**Do not use this form if any of the following apply:**

* If the organism is not a GMO because it was modified only by repair of breaks of genomic DNA induced by a site directed nuclease, if a nucleic acid template was not added to guide homology-directed repair (i.e. *the organism was modified by SDN-1 only‡*), **or**
* If the gene edited organism will remain at all times inside IBC approved physical containment facilities (*i.e*. *it will continue to be contained as if it were a GMO*), **or**
* If you intend to undertake an intentional release of the organism in accordance with a Dealing involving Intentional Release (DIR) licence issued by the Gene Technology Regulator (*i.e.* *it will be intentionally released as if it were a GMO*). You must [contact the IBC](mailto:ibc@adelaide.edu.au) to discuss this option.

**Use this form to apply for Institutional Biosafety Committee (IBC) approval to release non-GMO gene edited organism(s) generated under a GMO dealing from approved physical containment facilities.**

**Use this form if all of the following apply:**

* An organism has had its genome edited; **and**
* the gene editing involved introduction of translatable DNA or RNA, either transiently or by integration into the genome, in the course of a GMO dealing†; **and**
* you believe that the organism, or its offspring, could be considered “not a GMO” under the Gene Technology Regulations 2001; **and**
* you intend to release the organism from IBC approved containment facilities. For example, to move the organism to a facility of a lower containment level, or to intentionally release it into the environment.

This applies to gene edited organisms that have been generated by your own research, obtained from collaborators, or purchased from a commercial supplier.

† “Introduction of translatable DNA or RNA” includes introduction of nucleic acid encoding a site directed nuclease for the intention of creating a SDN-1 modification.

‡An organism “*modified with SDN-1 only*” is defined as:

* An organism supplied with a site directed nuclease (SDN) **protein** and guide RNA, but ***not*** supplied with **nucleic acid** encoding the SDN or guide RNA, and
* An organism that is not supplied with a nucleic acid template to guide genome repair through **homology-directed recombination**, and
* An organism that has **no other modifications** as a result of gene technology. The presence of a SDN-1 modification does not preclude the organism from being a GMO, if other modifications such as transgenes are present. Examples of transgenes are *Cas9*, or an antibiotic resistance gene.

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| IBC use | Application ID |  |

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| 1 | Preliminary information | | |
| **Organisation responsible for releasing the gene edited organism from containment facilities** | |  | |
| **Organisation where the gene edited organism was generated or sourced from**  If applicable, provide details of collaborators or commercial suppliers that you obtained the organism from | |  | |
| **Was the gene editing of the organism conducted as a GMO dealing authorised by an IBC, or under a licenced dealing?** | | Yes  No If yes, complete following details | |
| **IBC name** |  |
| **Dealing ID allocated by IBC or OGTR** |  |

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| 2 | Person responsible for the gene edited organism(s) | |
| Project supervisor | |  |
| Project Supervisor’s University ID | |  |
| Primary Employing Institution of Project Supervisor (if not the University of Adelaide) | |  |
| Email address | |  |
| Telephone | |  |
| School | |  |

|  |  |  |
| --- | --- | --- |
| 3 | About the gene edited organism(s) | |
| Species of the gene edited organism | |  |
| Gene editing technology used (e.g. CRISPR/Cas9, TALEN) | |  |
| Method of introduction of gene editing tools into the organism (e.g. biolistic, viral vector or agrobacterium mediated transformation) | |  |
| Was the gene editing construct expressed transiently in the organism, or integrated into the organism’s genome? If so, state which applies | |  |
| Genes that were targeted for editing, and their function (if known) | |  |
| Is the organism intended for release the progeny of a gene edited organism described in this section?  If yes, for how many generations has the organism been outcrossed prior to obtaining the particular organism(s) to be released? | |  |

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| 4 | Proposed methods to confirm absence of transgenes |
| **Describe the methods you will use to confirm the absence of any transgenes in the gene edited organism(s). The methods must aim to detect random insertions of DNA into any part of the genome, not just the target gene region.**  ***There is no permissible amount of transgene DNA in organisms that are “not a GMO”. All recognisable transgene fragments must be absent from the gene edited organism for it to be “not a GMO”. The IBC must be satisfied that the organisms have undergone appropriate testing to demonstrate that they are not GMOs.***  ***Ensure you describe the following:***   * *Number of individuals tested, use of pooled or individual samples* * *Any baiting methods or enrichment of particular regions of the genome* * *What size threshold will you use to define a transgene (e.g. >50bp fragment of non-homologous sequence)* * *For sequencing-based detection methods*    + *The depth of sequencing*   + *The sequencing platform, and any associated limitations such as GC bias or underrepresentation*   + *The availability of a complete reference genome for the organism. Indicate the RefSeq ID of the genome used for analysis* * *For probe hybridisation based approaches:*    + *Probe labelling and detection methods (radiation, digoxigenin)*   + *Number of unique probes to be used*   + *Sequences that will serve as probes*   + *Will the entire vector be used as a probe?* * *For PCR detection of transgenes*    + *Limits of detection*   + *Number of primer combinations to be used, coverage of the transgene and vector, degree of overlap of fragments*   + *Internal controls used to confirm amplification in the absence of transgene target*   + *Method of confirming identity of amplified sequences (sequencing of PCR products)* | |
|  | |
| Describe the limitations of the proposed methods of testing  *Include details of any thresholds of detection associated with this method* | |
|  | |
| If applicable, describe any factors that restrict the methods of testing available for this organism  *E.g. are the most appropriate methods for transgene detection in the organism not feasible due to funding constraints, lack of specialised equipment in containment facilities, or lack of reference sequence data for the organism?* | |
|  | |
| What evidence will be provided to the IBC to demonstrate that no transgenes are present in the organism? | |
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| 5 | Other comments for the IBC |
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| 6 | Project Supervisor Declaration | | |
| Project Supervisor Name | | Project Supervisor Signature | Date |