Introducing the Notification Form for Genom Editing in (GEd) Plants

(Contained use activity)

Session Objective

Objective of this session is to introduce the workflow and form for Genome Edited Plants in Contained Use Activities for Exemption by Minister

PENGECUALIAN OLEH MENTERI

DALAM menjalankan kuasa yang diberikan oleh seksyen 68 Akta Biokeselamatan 2007 [Akta 678], Menteri, atas syor Lembaga, mengecualikan daripada keperluan Bahagian IV Akta bagi aktiviti pengeksportan, kegunaan terkawal dan pengimportan untuk kegunaan terkawal organisma diubah suai yang hidup (tumbuhan) melibatkan penyuntingan genom dan perlu dipantau oleh jawatankuasa keinstitusian biokeselamatan organisasi yang berdaftar. Penyuntingan genom tumbuhan berikut dikecualikan –

1. sebarang aktiviti yang melibatkan *Site-Directed Nuclease* 1 (SDN-1); dan

2. sebarang aktiviti yang melibatkan *Site-Directed Nuclease* 2 (SDN-2) dan penyelitan 20 pasangan bes atau kurang asid deoksiribonukleik (DNA).

Tarikh 7 Mei 2025
[JBK(S)100-5/1/1 Jld. 6 (8)]

NIK NAZMI ~~BIN~~ NIK AHMAD
Menteri Sumber Asli dan Kelestarian Alam

EXEMPTION BY MINISTER

IN exercise of the powers conferred by section 68 of the Biosafety Act 2007 [Act 678], the Minister, upon recommendation of the Board, exempts from the requirements of Part IV of the Act for exportation, contained use activities and import for contained use activities for living modified organism (plants) involving genome editing and monitored by the registered organization's institutional biosafety committee. The following genome editing of plants is exempted –

1. any activity involving Site-Directed Nuclease 1 (SDN-1); and

2. any activity involving Site-Directed Nuclease 2 (SDN-2) and the insertion of 20 base pairs or less deoxyribonucleic acid (DNA).

Dated 7 May 2025
[JBK(S)100-5/1/1 Jld. 6 (9)]

NIK NAZMI BIN NIK AHMAD
Minister of Natural Resources and
Environmental Sustainability

Why This Form Matters

Biosafety & Governance

Supports **biosafety governance**

Facilitates **exemption** evaluation for eligible genome editing activities

Oversight & Responsibility

Supports **institutional oversight** via **IBC**

Promotes **responsible innovation** in plant genome editing within a clear regulatory **framework**

Documentation & Quality

Encourages **high-quality documentation**

Regulatory Context

Scope of Application

Applies to contained use, import for contained use and export of plants.

Oversight Body

Monitored by IBC (similar to how exempted activities under First schedule is currently being monitored by IBC).

Exemption Eligibility

Criteria must be met

Techniques Covered

- SDN-1
- SDN-2 (≤20 bp)

Does Your Activity Qualify?

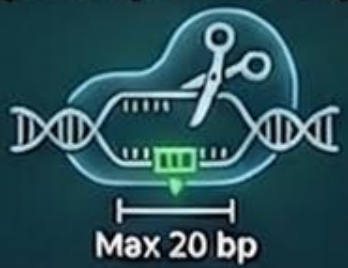
Exemption Eligibility

SDN-1

Site-Directed Nuclease-1

Exempted Activities

SDN-2
(≤ 20 bp insertion)



Site-Directed Nuclease-2 (limited insertion)

⚠ Important Note: Non-Exempt Activities

If your activity does not qualify for exemption, submit Form E to JBK via IBC

Overview of the Form Structure

Section A: PI / Person-in-Charge details

IBC contact information and principal investigator's details.

Part I: Project Information

Purpose, objectives, and duration of the research.

Part II: Description of the GEd Plant

Scientific name, edited trait, and phenotypic changes.

Part III: Editing Procedure & Tools

Specific gene editing methods, tools, and delivery systems used.

Part IV: Nature of DNA Changes

Details on target gene, mutation type, size, and sequence alignment.

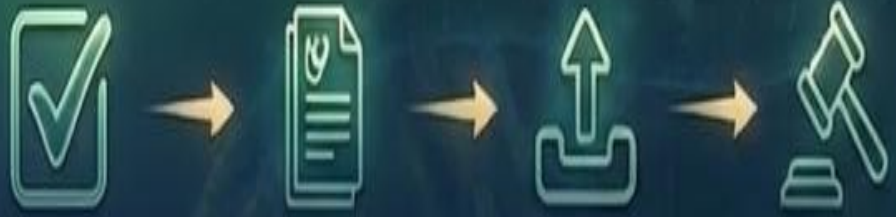
Part V: Imported GEd Plant (if applicable)

Declaration of regulatory status and import details.

Introduction Notification Form: GEd Plants - Workflow

Submission Workflow & Guidance

Step-by-Step Submission Workflow



1. Self-Assessment (Confirm SDN-1/ SDN-2 ≤20bp)
2. Documentation (Prepare Appendix & Flowchart)
3. Submission (Submit to IBC, Declare Accuracy)
4. Outcome (IBC Review)

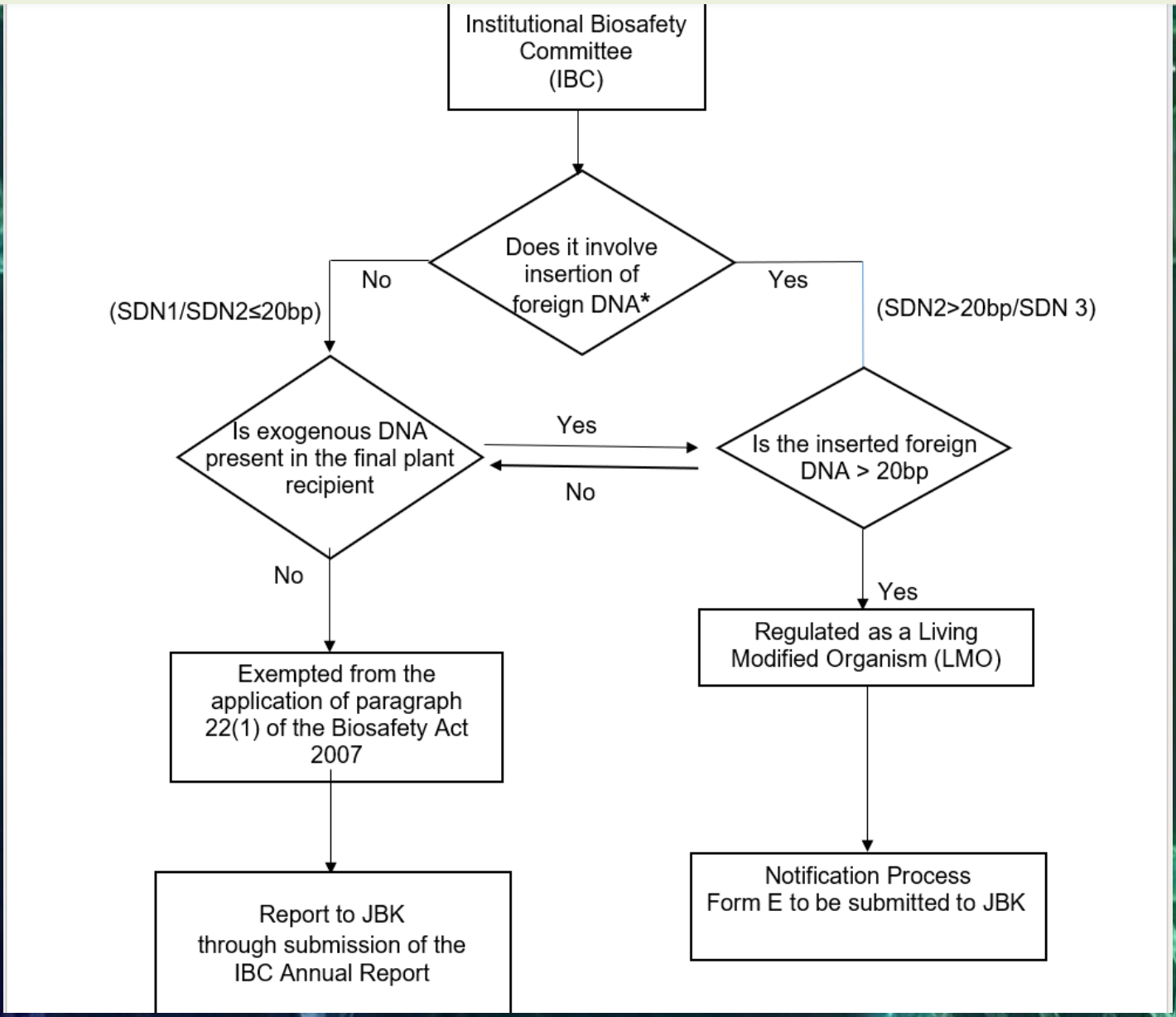
IBC Review & Possible Outcomes

IBC Review, ID Assigned.
Decision: Exempted or Non-Exempted (Requires JBK Notification)

Common Pitfalls to Avoid

Incomplete Descriptions, Unclear Mutation, Missing Appendix, Inconsistent Methods, >20bp (SDN-2)

FLOW CHART


Institutional Biosafety Committee (IBC)
Does it involve insertion of foreign DNA*
No
(SDN1/SDN2≤20bp)
Yes
(SDN2>20bp/SDN 3)
Is exogenous DNA present in the final plant recipient
Yes
No
Is the inserted foreign DNA > 20bp
No
Yes
Exempted from the application of paragraph 22(1) of the Biosafety Act 2007
Regulated as a Living Modified Organism (LMO)
Report to JBK through submission of the IBC Annual Report
Notification Process Form E to be submitted to JBK

Part I – Project Information

- Purpose of activity (research, teaching, etc.)
- Project title and duration
- Brief summary (≤200 words)
- Optional: flowchart as appendix
- Clear objectives and expected outcomes are essential

Part I – Project Information

Part I: Project Information		
1.	Purpose: (Please tick the options that apply.)	☐ Research ☐ Teaching ☐ Lab Service ☐ Commercial ☐ Storage ☐ Others (Specify): Click or tap here to enter text.
2.	Activity/Project Title:	Click or tap here to enter text.
3.	Start Date and End Date:	Click or tap here to enter text.
4.	Brief summary of the activity/project (if applicable, please include general objective, research methodology and expected outcome) not exceeding 200 words. (You may include a flowchart in addition to the narrative above as an appendix.)	

Part II – Description of the GEd Plant

- Scientific and common name
- Purpose of the edited trait
- Phenotypic features before editing
- Phenotypic features after editing
- Focus on measurable and observable changes

Part II – Description of the GEd Plant

Part II. Description of the Genome Edited (GEd) Plant	
Name of the GEd Plant	Scientific Name:
	Common Name:
Purpose of the GEd plant (e.g. improved trait, pest resistant, improved nutritional value, etc.)	
Phenotypic features before and after genetic change	Before Genetic Change:
	After Genetic Change:

Part III – Genome Editing Procedure

- Type of genetic change (SDN-1 or SDN-2 ≤20 bp)
- Gene editing tools used (e.g., CRISPR, TALEN, Zinc Finger)
- Delivery system (*Agrobacterium*, biolistic, PEG, floral-dip, etc.)
- Ensure consistency between method and reported mutation

Part III. Description of the GEd Plant Procedure	
Type of genetic change in the organism	☐ Site-directed nuclease 1 (SDN1) ☐ Site-directed nuclease 2 (SDN2), ≤20 bp
Gene editing tool(s) used	☐ CRISPR ☐ Zinc finger ☐ TALEN ☐ Other: _____
Delivery System	☐ Agrobacterium-mediated ☐ Particle bombardment/biolistic method ☐ Floral-dip ☐ PEG-mediated protoplast method ☐ Other (specify): _____

Part IV – Nature of DNA Changes

- Identify gene(s) targeted
- Describe gene product and function
- Specify target site location (bp)
- A→T Type of mutation (insertion, deletion, substitution)
- Size of change (bp)
- Include sequence alignment appendix

Part IV: Nature of DNA changes

(if more than 1 gene involved, please add more rows as needed)

***For SDN-2, Provide as appendix the alignment of sequences before and after genetic editing. Please ensure the changes are indicated clearly.**

1.	Gene 1				
2.	Product of gene				
3.	Function				
4.	Effect of Gene Editing				
5.	Target site	1	2	3	4
	Site location (bp)				
	Type of mutation (e.g.: insertion, deletion, substitution, etc.)				
	Size of changes (bp)				

Example of PART IV-_Nature of DNA Changes _

4.0 Example of Appendix of the Alignment of Sequences Before and After Genetic Editing

a. SDN-1 with single gene modification (with −2 bp deletion)

```
CLUSTAL O(1.2.4) multiple sequence alignment


WT      tatgtccaagacattggagagataccacagatacaattatggtacacttgaaggaaccca    60
GE      tatgtccaaga--cattggagagaccacagatacaattatggtacacttgaaggaaccca    58
        ***********       **** ************************************

WT      aacttcatcagattcacag     79
GE      aacttcatcagattcacag     77
        ******************
```

b. SDN-2 with one gene modification (with 1 bp substitution)

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CLUSTAL O(1.2.4) multiple sequence alignment


WT      tatgtccaagacattggagagataccacagatacaattatggtacacttgaaggaaccca    60
GE      tatgtccaagacattcgagagataccacagatacaattatggtacacttgaaggaaccca    60
        *************** ********************************************

WT      aacttcatcagattcacag     79
GE      aacttcatcagattcacag     79
        ******************
```

Part V – Imported GEd Plants (If Applicable)

- Declare regulatory status in issuing country
  - Describe precedent decisions (if any)
  - Ensure documentation supports exemption claim

Part V : For Imported GEd Plant		
1.	Any existing regulatory precedence on the GEd plant in the issuing country and purpose of the decision (if applicable).	

FAQ

QUESTION 1	ANSWER
Why is gene editing not mentioned in Biosafety Act 2007?	The Biosafety Act was drafted prior to the year 2007. CRISPR-Cas9 technology for gene editing was developed in 2012. However it is covered in the definition of modern biotechnology, *in vitro techniques.*

FAQ

QUESTION 2	ANSWER
If all the criteria for exemption are met, do the applicants still need to fill the form E?	Not required. Only fill in the Notification Form for Genome Editing in Plants.

FAQ

QUESTION 3	ANSWER
Is sequencing alignment mandatory to be provided as basis for exemption ?	SDN- 1 – Not mandatory. SDN-2 - Yes, the alignment of sequences before and after genome editing at the target site must be provided.

FAQ

QUESTION 4	ANSWER
Where can I get the form for exemption of activities involving gene edited plants for contained used activities?	It will be made available on the JBK website. It will be emailed out to all BSO/ IBC Chair.

FAQ

QUESTION 5	ANSWER
Is the exemption applicable for all plant species?	Yes, this exemption is applicable for all plant species.

FAQ

QUESTION 6	ANSWER
How long does it take for the exemption process to be approved?	Dependent of respective IBC's processing time. Delays are caused - if documents are not complete - there are queries Suggested for IBC to target processing time of 30 days.

FAQ

QUESTION 7	ANSWER
Can exempted plants be transported between premises?	Yes, however the recipient facility's IBC must be informed of the movement of gene edited plants.

FAQ

QUESTION 8	ANSWER
If the plant is exempted, can it also be exempted for field trial?	No, this exemption is not in place yet, and for now, it has to still be regulated as an LMO.

QUESTION 9	ANSWER
The outcome of SDN-1 editing is random, and the exact sequence changes will not be known until the gene edited plant has been characterized. How should the form be filled up before starting the activity?	SDN1 – Random. Include information about where they are targeting and the number of sites and indicate the possible type of mutation (e.g., deletion or insertion). A follow-up report detailing the correct mutation can be submitted to the IBC once the GE lines are constructed/ characterized. SDN2 – Precise. Researchers can fill in the predicted mutation.

QUESTION 10	ANSWER
What if there are off targets detected, does this affect the exemption status?	IBC Exemption is based on information provided in the form. If the gene edited plant has characteristics not mentioned in the Form, it will have to be re-evaluated. If there is integration of foreign DNA (e.g. vector sequences) into the plant genome, then it becomes an LMO (novel gene present), and proceed to submit Form E.

FAQ

QUESTION 11	ANSWER
Can ongoing activities (notifications that have been submitted to JBK) be exempted?	There will be no backdate exemptions. Ongoing activities will be regulated as LMOs. Activities currently being assessed by IBC - ?

FAQ

QUESTION 12	ANSWER
When do we start using these forms?	5 March 2026

FAQ

QUESTION 13	ANSWER
When reporting exempted contained use activity of gene edited plants, do the forms need to be submitted together with the Annual IBC Report?	No, the form is for IBC's internal record purposes. JBK may request to review the forms. The Annual IBC Report will contain a separate section to fill for exempted contained use activities involving gene edited plants.

FAQ

QUESTION 14	ANSWER
After starting the activity, it was found that it is more than 20 base pairs and no longer exempted, what should the researcher do?	Researcher should inform the IBC immediately and provide the details. IBC is to inform JBK immediately and will be provided with further instructions.

FAQ

QUESTION 15	ANSWER
Is there are several SDN1 edit sites, is there a limitation of how many sites can be done? Is there a limit on how many base pairs per edit site?	For contained use activity, there is no limit to how many edit sites you can do. There is a limit of 20 base pairs for each SDN1 site. Example – you may have 30 SDN1 insertions of 18 bps length for each site.