

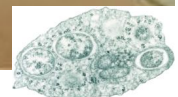
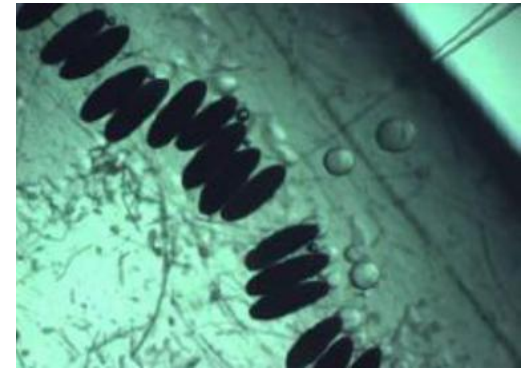
The Cartagena Protocol in the context of recent releases of GM and *Wolbachia*-infected mosquitoes

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**CARTAGENA
PROTOCOL
ON
BIOSAFETY
TO THE
CONVENTION
ON
BIOLOGICAL
DIVERSITY**



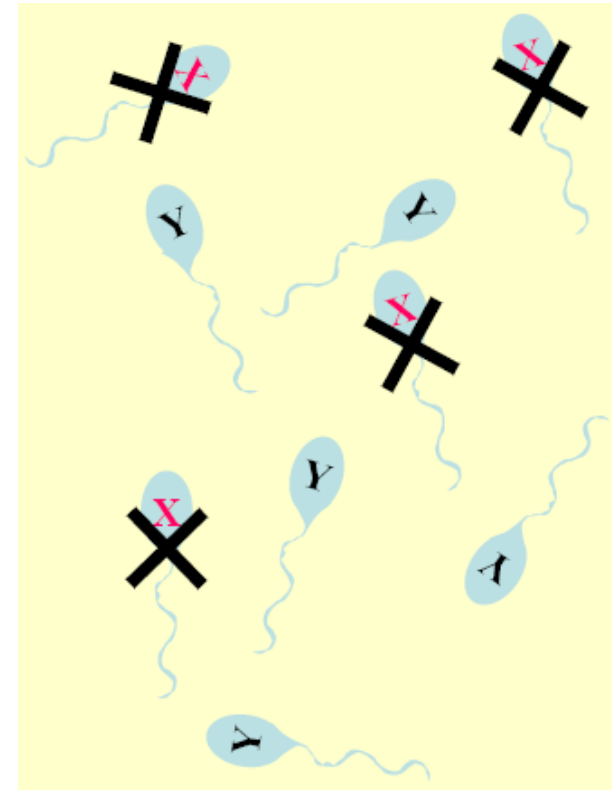
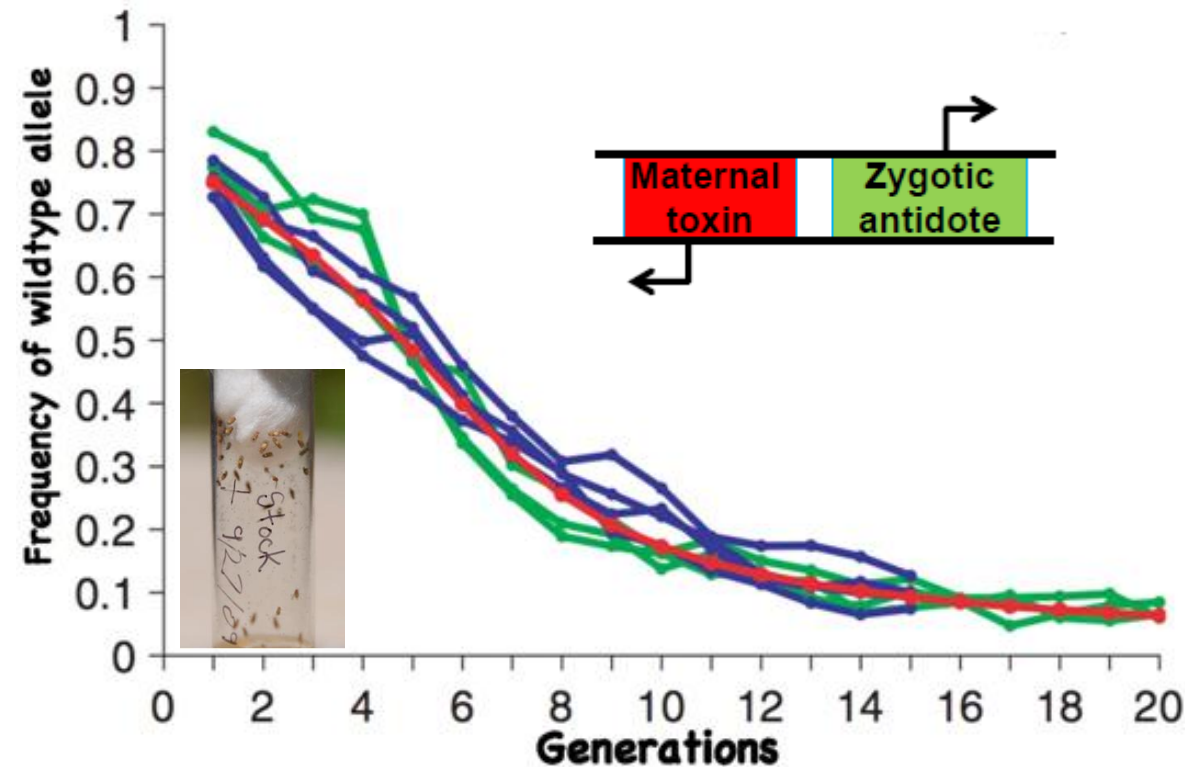
Self-propagating GM mosquitoes

- **Medea elements:**

- Capable of spreading disease-refractory genes into mosquito populations from low initial frequencies.

- **X-shredders:**

- Create a bias towards Y-bearing sperm, leading to an all-male population and a cascade of population crashes.



The Cartagena Protocol on Biosafety

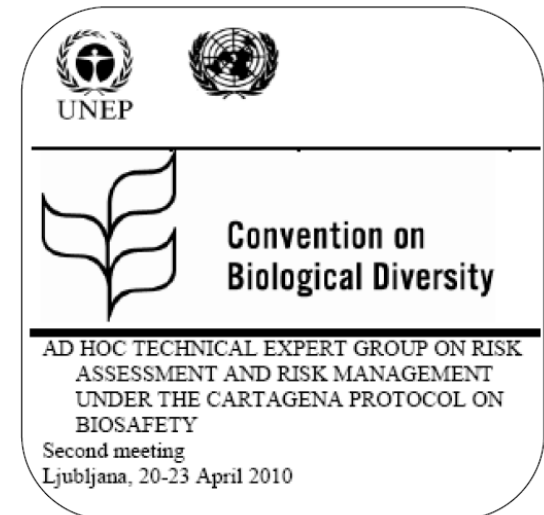
Applies to the **international movement of living modified (LM) organisms** with **possible adverse effects on biodiversity or human health.** (Article 3)

- **LM organism:**

- “any **living organism** that possesses a **novel combination of genetic material** obtained through the use of **modern biotechnology**” (Article 3)

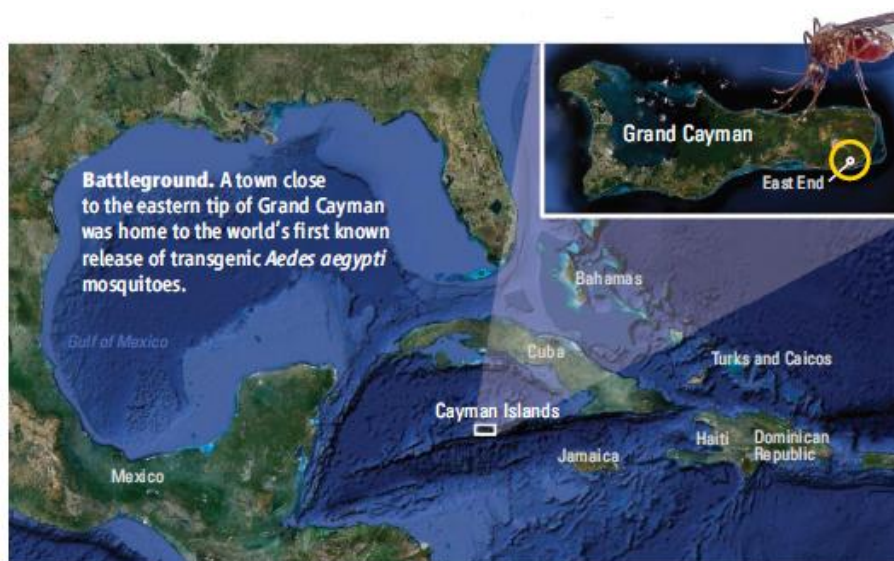
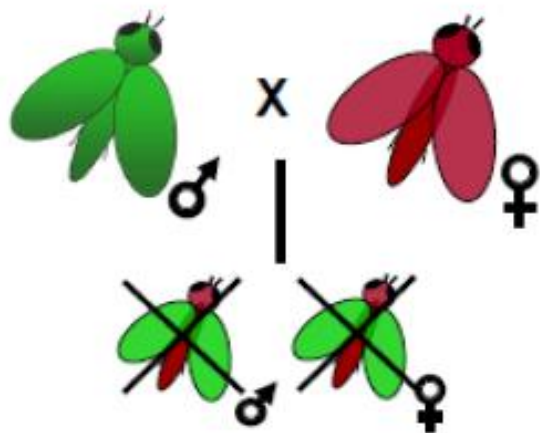
- **Modern biotechnology:**

- “...**in vitro nucleic acid techniques**, including **recombinant DNA** and **direct injection of nucleic acid**...” (Article 3)



Releases of GM sterile mosquitoes

Bi-sex lethal



Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

•Cartagena Protocol:

- Applies to the import of GM mosquitoes intended for release into the environment.

- Requires that Parties make decisions to import based on a scientifically-sound risk assessment (Article 15).

Risk analysis of a hypothetical open field release of a self-limiting transgenic *Aedes aegypti* mosquito strain to combat dengue

Camilla J. Beech¹, J. Nagaraju², S.S. Vasani^{1,3}, Robert I. Rose⁴, Rofina Yasmin Othman^{5,6}, Vilasini Pillai⁷, and T.S Saraswathy^{8*} (on behalf of the Working Groups^{**})

	Potential Hazard	Potential Consequence	Risk mitigation/management	Overall risk
1	Male starts to bite	Increased transmission of disease	Males do not have morphology to bite. The anatomical structure of the mouthparts and the anatomical structure of the stomach prevent are incompatible with males having the capacity to bite. Additionally anti-coagulant secretions are required for biting and this has not been observed in males	Negligible
2	Biting period (frequency and peak biting period) extended	Increased transmission of disease	Males cannot bite. Bionomic equivalence of females demonstrated that female GM mosquitoes are the same as the wild type female	Negligible
3	Cross mating with other mosquito species	Potential gene transfer to other mosquito species	Biological data from experiments conducted and literature shows that cross-species mating results in non-viable progeny. Existing data shows there is reproductive isolation between species due to the structure of the genitalia (e.g. between <i>Aedes</i> and <i>Culex</i>)	Negligible

The risk assessment for the GM sterile mosquitoes may not have been mandated by the Protocol

Article 6

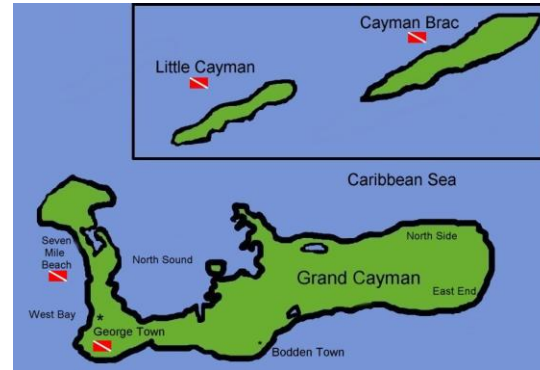
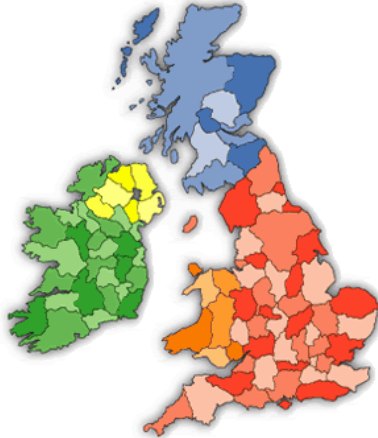
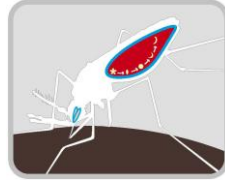
TRANSIT AND CONTAINED USE

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.



- Interestingly, the **UK** was **not obliged** to **perform a risk assessment** at its **own expense**.
- This is because the **GM mosquitoes** were **first exported** for **analysis** in **laboratory/cage studies** in the **receiving country** and hence were **exempt** from the AIA procedure.

The Protocol does apply to international movements between Parties and non-Parties



Cartagena Protocol does apply

• **Parliamentary discussions** suggest that the **provisions of the Protocol do not apply to movements between the UK (a Party) and the Cayman Islands (a non-Party to the UK's instrument of ratification).**

• This is in **contradiction to Article 24** of the Protocol.

Genetically-modified mosquitoes released for no reason

27-01-11

SCIENTISTS in Malaysia have unleashed giant, DNA-altered mosquitoes into the environment for the hell of it.

The insects, many of which are larger than adult labradors, kill their prey by pinning it down using razor-tipped forelegs then inserting a foot-long proboscis into an eye socket and sucking out the brain matter.

Geneticist Wayne Hayes, who works at the secretive laboratory near Kuala Lumpur, said: "When you work in science, you're always under a lot of pressure to be logical and rational and I think we were really feeling that last Tuesday.



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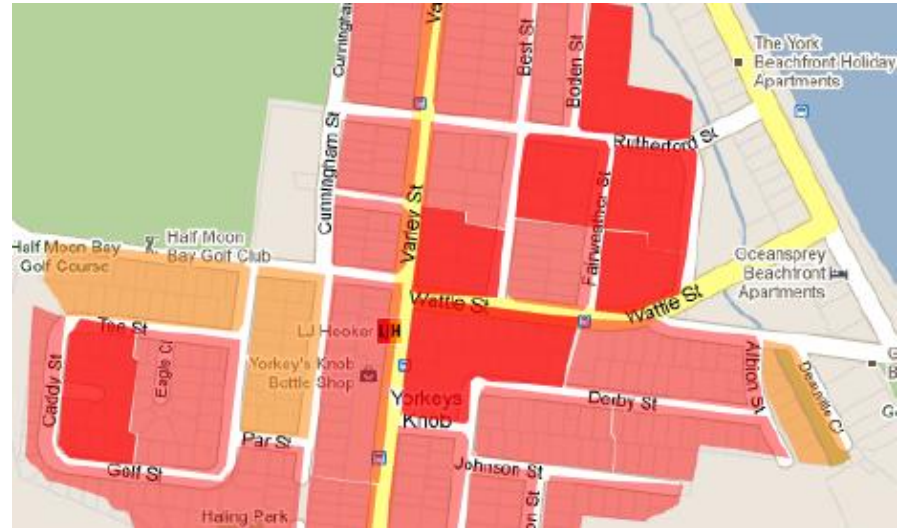
Tweet 0

+1 0

The new Mash Book -
Welcome to the Mental
Hospital



Releases of *Wolbachia*-infected mosquitoes



Article
3
USE OF TERMS

- (i) "Modern biotechnology" means the application of:
- In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
 - Fusion of cells beyond the taxonomic family,

•Similarities to self-propagating GM mosquitoes:

- Associated with **physiological changes** that are **beneficial** for **disease control**.
- Manipulates** host's **reproductive biology** to **promote** its **spread** through a **population**.

“A regulatory no man’s land”



An alternative strategy
to eliminate dengue fever



- *Wolbachia* and *Ae. aegypti* were already present individually.
- *Wolbachia*-infected *Ae. aegypti* was not considered a GMO.

Agricultural and Veterinary Chemicals Act 1994

- C2004A04712



Australian Government

ComLaw

- Ultimately it was considered a “**veterinary chemical product**” on the basis that *Wolbachia* is “a **substance** that is used for application to an animal... as a way of directly or indirectly **modifying** the **physiology** of the animal so as to **alter** its **natural development** or **reproductive capacity**.”

Risk assessment: acknowledged but didn't consider spread beyond the release site

www.csiro.au

Risk Analysis on the Australian release of *Aedes aegypti* (L.) (Diptera: Culicidae) containing *Wolbachia*

Murphy, B, Jansen, C, Murray, J & De Barro, P

March 2010

control programme with the expectation that the *Wolbachia Ae. aegypti* will be self sustaining after the inoculative release and the beneficial characteristics will be driven into the Australia *Ae. aegypti* populations by the CI mechanism.

• **Release took place** and may have taken place **even if *Wolbachia*-infected *Ae. aegypti* was within the remit of the Protocol** because:

1. **Several countries are not signatories (e.g. Australia).**
2. The **Protocol technically applies to movements between Parties and non-Parties**, but:
 - **Non-parties did not agree to its conditions.**
 - The **likelihood of damage** may be considered **minimal**.
 - **Liability issues** may **not** provide an **adequate disincentive**.

Implications for self-propagating GM mosquitoes

1. Address the exemption of GM mosquitoes from the AIA procedure when destined for initial laboratory/cage studies.



2. Clarify that the Protocol applies to exports of GM mosquitoes from Parties to non-Parties.



3. Decide upon a procedure for approving the release of self-propagating GM mosquitoes:

- A **Protocol** that is **almost impossible** to **satisfy** is **less likely** to be **abided by**.
- One **alternative** is an **independent review** of GM organisms with **international implications**.
- This would **consider**:
 - The **risks** of **GM mosquitoes**.
 - The **promise** that **GM mosquitoes** have for **disease reduction**.



Acknowledgements

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