Attachment 2: PEF for PBI Products

**Prior Evaluation Form (PEF) for Products of Plant Breeding Innovation (PBI)**

|  |  |
| --- | --- |
| **Part I. Background Information** | |
| 1. Name of Product Developer |  |
| 1. Office Address |  |
| 1. Telephone Number |  |
| 1. Email Address |  |
| 1. Website (if any) |  |
| 1. Name of Agent |  |
| 1. Position |  |
| 1. Mobile Number |  |
| 1. Email Address |  |

|  |  |
| --- | --- |
| **Part II. Description of the PBI Product** | |
| 1. Name of the PBI Product |  |
| 1. Identification of the PBI Product (organism) | Scientific Name: |
| Common Name: |
| 1. Phenotypic feature before and after genetic change (Explain in detail.) |  |

|  |  |  |
| --- | --- | --- |
| **Part III. Description of the Plant Breeding Innovation (PBI) Procedure Used (To Be Used)** | | **Reference/s (If applicable)** |
| 1. Purpose of the PBI |  |  |
| 1. PBI procedure | ⬜ Oligonucleotide-directed mutagenesis (ODM)  ⬜ Site-directed nuclease 1 (SDN1)  ⬜ Site-directed nuclease 2 (SDN2)  ⬜ Site-directed nuclease 3 (SDN3) cis insert  ⬜ Site-directed nuclease 3 (SDN3) with trans insert  ⬜ Cisgenesis  ⬜ Intragenesis  ⬜ RNA-dependent DNA methylation (RdDM)  ⬜ Reverse breeding  ⬜ Agro-inoculation of non-germline tissues  ⬜ Agro-inoculation of germline tissues with cis insert  ⬜ Agro-inoculation of germline tissues with trans insert  ⬜ Agro-infiltration  ⬜ Grafting with GM material  ⬜ Synthetic genomics with cis-like sequence integration or faithful genome reconstruction  ⬜ Synthetic genomics with trans-like sequence integration  ⬜ Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| 1. Genetic change in the organism | |  |
| 1. Name of the molecular tools used |  |  |
| 1. Description and nucleotide sequence of the molecular tools used 2. Guide RNA 3. Nuclease 4. Nucleotide sequence to be introduced (if applicable) 5. Vectors (if applicable) 6. Selection markers (if applicable) 7. Reporter gene (if applicable) |  |  |
| 1. Delivery system | ⬜ Agrobacterium-mediated  ⬜ Particle bombardment/biolistic method  ⬜ Floral-dip  ⬜ PEG-mediated protoplast method  ⬜ Others (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| 1. Nature of DNA changes | Original sequences (underline target bases):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Sequences after gene editing (underline new bases):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ⬜ Deletions -> *Proceed to Question 4.*  ☐ Additions and/or substitutions; involve a few base changes (specify how many bases) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  -> *Proceed to Question 4.*  ⬜ Insertions and/or gene replacements; involve more than a few base changes (specify how many bases) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  -> *Proceed to Question 3e.* |  |
| 1. Source of insertion or genes | ☐ Same species (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  -> *Proceed to Question 4.*  ☐ Cross-compatible species (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  -> *Proceed to Question 4.*  ☐ Cross-incompatible species  (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  -> End of inquiry. |  |
| 1. Experimental evidence showing the final PBI product has no new combination of genetic material in the form of foreign DNA insert or sequences from gene editing tool construct using appropriate molecular techniques. For PBI products developed with the introduction of whole genes into the cells of the target/host organism, molecular evidence must be presented to show that such gene/s was/were not incorporated in any part of the genome where it is/they are not intended to be. |  |  |
| 1. Any existing regulatory precedence on the PBI Product in the issuing country and purpose of the decision (if applicable). |  |  |

|  |
| --- |
| **Part IV. Scientific Studies, Experimental Evidences, and Others Submitted with This Form** |
| 1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| *Name* |  | *Designation* |  | *Signature* |  | *Date* |

|  |  |
| --- | --- |
| ***For the Biotech Core Team-Plant Breeding Innovation (BCT-PBI) TCED Group:***  Please check the appropriate box. | |
|  | Determined that the PBI Product is not a GMO and does not fall under the scope and coverage of the JDC1, s2021 based on the scientific evidence(s) presented by the Product Developer. |
|  | Determined that the PBI Product is a GMO and falls under the scope and coverage of the JDC1, s2021 based on the scientific evidence(s) presented by the Product Developer. |

|  |  |  |
| --- | --- | --- |
| ***Printed Name*** | ***Signature*** | ***Date*** |
|  |  |  |
|  |  |  |
|  |  |  |