s22

From: s22
Sent: Friday, 5 August 2016 16:37
To: s22

Subject: RE: Follow-up from Gene Drive Roundtable [SEC=No Protective Marking]

Hiya Owain – thanks for the email – re the PC/QC issue - below are the draft conclusions from a consensus paper on containment strategies for invasive genetic factors (some of which are still be discussed/contested by the co-authors)– please do not circulate these beyond this group – I'd be happy to circulate the entire paper once it is published.

Cheers

K

Conclusions

Previous guidance on facility design and operations at levels 2 and 3 should be consulted and serve as a starting basis for good physical containment for developing and testing driving transgenic arthropods like mosquitoes, with an appreciation that each IGF may need its own special considerations. Arthropods containing an IGF present additional concerns that are different from typical transgenic arthropods and arthropods infected with a pathogen, but there are several measures that can be put in place to ensure that inadvertent release, distribution and contamination of and by driving transgenes does not occur:

- Increased arthropod containment measures above typical level 2 measures and active and passive monitoring and buffer zones must be considered. Microbe-specific containment measures should be avoided.
- Where feasible, incorporating a unique dominant-acting marker into the driving transgene construct that allows the visual identification of IGF individuals, distinguishing them from non-driving strains. Working with unmarked driving transgenes or a common marker will not allow contamination to be easily recognized.
- Distribution of non-transgenic and wild-type strains of the same mating group by laboratories that also handle driving transgenes must be carefully scrutinized to assure against contamination and might need to be disallowed if undetected contamination is possible. If procedures allow for potential contamination then only individual arthropods that have been exhaustively screened immediately before shipment can be shared and only if it is confirmed with high confidence that they do not contain a driving transgene.
- Authentication of all strains in the insectary handling IGFs should be conducted routinely. Depending on the number of similarly marked strains and the stringency of containment, it may be necessary to develop strain-specific PCR assays.
- Routine assessments of the management and housing of strains held in insectaries should be performed and modified as holdings change.

- Multiple strains should be housed in a way that minimizes the probability of cross-mating, accidental transfer of all life stages and maximizing detecting contamination based on the mating group and markers.
- Containment of all IGF strains, including "model species", should be carefully assessed in view of the potential legal implications of their unintentional spread, particularly considering international trans-boundary issues.

Implementing some of the measures addressed here will require building a consensus of practice among those working with a species group, for example in the selection of a promoter-marker combination. Some can be implemented independently by those operating only one laboratory or within a consortium of collaborating laboratories.
Regardless, as is the case with many risk-related issues, the management and decisions must be made on a case-by-case basis. Investigators, regulatory authorities, IBCs and project donors must ensure appropriate procedures that prevent accidental release of arthropods containing an IGF. These authorities face great challenges in making the correct decisions that could be the subject of careful scrutiny by other authorities, by the public at large, and whose consequences may have legal ramifications. Laboratories that are suitable for handling driving transgenes in arthropods must be designed and managed with additional considerations in mind relative to conventional arthropod rearing facilities. Measures to prevent accidental export of driving transgenes should be carefully addressed by strain and facility design, and equally importantly, facility management.

From: s22
Sent: Friday, 5 August 2016 2:57 PM
To: s22
s22

Subject: Follow-up from Gene Drive Roundtable

Hi all,

Thanks again to everyone for participating in the roundtable discussion associated with the Gene Drive Workshop in Camberra in June. Attached is a follow-up summary, including actions, which we promised to circulate. Apologies that it has taken so long to get this organised.

You'll note that we have proposed the next meeting for October/November, not August/September as was suggested on the day. This is to allow all of us sufficient time to complete consultation within our organisations, and also so that we can provide feedback to this next meeting from an OECD conference on gene drive regulation in the USA in early October. Several of us will be attending both.

Please let me know if you have any comments or concerns about the content of this document.

Regards, Owain

Dr Owain Edwards
Group Leader | Environmental Genomics

Australian Government
Department of Health
Office of the Gene Technology Regulator

CSIRO

Australian Government
Australian Pesticides and Veterinary Medicines Authority

CSIRO-RSN Roundtable - Regulating Gene-drive Technology

Notes from the meeting held 30th June 2016, Boardroom, CSIRO Discovery Centre, Black Mountain, Canberra

Background and Purpose:

This meeting provided an opportunity for regulators and researchers to share information and ideas, identify gaps and opportunities, and create a forum for enhancing Australia's preparedness to govern the development and use of advanced genetic technologies. Key federal agencies potentially responsible for regulating gene technology applications attended along with leading researchers from the CSIRO and the University of Adelaide, as well as members of Island Conservation (http://www.islandconservation.org/).

The Group spent the day reflecting on issues raised during the previous day's Gene Drive Symposium as well as workshopping a case example – release of daughterless mice[1] on Australian islands – to identify potential pathways (and questions) for governance.

Attendees:

First Name	Last Name	Affiliation
Peter	Brown	CSIRO
Karl	Campbell	Island Conservation
Lucy	Carter	CSIRO
Edward	Cram	APVMA
Les	Davies	APVMA
Owain	Edwards	CSIRO
Andreas	Glanznig	IACRC-CISS
Keith	Hayes	CSIRO
Paul	Howles	Environment
Adil	Hussain	APVMA
Nicholas	Johnson	NHMRC
Todd	Kuiken	Wilson Institute/NCSU
s22		
Wendy	Odgers	DAWR
Royden	Saah	Island Conservation
s22		

[1] Modified using gene-drive technology

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Natalie	Smith	Environment
Paul	Thomas	University of Adelaide
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Mark	Tizard	CSIRO
s22		
Gaye	Weller	APVMA
Michelle	Wooster	APVMA

Action items:

1. A question was raised early in discussions about potentially absent regulators and others, including state representatives.

ACTION: s22 will invite the Department of Defence to participate in the next Roundtable meeting.

2. A suitable mechanism for this Group (and associates) to continue sharing information and raising issues for discussion was considered.

ACTION: Possible listserv system was proposed. For consideration by the Group at the next meeting.

3. Possible regulatory gap identified: There is potentially some overlap and lack of clarity between PC and QC containment requirements. Do these standards appropriately address all possible applications? Level of containment needs clarification.

ACTION: Keith Hayes (CSIRO) will follow up with others to gather more information.

4. Question was raised - Is there a role for the OGTR to provide messaging to Institutional Biosafety Committees (IBCs) around the gene drive (GD) issue with recommendations?

ACTION: OGTR will consider this question in time.

5. In relation to the Island Conservation case study – an internal legal question identified for APVMA. [Is this a pest control product?] Would the APVMA legislation capture this technology? [*See also 7. below.*]

ACTION: Owain Edwards (CSIRO) to interact with APVMA on the matter. APVMA to provide information to the group on how the APVMA legislation captured wolbachia-infected mosquitoes.

6. Potential trade impacts arising from the deployment of daughterless mouse gene drive technology was flagged as an issue for further discussion. Resolution not necessarily possible but caution recommended in tackling any perceived risks using a politically-sensible approach. Trade concerns are potentially related to any GM/synthetic biology application and other agricultural species.

ACTION: Owain Edwards (CSIRO) will take this issue to Andy Sheppard for further discussion with DAWR, and possibly GRDC.

7. Legal clarification about the 'regulatory reach' of the *Gene Technology Act 2000* and the *Agricultural and Veterinary Chemicals Code Act 1994* would be helpful; is it the case that this novel technology (gene drive), where it is utilised to manage pests or pest vectors, is picked up under both?

ACTION: CSIRO to liaise with the OGTR and APVMA and their relevant policy departments as appropriate – the Department of Health and the Department of Agriculture & Water Resources (DAWR).

8. Next steps and preferred output from this meeting going forward?

ACTION: Lucy Carter (CSIRO) to send condensed notes and action items to the Group asap.

ACTION: Day 3 (next Roundtable meeting) to occur around September following opportunity for individual organisations to consult internally on matters raised during this meeting.

ACTION: Owain Edwards (CSIRO) to follow up with Candice Sheldon about how CSIRO Institutional Biosafety Committees (IBCs) could be engaged to improve oversight. Awareness raising around peer expectations. Institutional Biosafety Committee, (IBC) and internal capacity building.

ACTION: Owain to circulate Akbari et al (2015) paper and Webber et al (2015) paper to the Group.

Next meeting – TBC, October or November 2016.