Genetically Modified Mosquitoes to Fight Malaria in Nigeria, Burkina Faso, Mali and Uganda: What Legal Response?

OJ Lim Tung*

Online ISSN
1727-3781

P·E·R
Pioneer in peer-reviewed, open access online law publications

Author

OJ Lim Tung

Affiliation

North-West University
South Africa

Email ojltmru@gmail.com

Date Submitted

18 October 2021

Date Revised

29 March 2022

Date Accepted

29 March 2022

Date published

7 June 2022

Editor Dr N Kilian

How to cite this article

Lim Tung OJ "Genetically Modified Mosquitoes to Fight Malaria in Nigeria, Burkina Faso, Mali and Uganda: What Legal Response?" *PER / PELJ* 2022(25) - DOI http://dx.doi.org/10.17159/1727-3781/2022/v25i0a12582

DOI
http://dx.doi.org/10.17159/1727-3781/2022/v25i0a12582

Abstract

Advanced applied research on genetically modified (hereafter GM) insects is being undertaken to control insect vectors of human diseases such as mosquitoes. GM insect technologies are being developed in countries where there is a legal framework for genetically modified mosquitoes (hereafter GMM), but the beneficiaries of such insect technologies to control insect-borne diseases are most likely to be in malaria-endemic countries where the regulation of GM insect technologies is inadequate. Although no commercial release of GMM has been conducted in Africa yet, there may be prospects for the use of GMM to control malaria in malaria-endemic countries such as Nigeria, Burkina Faso, Mali and Uganda. Nigeria has the highest rate of deaths related to malaria in Africa and will potentially be targeted by companies seeking to introduce GMM as a public health tool in African countries. Research is being carried out on GMM in Burkina Faso, Mali and Uganda in collaboration with foreign companies. Whereas the control of diseases is certainly needed and there are potential public health benefits for GM insect technologies to address mosquito control, there are environmental and health concerns, and there is also the potential of the misuse of such technologies. Consequently, the use of GMM requires prior robust domestic, regional and international regulation. While the Cartagena Protocol on Transboundary Movements of Living Modified Organisms (LMOs) to the Convention on Biological Diversity (hereafter the Cartagena Protocol) and voluntary guidelines on the testing of GM mosquitoes are applicable with respect to GM insect technologies, there is a lack of international and regional guidance on the regulation of such technologies. Domestic legislation tends to focus on GM crops and is inadequate for regulating GMM. This paper discusses the legal response for the above African countries which may perhaps use GMM as a public health tool and makes recommendations for the necessary regulatory response.

Keywords

Genetically modified mosquitoes; malaria; public health tool; legal response; prospective African countries; domestic regulation; African region.

.....

1 Introduction

According to the World Health Organisation (hereafter WHO), vector-borne diseases affect close to half of the world's population in more than 100 States.[1] Diseases such as malaria, dengue fever, chikungunya and zika can be transmitted to people by mosquitoes.[2] Malaria is prevalent in the tropical and subtropical regions of the world, particularly in Africa.[3] This continent records at least 90% of the deaths caused by malaria, and children under 5 years old account for 78% of all deaths.[4] Although many efforts are being made to control malaria and dengue, these diseases are still heavily affecting public health.[5] However, the lack of success of malaria control programmes in Africa may be due to insecticide resistance as well as financial and technical issues with respect to the implementation of public health strategies.[6] While there has been substantial progress in the development of malaria vaccine over the past ten years and negotiations have taken place between the African Union (hereafter AU) with the WHO regarding the first approved malaria vaccine to be used in Africa, a vaccine against malaria is not yet commercially available.[7]

Other methods being sought to fight against vector-borne diseases include genetically modified (GM) insects which have been created due to advances in insect molecular biology.[8] With genetic engineering techniques, a gene is inserted into a strain of mosquitoes to prevent the next generation from surviving. At the same time this helps to control mosquito-borne diseases.[9] Modern biotechnology has used self-limiting and self-propagating techniques to create genetically modified mosquitoes (GMM) to limit vector-borne diseases.[10] Over the past few years, experimental releases of GMM

---

* Odile Juliette Lim Tung. Licence en droit, Maîtrise en droit, DEA en droit, Doctorat en droit (Montpellier France). Extraordinary Research Fellow, Faculty of Law, North-West University. E-mail: ojltmru@gmail.com. ORCiD: https://orcid.org/ 0000-0003-4249-964X**.**

1 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xiii.

2 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xiii.

3 WHO *World Malaria Report* 2.

4 WHO *World Malaria Report* 2; Alonso and Tanner 2013 *Nature Medicine* 150.

5 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xiii.

6 Ostera and Gostin 2011 *Georgetown Public Law and Legal Theory* 930-931.

7 Reuters 2021 https://www.news24.com/news24/africa/news/african-union-to-start-talks-with-who-on-rollout-for-first-ever-malaria-vaccine-for-children-20211007; Greenwood *et al* 2017 *Malaria Journal*; Maiga *et al* 2016 *PLoS ONE.*

8 Powell 2014 *Nature Medicine* 216.

9 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* viii.

10 Self-limiting GMMs are genetically modified in view of the suppression of a specific mosquito population while self-propagating GMMs have been genetically modified to replace a specific mosquito population; Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 52; Marshall 2011 *Asia-Pacific Journal of Molecular Biology and Biotechnology* 93-94.

have reportedly been evaluated in a number of countries[11] while field trials of GMM (*Aedes aegypti*) have been conducted in the Cayman Islands (British islands) (2009), Malaysia (2010-2011) and Brazil (2011-2012).[12] Brazil was the first country to allow the commercial release of GMM to control dengue fever.[13] The GMM field trials in the Cayman Islands resulted in the suppression of the wild population by 80% in the nearby untreated areas[14] while 81% and 95% of the local *Aedes aegypti* mosquito population in Brazil were suppressed.[15] However it remains to be answered whether or not, GMM as a public health intervention tool, is effective in reducing the transmission of the targeted pathogen(s).[16] The efficacy of GMM would be demonstrated if the rate of infection or disease in human populations decreased in the release area.[17] It is necessary to monitor the health of human populations in the release area to measure how effective GMM are in reducing vector-borne diseases.[18] Would GMM as a public health tool to fight malaria attract African countries when agricultural biotechnology has not been adopted by a lot of them and it is mainly South Africa, Burkina Faso, Egypt and Sudan that have been commercialising GM crops over the past few decades?[19] Perceptions on GMM vary and they may generate similar controversies as have other biotech developments like GM crops and stem cell research.[20] There are nonetheless prospects for the use of GMM to control malaria in malaria-endemic countries such as Nigeria, Burkina Faso, Mali and Uganda.[21] Nigeria has the highest rate of deaths related to malaria in Africa[22] and will potentially be targeted by companies seeking to introduce the use of GMM as a public health tool in African countries. Burkina Faso is home to a high-profile laboratory for research on malaria in Africa where research is being carried out on GMM with a view

11 Namely France, Guatemala, India, Malaysia, Mexico, Panama, Philippines, Singapore, Thailand, United States (US) and Vietnam; Guy Reeves *et al* 2012 *PLoS Negl Trop Dis* 1.

12 Okorie *et al* 2014 *Malaria Journal*; Harris, Nimmo and Alphey 2011 *Nature Biotechnology* 1034-1039; Guy Reeves *et al* 2012 *PLoS Negl Trop Dis* 1-15; Marshall 2011 *Asia-Pacific Journal of Molecular Biology and Biotechnology* 93-100.

13 Joshi 2014 http://www.idsa.in/cbwmagazine/Geneticallyengineeredinsects_ajoshi; GeneWatch UK 2015 http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec_GWbrief_Mar15.pdf 1.

14 Harris, Nimmo and Alphey 2011 *Nature Biotechnology* 1034-1037; Harris *et al* 2012 *Nature Biotechnology* 828-830.

15 Carvalho *et al* 2015 *PLoS Negl Trop Dis*.

16 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

17 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

18 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 60.

19 See Wambugu "Importance of Political Will" 3.

20 Knols *et al* "Transgenic Mosquitoes and the Fight against Malaria" 5; ASSAF *GMOs for African Agriculture*.

21 Swetlitz 2017 https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/.

22 WHO 2021 https://www.who.int/news-room/fact-sheets/detail/malaria.

to their release.[23] Researchers in Mali and Uganda are collaborating with the "Target Malaria" project from the Bill and Melinda Gates Foundation as well as research laboratories in England and Italy to develop GMM to fight malaria.[24]

While the use of GMM is a potential public health tool, it also represents a biotechnological product which requires thorough testing in laboratories and field trials before being approved and released as a commercial product on the market. Hence, the use of GMM requires adequate regulation in countries where they will be developed, where field trials will be conducted and where commercial release will take place. GMM trials and the release of such mosquitoes raise ethical, legal, and social issues such as public health and environmental risks, public awareness and consultation, informed consent, and institutional oversight.[25] Further, mosquitoes are said to be able to travel far in vehicles, ships and airplanes and a self-propagating GMM population could spread over entire continents and go out of control.[26] Collaboration with neighbouring countries could be effective only if there is transparency about the use and release of GMM by the host country. Since the social and environmental implications of GMM may be significant and potentially irreversible, the release of such mosquitoes requires prior robust domestic legislation and international agreements.[27]

While GM insects are not contained by national boundaries, there is no consistent, internationally recognised protocol or convention for the testing and release of GM insects.[28] At the international level the *Cartagena Protocol*[29] to the *Convention on Biological Diversity*[30] (hereafter CBD) regulates the transboundary movement, transit, handling and use of LMOs and their adverse effects on biological diversity taking into consideration the concomitant health risks. While the *Cartagena Protocol* is considered to be important in the regulation of GMM and the evaluation of risks,[31] it was not drafted to regulate GM insects. A guidance document for risk assessment

23 Swetlitz 2017 https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/.

24 Swetlitz 2017 https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/.

25 Resnik 2014 *Developing World Bioethics* 37-46; Lee 2017 *American Journal of Bioethics* 5-12.

26 Beisel and Boëte 2013 *Science as Culture* 49; BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 3.

27 Beisel and Boëte 2013 *Science as Culture* 50.

28 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 1.

29 *Cartagena Protocol on Transboundary Movements of Living Modified Organisms* (2000).

30 *Convention on Biological Diversity* (1992).

31 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xxv.

and management on LMOs was completed in 2016 by the Ad Hoc Technical Expert Group (hereafter AHTEG) on Risk Assessment and Risk Management of LMOs to the Conference of the Parties of the *Cartagena Protocol* (AHTEG guidance document) addressing the evaluation of risks regarding GMM species which can be vectors of human and animal diseases.[32] However, expert advice on GMM under the *Cartagena Protocol* will serve mainly as guidance and may not be binding on State parties to this Protocol. Guidelines are also available on GMM under the WHO guidance framework on testing of GMM[33] (hereafter the WHO 2014 Guidance Framework) and the updated WHO guidance[34] on research on GMM to fight malaria and other vector borne diseases (hereafter the 2021 WHO Guidance). The main international regulation in terms of the prevention and regulation of insect warfare is to be found in the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*[35] (hereafter the *Biological and Toxin Weapons Convention*) with legally binding obligations for its States parties, and in the WHO International Health Regulations.[36] The Declaration of Helsinki sets out ethical principles with respect to human experiments issued by the World Medical Association (hereafter WMA) in view of the regulation of human subjects.[37] There is nonetheless a lack of international guidance on the specific regulation of GM insect technologies. Regional instruments pertaining to GM insects (including GMM) consist mainly of the European directives on genetically modified organisms (hereafter GMOs)[38] and the European Food Safety Authority (hereafter EFSA) Risk Assessment Criteria for GM Animals[39] as well as the North American Plant Protection Organisation (hereafter NAPPO) Regional Standards for Phytosanitary Measures[40] (RSPM)

32 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf.

33 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes*.

34 WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases.

35 *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction* (1975); Burkina Faso acceded to this Convention on 17 April 1991; Mali ratified this convention on 25 November 2002; Nigeria ratified this Convention on 3 July 1973; Uganda acceded to this Convention on 12 May 1992; United Kingdom ratified this Convention on 26 March 1975 (see UNODA date unknown http://disarmament.un.org/treaties/t/bwc).

36 Sture, Whitby and Perkins 2013 *Medicine Conflict and Survival* 311.

37 WMA date unknown http://www.wma.net/en/20activities/10ethics/10helsinki/.

38 See EC Directive 41/2009 (for contained use), EC Directive 18/2001 (for deliberate release) and EU Regulation 1946/2003 (for transboundary movements).

39 EFSA 2013 *EFSA Journal*.

40 For the United States (US), Canada and Mexico (Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf).

(hereafter the NAPPO RSPM). The African region does not have any regional instrument or guidelines on the regulation of GM insect technologies but only the *Draft Revised African Model Law on Biosafety* (hereafter DRAMLB) based on the proposal of the African Group for a biosafety protocol.[41] The African group can nonetheless be said to have taken a strong stand against major GM crop producers during the negotiations that led to the *Cartagena Protocol*.[42]

While GM insect technologies are being developed mainly in countries[43] where there is a legal framework for GMM, the beneficiaries of such insect technologies to control insect-borne diseases are most likely to be in

41 See Chambers *Biosafety of GM Crops* 10. The African Regional Biosafety Focal Point was created in 1990 in Harare (Zimbabwe) to guide biosafety regulation in African countries, but it did not make much impact due to financial obstacles and the different levels of development in African countries; Muzan 2018 *LEAD* 31; See the CBD; The 2008 DRAMLB is no longer publicly available. Please contact the author for a copy; See the African Union (AU) list of States parties (AU date unknown http://www.au.int/en/countryprofiles). The Southern African Development Community (SADC) established an advisory committee in 2003 to set guidelines for GMO policy in the region but it does not concern GMMs; UNEP 2006 http://new.unep.org/dewa/africa/docs/en/AEO2_Our_Environ_Our_Wealth.pdf. The Common Market for East and Southern Africa (COMESA) and the Economic Community for West African States (ECOWAS) appear keen to encourage their Member States in commercialising GM cotton with harmonised biosafety policies; Swanby *Cottoning on to the Lie* 4; See ECOWAS date unknown http://www.ecowas.int/; ISAAA 2015 http://www.isaaa.org/kc/cropbiotechupdate /article/default.asp?ID=13270. ECOWAS is preparing Regulation C/REG.5/05/08 in view of an Action Plan for the Development of Biotechnology and Biosafety for this region; In 2014 the COMESA Biotechnology and Biosafety Policy was approved to be implemented as the COMESA Biotechnology and Biosafety Policy Implementation Plan targeting increasing investments in biotechnology applications and agricultural commodity trade for COMESA; Akinbo *et al* 2021 https://www.frontiersin.org/articles/10.3389/fpls.2021.605937/full.

42 Chambers *Biosafety of GM Crops* 10.

43 For the United Kingdom (UK) see the Genetically Modified Organisms (Contained Use) Regulations, 2014 (5th ed of L29); Environmental Protection Act, 1990 (c. 43) (hereafter the EPA) and associated regulations; *Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations*, 1996 (SI 1996/1106), as amended by the *Genetically Modified Organisms (Deliberate Release and Risk Assessment – Amendment) Regulations*, 1997 (SI 1997/1900); *Genetically Modified Organisms (Deliberate Release) Regulations*, 2002 (SI 2002/2443); *Specified Animal Pathogens Order*, 2008 (SI 2008/944); *Specified Animal Pathogens (Wales) Order*, 2008 (SI 2008/1270 (W.129); *Specified Animal Pathogens (Scotland) Order*, 2009 (SI 2009/45); *Anti-terrorism, Crime and Security Act*, 2001 (c.24); HSE 2013 www.hse.gov.uk/pubns/misc208.htm; See SACGM date unknown https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/; The current regulatory framework for GM insects in the UK is inspired by two EU directives: contained use (EC Directive 41/2009) which assesses measures for the contained use of GMOs for example in research and deliberate release (EC Directive 18/2001), which outlines the risk assessment required before any release of GMOs into the environment. These directives have been transposed into UK law to create a set of national regulations; The US, Canada and Mexico, Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf.

malaria-endemic or zika-affected countries where the regulation of GM insect technologies is inadequate. This analysis targets mainly the adequacy of the regulatory framework pertaining to Nigeria, Burkina Faso, Mali and Uganda as prospective African countries regarding the use of GMM to fight against malaria amidst a lack of international and regional guidance on specific regulation of GM insect technologies.[44] The methodology used in this analysis is a desk study of the existing legal framework on GMOs in these African countries which could be used to regulate GMM in the absence of specific legislation on GMM. Since GMM are new biotechnological products that need comprehensive testing in the laboratory and field trials before being accepted as a public health tool, an overview on GMM as well as their key benefits and concerns will be presented first. This overview is followed by an analysis of the adequacy of current domestic and regional regulation for prospective African countries which may use GMM as a public health tool, and recommendations are made for an adequate decision-making process for the import, research and use of GMM, with a follow-up mechanism.

2 GMM to fight malaria: Key benefits and concerns

Advanced applied research on GM insects is being undertaken to control insect vectors of human diseases such as mosquitoes in the spread of malaria and dengue.[45] While considering the potential of new technologies to address the need for mosquito control, it is necessary to consider their benefits and risks.[46]

---

44 Mali (*Mali National Biosafety Law*, *Decree on GMOs* and the *Law on Sanitary Control*); Nigeria (the *National Biosafety Management Agency Act*, 2015 (NBMAA); Uzuazo 2015 *IUCN Academy of Environmental Law e-Journal*; *National Environmental Standards and Regulations Enforcement Agency Act* 57 of 2007); Uganda, the *National Council of Science and Technology Act*, 1990 (Chapter 209), Laws of Uganda, is applicable to GMO-related activities (the Ugandan Parliament voted the National Biosafety Bill in 2017, but it has not yet been signed by the President of Uganda; Schnurr 2017 http://gmosandpoverty.com/ugandas-national-biosafety-act/); Burkina Faso (*Burkina Faso Biosafety Law* (BFBL) and *Decree on Biotechnology*).

45 BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 1.

46 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xiii.

2.1 Background on mosquito control and GMM

The global response to mosquito-borne infections comprises low-technology interventions[47] and alternative control methods.[48]

Alternative control strategies comprise insecticide-free methods of controlling mosquitoes such as the Sterile Insect Technique (hereafter SIT) in which laboratory-reared male insects sterilised by radiation are released over an area.[49] These compete with fertile wild males to mate with wild females in a form of area-wide birth control with a view to the elimination of an insect population from an area.[50] Another alternative control strategy is the genetic modification of mosquitoes to prevent their ability to transmit a disease such as malaria, dengue, chikungunya or zika.[51] Mosquitoes may be genetically modified to suppress a specific mosquito population (self-limiting GMM) or with the purpose of population replacement (self-propagating GMM).[52] Population suppression is a technique used to engineer insects so that when they mate with wild individuals, their offspring are not viable.[53] If sufficient GM males are released to mate with wild females, this would help to eliminate the respective insect population from

47 Such as swamp drainage to reduce larval habitats, indoor spraying with residual insecticides and insecticide-impregnated nets; Ostera and Gostin 2011 *Georgetown Public Law and Legal Theory*. Chemical insecticides such as DDT, the use of insecticide-treated bed nets and indoor spraying with insecticides are the primary means of controlling insect pests for agriculture and public health; BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

48 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

49 Sterile Insect Technique (SIT), the inundative release of factory-produced sexually sterile insects into wild native insect populations so that there is a high ratio of sterile males to wild females; WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xi; BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2, xi. SIT is not classified as genetic modification according to the British Ecological Society; BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 3.

50 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

51 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

52 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 52; BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2; Legros *et al* 2012 *PLoS ONE.*

53 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 52; BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2. The release of insects carrying a dominant lethal (RIDL) gene is a genetic enhancement of the SIT whereby transgenic technology is used to insert a lethal gene into the insects; BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 3.

the area.[54] Population replacement is another technique used to permanently replace a wild populations of insects with GM varieties that have been engineered to be less able to transmit disease.[55] With GM technology, the insects are genetically modified to have the desired characteristics while a "gene drive" system may spread that desirable gene into populations.[56] A gene drive system ensures that this desirable gene is passed on to more than half of the offspring.[57] Consequently over time the desirable gene will spread through the population, eventually replacing it.[58] As opposed to self-limiting GMM, self-propagating GMM pass on the genetically modified trait to subsequent generations and spread to the target population, and also persist in the ecosystem at least for the medium term.[59] The use of GMM for the replacement or suppression of a specific mosquito population is meant to prevent a particular species of mosquito from transmitting disease, leading to public health gains. The key benefits of GMM as an alternative control strategy against vector-borne diseases are presented below.

2.2 Key benefits

GM insect technologies are said to offer the following advantages over conventional vector control strategies.[60] The use of GMM presents potential benefits in the case of malaria, particularly where mosquitoes are becoming more and more resistant to pesticides,[61] and for dengue, which does not have approved vaccines or specific therapy.[62] With GMM, mosquito populations and larval breeding sites that are not easy to access through normal mating and laying of eggs behaviour may be reached.[63] For instance GMM could reach areas in cities which are not easy to control due to their

54 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

55 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

56 A gene drive system is a method of introducing and spreading a desired gene into populations, e.g., a mosquito population; Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 52, 67; BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

57 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

58 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 2.

59 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 52.

60 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix.

61 BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 1.

62 BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 1.

63 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix.

containing numerous mosquito larval breeding sites.[64] Further, GMM may reach mosquitoes which bite during the day and during outdoor activities, rendering bed nets and indoor insecticide spraying ineffective.[65] Highly specific modifications on the target mosquito species could also be made to avoid environmental impacts associated with commonly-used broad-spectrum insecticides.[66] In contrast with broad spectrum insecticides, using GMM as a public health tool does not release toxic chemicals into the environment.[67] GMM could also be useful where other disease control methods are no longer in use and could limit the possibility for the pathogen to be reintroduced after successful elimination efforts.[68] But although GMM as a public health tool may have benefits, they also raise some concerns.

2.3 Main concerns

Concerns have been raised regarding the release of GMM, particularly due to their potential ecological, human health and animal health impacts, and the misuse of such mosquitoes.[69]

The potential ecological impacts of GMM in the WHO 2014 Guidance Framework, the AHTEG guidance document and the 2021 WHO Guidance include the unintended effects of GMM on biodiversity, the persistence of the transgene in GMM in wild mosquito populations, and unintentional transboundary movements.[70] According to the AHTEG guidance document, more information is needed in some areas where the GMM may be released, subject to the nature and size of the strategy that will be used.[71] According to the British Ecological Society (hereafter BES), the ecological

64 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix.

65 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix.

66 For instance, pollution of the soils and water during the fogging or spraying of insecticides; WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix.

67 BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 1-2.

68 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix.

69 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 3.

70 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xix; WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases; Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 53-59.

71 Marshall 2011 *Asia-Pacific Journal of Molecular Biology and Biotechnology*. Specific and comprehensive considerations and the potential adverse effects of a particular LM mosquito (species of the mosquito, the LM trait, the intended receiving environment, and the objective and scale of the intended release); Secretariat of the CBD 2010 https://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-15-en.pdf; Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 53-59.

impacts of GM insects vary depending on the techniques to be used, the mating behaviour, habitat, life cycle and ecology of the insect as well as the geography of the target population.[72] The BES also notes that the elimination of insects at the local level may impact on organisms at higher trophic levels which depend on them for food,[73] but there is not much evidence on which to establish such impacts.[74]

If GMM are used as a public health tool, an assessment is necessary regarding its impact on veterinary medicine, public health practices and national health priorities to address risks to human and animal health caused by the exposure to wild-type mosquitoes that are vectors of pathogens and parasites.[75] As a new alternative control method of vector-borne diseases, the health impacts of GMM on people living in the targeted and neighbouring area of the field trials or release need to be evaluated. Besides, mosquitoes engineered for a particular disease might still transmit other diseases.[76] An appropriate disease surveillance programme would also be needed for ongoing national disease control programmes.[77]

Another major concern which has been raised regarding GMM is their misuse through deliberate release or by accident. Where GMM are bred in mosquito farms, adequate protective measures and the regulation of such farms with a contingency plan in case of emergency are necessary. The misuse or the threat of the use of GMM or other GM insects as biological agents and weapons of biological warfare has long been of international concern and is not inconceivable in existing or future conflicts or in terrorist attacks.[78] Where GMM will be used, the effective implementation of biosafety measures is necessary not only to minimise the risks posed by

---

72 A massive release of GMMs for population suppression may not have the same effects as a release of GMMs for mosquito population replacement; BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 4.

73 BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 6. Amphibians, bats, birds, fish, insects and other species feed on mosquitoes at various stages of their life cycle; Resnik 2014 *Developing World Bioethics* 39.

74 BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf 6.

75 Secretariat of the CBD 2010 https://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-15-en.pdf 59. Nigerian scientists who participated in a survey on a potential release of GM Mosquitoes in Nigeria were concerned that GMMs may transmit unknown diseases and may become resistant to insecticides and fogging; Okorie *et al* 2014 *Malaria Journal*.

76 Powell 2014 *Nature Medicine*.

77 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 60.

78 Van Wynen Thomas and Thomas 1970 *Legal Limits* 27. See the deliberate release of pathogens or toxins causing disease in several countries during times of war; Frischknecht 2003 *EMBO Reports*.

accident and intentional release but also to minimise the potential for misusing such research.[79]

Whereas there are concerns regarding the potential ecological impacts, human health and animal health impacts, and the misuse of GMM, conventional mosquito control methods using chemicals also have ecological impacts and give rise to the negative accumulation of toxins in the food chain.[80] After assessing the benefits of and concerns about GMM, different countries may have different views regarding the impacts of such GM insects and an adequate regulatory framework for the use of such GM insects is necessary. Regulation has a key role to play in providing a framework which enables innovation and technological development while securing a balance of social and private benefits.

Since malaria is prevalent in Africa[81] with at least 90% of malaria-related deaths occurring on the continent, African countries will potentially be targeted by companies seeking to introduce GMM. The following sections discuss the adequacy of current domestic and regional regulation for African countries which may potentially use GMM as a public health tool in the coming years, and makes recommendations for the necessary regulatory response.

3 GMM in prospective African countries: What legal response at the domestic level?

With the prospect of the release of GMM in the coming years in malaria-endemic countries to control malaria and other mosquito-borne diseases, some African countries may import GMM, namely Burkina Faso, Mali, Nigeria and Uganda.[82] Scientists are working on the development of GMM to be released in Burkina Faso in the coming years[83] while researchers in Mali and Uganda are working on the "Target Malaria" project with similar goals.[84] With the highest rate of deaths related to malaria in Africa, Nigeria[85] will potentially be targeted by companies seeking to introduce the use of

79 Sture, Whitby and Perkins 2013 *Medicine, Conflict and Survival* 291.
80 Sanchez-Bayo "Ecological Impacts of Insecticides" 61-90.
81 WHO *World Malaria Report* 2.
82 Okorie *et al* 2014 *Malaria Journal*.
83 Swetlitz 2017 https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/.
84 Swetlitz 2017 https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/.
85 WHO 2021 https://www.who.int/news-room/fact-sheets/detail/malaria.

GMM as a public health tool. Burkina Faso,[86] Mali[87] and Nigeria[88] have promulgated new legislation, as opposed to strengthening (or amending) existing legislation to implement biosafety standards[89] covering any GMO-related damage.[90] However, in Uganda the National Parliament approved the National Biosafety Bill in 2017, but it has not yet been signed into law by the President.[91] The *National Council of Science and Technology Act*, 1990 is currently applicable to GMO field trials in Uganda.[92]

GMO regulation in African States was not designed for GM insect technologies but rather targets the regulation of GM crops,[93] and regulating GMM is not the same as regulating GM crops. In contrast with GM plants, GM insects pose biosafety and public health considerations which require specific regulation.[94] For instance, standards and guidelines need to be set for the evaluation of the risks pertaining to caged field trials and environmental release trials of GM insects and adequate mechanisms need to be developed to monitor such trials. Due to the potential of the misuse of GMM during research, development or at commercial stage through deliberate release or by accident, there is a need for adequate protective measures at the GMM containment facility, strict monitoring, and a contingency plan for GMM-related activities that differ from the regulation of

86 It has a GMO permit approval mechanism, a National Biosafety Agency (art 11 of the BFBL), an advance informed agreement (AIA), a risk assessment mechanism (arts 22-31 of the BFBL), an observation period for local and imported GMOs and a liability and redress mechanism. Burkina Faso ranked 14th in the world and was Africa's second GM crop producer (400 000 hectares) in 2015 (ISAAA 2014 http://www.isaaa.org/resources/publications/pocketk/16/) but is currently ranked not even among the 29 biggest producers of GM crops; ISAAA 2019 https://www.isaaa.org/resources/publications/pocketk/16/.

87 Art 1 of the *Mali National Biosafety Law*; *Decree on GMOs*; *Law on Sanitary Control*.

88 The NBMAA establishes a National Biosafety Agency and sets up a decision-making process for GMO-related activities (arts 22-30 of the NBMAA) with mandatory risk assessment and management requirements (arts 31-34) and liability for violation of the domestic legislation (arts 35-40).

89 Nang'ayo, Simiyu-Wafukho and Oikeh 2014 *Transgenic Research*.

90 Only seven African countries (including Burkina Faso, Uganda, Mali) have ratified the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety* (2010) (hereafter the NSP). Burkina Faso acceded to the NSP in 2013 (see arts 74-84 of the BFBL); Uganda in 2014; Mali in 2016 (see Annex I(VI) Liability of the Exporter of GMOs of the 2010 *Decree on GMOs*); Nigeria signed the NSP in 2012 (CBD date unknown https://bch.cbd.int/protocol/parties/#tab=1).

91 Schnurr 2017 http://gmosandpoverty.com/ugandas-national-biosafety-act/; *National Biosafety Act*, 2017.

92 *National Council of Science and Technology Act*, 1990 (Chapter 209), Laws of Uganda; Muheebwa 2017 https://www.ip-watch.org/2017/11/03/uganda-parliament-passes-bill-promote-use-genetically-modified-materials-biotech/.

93 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 4.

94 Quinlan "Assessing Risk of Transgenic Insects" 292; Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 52.

GM crops and the related activities. The contingency plan must address issues related to an accidental release or the theft of GMM or GM insects to be used as agents in biological warfare or terrorist attacks. Human subjects may be involved in GMM field trials, or people living in or near the selected site for GMM trials or release may be impacted by the released GMM. Hence, an ethics committee needs to oversee the ethical aspects of the research or the commercial release application for GMM. GMM research pertaining to patients or healthy volunteers must be overseen by a qualified physician or another health care professional.[95] A public health institution must also monitor the health of the human populations in the respective field trial and the release area to measure how effective GMM are in reducing vector-borne diseases.[96] An assessment regarding the impact of GMM on veterinary medicine is also necessary. Further, national GMO regulation does not make a difference between self-limiting population replacement strategies and self-propagating population replacement strategies for GM insects.[97] Self-limiting GMM and self-propagating GMM will differ, for instance in their ability to persist in the environment and to spread the inserted transgenes into the local mosquito population. Collaboration with neighbouring countries may be needed to prevent the transboundary movements of GMM. Consequently, an adequate regulatory response to the use of GMM is necessary in the host country. The regulation of GM insect technologies (particularly GMM) needs to include a decision-making process (a National Biosafety Agency, an ethics committee and health professionals, an authorisation system for the import, trial and release of GMM, a step-by-step GMO research process, risk assessment for persistent GMOs, public participation and the regulation of human subjects) and a follow-up system (a monitoring system including the potential transboundary effects, public health and disease monitoring, liability and redress for GMM-related damage).[98] The following sub-sections deal with the recommended legal response which could be made by the above prospective countries with respect to the use of GMM or GM insect technologies. These countries must ensure that there is a decision-making process and a follow-up procedure for the regulation of GM insect technologies in their respective countries at best, by enacting new legislation or by adapting their current GMO decision-making process to the new situation.

---

95 Principle 12 of the Declaration of Helsinki; See WMA date unknown http://www.wma.net/en/20activities/10ethics/10helsinki/.

96 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 60.

97 For instance, Burkina Faso's national biosafety legislation. However, the Nigerian NBMAA includes the requirement of a management plan in view of remediation measures if there is an escape or persistence in the environment of GMOs used for a confined field trial (s 23 of the NBMAA).

98 See WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 94.

3.1 Legal response in the decision-making process

The African countries that opt to use GMM may adopt a specific decision-making process for GM insect technologies (particularly GMM) or adapt their current decision-making process for GMOs. In any case, it is important that the decision-making process regarding GMM-related activities should include an adequate institutional framework as well as the regulation of the import, research and release of GMM.

3.1.1 An adequate institutional framework

Ideally a new national regulatory agency needs to be set up by GMM-related legislation in view of the need for decision-making and the follow-up of GMM-related activities in each of the countries. But since specific regulation on GMM is non-existent in the African countries that are targeted in this paper, the National Biosafety Agency set up as per the *Cartagena Protocol* requirements will be responsible for authorising permit applications and provide oversight regarding the safe evaluation of experiments pertaining to GMM or GM insects.[99] The National Biosafety Agency will be responsible for ensuring that the GMM-related activities performed respect the conditions set in the respective permit application, the adoption of adequate protective measures, strict monitoring and a contingency plan for emergency situations.

The main regulatory authorities for Burkina Faso to authorise the use of GMM include the National Biosafety Agency (as the National Focal Point (hereafter NFP) under the *Cartagena Protocol*) to oversee the permit application process for GMM, as well as the Ministry of Research and Innovation.[100] For Nigeria, the main regulatory authorities for GMM are the National Biosafety Management Agency, which focusses on the biosafety regulation of biotechnology-derived products in collaboration with the Public Health Department[101] under the Federal Ministry of Health, which is responsible for national malaria control programmes. The Ministry of Agriculture, the Ministry of Environment and Sanitation and the Ministry of Health may be the regulatory authorities concerning GMM for Mali.[102] Among the prospective African users of GMM, it seems that Uganda is the

---

99 Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene* 314.

100 Quemada "Regulation of Transgenic Mosquitoes" 364. Burkina Faso provides for rules regarding research ethics for human subjects and subjects the approval of a GMO permit to the respect of research ethics regarding human subjects involved in the particular GMO-related activity (art 46 of the BFBL).

101 Nigerian Federal Ministry of Health date unknown http://www.health.gov.ng/index.php/department/public-health.

102 See art 12 of the *Decree on GMOs* in Mali; *Mali National Biosafety Law*; *Law on Sanitary Control*.

less prepared nationally to allow for GMM in the country. The National Biosafety Bill has not yet been approved and it is the *National Council of Science and Technology Act*, 1990 which is currently applicable to GMO field trials in Uganda.[103] Since there is currently no National Biosafety Agency for Uganda, it is the Ministry of Environment which is the NFP for the *Cartagena Protocol*. The Uganda National Council for Science and Technology (UNCST) under the *National Council of Science and Technology Act*, 1990 handles the research aspects of modern biotechnology as part of its mandate to regulate research.[104] It would be better for Uganda not to introduce GMM until the National Biosafety Bill is signed and the National Biosafety Agency is set up. Until then, the NFP for the *Cartagena Protocol* and the UNCST will have to collaborate to regulate GMM in Uganda.

To better regulate GMM in the above African countries, it is recommended that an ethics committee be set up to regulate and oversee ethical aspects regarding human subjects involved in or potentially impacted on by trials of or the release of GMM in the host country's regulatory framework. It is also important that a public health institution provides surveillance for the use of GMM to fight malaria and their impacts on public health. A veterinary institution will need to assess the impacts of the released GMM on veterinary medicine used in the host country. An adequate institutional framework for GMM is imperative, since GMM-related activities need regulatory oversight and monitoring.

The testing and use of imported GMM in these African countries may currently fall under the jurisdiction of several public authorities which are responsible for biosafety, biodiversity, public health and ethics, giving rise to a need for multiple government sector coordination.[105] The WHO 2014 Guidance Framework recommends that if the release of GMM is known or expected to have transboundary impacts, multilateral regulatory approval will be needed by all the countries which might be impacted.[106] Importantly, the collaboration of regulatory authorities from neighbouring countries must be anticipated in the case of a release of GMM, particularly if self-propagating population replacement strategies for GMM are used.

---

103 *National Council of Science and Technology Act*, 1990 (Chapter 209), Laws of Uganda; Muheebwa 2017 https://www.ip-watch.org/2017/11/03/uganda-parliament-passes-bill-promote-use-genetically-modified-materials-biotech/.

104 *National Council of Science and Technology Act*, 1990 (Chapter 209), Laws of Uganda; Muheebwa 2017 https://www.ip-watch.org/2017/11/03/uganda-parliament-passes-bill-promote-use-genetically-modified-materials-biotech; Chambers *Biosafety of GM Crops* 10.

105 Quemada "Regulation of Transgenic Mosquitoes" 364.

106 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 99.

3.1.2 Decision-making process with respect to GMM

Regulation is necessary not only for the import of GMM but also for the research and implementation of GM technologies.[107] The decision-making process needs to include an authorisation procedure, a stepwise process for risk assessment, research and development, provisions regarding public participation and awareness with respect to GMM release, and the regulation of human subjects involved in GMM-related activities.

3.1.2.1 Authorisation process

It is important for African countries contemplating the use of GMM to provide an authorisation procedure for the import, research, trial release and release of GMM at best with specific GMM legislation or by adapting their current GMO decision-making mechanism. The applicant needs to provide adequate information to identify the specific types and quantity of mosquito eggs/GMM to be imported or released as well as the type of action proposed, and the risk assessment carried out. The applicant must provide an adequate genetic characterisation of the GMM to be imported, researched or released, an acceptable level of security in the containment facility and adequate restrictions on the dissemination of the GMM into the environment.[108]

Importantly, national GMO regulation in these countries needs to draw a distinction between self-limiting population replacement strategies and self-propagating population replacement strategies for GMM, due to the ability of the latter to persist in the environment and to spread the inserted transgenes into the local mosquito population. In the case of self-propagating population replacement strategies for GM insects, national GMO legislation or specific GMM legislation must provide for specific risk assessment, more stringent monitoring and a specific management plan (as in the case of Nigeria)[109] in view of the need for remediation measures.

An indication of the country or place of origin of the mosquito eggs/GMM and a list of any previous authorisations for import or movement of GMM should also be required by the authorisation procedure.[110] Approval to import GMM should be conditional on the sole use of such GMM at the

---

107 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xxv.

108 Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 10.

109 See the requirement of a management plan if there is an escape or persistence in the environment of GMOs used for a confined field trial in the Nigerian legislation (s 23 of the NBMAA).

110 Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 10.

specific location stipulated in the application.[111] The applicant should also provide documentation pertaining to the existing and ongoing training of the staff involved in the GMM activity as well as to the implementation of the relevant national biosafety legislation.[112] It is recommended that the authorisation process should require information regarding the approval or release of the GMOs to be imported elsewhere[113] to be made available before an import permit is granted. If the GMM has not been approved in the country of origin or other countries, the importation of the respective GMM cannot be allowed in any of the relevant African countries.

It is of the utmost importance that the GMM permit holder is mandated to monitor potential risks to human beings and environmental risks that can be caused by the GMM designated in the permit. In the case of an accident during transport, the contingency plan must be activated, and the regulatory authority of the host country must be promptly informed. In the case of a theft of GMM, the contingency plan must be activated and the NFP for the *Biological and Toxin Weapons Convention* for the respective host country must be promptly informed. Devitalisation protocols for GMM and their rearing media as well as protocols for disposing of GMM and their rearing media after devitalisation at the end of the proposed activity should also be provided in the GMM permit decision-making process.[114] Decisions pertaining to the importation and release into the environment of GMM need to be based on science on a case-by-case basis.[115]

3.1.2.2 A stepwise process for risk assessment, research and development

The regulatory authorities for the use of GMM should ensure that a stepwise process is adopted by the applicant for GMM-related research and development as recommended by the AHTEG guidance document under the *Cartagena Protocol*, the WHO 2014 Guidance Framework as well as the 2021 WHO Guidance.

According to the AHTEG guidance document, a step-wise process should be set up to identify LMOs or specific traits that may adversely impact on

111 Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 12.

112 Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 12.

113 See s 23(2)(d) of the NBMAA. If the GMO is prohibited in the country of origin, its import cannot be allowed into Burkina Faso (art 53 of the BFBL).

114 Means of devitalisation may include, but are not limited to, dry heat, steam heat, freezing, and/or chemical treatment; Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 12.

115 Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 9.

biological diversity.[116] The WHO 2014 Guidance Framework recommends a phased testing pathway for GMM with systematic assessment of safety and efficacy at each step.[117] This testing pathway includes the laboratory phase (phase 1) and testing under confined conditions (phase 2) that provide a more natural setting (a large cage equipped to simulate a disease-endemic setting, or under ecological confinement).[118] Following confined testing, GMM research may proceed to a series of open release trials in phase 3 to assess the ability of GMM to reduce infection or disease in human populations.[119] The results of phase 3 would determine if the GMM are to be deployed as a public health intervention and should lead to the long-term planning with respect to safety and efficacy monitoring in phase 4.[120] Burkina Faso, Nigeria and Mali do have a step-wise biosafety mechanism for GMO research and development[121] but not Uganda. It is recommended that the specific stepwise process for GMM research and development be adopted in all of these African countries as recommended by the AHTEG guidance document, the WHO 2014 Guidance Framework and the 2021 WHO Guidance.

Each African country contemplating the introduction of GMM needs to ensure that it has a transparent and complete procedure to prepare and conduct field trials for GMM as well as frameworks for environmental risk assessment.[122] The risk assessment report must fully consider all the different aspects pertaining to the GMM-related activity including handling, the human subjects, transport, the decontamination of the premises, the inactivation of the GMM, and disposal and waste management.[123] The risk assessment should consist of independent and interdisciplinary studies to minimise the risks of environmental impacts[124] and the risks associated with transport, as well as the potential transboundary impacts on neighbouring regions or States. The GMM permit holder must use adequate packaging and labelling, provide appropriate information to the person who will

116 Secretariat of the CBD 2010 https://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-15-en.pdf para 34.

117 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

118 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

119 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

120 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

121 See the biosafety legislation in Burkina Faso, Mali (*Mali National Biosafety Law* and *Decree on GMOs*) and Nigeria (the NBMAA).

122 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xiv.

123 Regulation 5(2) and Part 1 of Schedule 3 set out what to consider as part of the risk assessment. Genetically Modified Organisms (Contained Use) Regulations, 2014 (5th ed of L29). The European Food and Safety Authority (EFSA) guidance framework also recommends that an Environmental Risk Assessment should follow a step-by-step assessment approach; EFSA 2013 *EFSA Journal* 1.

124 A multidisciplinary team is needed for the risk assessment of GMMs including molecular biologists, immunologists, medical entomologists, and ecologists working in disease-endemic areas; Guy Reeves *et al* 2012 *PLoS Negl Trop Dis* 6, 10.

transport the GMOs, and anticipate possible accidents by developing an emergency plan.[125] The provisions to ensure safe packaging, labelling, segregation measures and transport in existing transport regulations will also apply.[126] The risk assessment report must contain evidence of contingency measures available to remove the GMM, should a hazard become evident during the course of the release.[127] An observation period could be adopted for imported GMM in African countries where GMM may be used.[128]

Importantly, GMOs designed to persist in the environment need to be adequately regulated in terms of risk assessment requirements as well as monitoring requirements. Self-limiting GMM and self-propagating GMM will not be similar in their ability to persist in the environment or to transmit the inserted transgenes into the local mosquito population.[129] With the ability of insects to travel long distances, self-propagating GMM may spread over entire continents.[130] Consequently, the requirements and criteria for the evaluation of risks will depend on whether the mosquitoes are self-limiting GMM or self-propagating GMM.[131] It is important that the domestic legislation of the relevant countries draws a distinction between self-limiting GMM (the population replacement strategy) and self-propagating GMM (the perpetuating population replacement strategy).[132] If the degree of persistence and spread of the genetically modified mosquitoes may affect the GMM release trial, prior and thorough planning is necessary.[133] Risk analysis and risk management plans should take into consideration that self-propagating GMM may disperse beyond State borders or into different

125 See the requirement for an emergency plan (art 35 of the BFBL); s 27(e) of the NBMAA.

126 The UK Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations, 2009.

127 For instance, most of the participants in a survey in Nigeria are sceptical about GMMs in general and encourage the use of genetic modification techniques to make mosquitoes incapable of spreading diseases only provided there are contingency measures to remove GMMs if a hazard becomes evident during the release; Okorie *et al* 2014 *Malaria Journal* 7.

128 For instance, art 20 of the BFBL.

129 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 53.

130 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 3.

131 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 53.

132 Burkinabe BFBL; *Mali National Biosafety Law*, *Decree on GMOs* and *Law on Sanitary Control*; see the NBMAA.

133 WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases 39.

regions through travelling and transport.[134] The 2021 WHO Guidance recommends buffer zones to help prevent or slow cross-contamination.[135] In addition, the collaboration of neighbouring States may be necessary to regulate GMM with gene drive systems which can move across borders in an autonomous way.[136] Adequate and comprehensive risk assessment guidelines regarding the use of GMM locally need to be developed.[137] Standards need to be set for the evaluation of risks pertaining to caged field trials and environmental release trials of GM insects as well as adequate mechanisms to monitor such trials.[138]

It is also recommended that African countries envisaging the use of GMM require that the risk assessment for such GMM be undertaken by the permit applicant and monitored by the national biosafety authority.[139] Since Uganda does not have a national biosafety authority, the Ugandan NFP for the *Cartagena Protocol* (the Ministry of Environment) will have to monitor the risk assessment for GMM. As in the *Nigerian National Biosafety Management Agency Act*, 2015 (hereafter the NBMAA), it is important for the relevant countries to require information regarding the intended release of the respective GMOs elsewhere and related risk assessment reports before an import permit is approved.[140] In Nigeria a risk assessment may be carried out by the National Biosafety Committee and the National Biosafety Management Agency may cause the applicant to bear the costs, even if the applicant has previously carried out a risk assessment.[141] Environmental assessments should take into consideration available alternatives alongside the activity described in the permit application. It is recommended that innovations which have the least environmental and human health risks, and the least harmful alternative should be chosen.[142]

3.1.2.3 Public participation and awareness with respect to GMM permit and release

It is important to ensure adequate public participation when applications for GMM-related activities and particularly GMM release are being considered.

---

134 WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases 125.

135 WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases 39.

136 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 99.

137 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xxi.

138 Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene* 312-318.

139 The National Biosafety Agency in Burkina Faso; Art 23 of the BFBL.

140 Arts 23(2)(d) and 23(2)(b) of the NBMAA.

141 Art 31(4) of the NBMAA.

142 Ostera and Gostin 2011 *Georgetown Public Law and Legal Theory* 931.

It is recommended that civil society, non-governmental organisations and lawyers should be involved in formal public consultation opportunities and public events regarding GMM-related activities.

Adequate public participation in the selection of an appropriate research field site for GMM is one of the most important aspects of the research process for GMM since there are debates regarding GMOs in developed and developing nations.[143] According to the WHO 2014 Guidance Framework, informed consent by key stakeholders or representatives of the public in the GMM regulatory process is essential to avoid negative public reaction.[144] The main risk involved in the selection of a field site for GMM may be the accidental release of GMM in caged field trials or research regarding the environmental release of GMM. GMM trials should not be conducted in an area unless the targeted disease is significant in this area and there are more benefits than risks for the local community for holding such trials.[145] The process of the determination of the site selected for the research, the field trials and the release of GMM must be open from its beginning, and the regulatory processes need to include formal public consultation opportunities and public events.[146] Involving community members in the field trial or GMM-related research and an exchange of information with them regarding field trials or release of the GMM will also help in the implementation of the disease control strategy.[147] Consequently, authorisation by the leaders of the local community and neighbouring communities is essential to the site selection decision before the application for the GMM permit is submitted to the authorities of the host country.

Transparency regarding the release of GMM in uninhabited areas as well as inhabited areas is important. If the field trials or the open release of GMM are intended to take place in uninhabited areas, neighbouring communities of such areas in the host country must also be informed. Importantly, the potential release of GMM raises issues for local communities in the host country as well as in neighbouring countries.[148] Developers, regulators and stakeholders need to agree on the monitoring requirements for GMM at the trial site before starting field testing.[149]

143 Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene* 312.

144 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.

145 Resnik 2014 *Developing World Bioethics* 37-46.

146 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xxv.

147 Marshall *et al* 2010 *Malaria Journal* 2.

148 Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene* 313-314.

149 WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases 39.

In Burkina Faso,[150] Nigeria[151] and Mali[152] public consultation may be organised regarding any proposed importation or confined use of a GMO while the costs are borne by the applicant for the GMO permit. It is recommended that Uganda provides legal procedures for a public consultation with respect to any proposed import of or confined use of GMM. The National Biosafety Agency[153] in Burkina Faso and the Nigerian National Biosafety Agency[154] are required to inform the public of their final decisions regarding the application for a permit, but legal provisions to inform the public regarding the approval of GMM need to be enacted in Uganda and Mali. In practice, in the African countries which are being targeted for the importation of GMM, not much data is available on GMOs.[155] Failure to involve local scientists at an early stage may affect the contained field trials.[156] For the purposes of public awareness it is important that an application for a permit pertaining to the trial release of GMM and/or their commercial use be published shortly after the application is deemed to be complete. It is also recommended that complete experimental data from field trials that have been conducted be made public.

3.1.2.4 Regulation of human subjects

Research on GMM or GMM commercialisation projects involves caged field trials and environmental release trials which need to be regulated to respect the ethics of research with human subjects.[157] The WHO 2014 Guidance Framework recommends that GMM trials and environmental release comply with international standards for research conduct as well as standards set by regulatory committees in the host country regarding the use of human subjects, biosafety and the use of animals.[158]

In the course of field trials, researchers will interact with different people, e.g. those participating in the research, those living in or near the trial site

150 Art 39 of the BFBL.

151 S 26(1) of the NBMAA; Muzan 2018 *LEAD*.

152 In Mali, the national competent authority (the Ministry of Environment) may decide to organise a public consultation regarding the application for a GMO permit. Art 14 of the *Mali National Biosafety Law*.

153 Art 41 of the BFBL.

154 S 28(c) of the NBMAA.

155 See the results concerning a survey on public attitudes to GM mosquitoes for malaria control in rural and urban areas of Mali, West Africa between the months of October 2008 and June 2009; Marshall *et al* 2010 *Malaria Journal*.

156 Okorie *et al* 2014 *Malaria Journal*.

157 Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene* 314; WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.

158 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 70; WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases.

who can be directly affected by the GMM, and those who may be interested in such research.[159] The GMM projects need to respect the ethical principles pertaining to human subjects (those participating in the research) as well as those pertaining to people living on a trial site, even if such people may not be directly involved in the research *per se*.[160] Measures must be taken to protect community members who are not involved in the trial.[161] Collaboration with the local community before, during and after GMM trials is necessary to avoid exploitation as well as to safeguard the rights of the research subjects.[162]

Guidance for research ethics at the national level and a review mechanism for such guidance in the light of the GMM trials and releases are essential.[163] The formulation of research ethics guidelines would better protect individuals involved in the research and ensure transparency.[164] Insights derived from experience gained during the research process could also be added to national research ethics guidelines to help local communities.[165] It should be made compulsory for GMM-related activities to comply with guidance or regulation covering research involving human subjects as recommended in the WHO 2014 Guidance Framework.[166]

It is commendable that Burkina Faso subjects the approval of a GMO permit to the standards of research ethics regarding human subjects involved in the particular GMO-related activity.[167] It is essential for all prospective African countries considering the use of GMM to provide for rules with respect to research ethics in accordance with the Declaration of Helsinki.[168] An ethics committee needs to be set up to monitor rules regarding human subjects involved in the GMM research or commercialisation project. In addition, research pertaining to patients or healthy volunteers must be overseen by a qualified physician or some other health care professional.[169] The best option is for new legislation to be enacted to regulate the use of human subjects involved in GMM-related activities.

159 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.
160 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.
161 For instance, inform the community about the trial or research and provide treatment to people who might be negatively impacted; Resnik 2014 *Developing World Bioethics* 37-46.
162 Resnik 2014 *Developing World Bioethics* 37-46.
163 Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene* 314.
164 WMA date unknown http://www.wma.net/en/20activities/10ethics/10helsinki/.
165 WMA date unknown http://www.wma.net/en/20activities/10ethics/10helsinki/.
166 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.
167 Art 46 of the BFBL.
168 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* viii.
169 Principle 12 of the Declaration of Helsinki; See WMA date unknown http://www.wma.net/en/20activities/10ethics/10helsinki/.

An adequate legal response is required not only in the decision-making process but also after the GMM permit has been approved, through a process which enables the monitoring and follow-up of the GMM-related activity in compliance with conditions stipulated in the permit.

3.2 Legal response in the follow-up process

It is recommended that the relevant countries ensure that their GMO decision-making process or decision-making process with respect to GMM includes a follow-up procedure for the use of GMM with post-release monitoring, public health and disease monitoring and a liability and redress mechanism in the case of the illegal or accidental release of GMM.

3.2.1 Post-release monitoring

Risk management and monitoring measures in the case of an unintentional release of GMM (e.g., during transport) and for persistent GMM need to be provided by the applicant for a GMM permit[170] prior to the intended release or trial as well as at the post-release stage.

It is important for regulatory agencies to be involved not only in the GMM research and development but also in post-implementation surveillance.[171] Regulatory authorities in the host country need to ensure that GMM-related activities respect the conditions stipulated in the approval. For instance, the use of the indicated site selected for the research or trial or the release of GMM must be respected. It is important to monitor the GMM as indicated in the GMM permit granted with monitoring tools adequate to detecting and identifying escaped GMM if there has been an unintentional release.[172] The regulatory authorities of the host country must verify compliance with the devitalisation protocols for GMM and their rearing media that are no longer required at the end of the activity and protocols pertaining to the disposal of GMM as indicated in the application for the GMM permit.[173]

Mechanisms will be needed in the host country to enable the effective post-release monitoring of GMM, particularly for GMM designed to persist in the environment and the "tracking of new genetic material promoted via gene

---

170 Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 12.

171 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 94.

172 Monitoring tools such as molecular analysis, phenotypic identification, and trapping; See Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 11.

173 The means of devitalisation may include, but are not limited to, dry heat, steam heat, freezing, and/or chemical treatment; Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf 12.

drives".[174] Technical and financial resources will also be required for ecological monitoring and GM screening. It is recommended that the relevant countries require the submission of information on the monitoring techniques and resources to be used by the applicant for a GMM permit.[175]

It is commendable that in Burkina Faso,[176] Nigeria[177] and Mali,[178] the applicant for a GMO permit needs to carry out periodic studies to control and follow-up on the evaluation of risks. Uganda needs to adopt similar monitoring and follow-up requirements regarding the use of GMM. It is recommended that these countries should include in their legislation a requirement that the applicant for a GMO permit needs to provide evidence of possessing the financial means to fulfil its obligations under the biosafety legislation to the NBA.[179] It is not only the post-release monitoring of the GMM that is important, but also the monitoring of public health in relation to the disease in respect of which the GMM will be used as a public health tool.

3.2.2 Public health and disease monitoring

The monitoring of public health needs to be carried out to verify how effective GMM can be as a public health intervention tool in decreasing the transmission of the targeted pathogen(s) in the host country.[180] GMM would be considered efficacious if their use decreases the incidence of infection or disease in human populations in the release area.[181] The health monitoring of the human populations in the release area must be carried out to ensure that the levels of efficacy that were anticipated have been achieved.[182] The host countries must ensure that they have adequate staff and means to carry out such health monitoring.

---

174 A release of GM mosquitoes with invasive gene drive systems could propagate transgenes over entire continents; Marshall 2011 *Asia-Pacific Journal of Molecular Biology and Biotechnology* 97.

175 The Second Schedule of the NBMAA (Part E: Information on monitoring, control, wastes treatment and emergency response plans), requires information on monitoring techniques to be used by the applicant (methods for tracing the GMO and monitoring their effects).

176 Art 44 of the BFBL.

177 Periodic report of the monitoring and evaluation of risk carried out after the approval or permit granted (s 34(d) of the NBMAA).

178 Periodic reports in view of risk assessment and management may be requested by the regulatory authority every three months for trials in confined use, every six months and annually for field trials. Art 9 of the Mali *Decree on GMOs*. An applicant needs to continuously make studies to control and assess risks during the life cycle of the particular species of GMOs as directed by the national competent authority - the Ministry of Environment (art 23 of the *Mali National Biosafety Law*).

179 Art 45 of the BFBL.

180 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

181 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* xx.

182 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 60.

It is recommended that they adopt a disease monitoring strategy to determine the extent of the decrease in the incidence of infection or disease in the human populations in the release area.[183] This strategy would require the respective community members to participate in the decisions to be taken with respect to field trials or the release of GMM,[184] the absence of which participation might have a deleterious effect on the disease monitoring strategy.

Legal response in the follow up process is also necessary to ensure that the African countries which use GMM have legal provisions regarding liability and redress in the case of the illegal use or accidental release of the GMM.

3.2.3 Liability and redress

A liability and redress mechanism to sanction the illegal use or accidental release of GMM is important if the use of GMM is adopted in a host country. If GMM-related activities are carried out without prior approval or where an individual (or entity) supplies false information relating to GMO activities or biosafety legislation is contravened, liability may be incurred for any damage that may occur as a result.

However, it must be pointed out that due to the lack of transparency regarding research on GMM and their trial release, it might be difficult to detect the illegal use of GMM. Further, if and when the illegal use of GMM is discovered, it may be even more difficult to establish the causal nexus between the GMM and the developer/user, and identify and sanction the developer/user.

Burkina Faso and Mali have a liability and redress mechanism for GMO-related damage[185] while the Nigerian NBMAA provides for sanctions in the case of the violation of the domestic legislation.[186] Burkina Faso, Uganda and Mali are among the seven African countries that have ratified the 2010 *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress* (hereafter the NSP) to the *Cartagena Protocol,* while Nigeria only signed the NSP in 2012.[187] In Burkina Faso any person, group of persons, private organisation or public organisation may lodge a complaint and claim reparation/compensation in case of a violation of the *Burkina Faso Biosafety*

183 Marshall *et al* 2010 *Malaria Journal* 2.

184 Marshall *et al* 2010 *Malaria Journal* 2.

185 See the liability and redress mechanism for Burkina Faso (BFBL and *Decree on Biotechnology*); Mali (see Annex I(VI) Liability of the Exporter of GMOs in the *Decree on GMOs*).

186 Ss 24(1) and 35-40 of the NBMAA.

187 CBD date unknown https://bch.cbd.int/protocol/parties/#tab=1.

Law (BFBL) and GMO-related damage.[188] As for Uganda, the *National Biosafety Act*, 2017[189] was reworked in 2018 and it includes a strict liability clause which may result in scientists being held responsible if there is a complaint pertaining to their research, whether the "particular anomaly was directly caused by the scientist" or not.[190] It is recommended that Uganda provides for liability provisions regarding the illegal use of GMM and the commission of GMO-related damage.

The Nigerian NBMAA sanctions illegal GMO-related activities but provisions for liability and redress regarding GMO-related damage must be expressly provided in the NBMAA.[191] It is recommended that Nigeria, Uganda and Mali include in their national biosafety legislation provisions for joint liability for those involved in a GMO-related activity in the case of damage (particularly transboundary damage) and the requirement for operators to provide financial guarantees covering their potential liability similar to what is required in Burkina Faso.[192]

Since flying insects know no boundaries, the regulation of GMM at a regional level is of the utmost importance. Whether genetically modified or not, mosquitoes have dispersal distances commonly of less than 5 km and the risk of dispersal increases due to anthropogenic activities.[193]

There is no regulation of GMM at the pan-African level.

4 Absence of regulation of GMM at the African level

There is no pan-African instrument on the regulation of GM insect technologies and the DRAMLB targets mainly GM crops.[194] Although the DRAMLB was not drafted with GMM in mind, it has some important provisions which are not included in the *Cartagena Protocol* which may contribute to regulating GMM. The written application for a GMO permit

188 Art 85 of the BFBL.

189 Schnurr 2017 http://gmosandpoverty.com/ugandas-national-biosafety-act/; however, this Act has not yet been signed.

190 Agaba 2018 https://allianceforscience.cornell.edu/blog/2018/11/ugandan-scientists-skeptical-revised-gmo-bill/. Fault-based liability means that the person who conducts a GMO-related activity is liable for damage if that person is at fault or has acted in a negligent way, whereas for strict liability, the person who conducts a GMO-related activity is liable irrespective of any fault or negligence.

191 S 41 of the NBMAA lays down that the Governing Board under this legislation may make regulations for fault-based liability and redress for damage resulting from GMO-related activities.

192 Arts 81 and 93 of the BFBL; Arts 10-12 of the NSP.

193 Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf 8.

194 See Chambers *Biosafety of GM Crops* 10. The 2008 DRAMLB is no longer publicly available. Please contact the author for a copy; AU date unknown http://www.au.int/en/countryprofiles.

needs to include a risk assessment report on the GMO (even for contained uses of GMOs) upon the environment, biological diversity or human health and the consequences of its unintentional release.[195] Importantly, information pertaining to the previous or current release of the GMO in any other country is also necessary in the application for a GMO permit.[196] Under the DRAMLB, the competent authority of a host country may subject any GMO to a period of observation in proportion to its life-cycle and its costs are to be borne by the applicant before its intended use.[197] The DRAMLB also lays down community rights for GM-free zones while the national competent authority in the host country is called to develop policies that protect people's rights in such GMO-free zones.[198] However, the DRAMLB is merely a set of recommendations for African countries and is still to be finalised.

Existing regional instruments with respect to GM insects (including GMM) consist mainly of the European Union (EU) Directives[199] and the EFSA Risk Assessment Criteria for GM Animals[200] as well as the NAPPO RSPM. These regulatory instruments apply only to trials and commercial releases in their regional purview (in the EU and the US/Canada/Mexico) while GM insect technologies are likely to be used for public health purposes in other regions.[201]

---

195 Art 6(3)(b) of the DRAMLB. According to the *Cartagena Protocol*, risk assessment requirements and the AIA requirements do not apply to transboundary movements of contained uses of LMOs although States parties to this protocol have the right to subject contained uses of LMOs to risk assessment requirements; Art 6(2) of the *Cartagena Protocol*.

196 Art 6(3(c) of the DRAMLB. This is not required by the *Cartagena Protocol*, but this Protocol has information-sharing obligations and a biosafety clearinghouse (BCH) mechanism. Art 20 of the *Cartagena Protocol*.

197 Art 11(2)(a) of the DRAMLB.

198 Art 21 of the DRAMLB.

199 Two EU directives are concerned with GMMs (for contained use (EC Directive 41/2009), for deliberate release (EC Directive 18/2001)); See EU Regulation 1946/2003, which provides for implementation of the international Cartagena Protocol on Biosafety. The first export of a given LMOs for open release must also be notified to the importing Party and the exporter must provide information as part of the notification, including a risk assessment.

200 The EFSA guidance provides guidance on the environmental risk assessment of living genetically modified animals, namely fish, insects, mammals and birds to be placed on the EU market in accordance with EC Regulation 1829/2003 and EC Directive 18/2001 (EFSA 2013 *EFSA Journal*).

201 The South American continent and in the African continent, see GeneWatch UK 2010 http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitecbrief_fin.pdf 1; Okorie *et al* 2014 *Malaria Journal*; Harris, Nimmo and Alphey 2011 *Nature Biotechnology* 1034-1039). No application has been made to release GM insects in the UK for research purposes, and across all EU Member States there has only been one national application for a trial release of GM olive flies in Spain in accordance with part B of EC Directive 18/2001.

Importantly, the technologies used for GMM were not developed in Africa, yet they will most likely be used in Africa.[202] Unified guidance is highly recommended for consistency in the evaluation and regulation of this technology and to help develop harmonised legal frameworks to evaluate the use of GM insects in different States. The African countries where GMM are likely to be used or released would definitely need an adequate regulatory mechanism if they choose to use GMM as a public health tool against malaria in the coming years.

5 Conclusion

While it remains unclear if the effects of GMM can be controlled once they have been let out of their cages, GMM are already being released elsewhere before their full consequences are known and understood. The full investigation of whether GMM could reduce the burden of malaria or other vector-borne diseases without giving rise to any possible unintended consequences or adverse effects on human health and the environment is necessary.

The development of a GMM regulatory process that is based on science with a transparent procedure and with public participation is of the utmost importance.[203] The public perception of GM insects varies greatly among nations and the involvement of the communities that will be impacted by GMM is imperative.[204] The success of scientific and public health endeavours such as GMM trials or releases may depend on good will and cooperation of the public.[205]

After having examined the GMO regulatory framework of the four African countries considered in this paper, Burkina Faso seems to be the country with the better regulatory response to the importation of GMM, whereas more effort needs to be made by Nigeria, Uganda and Mali to improve their regulatory frameworks as per the recommendations made in this paper before they import GMM for trial or commercial release. Uganda should best wait until its national biosafety legislation is signed and is enforceable before approving the local use of GMM. Since there is no pan-African instrument on the regulation of GM insect technologies, it is strongly recommended for these countries not to use self-propagating GMM, which could have significant and irreversible consequences in terms of transboundary movements. Finally, as the AU is starting talks with the WHO about getting

202 Mshinda *et al* 2004 *Lancet Infections Diseases* 264.
203 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.
204 BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf 4.
205 WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes* 69.

the first approved malaria vaccine to the continent[206] one may wonder whether the option of using GMM as a public health tool will be preferred to the use of the vaccine against malaria in Africa in the coming years.

Bibliography

Literature

Alonso and Tanner 2013 *Nature Medicine*
Alonso PL and Tanner M "Public Health Challenges and Prospects for Malaria Control and Elimination" 2013 *Nature Medicine* 150-155

ASSAF *GMOs for African Agriculture*
Academy of Science of South Africa *GMOs for African Agriculture: Challenges and Opportunities - Workshop Proceedings Report* (Academy of Science of South Africa Pretoria 2010)

Beisel and Boëte 2013 *Science as Culture*
Beisel U and Boëte C "The Flying Public Health Tool: Genetically Modified Mosquitoes and Malaria Control" 2013 *Science as Culture* 38-60

Carvalho *et al* 2015 *PLoS Negl Trop Dis*
Carvalho DO *et al* "Suppression of a Field Population of *Aedes Aegypti* in Brazil by Sustained Release of Transgenic Male Mosquitoes" 2015 *PLoS Negl Trop Dis* 1-15 https://doi.org/10.1371/journal.pntd.0003864

Chambers *Biosafety of GM Crops*
Chambers JA *Biosafety of GM Crops in Kenya, Uganda and Tanzania: An Evolving Landscape of Regulatory Progress and Retreat* (Center for Strategic and International Studies Washington DC 2013)

EFSA 2013 *EFSA Journal*
European Food Safety Authority Panel on Genetically Modified Organisms "Guidance on the Environmental Risk Assessment of Genetically Modified Animals" 2013 *EFSA Journal* 1-190 https://doi.org/10.2903/j.efsa.2013.3200

Frischknecht 2003 *EMBO Reports*
Frischknecht F "The History of Biological Warfare" 2003 *EMBO Reports* S47-52

206 Reuters 2021 https://www.news24.com/news24/africa/news/african-union-to-start-talks-with-who-on-rollout-for-first-ever-malaria-vaccine-for-children-20211007.

Greenwood *et al* 2017 *Malaria Journal*
Greenwood B *et al* "Seasonal Vaccination against Malaria: A Potential Use for an Imperfect Malaria Vaccine" 2017 *Malaria Journal* 1-5 https://doi.org/10.1186/s12936-017-1841-9

Guy Reeves *et al* 2012 *PLoS Negl Trop Dis*
Guy Reeves R *et al* "Scientific Standards and the Regulation of Genetically Modified Insects" 2012 *PLoS Negl Trop Dis* 1-15 https://doi.org/10.1371/journal.pntd.0001502

Harris, Nimmo and Alphey 2011 *Nature Biotechnology*
Harris A, Nimmo D and Alphey L "Field Performance of Engineered Male Mosquitoes" 2011 *Nature Biotechnology* 1034-1039

Harris *et al* 2012 *Nature Biotechnology*
Harris A *et al* "Successful Suppression of a Field Mosquito Population by Sustained Release of Engineered Male Mosquitoes" 2012 *Nature Biotechnology* 828-830

Knols *et al* "Transgenic Mosquitoes and the Fight against Malaria"
Knols BGJ *et al* "Transgenic Mosquitoes and the Fight against Malaria: Managing Technology Push in a Turbulent GMO World" in Breman JG, Alilio MS and White NJ (eds) *Defining and Defeating the Intolerable Burden of Malaria III: Progress and Perspectives* (American Society of Tropical Medicine and Hygiene Cleveland 2007) 232-242

Lavery, Harrington and Scott 2008 *American Journal of Tropical Medicine and Hygiene*
Lavery JV, Harrington LC and Scott TW "Ethical, Social and Cultural Considerations for Site Selection for Research with Genetically Modified Mosquitoes" 2008 *American Journal of Tropical Medicine and Hygiene* 312-318

Lee 2017 *American Journal of Bioethics*
Lee LM "A Bridge Back to the Future: Public Health Ethics, Bioethics, and Environmental Ethics" 2017 *American Journal of Bioethics* 5-12

Legros *et al* 2012 *PLoS ONE*
Legros M *et al* "Assessing the Feasibility of Controlling *Aedes Aegypti* with Transgenic Methods: A Model-based Evaluation" 2012 *PLoS ONE* 1-12 https://doi.org/10.1371/journal.pone.0052235

Maiga *et al* 2016 *PLoS ONE*
Maiga H *et al* "Seasonal Malaria Chemoprevention with Sulphadoxine-pyrimethamine and Amodiaquine Selects *Pfdhfr-dhps* Quintuple Mutant

Genotype in Mali" 2016 *PLoS ONE* 1-12 https://doi.org/10.1371/journal.pone.0162718

Marshall *et al* 2010 *Malaria Journal*
Marshall JM *et al* "Perspectives of People in Mali Toward Genetically-modified Mosquitoes for Malaria Control" 2010 *Malaria Journal* 1-12 https://doi.org/10.1186/1475-2875-9-128

Marshall 2011 *Asia-Pacific Journal of Molecular Biology and Biotechnology*
Marshall JM "Commentary: The Cartagena Protocol in the Context of Recent Releases of Transgenic and Wolbachia-infected Mosquitoes" 2011 *Asia-Pacific Journal of Molecular Biology and Biotechnology* 93-100

Mshinda *et al* 2004 *Lancet Infections Diseases*
Mshinda H *et al* "Development of Genetically Modified Mosquitoes in Africa" 2004 *The Lancet Infections Diseases* 264-265

Muzan 2018 *LEAD*

Muzan MA "Institutional Mechanisms for Biosafety in Nigeria: An Appraisal of the Legal Regime under the National Biosafety Management Agency Act, 2015" 2018 *LEAD* 23-48

Nang'ayo, Simiyu-Wafukho and Oikeh 2014 *Transgenic Research*
Nang'ayo F, Simiyu-Wafukho S and Oikeh SO "Regulatory Challenges for GM Crops in Developing Economies: The African Experience" 2014 *Transgenic Research* 1049-1055

Okorie *et al* 2014 *Malaria Journal*
Okorie PN *et al* "Perceptions and Recommendations by Scientists for a Potential Release of Genetically Modified Mosquitoes in Nigeria" 2014 *Malaria Journal* 1-8 https://doi.org/10.1186/1475-2875-13-154

Ostera and Gostin 2011 *Georgetown Public Law and Legal Theory*
Ostera G and Gostin L "Biosafety Concerns Involving Genetically Modified Mosquitoes to Combat Malaria and Dengue in Developing Countries" 2011 *Georgetown Public Law and Legal Theory* 930-931

Powell 2014 *Nature Medicine*

Powell K "Biologists Try to Work Out Bugs in GM Insect Technology" 2014 *Nature Medicine* 216

Quemada "Regulation of Transgenic Mosquitoes"
Quemada H "Regulation of Transgenic Mosquitoes" in Adelman ZN (ed) *Genetic Control of Malaria and Dengue* (Academic Press Elsevier Amsterdam 2016) 363-372

Quinlan "Assessing Risk of Transgenic Insects"
Quinlan MM "Assessing Risk of Transgenic Insects" in Benedict MQ (ed) *Transgenic Insects: Technique and Applications* (CABI Wallingford 2014) 282-305

Resnik 2014 *Developing World Bioethics*
Resnik DB "Ethical Issues in Field Trials of Genetically Modified Disease-resistant Mosquitoes" 2014 *Developing World Bioethics* 37-46

Sanchez-Bayo "Ecological impacts of Insecticides"

Sanchez-Bayo F "Ecological Impacts of Insecticides" in Farzana P (ed) *Insecticides: Advances in Integrated Pest Management* (InTech Rijeka 2012) 61-90

Sture, Whitby and Perkins 2013 *Medicine, Conflict and Survival*
Sture J, Whitby S and Perkins S "Biosafety, Biosecurity and Internationally Mandated Regulatory Regimes: Compliance Mechanisms for Education and Global Health Security" 2013 *Medicine Conflict and Survival* 289-321

Swanby *Cottoning on to the Lie*
Swanby H *Cottoning on to the Lie: The Introduction of Genetically Modified Cotton in Africa will Harm, not Help, Smallholder Farmers* (African Centre for Biodiversity Johannesburg 2015)

Uzuazo 2015 *IUCN Academy of Environmental Law e-Journal*
Uzuazo E "Country Report: Nigeria – The Cart before the Horse? Biosafety Regulations and Modern Biotechnology Activities in Nigeria" 2015 *IUCN Academy of Environmental Law e-Journal* 312-321

Van Wynen Thomas and Thomas 1970 *Legal Limits*
Van Wynen Thomas A and Thomas AJ Jr *Legal Limits on the Use of Chemical and Biological Weapons* (Southern Methodist University Press Dallas 1970)

Wambugu "Importance of Political Will"
Wambugu FM "The Importance of Political Will in Contributions of Agricultural Biotechnology Towards Economic Growth, Food and Nutritional Securities in Africa" in Wambugu F and Kamanga D (eds) *Biotechnology in Africa: Emergence, Initiatives and Future* (Springer Cham 2014) 1-14

WHO *Guidance Framework for Testing of Genetically Modified Mosquitoes*
World Health Organisation *Guidance Framework for Testing of Genetically Modified Mosquitoes* (World Health Organisation Geneva 2014)

WHO *World Malaria Report*
World Health Organisation *World Malaria Report* (World Health Organisation Geneva 2014)

Legislation

Burkina Faso

Décret présidentiel nº 2013-046 promulguant la loi n° 064-2012/an du 20 décembre 2012 portant régime de sécurité en matière de biotechnologie. Journal Officiel n°25 du 20 juin 2013 p 5410 (2013 Presidential Decree nº 2013-046 promulgating the Law n° 064-2012/an of 20 December 2012 on the security regime with respect to biotechnology (the *Decree on Biotechnology*)

Loi n° 064-2012/AN du 20 décembre 2012 portant régime de sécurité en matière de biotechnologie (2012 Law 064-2012/AN of 20 December 2012 on the security regime with respect to biotechnology (the *Burkina Faso Biosafety Law* (BFBL))

European Union

EC Directive 18/2001 (12 March 2001)

EC Directive 41/2009 (6 May 2009)

EC Regulation 1829/2003 (22 September 2003)

EU Regulation 1946/2003 (15 July 2003)

Mali

Décret N°10-682/P-RM du 30 Décembre 2010 déterminant les modalités d'expérimentation des organismes génétiquement modifiés (Decree N°10-682/P-RM of 30 December 2010 on the modalities relating to experiments on genetically modified organisms (the *Decree on GMOs*))

Loi N°08-042 du 1er décembre 2008 relative à la sécurité en biotechnologie en République du Mali (Law N°08-042 of 1 December 2008 relating to security in biotechnology in the Republic of Mali (the *Mali National Biosafety Law*)

Loi N°02-013 du 3 juin 2002 instituant le contrôle sanitaire en République du Mali (Law N°02-013 of 3 June 2002 establishing sanitary control in the Republic of Mali (the *Law on Sanitary Control*)

Nigeria

National Biosafety Management Agency Act, 2015, Laws of the Federation of Nigeria (NBMAA)

National Environmental Standards and Regulations Enforcement Agency Act, 2007, Laws of the Federation of Nigeria

Uganda

National Biosafety Act, 2017

National Council of Science and Technology Act, 1990 (Chapter 209), Laws of Uganda

United Kingdom

Anti-terrorism, Crime and Security Act, 2001 (c. 24)

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations, 2009

Environmental Protection Act, 1990 (c. 43)

Genetically Modified Organisms (Contained Use) Regulations, 2014 (5th ed of L29)

Genetically Modified Organisms (Deliberate Release) Regulations, 2002 (SI 2002/2443)

Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations, 1996 (SI 1996/1106), as amended by the Genetically Modified Organisms (Deliberate Release and Risk Assessment – Amendment) Regulations, 1997 (SI 1997/1900)

Specified Animal Pathogens Order, 2008 (SI 2008/944)

Specified Animal Pathogens (Scotland) Order, 2009 (SI 2009/45)

Specified Animal Pathogens (Wales) Order, 2008 (SI 2008/1270 (W.129))

International instruments

Cartagena Protocol on Transboundary Movements of Living Modified Organisms (2000)

Convention on Biological Diversity (1992)

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1975)

Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (2010)

Internet sources

Agaba 2018 https://allianceforscience.cornell.edu/blog/2018/11/ugandan-scientists-skeptical-revised-gmo-bill/
Agaba J 2018 *Ugandan Scientists Skeptical of Revised GMO Bill* https://allianceforscience.cornell.edu/blog/2018/11/ugandan-scientists-skeptical-revised-gmo-bill/ accessed 15 September 2021

Akinbo *et al* 2021 https://www.frontiersin.org/articles/10.3389/fpls.2021.605937/full
Akinbo O *et al* 2021 *Commercial Release of Genetically Modified Crops in Africa: Interface Between Biosafety Regulatory Systems and Varietal Release Systems* https://www.frontiersin.org/articles/10.3389/fpls.2021.605937/full accessed 8 March 2021

AU date unknown http://www.au.int/en/countryprofiles
African Union date unknown *List of States Parties* http://www.au.int/en/countryprofiles accessed 7 March 2017

BES 2015 http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf
British Ecological Society 2015 *Genetically Modified Insects: A Response from the British Ecological Society to the House of Lords Science & Technology Committee* http://www.britishecologicalsociety.org/wp-content/uploads/GM-Insects_BES-Response_Final.pdf accessed 13 April 2017

BPOST 2010 https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf
British Parliamentary Office of Science and Technology 2010 *Genetically Modified Insects* https://www.parliament.uk/globalassets/documents/post/postpn360-gm-insects.pdf accessed 7 April 2022

CBD date unknown https://bch.cbd.int/protocol/parties/#tab=1
Convention on Biological Diversity date unknown *List of States Parties having Ratified the NSP* available at: https://bch.cbd.int/protocol/parties/#tab=1 accessed 10 October 2021

ECOWAS date unknown http://www.ecowas.int/
Economic Community for West African States date unknown *Home Page* http://www.ecowas.int/ accessed 7 April 2022

GeneWatch UK 2010 http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitecbrief_fin.pdf
GeneWatch UK 2010 *Oxitec's Genetically Modified Mosquitoes: In the Public Interest?* http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitecbrief_fin.pdf accessed 7 April 2022

GeneWatch UK 2015 http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec_GWbrief_Mar15.pdf
GeneWatch UK 2015 *Oxitec's Genetically Modified Mosquitoes: A Credible Approach to Dengue Fever?* http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec_GWbrief_Mar15.pdf accessed 7 April 2022

HSE 2013 www.hse.gov.uk/pubns/misc208.htm
Health and Safety Executive 2013 *The Approved List of Biological Agents* www.hse.gov.uk/pubns/misc208.htm accessed 15 October 2021

ISAAA 2014 http://www.isaaa.org/resources/publications/pocketk/16/
International Service for the Acquisition of Agri-biotech Applications 2014 *Pocket K No 16: Global Status of Commercialized Biotech/GM Crops in 2014* http://www.isaaa.org/resources/publications/pocketk/16/ accessed March 2017

ISAAA 2015 http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=13270
International Service for the Acquisition of Agri-biotech Applications 2015 *COMESA Regional Biotechnology and Biosafety Policy Implementation Plan Validated* http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=13270 accessed 8 March 2017

ISAAA 2019 https://www.isaaa.org/resources/publications/pocketk/16/
International Service for the Acquisition of Agri-biotech Applications 2019 *Pocket K No 16: Biotech Crop Highlights in 2019* https://www.isaaa.org/resources/publications/pocketk/16/ accessed 18 September 2021

Joshi 2014 http://www.idsa.in/cbwmagazine/Geneticallyengineered insects_ajoshi
Joshi A 2014 *Genetically Engineered Insects: A Boon or Curse?* http://www.idsa.in/cbwmagazine/Geneticallyengineeredinsects_ajoshi accessed 16 March 2017

Muheebwa 2017 https://www.ip-watch.org/2017/11/03/uganda-parliament-passes-bill-promote-use-genetically-modified-materials-biotech/

Muheebwa H 2017 *Uganda Parliament Passes Bill to Promote Use of Genetically Modified Materials* https://www.ip-watch.org/ 2017/11/03/uganda-parliament-passes-bill-promote-use-genetically-modified-materials-biotech/ accessed 31 January 2018

Nigerian Federal Ministry of Health date unknown http://www.health.gov.ng/index.php/department/public-health

Nigerian Federal Ministry of Health date unknown *Department of Public Health* http://www.health.gov.ng/index.php/department/public-health accessed 31 January 2018

Reuters 2021 https://www.news24.com/news24/africa/news/african-union-to-start-talks-with-who-on-rollout-for-first-ever-malaria-vaccine-for-children-20211007

Reuters 2021 *African Union to Start Talks with WHO on Rollout for First Ever Malaria Vaccine for Children* https://www.news24.com/ news24/africa/news/african-union-to-start-talks-with-who-on-rollout-for-first-ever-malaria-vaccine-for-children-20211007 accessed 8 October 2021

SACGM date unknown https://www.hse.gov.uk/biosafety/gmo/acgm/ acgmcomp/
Scientific Advisory Committee on Genetic Modification date unknown *Compendium of Guidance* https://www.hse.gov.uk/biosafety/gmo/acgm/ acgmcomp/ accessed 5 October 2021

Schnurr 2017 http://gmosandpoverty.com/ugandas-national-biosafety-act/
Schnurr M 2017 *Uganda's National Biosafety Act: Can Genetically Modified Crops Help the Poor?* http://gmosandpoverty.com/ugandas-national-biosafety-act/ accessed 31 January 2018

Secretariat of the CBD 2010 https://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-15-en.pdf
Secretariat of the Convention on Biological Diversity 2010 *Final Report of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety* https://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-15-en.pdf accessed 7 April 2022

Secretariat of the CBD 2016 https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf
Secretariat of the Convention on Biological Diversity 2016 *Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment* https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf accessed 7 April 2022

Secretariat of the NAPPO 2007 https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf
Secretariat of the North American Plant Protection Organisation 2007 *Guidelines for Importation and Confined Field Release of Transgenic Arthropods in NAPPO Member Countries* https://www.nappo.org/files/1814/3753/9399/RSPM27-e.pdf accessed 20 April 2017

Swetlitz 2017 https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/
Swetlitz I 2017 *A Revolutionary Genetic Experiment is Planned for a West African Village - If Residents Agree* https://www.scientificamerican.com/article/a-revolutionary-genetic-experiment-is-planned-for-a-west-african-village-if-residents-agree/ accessed 9 May 2017

UNEP 2006 http://new.unep.org/dewa/africa/docs/en/AEO2_Our_Environ_Our_Wealth.pdf
United Nations Environment Programme 2006 *Africa Environmental Outlook 2, 2006* http://new.unep.org/dewa/africa/docs/en/AEO2_Our_Environ_Our_Wealth.pdf accessed 8 March 2017

UNODA date unknown http://disarmament.un.org/treaties/t/bwc
United Nations Office for Disarmament Affairs date unknown *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Status of the Treaty* http://disarmament.un.org/treaties/t/bwc accessed 17 January 2018

WHO 2021 https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases
World Health Organisation 2021 *WHO Issues New Guidance for Research on Genetically Modified Mosquitoes to Fight Malaria and Other Vector-borne Diseases* https://www.who.int/news/item/19-05-2021-who-issues-new-guidance-for-research-on-genetically-modified-mosquitoes-to-fight-malaria-and-other-vector-borne-diseases accessed 15 September 2021

WHO 2021 https://www.who.int/news-room/fact-sheets/detail/malaria
World Health Organisation 2021 *Malaria* https://www.who.int/news-room/fact-sheets/detail/malaria accessed 9 March 2022

WMA date unknown http://www.wma.net/en/20activities/10ethics/0helsinki/
World Medical Association date unknown *Declaration of Helsinki* http://www.wma.net/en/20activities/10ethics/10helsinki/ accessed 16 March 2017

List of Abbreviations

AHTEG	Ad Hoc Technical Expert Group
AIA	Advance informed agreement
ASSAF	Academy of Science of South Africa
AU	African Union
BCH	Biosafety Clearing-House
BES	British Ecological Society
BFBL	Burkina Faso Biosafety Law
BPOST	British Parliamentary Office of Science and Technology
CBD	Convention on Biological Diversity
COMESA	Common Market for East and Southern Africa
DRAMLB	Draft Revised African Model Law on Biosafety
ECOWAS	Economic Community for West African States
EFSA	European Food Safety Authority
EMBO Reports	European Molecular Biology Organisation Reports
EPA	Environment Protection Act
EU	European Union
GM	genetically modified
GMM	genetically modified mosquitoes

GMOs	genetically modified organisms
HSE	Health and Safety Executive
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LEAD	Law, Environment and Development Journal
LMOs	living modified organisms
NAPPO	North American Plant Protection Organisation
NBMAA	National Biosafety Management Agency Act
NFP	National Focal Point
NSP	Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol
PLoS Negl Trop Dis	PLoS Neglected Tropical Diseases
RSPM	Regional Standards for Phytosanitary Measures
SACGM	Scientific Advisory Committee on Genetic Modification
SIT	Sterile Insect Technique
UK	United Kingdom
UNEP	United Nations Environment Programme
UNODA	United Nations Office for Disarmament Affairs
UNCST	Uganda National Council for Science and Technology
US	United States
WHO	World Health Organisation
WMA	World Medical Association