AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Guidelines for Importation, Exportation, Handling, Labelling and Storage of Genetically Modified Mosquitoes

West Africa Integrated Vector Management Programme

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About The AU, AUDA-NEPAD and WAHO

The African Union (AU)

The African Union (AU) is a body of 55 member states that make up the countries of the African Continent. It was officially launched in 2002 as a successor to the Organization of African Unity (OAU), which ran from 1963 to1999. The decision to re-launch Africa's pan-African organisation was the outcome of a consensus by African leaders that in order to realise Africa's potential, there was a need to re-focus attention from the fight for decolonisation and ridding the continent of apartheid hitherto pursued under the OAU, towards increased cooperation and integration of African states to drive Africa's growth and economic development. The AU is guided by its vision of *An integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in the global arena [1].*

To realise this vision, the Africa Union developed and adopted a 50-year strategic plan called Agenda 2063 [2]. Agenda 2063 is the continent's strategic framework that aims to deliver on its goal for inclusive and sustainable development and is a concrete manifestation of the pan-African drive for unity, self-determination, freedom, progress and collective prosperity pursued under Pan-Africanism and African Renaissance.

The AU has been steadfast in proposing more enabling and science-based approaches to the challenges of the continent. Its report on gene drives clearly embraces the technology as a realistic option for effective disease control. A constructive development along this path was witnessed at the 29th Ordinary Session of Heads of State and Government of the African Union in Addis Ababa, where pursuant to Decision *Assembly/AU/Dec.649 (XXIX),* the session embraced the gene drive technology as a realistic option for malaria control. The session, in its decision, requested the African Union Commission (AUC), West African Health Organization (WAHO) and African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD) to collectively support the initiative [3].

In 2018, through recommendations of the African ministers responsible for science and technology *EX.CL/Dec. 987(XXXII),* the Executive Council of the African Union encouraged member states to harness emerging technologies, including gene drive, in their development initiatives [4].

The decisions above have offered solid policy statements for the continent regarding gene drives for human health purposes, which have impacted discussions in AU member states. It is a basis for a harmonised approach for Africa in the development of policy regulations and guidelines such as this to facilitate the responsible and safe application of the technologies for research and subsequent deployment.

The African Union Development Agency - NEPAD (AUDA-NEPAD)

At the 31st Ordinary Session of the Assembly of African Union Heads of State and Government held in Nouakchott, Mauritania from 25th June to 2nd July 2018, the Heads of State and Government approved the transformation of the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency into the African Union Development Agency (AUDA) as the technical body of the African Union with its own legal identity, defined by its own statute [6]. The objectives of AUDA-NEPAD are to: a) coordinate and execute priority regional and continental projects to promote regional integration towards the accelerated realisation of Agenda 2063; b) strengthen capacity of African Union Member States and regional bodies; c) advance knowledge-based advisory support; d) undertake the full range of resource mobilisation; and e) serve as the continent's technical interface with all Africa's development stakeholders and development partners.

The West African Health Organization (WAHO)

The West African Health Organization (WAHO) was established in 1987 when the Heads of State and Government from all fifteen countries in the Economic Community of West African States (ECOWAS) adopted and thereafter ratified the protocol for its creation. WAHO has transcended linguistic borders and hurdles in the sub-region to serve all fifteen ECOWAS Member States. The protocol grants WAHO the status of a specialised agency of ECOWAS and, as guided by its mission statement, 'the attainment of the highest possible standard and protection."

The regional agency is charged with the responsibility of safeguarding the health of the peoples in the sub-region through initiation and harmonisation of relevant policies of Member States, pooling of resources, and in cooperation with one another, maintaining a collective and strategic focus on important health problems of the sub-region.

WAHO has, through its strategic programmes, undertaken measures to combat malaria, malnutrition, HIV/AIDS as well as maternal and infant mortality. It has also spearheaded the prevention of blindness, increased access to medicines and vaccines, epidemiological surveillance as well as training and health information management in the sub-region.

Through its second strategic plan, WAHO is currently implementing various cutting-edge programmes in the sub-region to improve the overall health systems, ensure high-quality health services, develop sustainable financing of health and support institutional development within WAHO itself.

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Abbreviations and Acronyms

AU	African Union
AUDA-NEPAD	African Union Development Agency-NEPAD
DNA	Deoxyribonucleic acid
ECOWAS	Economic Community of West African States
GM	Genetically Modified
GDM	Gene Drive Modified Mosquitos
GMM	Genetically Modified Mosquito
GMO	Genetically Modified Organism
VBDs	Vector-borne diseases
WAHO	West African Health Organisation
WA-IVM	West Africa Integrated Vector Management
TWGs	Technical Working Groups

Foreword

Approximately 80% of the world's population is at risk of one or more vector-borne diseases (VBDs), which together are responsible for 17% of the global burden of diseases [4]. Considering the significance of these diseases, the Economic Community of West African States (ECOWAS) has agreed on the establishment of a West Africa- Integrated Vector Management (WA-IVM) Programme. The purpose of this Programme is to establish and operationalise a platform for the region to build strong collaborations among member countries on issues relevant to effective control of the vectors. Some of the key elements being considered include biosafety, environment, ethics, regulatory oversight, and health systems, among others. The WA-IVM platform also aims to equip and capacitate the region with innovative technologies and novel approaches for controlling the arthropod vectors. Considering that malaria is the most important vector-borne disease in sub-Saharan Africa, the WA-IVM Programme will use malaria as a pathfinder disease for developing its platform activities.

The emergence of gene drive technologies holds prospects for future deployment to significantly improve control and accelerate efforts towards the elimination of malaria [5, 6]. Current approaches can be used to either suppress malaria vector populations or to alter them such that they no longer transmit malaria [7]. Due to the biased inheritance of traits, gene drive modified mosquitoes spread faster than the limits imposed by Mendelian inheritance [7]. There are, however, still many unknowns regarding the safety and field-efficacy of these technologies; thus, further evaluation is necessary for both laboratory and real-field settings. Recent mathematical simulations in West Africa indicated considerable suppression of vector populations could be achieved within a few years of using a female sterility gene drive, though the impact is likely to be heterogeneous in space and time [8]. It was observed that using a CRISPR-Cas9 gene drive to reduce female fertility could result in a 95% decrease in the relevant mosquito population on a regional scale after 4 years of deployment. The actual spread in the wild will likely be patchy and slow, but most available evidence suggests that these gene drives will be highly impactful against malaria even if they themselves are not a silver bullet and are only used to complement existing interventions [7-9]. Due to the flight nature of mosquitoes, modified mosquitoes could have negative or positive transboundary impacts depending on the expression of the traits they carry. There are, therefore, regional regulatory implications in their deployment.

As part of the WA-IVM initiative, a number of guidelines have been created to provide an improved protocol for the prevention of biosafety risks while ensuring beneficial and sustainable applications of gene drive technology. These guidelines refer to multiple processes but also anticipate the potential transboundary movement of gene drive modified mosquitoes (GDMs) and how to address any adverse effects. The guidelines will advance consultations, ethical applications, and sustainable use of GDMs. This specific guideline focuses on procedures around the intentional movement of GDMs, and therefore covers importation, exportation, transfer, labelling, and storage processes.

Glossary

Biological diversity - the variability of living organisms from all sources including, inter aerial, terrestrial, marine, and other aquatic ecosystems, and the ecological complexes of which they are part; this includes diversity within and between species and ecosystems.

Competent authority - is the one responsible for performing the administrative functions required

Contained use - activities in which organisms are genetically modified (GM) or in which such genetically modified organisms (GMOs) are cultured, stored, transported, or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.

Exporter - any natural or legal person by whom or on whose behalf a notification is made, that is to say, the person who, at the time when the notification is sent, holds the contract with the consignee in the third country and has the power to determine that the GMO is to be sent out of the customs territory of the Community.

Genetically Modified Mosquitoes (GMM) – mosquitoes that have heritable traits derived through the use of recombinant DNA technology.

Genetically Modified Organism (GMO) – also called genetically engineered organism, transgenic organism, or living modified organism – any organism that has in its genome novel DNA of endogenous, exogenous, or mixed origin that was made using recombinant DNA technology.

Gene Drive (three dimensions in its definition) - a process that promotes or favours the biased inheritance of certain genes from generation to generation - any genetic element able to bias its inheritance within a population. - a tool to effect certain changes in a population

Genotype – the genetic constitution of an organism.

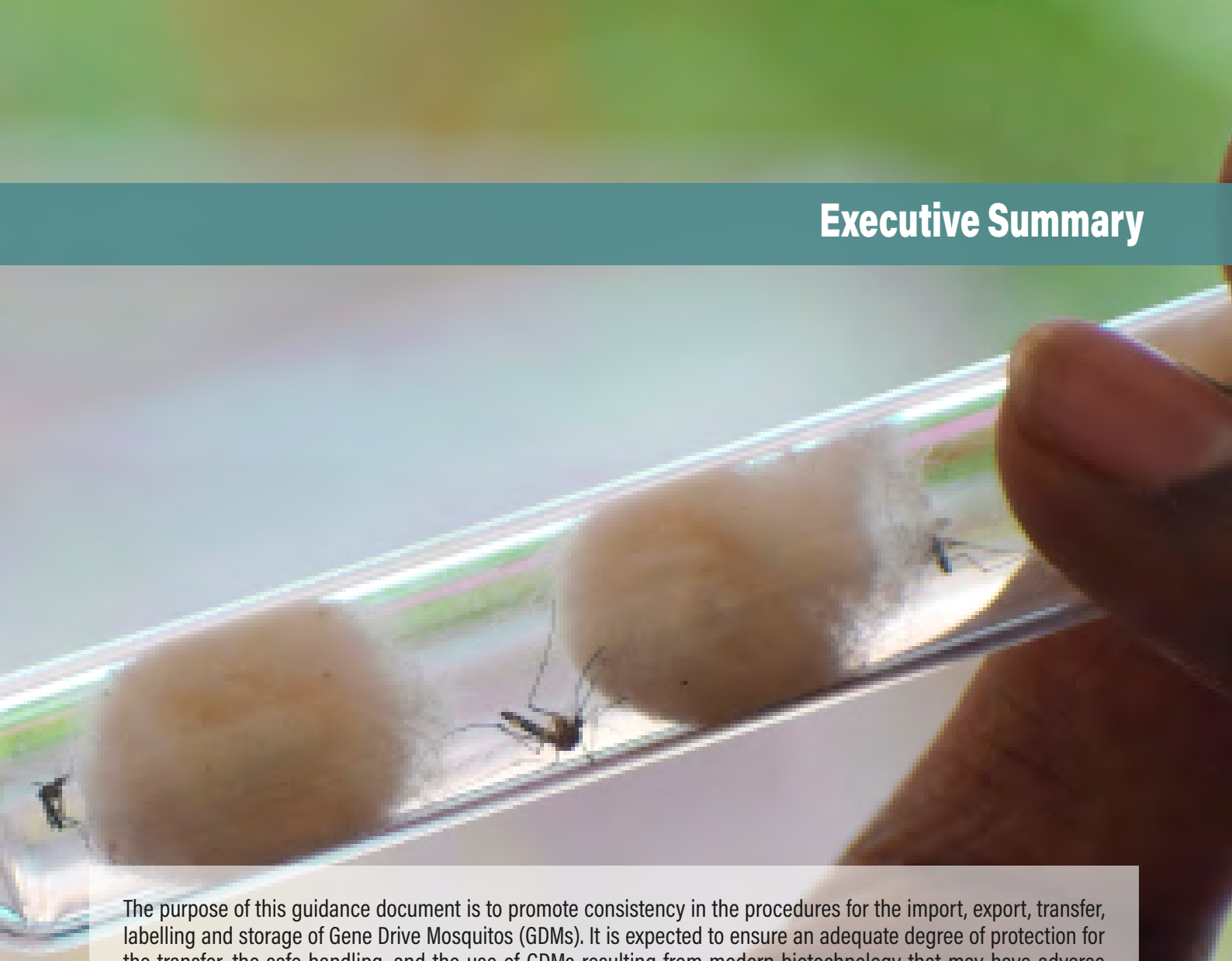
Importer - any natural or legal person, under the jurisdiction of the Party or non-Party of Import, who arranges for a GMO to be imported.

Labelling - Logo, content, brands, features, presence indicators, genetically modified organisms, and products thereof.

Notification - the submission of the information required from the exporter to the competent authority of a party.

Transboundary movement – movement across national, state, or other political lines of demarcation.

Executive Summary



The purpose of this guidance document is to promote consistency in the procedures for the import, export, transfer, labelling and storage of Gene Drive Mosquitos (GDMs). It is expected to ensure an adequate degree of protection for the transfer, the safe handling, and the use of GDMs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. The guidelines take into account potential risks to humans, animals and the environment by specifically focusing on transboundary movements of Gene Drive Mosquitos.

The African continent, in particular, the sub-Saharan region, is the most affected by malaria parasites, which are transmitted by females Anopheles mosquitoes. There were an estimated 229 million malaria cases and 409,000 deaths worldwide, about 94% of which were in Africa [10]. Starting from 2000, global malaria mortality declined by 60%, most of these gains being attributed to vector control interventions, notably insecticide-treated nets (ITNs) and indoor residual spraying (IRS) [11]. Unfortunately, challenges such as high costs, resistance to insecticides and suboptimal utilisation have impaired the progress towards elimination. Evidence from recent years shows that current tools will be inadequate for achieving the goal of malaria eradication and that new complementary approaches are necessary. Gene drive technologies hold prospects for future deployment to significantly improve malaria control by complementing existing initiatives. Current gene drive approaches have been demonstrated to either suppress malaria vector populations or to alter them such that they can no longer transmit malaria parasites. Due to the biased inheritance of traits, gene drive modified mosquitoes spread faster than the limits imposed by Mendelian inheritance [7, 12]. Due to the flight nature of mosquitoes, modified mosquitoes could have negative or positive transboundary impacts depending on the expression of the traits they carry. There are, therefore, regional regulatory implications in their deployment. In particular, since the organisms are mobile, regulation of transgenic insects will have to take into account transboundary movement, thus emphasising the need for a regional regulatory approach.

The import contained use, intentional release, and marketing of GDMs are subject to the prior written authorisation of the competent authority in Member States, following a written request by any interested person. These guidelines, therefore, focus on procedures to ensure appropriate levels of biosafety during such intentional movement of GDMs and covers importation, exportation, transfer, labelling, and storage processes.

Introduction

Insects are among the deadliest animals on earth, and mosquitoes alone are responsible for more than 700,000 deaths and hundreds of millions of cases each year [4]. There are more than 3500 species of mosquitoes, but only Aedes, Culex and Anopheles are responsible for the majority of the diseases, which include dengue fever, Zika, yellow fever, encephalitis, and malaria, among others. In 2019 alone, there were 229 million malaria cases and 409,000 deaths, nearly all of these in sub-Saharan Africa [10].

Since 2000, malaria vector control has relied mostly on the use of insecticide-treated nets and indoor residual spraying as the core tools. These two have contributed significantly to the nearly 80% decline of malaria burden observed in the past two decades [10, 11]. There is, however, great recognition that these existing approaches will be inadequate for the goal of malaria eradication. Moreover, sustaining these practices requires significant resources, which are not necessarily available. In 2019 alone, more than three billion US dollars was invested against an actual budget requirement of nearly six billion [10]. To complement existing efforts, sustain gains and accelerate progress, scientists have been working on Genetically Modified Mosquitoes (GMMs), including deployment of gene drives to accelerate the spread of desired traits to either suppress or modify malaria vectors

Based on available laboratory evidence [5, 6, 13, 14] and mathematical simulations [8, 9], gene drives have enormous potential for the control of mosquito-borne diseases. The approach works by preferentially biasing mosquito inheritance and can rapidly introduce desired genetic traits, which confer a negative fitness effect on the population. Because of its potential for rapid spread, gene drive products have the potential to cause long-lasting, sustainable population suppression or to transform the Anopheles into refractory populations.

The regulation of gene drive technology is currently embedded in the broad regulation of genetic modification and the Cartagena Protocol on Biosafety [15]. However, there is the need to develop organism-specific guidelines to manage potential risks that may occur due to certain unique characteristics of the gene-drive modified mosquitos. This will ensure safety during laboratory experimentation and subsequent phases of research and development until the deliberate release of the organisms into the wild. All these regulations must, however, also consider the potential benefits associated with the technology, especially its favourable characteristics as a potentially high-impact, cost-effective, rapid, and sustainable method for malaria control.

In August 2018, AUDA-NEPAD Agency, in collaboration with the West African Health Organization (WAHO), established the West Africa Integrated Vector Management (WA-IVM) Programme in Accra. The inauguration of the WA-IVM Steering Committee took place in October 2018. The main objective of this programme is for the regulation of priority vector control tools and approaches using malaria as a pathfinder disease and gene drive as a pathfinder approach. The teams are working to establish a common biosafety regulation, to guide research and development in the ECOWAS region and to provide a mechanism for the evaluation, management, and control of risks inherent to the transboundary movement of GDMs, while maximising the benefits of biotechnology. The WA-IVM has technical working groups (TWGs) to develop guidelines and other technical documents to promote its agenda.

This document presents the guidelines necessary to ensure safe transportation and importation of genetically modified mosquitos, fulfil obligations under the Cartagena Protocol, safeguard consumer choices and prevent adverse effects of GDMs.

Scope

These guidelines may be invoked as necessary or convenient for ensuring safe handling and transfer of GDMs with a focus on cross-border movements, which include Importation, Exportation, Handling, Labelling and Storage of Gene Drive Mosquitos (GDMs) for purposes of contained use and intentional release.

The provisions in SECTION II that govern transport and import shall apply to GDMs that are approved within a party's national legislations for deliberate release or contained use or have been reported pursuant to the appropriate national regulatory authority for contained use as provided for in the appropriate law.

The conditions stipulated in SECTION V that govern labelling shall apply to GDM as stated in the first paragraph of SECTION V, in addition to GDM that are approved pursuant to the provisions in the appropriate law for deliberate release, or that may be transported pursuant to the provisions in the appropriate law.

GDMs that are subject to rules that apply to the transport of dangerous goods may not be considered as appropriate legislation may be required.

General Precautions

Persons responsible for labelling, transport, import, export, transfer, handling, and storage of GDM shall ensure that the conditions stated in these Guidelines are complied with, and otherwise show due care and take reasonable measures to ensure that all handling of GDM are undertaken without any adverse effects on human health, animals and on the environment.

Other Regulations

These Guidelines may in no way limit any requirements following from other regulations on the labelling, transport, import, export, handling and storage of insects, other animals, or microorganisms.

Transport and Import

The general rule for transport and import

With the exception of genetically modified organisms exempted under any given law, the transport and import of GDM may take place with respect to the advance informed agreement procedure when the requirements in these Guidelines regarding labelling and packaging are fulfilled.

The Party of transport or import shall notify the competent national authority of the Party of import in writing, with prior consent for intentional transboundary movement of a genetically modified mosquito.

Transport and import for which approval is required

Approval is required for the transport and import of the following:

1. GDMs where the activity is classified in risk classes in any appropriate law.
2. Volume of culture exceeding ten litres of GDM where the activity is classified in a risk class in any appropriate law.
3. Live animals used as host organisms for GDM.
4. Transport where it is not possible to satisfy the requirements in these Guidelines regarding packaging and labelling.
5. First transboundary movement of genetically modified mosquito intended for direct introduction into the environment

Contents of the application

Generally, applications for transport and import shall include the following information:

1. Name, address, telephone, email, and fax numbers of the following: applicant, person responsible, sender, recipient, and carrier.
2. Information concerning packaging, means of transport, transport route and dates of dispatch and delivery.
3. Information concerning the GDM: taxonomic status, scientific name, common name, characteristics of the genetically modified mosquito and donor, recipient organism or (if applicable) parental organisms.
4. Quantity: number of organisms or litres of culture and number of consignments to be transported and/or imported.
5. An assessment of the risks to health and the environment during the transport or in the country of importation.
6. Information concerning when and by which authority the genetically modified mosquito was approved or reported for contained use or deliberate release.
7. Precautions to be taken when handling the GDMs.
8. Methods and plans for safe handling, storage, transport, and use, including packaging and labelling procedures.
9. Emergency procedures that will apply in the event of an accident with the GDM.
10. Scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified mosquito on the conservation and sustainable use of biological diversity in the country of import.
11. A complete affidavit to declare that the information provided is factually correct and signed by the applicant.

If necessary, the authority responsible for granting approval may request further information from the applicant in line with national legislation.

Records

All transport and import of GDM shall be recorded by the recipient in a given country of destination and also by the sender, where both are located within the same country.

The record shall describe the GDM in question, state the dates of dispatch, evidence of delivery and an assessment note showing that everything has been received.

The record shall be available at all times for inspection by the supervisory authority. Copies of the transport documents shall be included in the record.

Accompanying documents during transport (transport documents)

Transport documents shall be included in all consignments of GDM from sender to recipient. The documents shall contain the following information.

For GDM intended for contained use:

1. Information that the mosquito is intended for contained use,
2. A description of the mosquito, including common, scientific and (if available) commercial names of the mosquito,
3. A description of genetic modification, applied technique and the subsequent changes in the properties of the mosquito
4. Precautions in connection with handling, storage, transport, and use,
5. Risk class
6. Specifications for the use of the GDM
7. Unique identification if such exists
8. Specification of a contact point for further information, including the recipient of the organism and exporter or importer.

For GDM intended for deliberate release:

1. A declaration that the transport complies with the requirements of the Cartagena Protocol and/or the relevant national legislation
2. a description of the GDM, including common, scientific and (if available) commercial names of the organism,
3. A description of genetic modification applied technique and the subsequent changes in the properties of the insect.
4. A unique identification code, if such exists,
5. Precautions in connection with handling, storage, transport, and use,
6. Risk class
7. Import permit if this is required,
8. Specifications for the use of the GDM
9. Specification of a contact point for further information, including the sender/exporter and recipient/importer.

Packaging of GDMs

GDM shall be packaged for transport as stipulated in an appropriate manner provided by national legislation. The authority responsible for granting approval may make other packaging requirements as a condition of approval.

In any case, packaging shall consist of either a cage or a container that ensures that the GDM cannot escape or cross with other mosquitos outside the cage or container.

Packaging of mosquitos must respect the regulations on the transportation of biological agents and live vectors, which aim to ensure that the public and workers in the transportation chain are protected from exposure to any agent that might be in the package and that the package prevents the agent or live vector from escaping. Such protection is achieved through:

1. the requirements for rigorous packaging that will withstand rough handling and contain all liquid material within the package without leakage to the outside.
2. appropriate labelling of the package with the biohazard symbol and other labels to alert workers in the transportation chain to the hazardous contents.
3. the availability of documentation of the hazardous contents of the package should such information be necessary for an emergency situation.
4. training of workers in the transportation chain so that they are able to respond appropriately to emergency situations.

Export

The requirement of prior authorisation

Prior to the initial export of GDM intended for deliberate release into the environment in other countries, the exporter shall obtain prior consent from the competent national authority in the country of import or see to it that this is obtained.

The exporter shall ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the first intentional transboundary movement of a GDM intended for deliberate release into the environment and destined for the use specified in accordance with section III III-2. The notification shall contain, as a minimum, the information specified in section III III-2. The exporter shall ensure the accuracy of the information contained in the notification.

The exporter shall, for a period of a minimum of five years, keep a record of the notification and the acknowledgement of receipt and the decision of the Party or, where appropriate, non-Party of import and send a copy of these documents to the competent authority of the Member State from which the GDM is exported. Export is not approved and cannot be undertaken until the authority in the country of import has given its written consent to the undertaking. The exporter shall ensure the accuracy of the information contained in the notification and make sure that the information provided is correct.

The exporter is under obligation to keep a copy of the notification, the import country's confirmation of receipt and written import permit for at least five years and send a copy of these documents to the appropriate National Competent Authority.

The following are exempt from the requirements in the first and second paragraphs:

1. GDM in transit or exports of genetically modified mosquito intended for contained use when the transfer takes place in compliance with the requirements in the country of import.
2. Exports of GDM to countries that have stated to the Mechanism for Information Exchange under the Cartagena Protocol that import can take place without prior informed consent, provided that sufficient measures are initiated to ensure safe transboundary movement of GDM in accordance with the objective of the Cartagena Protocol.

Notification of export of GDM

Notification prior to the export of GDM shall contain the following information:

1. Exporter's name, address, and contact details
2. Importer's name, address, and contact details
3. Name and identity of the living modified mosquito, if applicable with the national classification of biosafety level
4. Intended date or dates for transboundary movement, if known
5. Taxonomic status, scientific name, common name, place of collection or procurement and characteristics of the recipient organism or parental organisms relevant to biosafety
6. Centres of origin and centres of genetic diversity, if known, for the recipient organism and/or parental organisms and a description of habitats where the insect's insect may persist and proliferate
7. Taxonomic status, scientific name, common name, place of collection or procurement and characteristics of donor organism(s) relevant to biosafety
8. Description of the inserted nucleic acid or the modification carried out, applied technique and the subsequent changes in the characteristics of the GMM.
9. Intended use of the GMM or products thereof, namely, processed materials that are of GMM origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
10. Quantity or volume of GMM to be transferred
11. Risk assessment report
12. Proposed methods for safe handling, storage, transport, and use, including packaging, labelling, documentation, disposal, and contingency procedures, where applicable

13. The result and purpose of every notification from the exporter to other states about the GMM to be transferred
14. A declaration that the above information is in agreement with the facts.

Dispatch of information relating to the export of GDM

The exporter shall make sure that the following information, in addition to the information listed in III-2, can be seen from the accompanying documents and is sent to the importer who receives the GDM:

1. In the case of GDM intended for contained use, the common and scientific names of the organism, information that it is intended for contained use, precautions necessary for handling, storage, transport and use, and information about a contact point for further information, including the name and address of the recipient of the organisms.
2. In the case of GDM intended for deliberate release into the environment in the importing country and any other GDM that is covered by these Guidelines, a declaration from the exporter that the transport complies with the requirements in the Cartagena Protocol regarding the exporter and the following additional information:
    a. Information about the insects: common and scientific names, characteristics of the GDM or a unique identification code if such exists,
    b. precautions relating to the handling, storage, transport, and use
    c. a contact point for further information, including exporter and importer.

Transit

The NCA shall ensure notification of the transit of GDMs to Regional Economic Community (e.g., ECOWAS) member states that have taken the decision to regulate the transit of GDMs through their territory.

Transfer, Handling and Storage

This section covers all processes and areas where the holding of stock of insects or cell cultures may occur. It also covers the act of holding a genetically modified organism or part of a genetically modified organism without undertaking any experimentation or other procedures on the GDMs or part of the GDMs

Genetically Modified Mosquitos should be handled, packaged, and stored under conditions of safety, as per relevant international rules and standards as provided in the appropriate national legislation, provided it meets the required agreed standard under international rules.

GDM destined for contained use should specify the requirements for safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the GDM are consigned.

Labelling

Products consisting of or containing genetically modified mosquitos shall be labelled clearly with the words "Contains GDM." If the package contains multiple units, the information shall be given on a label on each packaged unit. The key information should include the product's commercial name, name, and address of the manufacturer, including date of manufacture, expiring date and other details required to obtain more information on the product.

In the case of GDMs approved for sale, a unique identification code shall also be stated in the accompanying document. All markings on the packaging must be affixed in a clearly visible manner and cannot be covered by another label or marking.

Each labelling must include the following information on the packaging:

- the name and full address of the sender and recipient
- the phone number of a sender and recipient

The purpose for importation or exportation of genetically modified mosquitoes should be clearly stated on the label (e.g., research or commercial) to facilitate customs inspection and clearance.

Accidents

Obligation to report

Accidents can occur during the transportation of imported or exported genetically modified mosquitoes. In the event of an accident, a concise and well-articulated report should be written by the sender and or recipient to inform without undue delay the Regulatory Authority, including Ministries of Environment, Health, and others.

Duty in connection with accidents

The person responsible pursuant to I.4 of these Guidelines has a duty to prevent, limit and repair damage that may occur due to an accident.

Implementation and Enforcement

Approval and supervision

The designated National Regulatory Authority is responsible for approving applications for the transport or importation of GDM. The authority also supervises compliance with the provisions in these Guidelines. It is important to organise the supervision and control of the transboundary movements of GDMs in order to contribute to ensuring the conservation and sustainable use of biological diversity, also taking into account risks to human health.

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