

Agenda
Issues in Regulatory Science for Gene Drive Modified Insects
December 4-5, 2019
Sheraton Reston, Virginia

Objective: Advancing the development of gene drive modified insects for a variety of needs including pest elimination and vector borne human disease eradication has focused largely on issues of discovery science with limited extension to exploration of issues of regulatory science. This workshop aims to create a deliberative space for experts to explore current best thoughts on regulatory science related to the characteristics of gene drive-modified insects developed for both population modification and population suppression strategies. Participants will consider whether there are new regulatory science issues that are raised by gene drive products that are not addressed by existing regulatory and risk assessment approaches applied to regulated insects or regulated insect control products. Specific discussions topics will include:

- Implications of product design and potential use
- Issues that distinguish gene drive-modified insect products from other regulated insect or insect control products at different phases of product testing and development
- Expectations of dossier submissions for biosafety and regulatory requirements

Target participants: Experts and practitioners in regulatory science, risk assessment, vector control, biocontrol, entomology, gene drive research, biotechnology, and policy related to genetically modified insects/animals.

Target audience for output: Gene drive researchers and product developers.

Agenda

Wednesday, December 4

8:00 – 8:45 Registration and breakfast

8:45 – 10:00 **Welcome and introductions** (15 mins)- Brinda Dass FNIH
Workshop goals and expectation (5 mins)- Brinda Dass FNIH
Types of putative gene drive insect products possible (30 mins)- Dave O’Brochta FNIH
Pathways paper as an overarching framework (20 minutes)– Stephanie James FNIH

10:00 – 10:15 *Coffee/tea*

10:15 – 12:30 **Regulatory perspectives**

Moderator: Dorington Ogoyi

Gene drive products as LMOs/GMOs (20 mins)- Willy Tonui, EHS Consultancy
Regulatory Coordination (20 mins)- Olalekan Akinbo (AUDA-NEPAD representative)
Parallels to classical biocontrol agents (25 mins) – Lisa Knolhoff and Bob Pfannenstiel (USDA)
Parallels to GM SIT products (15 mins) - Nathan Rose, Oxitec
Group Discussion (50 minutes)

12:30 – 1:15 *Lunch*

1:15 – 3:15 **Implications of product design and potential uses** - Group Discussion (2 hrs)

Moderator: Dave O'Brochta

Potential Discussion Topics:

- Suppression or modification - different characteristics of these product types Molecular characterization, lineage establishment/maintenance, refreshing genetics
- Multiple component systems – drive designs including stacked traits, multi-locus or split drives, daisy drives

3:15 – 3:30 *Coffee/ tea*

3:30 – 5:30 **Implications of spread and persistence** - Group Discussion (2 hrs)

Moderator: Chris Wozniak

Potential Discussion Topics:

- Comparator for phenotypic characterization- gene expression, protein levels, fitness, vectorial capacity, fertility/fecundity, behavior of mosquito, behavior of parasite, allergenicity/toxicity
- Comparator for Insecticide resistance
- Drive biology – potential for different types of gene drive systems to spread to related interbreeding insect species
- Product quality - Impact of the driving nature, resistance, genomic plasticity, selection pressures, fitness costs on the expectations for product stability and durability. What does stability mean for a driving product that is expected to move freely and spread through populations?
- Post-implementation conditions of use including use of multiple products in an area

6:30 *Group dinner*

Thursday, December 5

8:00 – 8:30 *Breakfast*

8:30 – 10:30 **Safety criteria for moving to the field** - Group Discussion

Moderator: Vibha Ahuja

Potential Discussion Topics:

- Safety criteria for other insect control tools e.g. biocontrol or GM SIT
- Applicability of proposed go/no-go standard: justification that the gene drive investigational product will do “no more harm to human/animal health than wild-type insects of the same genetic background and no more harm to the ecosystem than other conventional insect control interventions.”

10:30 – 10:45 *Coffee/tea*

10:45 – 11:00 **Expectations of dossier submissions for biosafety and regulatory requirements**- Willy Tonui

11:00 – 1:00 Dossier/regulatory requirements- Group Discussion

Moderator: Willy Tonui

Would gene drive insects require any different information- risk assessments, modelling, effect of not taking the action

1:00- 2:00 *Lunch*

2:00 – 5:00 Considerations for initial field testing- Group Discussion

Moderator: Prosper Chaki

Discussion Topics:

- Nature of claim- pest/vector +/- disease mitigation (population suppression or modification)
- Expectations for confined field testing
- Expectations for trial termination
- Integration with existing insect control strategies
- Monitoring expectations

5:00 – 5:30 Discussion of next steps (including output of workshop) - Stephanie James