WHO guidelines and review processes for gene drive technologies

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World Health Organization

New WHO Science Division

Chief Scientist

Research for Health

Quality Assurance of Norms and Standards

Digital Health and Innovation

WHO Departments

TDR (Special Programme for Research and Training in Tropical Diseases)

Alliance for Health Policy and Systems Research

Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Research Programmes

Gene drive: Building on existing guidance

- Guidance framework for testing of genetically modified mosquitoes published in 2014 following extensive public consultation
- Currently being updated by WHO to include gene drive

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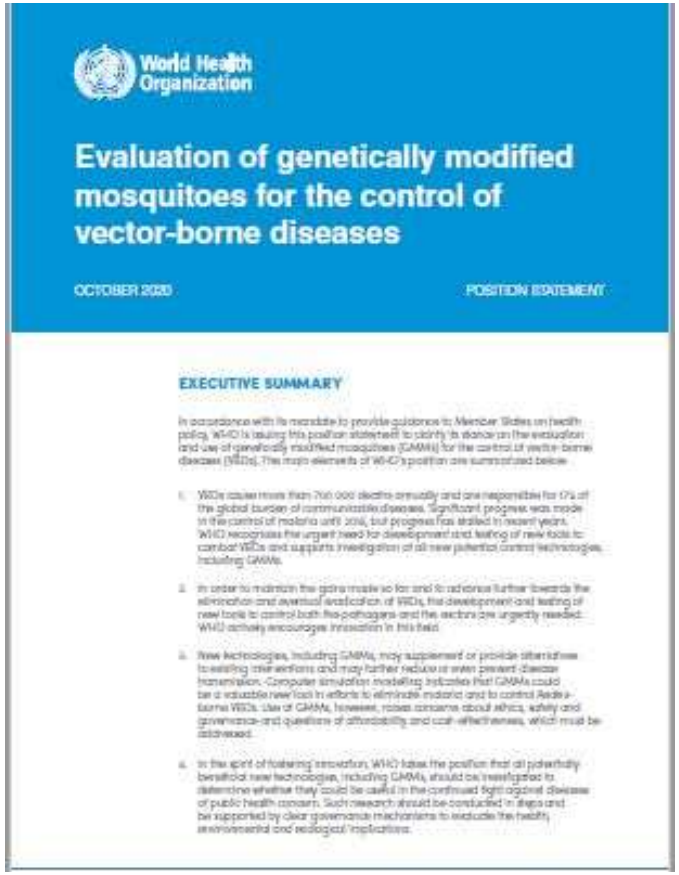
New position statement on genetically modified mosquitoes launched on 14 October 2020


World Health Organization

Evaluation of genetically modified mosquitoes for the control of vector-borne diseases

OCTOBER 2020 POSITION STATEMENT

EXECUTIVE SUMMARY

Key messages:

- **Vector-borne diseases cause a considerable burden on global health** (more than 700 000 deaths annually; responsible for 17% of the global burden of communicable diseases).
- **WHO encourages innovation, including GMMs, and evaluation of their potential to contribute to the available tools to reduce the global burden of vector-borne diseases**
- **Evaluation should follow a step-wise approach**

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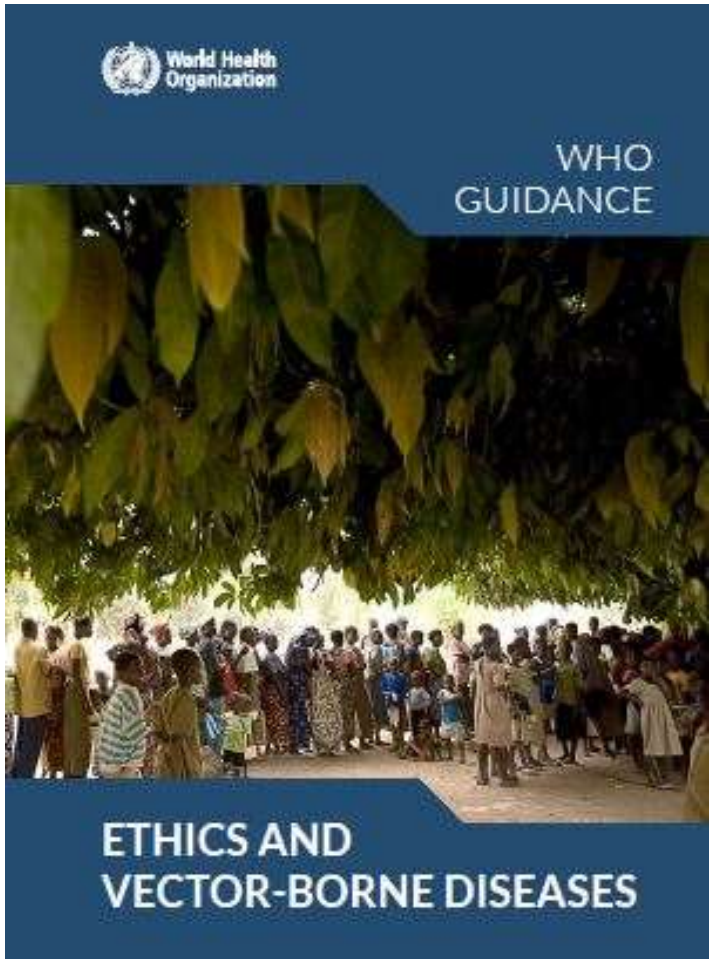
Feedback mechanism for position statement

- A feedback mechanism has been created specifically on this topic:
  geneticallymodifiedmosquitoes@who.int
  WHO will use this to further enhance its guidance and provide support to Member States.

- Translations into Spanish and French underway

New guidance on ethics and vector-borne diseases launched on 14 October 2020



- Examines a broad range of ethical considerations related to VBD prevention and control, including:
  -social and environmental determinants of health
  -vector control methods, including emerging technologies
  -screening, surveillance and research
  -vaccine campaigns and mass drug administration

- Emphasizes the critical role of community engagement in designing and implementing an appropriate, sustainable public health response

World Health Organization

WHO Vector Control Advisory Group

- Formed in 2012 by WHO to provide guidance to product developers, innovators and researchers on the generation of epidemiological data and study designs to enable assessment of the public health value of new vector control interventions submitted to WHO
- Jointly managed by the Global Malaria Programme, the Department of Control of Neglected Tropical Diseases, and the Prequalification Team for vector control products.
- Gene drive technologies currently under review:
  -Population reduction (developed by Target Malaria)
  -Population alteration (developed by Tata Institute for Genetics and Society and the University of California, Irvine Malaria Initiative)

Monitoring and Surveillance of gene drive vector control products

To ensure compliance imposed by the regulatory approval, monitor the quality and performance of the product when deployed and the emergence of any adverse effects/impacts and adherence to compliance procedures and processes

Examples of indicators to monitor :

- Adherence to appropriate deployment procedures and standards (inspection & auditing)
- Effectiveness of the GMM product under operational conditions
- Long term effect on human and animal health and effects on the environment
- Development of resistance of vector population to the GMM
- Ongoing stakeholder engagement & community acceptance