

## *Biosecurity (SDN-1 Modified Organism) Regulations 2020*

### FACT SHEET

## Background

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As of October 2019, organisms modified using a gene editing technique known as SDN-1 are no longer regulated as genetically modified organisms (GMOs), under the National Gene Technology Scheme.

The decision not to regulate SDN-1 modified organisms under the National Scheme was made on the basis that organisms modified using this technique pose the same risk as, and are indistinguishable from, organisms carrying naturally occurring genetic changes.

Whilst the national decision does not prevent Tasmania from having a moratorium on GMOs, it does complicate matters for businesses that export to markets where SDN-1 modified organisms continue to be considered GMOs.

To address these potential marketing concerns, in August 2019 the Tasmanian Government committed to work with stakeholders to develop state-based regulation to control the commercial release into the Tasmanian environment of SDN-1 modified organisms to ensure that, in Tasmania, these organisms are effectively regulated the same as GMOs in the agri-food sector for marketing purposes. This is outlined in the [Tasmanian Gene Technology Policy 2019-2029](#).

The *Biosecurity (SDN-1 Modified Organism) Regulations 2020* (the SDN-1 regulations) will regulate the entry of SDN-1 modified organisms to Tasmania and any activities with organisms modified using SDN-1 techniques.

This will maintain the status quo for businesses that rely on Tasmania's GMO-free status and ensure that Tasmania continues to be able to confidently trade as GMO-free in markets that are sensitive to SDN-1 modified organisms.

## What does the Act say and what does it mean?

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The *Biosecurity Act 2019* provides that biosecurity matter or dealings with biosecurity matter can have a biosecurity impact (an adverse effect on the environment, the community or the economy) and can prescribe dealings with biosecurity matter as a "regulated dealing," requiring registration under the Act.

Identifying what is a "biosecurity impact", "biosecurity matter" and "regulated dealing" can be achieved through regulations under the Biosecurity Act.

The SDN-1 regulations outline how the Act applies to SDN-1 modified organisms by:

1. defining SDN-1 modified organisms in manner consistent with the National Gene Technology Scheme (regulation 3);

2. outlining that an adverse impact arising from the introduction, presence, spread or increase of SDN-1 organisms in Tasmania amounts to a “biosecurity impact” for the purposes of the Act (regulation 4(a));
3. identifying SDN-1 organisms as a class of biosecurity matter (regulation 4(b); and
4. prescribing that any dealings with SDN-1 organisms are a “regulated dealing” for the purposes of the Act, thereby requiring persons engaging in such dealings to be registered (regulation 4(c)).

The registration process is provided for under the Biosecurity Act (Part 6).

This means that any person (or entity) intending to import, use or create SDN-1 modified organisms in any commercial, scientific research or other activity will need to be registered with Biosecurity Tasmania.

This will ensure traceability of SDN-1 modified organisms in the State and ensure control of the commercial release of these organisms to the Tasmanian environment, consistent as if the organisms were controlled as GMOs in Tasmania for marketing purposes.

An overview of the specific legislative provisions is provided under Frequently Asked Questions.

## How will the registration scheme operate practically?

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Most human activities involving biosecurity matter fall within the Act’s definition of dealings and include breeding, selling, transporting, or importing biosecurity matter, as well as propagating, growing, cultivating, or creating it.

The regulations will prescribe that any dealings with SDN-1 organisms are a “regulated dealing” for the purposes of the Act, meaning that persons must not engage in activities with them unless they are registered under Part 6 of the Act.

Importers will be required to complete a declaration (Notice of Intention) that the product that they are importing is, to their knowledge, free from SDN-1 modified organisms. This will be enforced at the border by Biosecurity Tasmania.

The details of the declaration scheme will be simple

Researchers wishing to use and/or create SDN-1 modified organisms will be required to register under Part 6 of the Biosecurity Act. Biosecurity Tasmania is working through the detail of a simple registration process that is administratively light and does not provide a barrier to research using SDN-1 in Tasmania, or affect the competitiveness of our research institutions.

Registration will be granted at the institutional or organisational level for up to 5 years and cover all activities (dealings) with SDN-1, including importation and breeding. It is not intended that there will be any additional reporting required as it is assumed that the institution/organisation will have appropriate records of the research to enable traceability of SDN-1 modified organisms in Tasmania.

The registration will limit activities to Physical Containment Facilities. That is, certified facilities such as laboratories that are designed to prevent the release of viable organisms into the environment.

Summary of requirements:

Activity	Requirements	Current Situation
Importation of fruit, vegetables, plants, plant products, animals, animal products, grains and seeds for sowing	All animal and plant imports to Tasmania from interstate must be in accordance with an import permit issued under the new Biosecurity Act. The import permit process will be straightforward, and require importers to indicate whether, (to their knowledge) the imported material contains SDN-1 modified organisms.	Importers of all plant and animal products are currently required to comply with a range of regulatory requirements under multiple pieces of legislation. For example, plant importers must complete a Notice of Intent to import the listed products under the <i>Plant Quarantine Act 1997</i> . SDN-1 declarations would be incorporated into these processes if they were not to be replaced by the simplified system under the new Biosecurity Act
Research using /creating SDN-1	Institutions undertaking research using SDN-1 modified organisms will need to be registered under Part 6 of the Biosecurity Act.	There are no current regulatory requirements for research using SDN-1 modified organisms.

## How will it be enforced?

Biosecurity Tasmania will have primary responsibility for enforcement and administration of the *Biosecurity Act 2019*. It will be an offence under the Act for a person to engage in a regulated dealing (i.e. dealing with SDN-1) without being registered. It will also be an offence for a person to import SDN-1 plants or animals without an import permit; and to provide any false or misleading information in respect of dealings with SDN-1. Breaches can result in criminal sanctions such as infringement notices (fines) and prosecutions, and civil sanctions such as suspension or cancellation of registration.

## *Biosecurity (SDN-1 Modified Organism) Regulations 2020*

### FREQUENTLY ASKED QUESTIONS

#### What is SDN-1?

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It is a gene editing technique.

Site-Directed Nuclease (SDN) involves directing DNA-cutting enzymes (nucleases) to cut DNA at a predetermined location.

After the cut is made, the cell's own DNA repair mechanism recognises the break and repairs the damage in the same way that it would repair a naturally occurring DNA break.

This means that the range of possible changes to the DNA sequence is the same as would occur naturally.

In 2019, the Australian Government decided not to regulate SDN-1 techniques under the National Gene Technology Scheme on the basis that the process presents the same risk as a naturally-occurring genetic change.

Other SDN editing techniques such as SDN-2 and SDN-3 involve the introduction of a DNA template to 'guide' the repair process and these techniques are still regulated under the National Gene Technology Scheme.

#### Why regulate SDN-1 modified organisms in Tasmania?

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This is a cautious approach.

There is uncertainty about the implications of the national decision not to regulate SDN-1 modified organisms for some Tasmanian businesses that supply markets where SDN-1 organisms continue to be regulated as GMOs. A regulation will provide protection to these businesses.

There is also uncertainty around the benefits that SDN-1 technologies may provide to Tasmanian businesses and industry. This is an area that is evolving rapidly.

The monitoring and review provisions in the [Tasmanian Gene Technology Policy 2019-2029](#) will ensure that Tasmania does not miss out on the opportunities that these developments provide.

Also, should the regulation be found to have implications that constrain the marketing advantage or competitiveness of Tasmanian producers and businesses in the future, removing the regulation would be straightforward.

The purpose of the regulation to control SDN-1 dealings and modified organisms in Tasmania is to maintain the status quo for agri-food businesses and industries that rely on Tasmania's GMO-free status in their marketing.

## Detail of regulation 4

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High level detail of regulation 4:

No	Regulation	What does the legislation say?
(a)	For the purposes of section 11(1)(d) of the Act, the introduction, presence, spread or increase of a SDN-1 modified organism is prescribed to have a biosecurity impact	Section 11(1)(d) defines a biosecurity impact as “an adverse effect on the environment, the community or the economy” arising from biosecurity matter that includes “any thing, or circumstances, prescribed to have a biosecurity impact”.
(b)	For the purposes of section 12(h) of the Act, a SDN-1 modified organism is prescribed as biosecurity matter	Biosecurity matter includes “any prescribed thing” under section 12(h).
(c)	For the purposes of section 17(1) of the Act, engaging in a dealing with a SDN-1 modified organism is prescribed to be a regulated dealing.	Under section (17)(1), a reference to a regulated dealing is a reference to a dealing that is prescribed to be a regulated dealing, requiring registration under section (77) of the Act. Section (78) outlines the registration process.

## What are the monitoring provisions in the Gene Tech Policy?

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Emerging technologies including GMOs may provide opportunities to enhance the competitiveness of the State’s agricultural sector. However, the potential use of GMOs requires careful consideration to ensure there are no negative impacts on markets or on the State’s brand.

A full review of the [Tasmanian Gene Technology Policy 2019-2029](#) will be undertaken before November 2029 to inform a decision on whether to further extend or amend the GMO moratorium prior to its expiry.

DPIPWE will implement evidence-based GMO monitoring and review to continuously assess developments in gene technology during the period of the moratorium, including emerging technologies, policy changes, consumer sentiment and market and branding implications.

At least every three years DPIPWE will provide a report to the Minister on developments in gene technology and market changes. Specific matters to be reported include:

- consumer sentiment in important current and potential future markets;
- new gene technologies that provide positive benefits to primary industry sectors and Tasmania as a whole; and

- development of new generation GMOs that provide health or other benefits.

DPIPWE will advise the Minister if, based on evidence, there are significant developments in these areas that warrant triggering an earlier review of this Policy before the maximum ten years.

The Minister can also direct a full review of the Policy at any stage during the period of the moratorium if developments warrant it.

The Tasmanian Government will strive to ensure that measures to safeguard Tasmania's GMO-free status remain appropriate to a changing risk environment, particularly as more GMOs are adopted in international and national jurisdictions and in markets that supply products to Tasmanian primary industries.

DPIPWE will also monitor the risks associated with maintaining Tasmania's current GMO threshold levels and any alternative options.

## What SDN-1 organisms are already approved for commercial use?

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None commercially.

Research to develop a more palatable perennial ryegrass variety using the SDN-1 gene editing technique (Exzact™) is ongoing, and so is gene editing sorghum to increase the digestibility level of grain protein for stockfeed. Neither are developed to the stage to be commercially available in Australia.

There is also a lot of ongoing research using SDN-1 to inactivate chosen genes to study gene function and create models for the study of human diseases. This includes identifying cancer drivers and identifying genes involved in Zika virus infection.

## Will the regulation provide a barrier to research?

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The Tasmanian Government recognises the importance of research to Tasmania and its contribution to the economic and social development of the State.

We also acknowledge the tremendous capacity for innovation here amongst our local scientific community, not just in primary industries but across the board.

We will ensure that regulating SDN-1 modified organisms for agri-food and marketing purposes through the Biosecurity Act provides a simple registration scheme that does not provide a barrier to the use of SDN-1 modified organisms for research in specific purposes, including but not limited to medical and pharmaceutical applications.

Researchers wishing to use and/or create SDN-1 modified organisms will be required to register under Part 6 of the Biosecurity Act. Biosecurity Tasmania is working through the detail of a simple registration process that is administratively light and does not provide a barrier to research using SDN-1 in Tasmania, or adversely affect the competitiveness of our research institutions.

Registration will be granted at the institutional or organisational level for up to 5 years and cover all activities (dealings) with SDN-1, including importation and breeding, as well as any permit requirements. It is not intended that additional reporting will be required if the institution/organisation maintains appropriate records to enable traceability of SDN-1 modified organisms in Tasmania. The registration will limit activities to Physical Containment Facilities. That is, certified facilities such as laboratories that are designed to prevent the release of viable organisms into the environment.

## Why regulate SDN-1 under the Biosecurity Act?

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The advantage of regulating SDN-1 modified organisms under the Biosecurity Act is that they will be regulated under the same system that regulates other activities that pose a biosecurity risk – like the importation of raw honeycomb, the sale and movement of livestock, and commercial beekeeping.

Regulating dealings with SDN-1 modified organisms for agri-food and marketing purposes will ensure that there is no unintended or unauthorised release of SDN-1 modified organisms into the Tasmanian environment.

## Should SDN-1 be declared as “restricted matter”?

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Under the Biosecurity Act, all plants and animals, and plant and animal products are automatically classed as restricted matter (which can only be imported into the State under a permit) unless they are listed as either “permitted matter” (which can be imported without a permit) or prohibited matter (for which all dealings are prohibited).

It is not intended that SDN-1 organisms be listed as either permitted or prohibited matter, which means that SDN-1 plants and animals (and derived products) would remain a class of restricted matter that can only be imported to Tasmania under a permit by a registered SDN-1 entity.

The administrative processes (e.g. standard forms and procedures) applying to SDN-1 permits and registration under the Biosecurity Act will align with those applying to all other standard commodities and dealings.

## Should certain RNA interference techniques also be regulated ?

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It is not intended to regulate the RNA interference techniques no longer captured under the National Gene Technology Scheme as, unlike SDN-1, these RNA interference techniques do not result in permanent changes to the DNA sequence.

These RNA interference techniques should be treated like any other agricultural and veterinary chemical and regulated, where appropriate, under the Australian Pesticides and Veterinary Medicines Authority.

## What happens if SDN-1 modified organisms are not regulated?

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The Government's view is that some of our key markets such as Japan, China and the EU may expect SDN-1 modified organisms to be regulated to meet that country's expectation of Tasmania's GMO-free status and branding.

## Who is being consulted?

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The SDN-1 regulations are published on the Department's website and submissions are invited on the operation of the draft regulation until 15 January 2021.

Broader considerations around gene technology policy in Tasmania, including whether Tasmania should maintain a moratorium on GMOs will not be covered as part of this consultation process as these matters were considered in detail during last year's review of the State's GMO moratorium.

In 2019, the Tasmanian Government extended the State's moratorium on GMOs until 2029 through an amendment to the *Genetically Modified Organisms Control Act 2004*.

The decision to extend the moratorium followed a comprehensive review carried out by DPIPWE, which received 76 submissions, with an overwhelming number of respondents in favour of extending the moratorium.

The review found the benefits of maintaining the GMO moratorium in Tasmania still greatly outweighed the risks or any benefits from ending the moratorium.

The [Tasmanian Gene Technology Policy](#) and associated [Gene Technology Guidelines](#) provide the necessary detail on how the moratorium will be implemented, will also be updated.

There will continue to be regular reviews of developments in gene technology, markets and consumer sentiment, which can trigger a review of the Policy earlier should developments warrant it.

For more information on GMOs in Tasmania go to the DPIPWE website: [www.dpipwe.tas.gov.au](http://www.dpipwe.tas.gov.au)