL-1	Foxtail millet
69.	Regional Centre for Biotechnology, Faridabad	BSL-1 and BSL-2	Rice, Chickpea

70.	Rubber Research Institute of India, Kottayam	BSL-1	Rubber
71.	Sharda University, Greater Noida	BSL-1 and BSL-2	Mustard
72.	Sher-e-Kashmir University of Agricultural Sciences and Technology of Kashmir, Srinagar	BSL-1	Apple
73.	Siksha 'O' Anusandhan university, Bhubaneswar	BSL-1 and BSL-2	Rice
74.	South Asian University, Delhi	BSL-1 and BSL-2	Rice
75.	SRM University, Kattankulathur	BSL-1 and BSL-2	Tobacco
76.	Tamil Nadu Agricultural University, Coimbatore	BSL-1 and BSL-2	Rice, Tomato, Brinjal, Sesame
77.	Tata Institute for Genetics and Society, Bangalore	BSL-1 and BSL-2	Finger millet, Rice
78.	The Energy and Resource Institute, New Delhi	BSL-1	Potato, Mustard
79.	<i>University of Agricultural Sciences, Bangalore</i>	BSL-1	Potato
80.	University of Delhi North Campus, Delhi	BSL-1 and BSL-2	Mustard
81.	University of Delhi South Campus, New Delhi	BSL-1 and BSL-2	Tomato, Rice, Papaya, Mustard
82.	University of Hyderabad, Hyderabad	BSL-1 and BSL-2	Tomato

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