



File No. PID-15011/1/2022-PPB-DBT (Comp. No. 16090)

Date: 14.09.2026

OFFICE MEMORANDUM

Subject: Notification of Regulatory Pathway for Import of SDN-1/SDN-2 Genome Edited Plants claimed to be free from exogenously introduced DNA and Revised Annexure-IV to 'SOPs, 2022' - reg.

Activities related to Genetically Engineered organisms or cells, hazardous microorganisms and products thereof are regulated in India under the Rules for Manufacture, Use/Import/Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or Cells, 1989 notified by the Ministry of Environment, Forest and Climate Change under the Environment (Protection) Act, 1986.

2. Vide Office Memorandum F. No. C-12013/3/2020-CS-III dated 30.03.2022, Ministry of Environment, Forest and Climate Change (MoEF&CC) has exempted genome edited plants falling under SDN-1 and SDN-2 categories and free from exogenously introduced DNA from the purview of Rules 7 to 11 (both inclusive) of the Rules, 1989 under Rule 20 thereof. Pursuant thereto, the Department of Biotechnology, Ministry of Science and Technology in exercise of powers conferred on the Review Committee on Genetic Manipulation (RCGM) under the said Rules, notified the "Guidelines for Safety Assessment of Genome Edited Plants, 2022" on 17.05.2022 and the "Standard Operating Procedures for Regulatory Review of Genome Edited Plants under SDN-1 and SDN-2 Categories, 2022" on 04.10.2022.

3. The 'SOPs, 2022' prescribe the regulatory pathway and information requirements for research, development, handling and import of SDN-1 and SDN-2 genome edited plants claimed to be free from exogenously introduced DNA and seeking exemption from Rules 7 to 11 (both inclusive) of the Rules, 1989.

4. While Form B1 is the prescribed route for import of Genetically Engineered and genome edited planting material containing exogenously introduced DNA, the 'SOPs, 2022' provide a distinct pathway for import of SDN-1 and SDN-2 genome edited planting material claimed to be free from such DNA.

5. To ensure greater clarity, uniformity and streamlined processing of import applications, without diluting biosafety assessment and regulatory oversight, a dedicated Regulatory

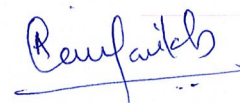
Pathway for Import of SDN-1/SDN-2 genome edited Plants for research, testing and development purposes, claimed to be free from exogenously introduced DNA and seeking exemption from Rules 7 to 11 (both inclusive) of the Rules, 1989, along with Revised Annexure-IV to the 'SOPs, 2022' has been approved and recommended for notification by RCGM in its 342nd meeting held on 19.08.2026.

6. Accordingly, the Department of Biotechnology hereby notifies the 'Regulatory Pathway for Import of SDN-1/SDN-2 Genome Edited Plants (for research, testing and development) claimed to be free from exogenously introduced DNA and seeking exemption from Rules 7 to 11 (both inclusive) of the Rules, 1989', along with 'Revised Annexure-IV' to the SOPs, 2022.

7. The Regulatory Pathway and Revised Annexure-IV shall supersede the existing Annexure-IV to the 'SOPs, 2022' with effect from the date of issue of this Office Memorandum. The 'SOPs, 2022' shall be read in conjunction with this Office Memorandum.

8. This Regulatory Pathway shall be applicable to all organizations engaged in import, research, development and handling of SDN-1 and SDN-2 genome edited plants.

9. The Regulatory Pathway and Revised Annexure-IV to the 'SOPs, 2022' are available at <https://dbt.gov.in/> and <https://ibkp.dbt.gov.in/>.



(Dr. Amit P. Parikh)

Member Secretary, RCGM &
Scientist-'G', DBT

To,
All IBSCs (by email)

Regulatory pathway for import of SDN-1/SDN-2 genome-edited planting materials claimed to be free from exogenous introduced DNA and seeking exemption from the provisions of Rules 7 to 11 (both inclusive) of the Rules, 1989.

Pursuant to the Guidelines for Safety Assessment of Genome Edited Plants, 2022 and SOPs for Regulatory Review of Genome Edited Plants under SDN-1 and SDN-2 Categories, 2022, the following pathway shall apply to import of SDN-1/SDN-2 genome-edited planting material for research, testing and product development where exemption from the provisions of Rules 7 to 11 (both inclusive) of Rules, 1989 is sought:

A. For import proposal not claiming exogenous-DNA-free status

For import of SDN-1/SDN-2 genome-edited planting material where the applicant does not claim that the material is free from exogenous introduced DNA at the time of import, Form B1 shall be submitted as per the existing procedure for import of **genetically engineered (GE)** plants, and the import pathway applicable to GE material shall apply.

B. For import proposal claiming exogenous-DNA-free status

For import of SDN-1/SDN-2 genome-edited planting material where the applicant claims that the material is free from exogenous introduced DNA and seeks exemption from the provisions of Rules 7 to 11 (both inclusive) of the Rules, 1989, submission of Form B1 shall not be required under this pathway.

The following shall be the procedure:

1. Submission to IBSC:

- a) The applicant shall submit a complete proposal to the concerned IBSC, containing the following information and supporting documentation. This proposal shall be for conducting research and development activities, including testing and product development, using SDN-1/SDN-2 genome-edited planting material *to be imported* that is claimed to be free from exogenous introduced DNA and seeking exemption from the provisions of Rules 7 to 11 (both inclusive) of the Rules, 1989.
- i) **Form D1:** The online application form available on IBKP shall be duly filled and submitted for consideration by the IBSC. The application title of form D1 shall clearly specify *"To carry out R&D on SDN-1/SDN-2 genome-edited planting material to be imported [with identity as type of material (seed/tuber/propagule), Name, cultivar, edited gene(s) and quantity] and claimed to be free from*

exogenous introduced DNA, for research, testing, and product development." The submission must include the material's identity, quantity, description, and SDN-1/SDN-2 categorization.

- ii) Duly completed **Annexure-III** and **revised Annexure-IV** of the 'SOPs, 2022'
- iii) Relevant data as per the 'SOPs, 2022', demonstrating that the SDN-1/SDN-2 categories of genome-edited plants to be imported are free from exogenous introduced DNA.
- iv) Deregulation status in the country of origin. If deregulated, documentary evidence thereof.
- v) The nomenclature of genome-edited lines to be imported as per Section 6 of the 'SOPs 2022', and a conversion table of these lines from the name assigned by the exporter shall also be submitted.

(#) The nomenclature submitted at this stage shall include all applicable prefixes and suffixes prescribed under Section 6 of 'SOPs, 2022', except the UAC. The UAC shall be generated after due assessment of the initial Form D1.

- b) **IBSC approval:** An applicant shall obtain IBSC approval once, except where the proposal undergoes substantive revision or the IBSC desires additional information. The submission to the IBSC, including all prescribed Annexures and supporting documentation, shall contain sufficient information to enable the IBSC to reach a decision in a single deliberation.

2. IBSC deliberation and approval:

- a) The IBSC shall examine the complete proposal, including Annexure-III and revised Annexure-IV along with all supporting data, and its deliberations shall specifically include the following for the decision taken by the IBSC:
 - i) The identity and description of the genome-edited material proposed to be imported;
 - ii) The SDN-1/SDN-2 category of the edit;
 - iii) The evidence demonstrating the absence of exogenous introduced DNA; and
 - iv) The suitability of the proposed material to be imported and intended use.

Revised

- b) The IBSC minutes shall clearly document:
- i) The explicit scientific considerations on which the applicant's proposal regarding the absence of exogenous introduced DNA has been approved. Where methods other than those specified in the 'SOPs, 2022', have been used to demonstrate the absence of exogenous introduced DNA, the IBSC shall confirm and highlight this deviation in the meeting minutes."
 - ii) Confirmation that the IBSC has at least one experienced subject matter expert on plant genome editing or related disciplines.
- c) Where data submitted by the applicant are inadequate or do not meet the terms and conditions of the 'SOPs, 2022', the IBSC shall advise the applicant to follow the existing import pathway by submitting **Form B1**. The decision and reasons shall be duly recorded in the IBSC meeting minutes.

3. Submission at IBKP:

- a) Submit the complete Form D1, as deliberated and approved by IBSC at IBKP, for the import proposal seeking exemption from the provisions of Rules 7 to 11 (both inclusive) of the Rules, 1989 on the claim of being free from exogenously introduced DNA.
- b) Along with Form D1, submit all documents deliberated and approved by IBSC as per Section 1 of this pathway, including Annexure-III and revised Annexure-IV of 'SOPs, 2022', relevant data, deregulation details in the country of origin, nomenclature of genome-edited lines to be imported as per Section 6 of 'SOPs, 2022', and a conversion table for such lines.
- c) On submission of a complete Form D1, a UAC number will be generated, which shall be used for completing the nomenclature of the genome-edited line(s) proposed for import as per Section 6 of 'SOPs, 2022'.
- d) The IBSC shall upload the complete proposal, including nomenclature with the UAC number and relevant meeting minutes, on the IBSC Dashboard of IBKP and in the query response section of the respective Form D1.

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(#) The applicant shall incorporate the UAC number into the nomenclature in subsequent revisions, if any, or in the final dossier.

4. RCGM consideration and acceptance:

- a) RCGM shall consider the complete proposal and IBSC recommendation, including evidence regarding absence of exogenously introduced DNA.
- b) If the submission is found satisfactory, RCGM shall **accept** the IBSC meeting minutes (along with Form D1, Annexure-III, revised Annexure-IV, and supporting data) for documentation completeness at IBKP for the material to be imported.

5. Certification of absence of exogenous introduced DNA:

- a) Following RCGM acceptance of the IBSC meeting minutes and complete proposal, the IBSC shall communicate the decision to the applicant in the format prescribed at ***Annexure-V*** in the 'SOPs, 2022'.
- b) Annexure-V constitutes formal documentation of IBSC approval already granted and does not constitute a separate IBSC approval.

6. Submission to Plant quarantine/import procedure:

- a) The applicant shall submit the Plant Quarantine application (PQ Form-08) to the National Bureau of Plant Genetic Resources (NBPGR), New Delhi, enclosing the RCGM acceptance of the IBSC meeting minutes and other applicable documents for the material to be imported.
- b) The material shall be imported only after obtaining the applicable plant quarantine/import permission from the competent authority.



**Format for seeking permission to import SDN-1 and/or SDN-2
genome edited plants for research, testing, and development
purposes**

A: Details about the Importer		
Sr.	Item	Information
1.	Applicant information: - Name and position - Organization - Contact details - Collaborators, if any	
2.	Source of import - Name and position - Organization - Contact details	
3.	Status of use in the country of origin and export - Research - Commercial use "Not regulated as GMO" or equivalent status under biosafety rules (please attach relevant documents)	
4.	Status of use in countries other than the country of origin and export	
5.	a). Name of planting material (<i>including genus, species, genotype</i>) b). Quantities to be imported c). Justify the proposed quantity of the import	
6.	Duly signed Material Transfer Agreement (MTA) explicitly specifying materials & quantity to be imported, the cultivar name, edited gene(s), proposed purpose, intended use, and associated IPR liabilities	
7.	Developer's letter describing editing methodology and confirming absence of exogenous DNA, and certifying that the material to be exported is free from exogenously introduced DNA	
8.	Transport & Shipment: - Type & Size of Packaging - Mode of Transport - Safety norms & containment measures to be observed during transit	
9.	Details of the IBSC/RCGM approval (UAC No. of Form D1)	
10.	Name of the Chairperson and Member Secretary, IBSC of the importing organization	

B: Details about the genome edited plant(s)		
Sr.	Item	Information
1.	Name of the plant species and genotype	
2.	Targeted trait(s)	
3.	Name of the genome edited line(s) - In the country of origin - as indicated in Section 6 of the SOPs	
4.	Targeted genomic region - a). Name of the gene(s) or locus/loci - b). specific region of the gene or locus (promoter, terminator, other regulatory elements, coding region, intron, etc.) - c). Nucleotide sequence of the parental allele - d). Specific site(s) chosen for editing (in case of SDN-2)	
5.	Category of genome editing: SDN-1 and/or SDN-2	
6.	Genome editing method used including CRISPR- Cas, TALEN, ZFN, RNPs, Base editing, prime editing, etc.	
7.	Details of vector, gene construct, editing reagents (molecular tools) including maps and nucleotide sequences	
8.	The method used for delivery of gene editing reagents (Agrobacterium-mediated, Biolistic, etc.)	
9.	Current Generation of the genome edited plant(s) (T0, T1, T2, etc.)	
10.	Data on Phenotypic expression of the target trait(s) as assessed under containment conditions, if applicable	
11.	Molecular data for confirmation of the targeted editing - a). By sequencing of the parental and the modified allele(s) using Sanger or other Sequencing technologies with a minimum 10X coverage of the edited region(s) and base quality of a minimum Phred score 30 - b). Sequence difference between parental and modified/edited allele through sequence alignment	
12.	Whether the mutation is homozygous or heterozygous. Provide evidence for inheritance of the mutation through two generations using sequencing.	
13.	Whether selfing and/or backcrossing has been carried out to segregate the exogenous introduced DNA? If yes, offer explicit details.	
14.	Whether any DNA-free method such as RNA-protein complex was used for genome editing? If yes, offer explicit details.	
15.	Provide evidence to confirm the absence of exogenous introduced DNA in genome edited plant by phenotypic selection (sensitivity to herbicide/ antibiotic, or absence of scorable marker) and using overlapping PCR/	

	Nested PCR/other appropriate methodology (as per Section 5).	
16.	In case, any unintended phenotypic changes were observed on the genome edited plant, whether it was selected/ segregated out. If selected, offer explicit details.	
17.	In the case of nutrition-related traits, provide data on the targeted nutritional trait in comparison to the parental line.	

Chaitanya