

Regulatory Status of Site-Directed Nuclease-1 (SDN-1) Genome Editing Technologies

SDN-1 techniques involve genome editing with unguided repair. Unguided repair means that no nucleic acid template is added to cells to guide genome repair following SDN application. SDNs include, but are not limited to, CRISPR/Cas9, zinc finger nucleases, meganucleases and TALENs.

The table below presents the regulatory status of SDN-1 technology under the current version of the Gene Technology Regulations 2001.

	Method of site-directed nuclease-1 application		
	SDN protein (with or without sgRNA) e.g., an organism supplied with Cas9 protein and guide RNA/s.	SDN expressed from a transgene that is only transiently present in the organism e.g., an organism expressing Cas9 and guide RNA/s from an expression cassette not integrated into the genome.	SDN expressed from a transgene integrated in the genome e.g., an organism with Cas9 and guide RNA transgenes integrated into its genome.
Status of the initial organism modified using SDN-1 technology	Not a GMO Schedule 1, Item 4 No IBC approval needed	GMO while transgene or its expressed products are present. GMO dealing approval is required from IBC. Use the GMO Dealing application form.	GMO GMO dealing approval is required from the IBC. Use the GMO Dealing application form.
		Not a GMO when transgene and expressed products have degraded. Schedule 1, Items 4 + 10 IBC must confirm non-GM status before the organisms are removed from containment facilities. Contact the IBC for further information on the release process.	
Status of offspring inheriting the SDN-1 modification	Not a GMO Schedule 1, Item 9(a) No IBC approval needed	Not a GMO Schedule 1, Item 9(b) IBC must confirm non-GM status before the organisms are removed from containment facilities. Contact the IBC for further information on the release process.	GMO if SDN transgene is also inherited. GMO dealing approval is required from the IBC. Use the GMO Dealing application form.
			Not a GMO if no SDN transgene inherited. Schedule 1, Item 9(b) IBC must confirm non-GM status before the organisms are removed from containment facilities. Contact the IBC for further information on the release process.

***Important note:** Base editing, prime editing and other genome editing technologies that utilise a non-nuclease enzymatic domain remain regulated regardless of the presence or absence of a transgene or repair template.