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From: s22
Sent: Thursday, 8 December 2016 13:32
To: s22

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Subject: RSN gene drive follow up meeting [SEC=No Protective Marking]
Attachments: Gene drives V5 011216.docx; CSIRO-RSN RoundtableMeeting #2_Dec2016 _agenda.docx

Hi all,

Attached is the agenda for next Tuesday's CSIRO/RSN Round Table Meeting on Gene Drive Regulation. Thanks to everyone who has agreed to attend, and for the suggestions regarding additional attendees.

Also attached is the most recent draft of the Academy of Science position paper on gene drive technology, which we will be discussing on the day. Please take the time to read this in advance to provide comments on the day.

The venue for the meeting is the same as the last round table discussion in June - the boardroom on the main floor of the Discovery Centre on CSIRO's Black Mountain campus. I will provide reception with a list of attendees so that everyone does not have to go to main reception (Bldg 101) to sign in before proceeding to Discovery. For those of you who did not attend the last meeting, the doorway to the boardroom is on the opposite side to the cafe. It is locked - and someone will be at the door between 8:30 and 9:00 (or soon thereafter) to let people in and guide them to the boardroom. For those with a CSIRO ID that provides them access, the boardroom is on the first corridor to the left after entry, then on the right hand side.

Please send me any questions you might have. If there are problems on the day, please contact me on my mobile number beneath my signature below.

Regards, Owain

Dr Owain Edwards
Group Leader | Environmental Synthetic Genomics

Senior Principal Research Scientist
CSIRO Land & Water
Underwood Avenue, Floreat WA 6014 | Clunies Ross St, Canberra, ACT 2601

Phone: +61 s22) | Mobile: s22 | s22

Australian Government
Department of Health
Office of the Gene Technology Regulator

CSIRO

Australian Government
Australian Pesticides and Veterinary Medicines Authority

CSIRO-RSN Roundtable Follow-Up Meeting

December 13th 2016, Boardroom, Discovery Centre, Black Mountain, Canberra

Agenda:

9.00am: Welcome, introductions (Owain Edwards, CSIRO)

9.15am: Background recap (Owain Edwards, CSIRO)

9:30am: Previous action items – from June 30th Roundtable meeting (All)

10:00am: OGTR Regulations Review (s22)

10:15am: Brief updates on recent international meetings and consultations

- OECD-sponsored workshop, North Carolina, United States, *Environmental Release of Engineered Pests: Building an International Governance Framework* (Lucy Carter and Owain Edwards, CSIRO)
- COP 13 Convention on Biological Diversity, Cancun, Mexico (Mark Tizard, CSIRO, via video link)
- Technical review of the Gene Technology Regulations 2001 (Peter Thygesen, OGTR)

10.45am: Coffee break

11:00am: Discussion of the Australian Academy of Science, *Gene Drives in Australia* report, and feedback (facilitated by Owain Edwards)

12.00pm: Wrap up, next steps

12:30pm: Lunch provided

GENE DRIVES IN AUSTRALIA

VERSION 5 DISCUSSION PAPER. DECEMBER, 2016

INTRODUCTION

Gene drive mechanisms (or gene drives) cause a gene to spread throughout a population at a rate higher than would be predicted normally. Scientists have been observing examples of biased inheritance generated by natural gene drive mechanisms for many years. However, significant advances in genome editing tools have brought synthetic gene drive technology within the reach of many more researchers, and research has accelerated greatly in recent years. Since 2015 scientists have published four proof of concept studies in yeast, mosquitoes and the fruit fly *Drosophila* to demonstrate the feasibility of using synthetic gene drives for purposes such as combating vector-borne disease, suppressing pest populations, or for introducing desired characteristics into target organisms. As with many new technologies, the potential applications and benefits are far reaching, as are the potential impacts—both intended and unintended—on public health, conservation and ecology. This rapidly developing area represents an additional method of manipulating populations alongside traditional and other methods, as listed in Table 1.

The pace at which the gene drive research is moving has triggered international discussion on gene drives (for example, Nuffield, 2016; NAS, 2016a). Governments and communities around the world need to consider the circumstances in which organisms with synthetic gene drives may be used in closed systems (e.g. biochemical drug synthesis), and also if, when and how they could be considered for release into the environment. The scientific community has raised concerns as to when organisms modified with synthetic gene drives should be released, and there is significant discussion amongst scientists regarding best practice and strategies to manage and mitigate any hazards involved (Akbari et al., 2015; Oye et al., 2014).

This discussion paper considers synthetic gene drives in a specifically Australian context and highlights the potential benefits and hazards of possible applications, emphasizing the need to eventually consider these within a risk assessment framework. The paper discusses environmental hazards, social and economic issues (including trade implications) and how the technology can be managed within Australia's governance arrangements. Our unique Australian environment generates a number of issues specific to our country: the Australian Academy of Science intends this discussion paper to complement the international discussion underway and to inform Australian governments and our community about gene drives in Australia.

Table 1: Description of various methods of biological manipulation of populations.

METHOD OF MANIPULATION	DESCRIPTION
Biological control	A method of controlling invasive weeds and pests using their own natural predators or parasites against them. Successful Australian examples include the control of prickly pear and skeleton weed. This approach is itself not without risk, as famously demonstrated by the cane toad in northern Australia.
Plant breeding	A systematic method of selecting plants with desirable characteristics for further breeding. It may include crossing closely related plant species to produce new crop varieties, or the use of chemicals or radiation to randomly generate mutants that happen to display desirable traits.
Animal breeding	As for plant breeding, this method aims to establish a line of animals with specific traits based on selective breeding, although related species are less commonly crossed and animals are less commonly exposed to radiation and mutagenic chemicals for this purpose.
Gene technology	This is a broad term that includes a variety of genetic technologies to alter an organism's genome.
Gene therapy	A special case of gene technology involving the introduction of corrective genes to replace defective or missing genes to treat genetic disorders, usually in humans.
Synthetic gene drive	A special case of gene technology that increases the prevalence of a genetic variant within a population using an engineered mechanism of biased inheritance. Also known as a 'selfish genetic element', gene drive systems are referred to in this paper as a synthetic gene drive. Natural gene drive mechanisms are also known and sometimes harnessed as a technology.

BACKGROUND

Gene drives produce a biased form of inheritance. They overcome normal Mendelian inheritance (i.e. where one copy of a gene is inherited from each parent) and greatly increase the chances of a genetic element passing from a parent to its offspring (Figure 1). This results in the preferential increase in the frequency of a specific genotype over many generations and the entire population may eventually come to possess only that genotype.

Synthetic gene drives are being developed to influence a target population via two primary methods: population suppression or population alteration. A synthetic gene drive that is designed to suppress a population would (over many generations) reduce the number of individuals within a population following its introduction, possibly to zero. A synthetic gene drive designed to alter some characteristic of a population would involve a modified genetic element that is then spread throughout the population, for example to confer resistance or immunity to a certain parasite or disease.