

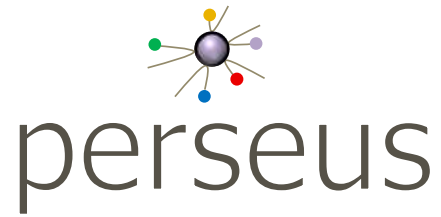
Informing regulatory developments and decision making

**Web-conference Research and innovation for
biodiversity: What role for gene drive research?"**

29 October, 2020

Prof. Dr. Patrick Rüdelsheim



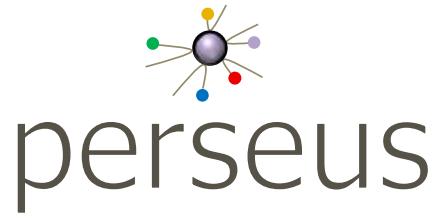


Perseus bv



We support organisations
realising the potential of biologicals
by implementing biorisk management
and complying with legal obligations
in an efficient and affordable way



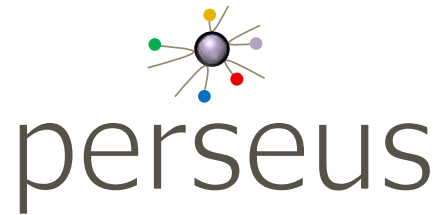


COGEM
Research project

Commission on Genetic Modification (Netherlands)

- independent scientific advisory body to the government
- **advise** on the risks to human health and the environment of the production and use of GMOs, and **informs** the government of ethical and societal issues linked to genetic modification.
- **2018 Research project:**
Gene drives in the environment:
facts and experience to inform risk assessment

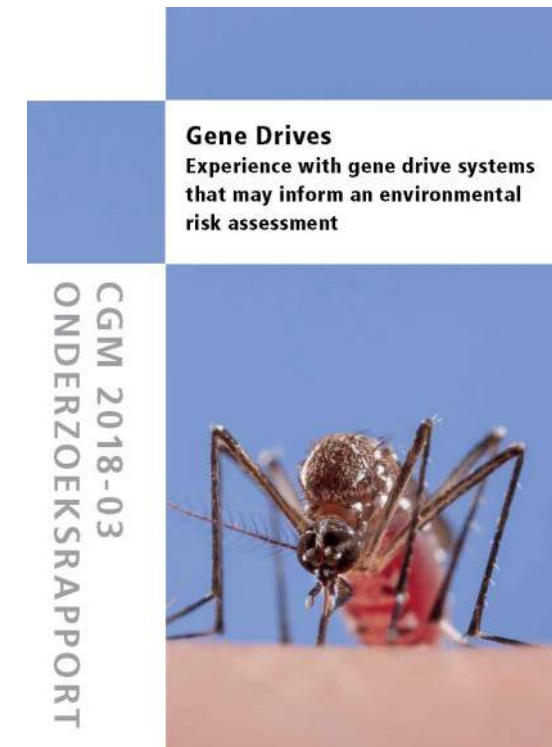


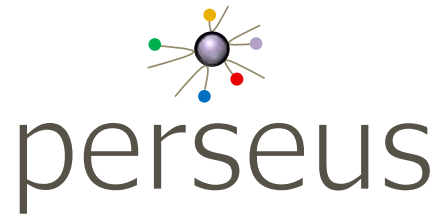


- **Natural and synthetic** gene drives have been explored
- Field (cage) experiments and releases are almost exclusively with **mosquitoes**
- The most advanced programme is the release of *Wolbachia*-infected *Aedes aegypti* in several parts of the world to fight mosquito-vectored human diseases
- **Case-by-case** risk assessment as different systems have different characteristics

www.cogem.net

Findings

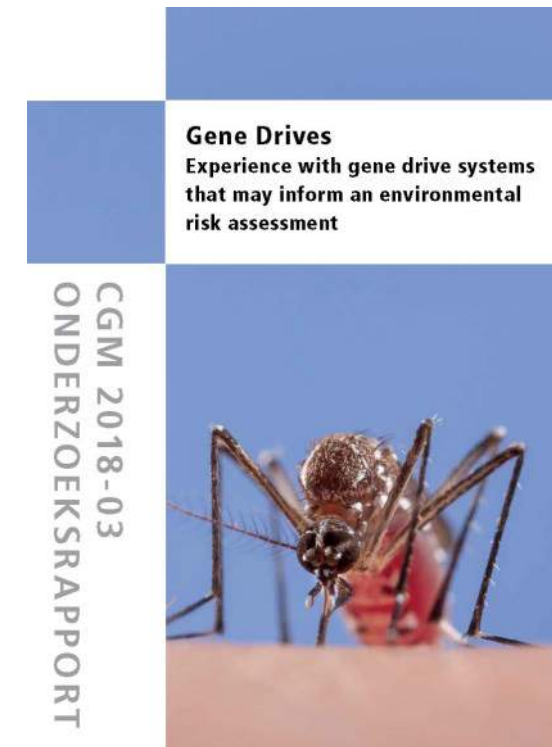




- **No harmful effects** to human health or the environment have been observed so far
- Gene drives are **delicate constructs** and safeguards can be designed e.g. when working with CRISPR/Cas systems to avoid that they are created by chance
- **Concerns that the release of organisms with gene drives will inevitably lead to the suppression or replacement of all wild-type individuals should be nuanced**

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Findings





- No indications that gene drives are able to spread uncontrollably after their release
- Not necessary to assign activities with CRISPR gene drives to the highest containment level
- Containment measures can be determined using standard procedures



perseus

Informing regulatory system

COGEM
Commissie voor de Genetisch Gemodificeerde Organismen

Aan de voorzitter van
Biodiversiteit en Natuurwet
dhr. C. van Nieuwenhuijzen-Wigboldus
Postbus 20001
2200 EX, Duizend

datum: 05 juni 2019
aantal: COGEM0005-01
omschrijving: Adviesrolle met betrekking tot de toelating van CRISPR-gedirecteerd geredigeerde organismen

Gedachte raadsvergadering van Nieuwenhuijzen.

In 2015 verschenen er verschillende publicaties over genetisch gemodificeerde organismen die op zijn minst waren vervaardigd door de Nederlandse landbouw, ook geredigeerd door een populair van een soort van kous CRISPR. Ook verschenen van een in Wageningen bij de landbouwministerie verschenen publicaties van een in Wageningen van de publieke opinie representatie van CRISPR-gedirecteerd geredigeerde organismen die door de Nederlandse landbouw geredigeerd werden.

Dit is bekend dat gene drives ook kunnen worden gebruikt, mogelijk om ziekten te verspreiden of te bestrijden, maar dat er ook andere toepassingen zijn voor gene drives, zoals de CRISPR-gedirecteerd geredigeerde organismen.

¹ Nieuwenhuijzen (2018), Koning van de CRISPR-gedirecteerd geredigeerde organismen 2015 (ongepubliceerd).
² Koning van de CRISPR-gedirecteerd geredigeerde organismen 2015 (ongepubliceerd).
³ Koning van de CRISPR-gedirecteerd geredigeerde organismen 2015 (ongepubliceerd).
⁴ Koning van de CRISPR-gedirecteerd geredigeerde organismen 2015 (ongepubliceerd).

Gene Drives
Experience with gene drive systems that may inform an environmental risk assessment

CGM 2018-03
ONDERZOEKSRAPPORT



efsa
European Food Safety Authority

Evaluation of existing EFSA guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified insects with synthetically engineered gene drives

EFSA GMO Panel

Abstract

Recent advances in molecular and synthetic biology are enabling the engineering of gene drives that spread genes of interest through interbreeding populations at a frequency greater than the rate expected by simple Mendelian inheritance, even if they incur a fitness cost. At present, insects represent the most likely cases of gene drive modified organisms for deliberate release into the environment. The application of synthetically engineered gene drives is expected to complement and substantially expand the existing range of genetic methods for insect vector/pest control, especially for population replacement. While gene drive modified insects (GDMIs) have been tested experimentally in the laboratory, none has been assessed in small-scale confined field trials, or in open release trials yet. As a proactive measure and due to the potential for gene drives to spread through populations, persist in the environment, and potentially cause irreversible effects on organisms and ecosystems, the European Food Safety Authority (EFSA) has been requested by the European Commission to review whether its previously published guidelines for the risk assessment of genetically modified animals (EFSA, 2012 and 2013) are adequate for the molecular characterisation (MC) and environmental risk assessment (ESA) of gene drive modified disease-spreading mosquitoes and agricultural insect pests for deliberate release into the environment. The considerations/requirements given in the guidelines are broadly adequate for the GDMIs addressed in this GMO Panel Scientific Opinion, confirming that the ERA of GDMIs can build on the existing risk assessment frame for non-GDMIs. Given the non-food/feed uses of GDMIs and the self-replicating nature of gene drives, the guidelines would benefit from revisions particularly focussing on MC, the assessment of persistence and invasiveness, modelling and post-market environmental monitoring. Consistent with EFSA (2013), the ERA of GDMIs should begin with an explicit problem formulation that follows the case-by-case approach, and that is framed by relevant protection goals and experience gained with existing insect vector/pest control strategies. Enhanced dialogue between risk assessors, risk managers and stakeholders is advocated to define clear protection goals and decision-making criteria for the ERA of GDMIs.

UN
environment
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Convention on Biological Diversity

Chair: GENERAL
CBD/CP/RA/AHTEG/2020/1/4
21 February 2020
ENGLISH ONLY

AD HOC TECHNICAL EXPERT GROUP ON
RISK ASSESSMENT AND RISK MANAGEMENT
Montreal, Canada, 31 March to 3 April 2020
Item 3 of the provisional agenda*

STUDY ON RISK ASSESSMENT: APPLICATION OF ANNEX I OF DECISION CP-9/13 TO LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES

Note by the Executive Secretary

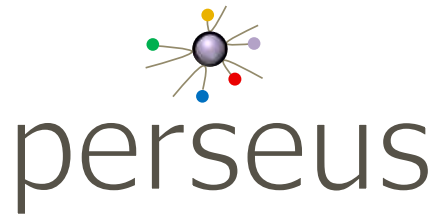
INTRODUCTION

- In decision CP-9/13, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety decided to establish an Ad Hoc Technical Expert Group (AHTEG) on risk assessment and risk management to work in accordance with the terms of reference contained in annex II to that decision. In the same decision, the Parties to the Protocol requested the Executive Secretary to commission a study informing the applications of annex I of the decision to (a) living modified organisms containing engineered gene drives and (b) living modified fish and present it to the open-ended online forum and the AHTEG.
- Based on the above, and with the financial support of the Government of Germany, the Secretariat commissioned a study informing the application of annex I to living modified organisms containing engineered gene drives to facilitate the process referred to in paragraph 6 of decision CP-9/13. The study was presented to the Open-Ended Online Forum on Risk Assessment and Risk Management, which was held from 20 January to 1 February 2020, during which registered participants provided feedback and comments.¹
- Following the Online Forum, the consultants revised and finalized the study as presented herein. Any views expressed in the study are those of the author or the sources cited in the study and do not necessarily reflect the views of the Secretariat.
- The AHTEG will be invited to review the study and perform an analysis on living modified organisms containing engineered gene drives, according to annex I of decision CP-9/13 and supported by the data in the study.
- The executive summary of the study is presented below, and the entire study contained in the annex. The study is presented in the form and language in which it was received by the Secretariat.

EXECUTIVE SUMMARY

- Gene drives allow for a trait to be distributed across generations deviating from Mendelian inheritance. For decades, attempts have been made to use or modify naturally occurring gene drive mechanisms. In recent years, advances in genetics have allowed for modifying natural gene drive systems

¹ See http://cbh.cbd.int/onlineconferences/forum_ra/discussion.html



Key points

- **Diversity** of “Gene drives” to be considered in **broader picture**
- **Regulatory** setting is prepared ahead of introduction of new systems
- **Gap and uncertainty** analysis in line with precautionary approach
- Unequalled effort of all stakeholders to **identify and reduce risks** accompanying scientific development

