SUSTAINABILITY COUNCIL of NEW ZEALAND

Submission of Information on Synthetic Biology: Experience from New Zealand

Prepared by Sustainability Council of New Zealand, June 2017

Overview

- New Zealand's approach to regulating modern biotechnology contains a number of elements important to good governance, including some that are novel.
- Under New Zealand law, all "gene editing" techniques are regulated as GMOs. A High Court judgment clarified this in 2014 and a government review of the relevant law confirmed the position in 2016.
- A prerequisite to considering a gene drive release is the existence of international governance arrangements that are fit for purpose.

Introduction

This note details experience from New Zealand relevant to the Open-ended Online Forum on Synthetic Biology and the AHTEG on Synthetic Biology. It responds to the CBD's request for useful examples of risk assessment and regulation (parts (c), (d) and (e) of the notification).[1]

1. Elements of Interest from the New Zealand Approach

The following elements of New Zealand GMO regulation support good risk assessment and management of modern biotechnology, including what the CBD defines as "synthetic biology". These are contained in the central legislation for this purpose, the Hazardous Substances and New Organisms Act 1996 (HSNO),[2] administered by the nation's Environmental Protection Authority (EPA).

Coverage

- All modern biotechnology is covered by HSNO, in line with the definition of this set out in the Cartagena Protocol, and adopted by other parties such as the EU.
- In addition, any organism not present in the country at the trigger date of 29 July 1998 is deemed a new organism and is also covered by the Act. Just as Cartagena exempts organisms created through "traditional breeding", HSNO exempts specified techniques in line with this approach under a white list.

[1] Notification: Ref.: SCBD/SPS/DC/DA/MW/86375

[2] http://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html?src=qs

Assessment Process

- Any proposed use of GMOs outside laboratory containment must obtain **prior regulatory approval**.
- All applications must be publicly notified, subject to **public consultation,** open to submissions by any stakeholder, and involve a public hearing.
- **Economic impacts** (costs as well as benefits) of the proposed use must be considered by the regulator in making an assessment, in addition to scientific, ethical and social matters.
- The relevant comparator used by the regulator to assess an application is the **best practicable alternative** (BPA). This is designed to incentivise consideration of alternatives prior to application.[3]
- **Field trials must be contained** such that heritable genetic material does not leave the site during the trial and is removed after the trial.

While it has been argued that the structure of the legislation is precautionary in its intent, the law states only that decision makers should "take into account the need for caution". This weak formulation of the precautionary principle and other features, such as liability for harm applying only when an agent acts without approval or breaches conditions of an approval, mean that while HSNO demonstrates important elements of good regulation, it has substantial limitations as a model.

2. Regulatory Status of Gene Editing and Synthetic Biology

Gene Editing

- New Zealand has determined that all gene editing and other new techniques are covered by HSNO, that their products are regulated as GMOs, and that field trials and releases of gene edited organisms require risk assessment and prior regulatory approval.
- This was confirmed firstly by the courts and subsequently affirmed following a government review of the regulations.
    - The court ruling was issued in response to an EPA decision that deemed two gene editing techniques (ZFN-1 and TALEs) not to be GMOs, as defined by the HSNO Act.
    - The Sustainability Council, a charitable trust, appealed the regulator's decision to the High Court which quashed the EPA's decision. The court ruled that the techniques did meet the regulatory definition of a GMO and that the regulator exceeded its authority as only the minister or Parliament could redetermine the scope of the law.[4]
    - A subsequent government review of the scope of the regulations considered whether to deregulate all or some of the new gene editing

[3] Note that this is an EPA practice adopted in guideance notes, where other elements listed are legal requirements.

[4] [2014] NZHC 1067 https://forms.justice.govt.nz/search/Documents/pdf/jdo/76/alfresco/service/api/node/content/workspace/SpacesStore/1594ff52-8c2c-4bf5-8f15-29dbcecc6fa9/1594ff52-8c2c-4bf5-8f15-29dbcecc6fa9.pdf

techniques and other emerging approaches.[5] The Government decided to continue regulating all gene editing techniques as GM, including for example cisgenics.

Synthetic Biology

As the HSNO Act uses very similar definitions and approaches to the Cartagena Protocol, so it will generally cover other examples of synthetic biology in much the same way that the protocol does.[6]

3. Gene Drive and other Techniques Targeting Species Elimination

Due to their very purpose, gene drive and other GM approaches that are designed to spread through ecological systems and eliminate species pose greater challenges to risk assessment and risk management than currently established genetic engineering applications.

In order to meet those challenges, not only New Zealand's but also other nation's GM regulatory regimes will need strengthening. The full scope of reform requirements remains to be identified but two fundamental changes required are: identification of standards and procedures to allow appropriate ecological risk assessment, and establishment of an international governance regime.

With respect to standards for ecological risk assessment, these should be identified and signalled well in advance of an application to trial or release a gene drive to 1) allow for their adequacy to be properly scrutinised and adjustments to be made and 2) make clear to developers the information requirements they will need to meet.

The case for international governance arises from the very design of the gene drive. Most other forms of genetic modification, such as GM crops, are submitted for regulatory approvals on the basis that they can be managed within certain areas, or at least national boundaries. However the intent behind a gene drive is for the target gene to be passed on in a cascade that reaches into every available biological corner, without respect for political borders. As a National Academies of Sciences (NAS) review of gene drive in 2016 stated:

> After release into the environment, a gene drive knows no political boundaries.[7]

[5] The EPA consultation document is here: http://www.epa.govt.nz/Publications/Consultation_Document.pdf
The Government press release announcing the decision is here: https://www.beehive.govt.nz/release/gmo-regulations-clarified

[6] Secretariat of the Convention on Biological Diversity (2015). *Synthetic biology.* Montreal, Technical Series No. 82. https://www.cbd.int/doc/publications/cbd-ts-82-en.pdf

[7] National Academies of Sciences, *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*, 2016, p. 6.

With respect to governance, the Academy noted that:

> Gene drives do not fit well within the existing regulatory logic of confinement and containment because they are designed to spread a genotype through a population, making confinement and containment much more difficult (or even irrelevant) and the environmental changes introduced by release potentially irreversible.
> …
> Research on gene drives is global. Responsible governance will need to be international and inclusive, with clearly-defined global regulatory frameworks, policies, and best practice standards for implementation.[8]

The Cartagena Protocol is founded on the principle of prior informed consent with respect to the transboundary movement of living modified organisms (LMOs). It puts a duty on an exporting party to seek prior informed consent from the destination country (Article 7).

However the protocol's procedures were framed to regulate intended movements across the border of a single nation. Due to the nature of gene drives, all potentially affected countries would need to be taken into a process of advance joint consideration and the protocol's procedures are not set up with this in mind. That is just the procedural framing. A paper co-authored by one of the developers of the CRISPR technique (that can be used to power a gene drive) identifies a series of gaps in the protocol including that it does not "define standards for assessing effects, estimating damages, or mitigating harms" and that its sister Nagoya Protocol does not "define rules governing liability and redress for damage".[9]

The NAS also identifies gaps, including:

> Given that the United States is not a Party to the Cartagena Protocol, it is a major gap in international governance that the United States does not have a clear policy for collaborating with other countries with divergent systems of governance, especially when such countries may, in fact, lack the capacity to assess the safety of gene drive research, undertake public engagement and societal dialogue, and maintain regulatory institutions.[10]

Purpose-built international regulation is a minimum condition recognised even by free market traders in support of biotechnology. As *The Economist* magazine puts it: "A decision by one nation, or one group, to release them might eventually affect every country where the species exists. Governance arrangements must be international from the start".[11]

Thus a prerequisite to considering a release is the existence of international governance arrangements that are fit for purpose.

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[8] Ibid
[9] Kenneth Oye, Kevin Esvelt et al, *Regulating gene drives*, Science Express, 17 July 2014.
[10] National Academies of Sciences, *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*, 2016.
[11] The Economist, *Extinctions to Order*, 17 September 2016.