GENECONVENE GLOBAL COLLABORATIVE
Advancing Best Practices in Genetic Biocontrol Technology

FNIH
Foundation for the National Institutes of Health

Global governance of GMOs and gene drive organisms

International frameworks and the 2026 Yerevan decisions

CBD COP-17 · CP-MOP 12

Brinda Dass, MS MPH PhD

GeneConvene Global Collaborative, Foundation for the NIH

ONGDR – ISAAA webinar | Gene Drive Applications in the Lab and Beyond

24 November 2026

bdass@fnih.org

No single authority: four levels of oversight

All four apply to the same organism – often at the same time

INTERNATIONAL

CBD · Cartagena Protocol · WHO · IUCN

Sets the shared floor: treaty obligations and global guidance; capacity building; international standards

REGIONAL

Regional Economic Communities · African Union

Harmonises standards; pools expertise and data across borders; bilateral and multilateral agreements

NATIONAL

Biosafety law · National Biosafety Authority · ministries

Where applications are assessed and permits issued, refused or withdrawn

LOCAL & INSTITUTIONAL

Institutional biosafety & ethics committees · communities

Containment, study protocols, engagement and consent



Binding or voluntary?

LAWS

Binding and enforced – Acts, Bills, treaties once ratified

REGULATIONS

Put the law into practice – decrees, rules, permits

GUIDANCE

Voluntary – how to meet requirements (e.g. BTS7, WHO framework)

Gene drive organisms are covered by binding treaty and national law; most gene drive-specific text is guidance.

GENE CONVENE GLOBAL COLLABORATIVE

FNIH Foundation for the National Institutes of Health

Why gene drives stretch existing frameworks

The property that makes them powerful is the one that challenges case-by-case, site-based regulation

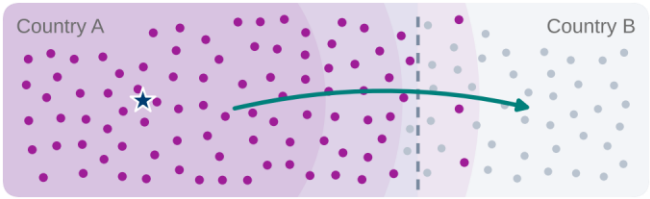
	Most GMO approvals to date	Engineered gene drive organisms
Where	A defined field, farm or release site	**Spreads through wild populations across a landscape**
How long	Stops when releases stop	**Designed to persist and sustain itself**
Reversibility	Can be withdrawn	**Not easily recalled – closer to classical biocontrol**
Who is affected	Largely one country's decision	**Neighbours affected – regional coordination advantageous**
Monitoring	Local, site-based	**Longer-term, larger spatial scale**
Acceptance	Individual users or farmers	**Communities and societies at scale**

Most GMO releases



Stays near the site; ends when releases stop

Engineered gene drive



Spreads, persists and can cross borders

● carries modification ● wild type ★ release site

Status: no gene drive organism has yet been released into the environment anywhere; malaria applications currently most advanced (in contained studies).

Upside: area-wide, sustained, potentially low-cost impact where nets, spraying and drugs are struggling. First mile/ last mile

GENE CONVENE GLOBAL COLLABORATIVE FNIH

The treaty floor: the CBD family of agreements

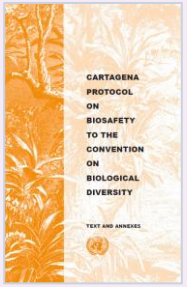
Gene drive organisms are living modified organisms (LMOs), so Cartagena Protocol obligations apply

196 Parties

Convention on Biological Diversity

In force 1993 · conservation, sustainable use, fair and equitable sharing of benefits

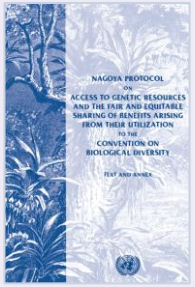
Parent treaty of all three protocols



173 Parties

Cartagena Protocol on Biosafety

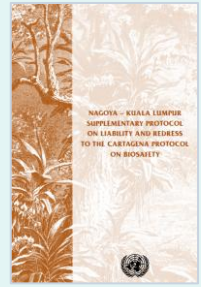
In force 2003 · safe transfer, handling and use of LMOs



143 Parties

Nagoya Protocol

In force 2014 · access to genetic resources and benefit-sharing



55 Parties

Nagoya–Kuala Lumpur Supplementary Protocol

In force 2018 · liability and redress for damage from LMOs

What the Cartagena Protocol asks of each Party

Arts 7–10	Advance informed agreement before the first transboundary movement for release
Art 15 · Annex III	Science-based, case-by-case risk assessment
Art 17	Notify affected States of unintentional transboundary movements
Art 20	Share decisions and risk assessments on the Biosafety Clearing-House
Art 23	Public awareness and participation in decision-making
Art 26	Socio-economic considerations may be taken into account

GENE CONVENE GLOBAL COLLABORATIVE

FNIH Foundation for the National Institutes of Health

Global guidance: voluntary, but influential

Non-binding instruments that shape how GM & gene drive organisms are assessed, tested and debated

CBD Biosafety Technical Series 07

Welcomed in 2024 (CP-11/7)

- Voluntary risk assessment guidance for LMOs containing engineered gene drives (published 2025)
- Operationalises Annex III: problem formulation, pathways to harm, risk hypotheses, uncertainty
- Mosquito examples; the method applies to any other LMO



WHO Guidance Framework for testing GM mosquitoes

2nd edition, 2021

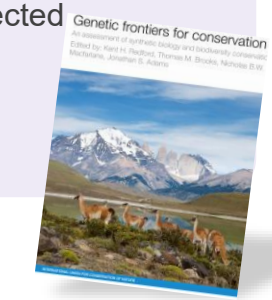
- Phased pathway from laboratory to staged open release
- Go/no-go decisions between phases
- WHO policy and prequalification route for vector control products



IUCN Policy on Synthetic Biology

Motion 087 · October 2025

- First global conservation policy on synthetic biology
- Case-by-case and science-based
- Proposed moratorium on engineering wild species (Motion 133) rejected



African Union / AUDA-NEPAD

APET reports 2018 and 2025

- Gene drive identified as a malaria tool for Africa
- Guidelines for risk analysis of GM mosquitoes and for biosafety committees
- Calls for harmonised regional biosafety standards



GENE CONVENE GLOBAL COLLABORATIVE

FNIH Foundation for the National Institutes of Health

Yerevan 2026: what changed?

CBD COP-17 · CP-MOP 12 · NP-MOP 6 | Yerevan, Armenia, 19–31 October 2026

The road to Yerevan: eight years of process

How gene drive guidance moved through the Cartagena Protocol's decision cycle

2018

CP-MOP 9 · Egypt

CP-9/13: gene drives a priority topic; criteria for new guidance

2022

CP-MOP 10 · Montreal

CP-10/10: develop voluntary gene drive guidance

2023–24

Expert group (AHTEG)

Two meetings; consensus text by ~30 experts

2024

CP-MOP 11 · Cali

CP-11/7 welcomes the guidance; new AHTEG to prioritise next topics

2025

SBSTTA-27 · Panama

BTS7 published; AHTEG reviewed 15 topics (7 met criteria); Rec. 27/7 heavily bracketed

2026

CP-MOP 12 · Yerevan

Decides LM Fish is next guidance, expert group and capacity-building

2028

CP-MOP 13 · Quito

Next decision point (last quarter of 2028)

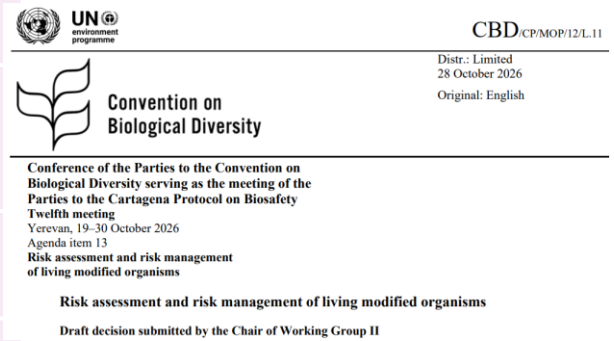
By Panama, the technical work was largely done. Yerevan was about process, scale and mandate.

CP-MOP 12 on risk assessment: proposed vs decided

Agenda item 13 · draft decision CBD/CP/MOP/12/L.11, adopted in plenary

Issue	SBSTTA-27 draft · Panama, Oct 2025	Decided in Yerevan · Oct 2026
New guidance	Up to two materials (bracketed); draft terms of reference named LM microorganisms and LM fish	**One** voluntary guidance material: **living modified fish** – non-prescriptive, retaining BTS7 as methodology, no new obligations
Technical notes	Option for notes on protection goals and centres of origin	**Not taken forward**
Expert group	New AHTEG; terms of reference fully bracketed	**New AHTEG established**: ≥2 meetings (one in person) before CP-MOP 13; academia, international organisations, IPLCs, women and youth
Process efficiency	–	**New:** recommend ways to streamline the CP-9/13 prioritisation process, including AI tools
Capacity-building	Agreed in principle; two rival wordings on citing BTS7	**Expanded**, drawing “in particular” on BTS7
Forum and submissions	Bracketed	**Online forum extended**; submissions on BTS7 experience, needs and priorities, and Articles 13 and 14

COP17
YEREVAN ARMENIA


UN environment programme

CBD/CP/MOP/12/L.11

Distr.: Limited
28 October 2026
Original: English

Convention on Biological Diversity

Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety
Twelfth meeting
Yerevan, 19–30 October 2026
Agenda item 13
Risk assessment and risk management of living modified organisms

Risk assessment and risk management of living modified organisms

Draft decision submitted by the Chair of Working Group II

Sources: CBD/CP/MOP/12/L.11 (28 Oct 2026), adopted with bracket on expert group composition lifted; CBD/SBSTTA/REC/27/7 (24 Oct 2025)

GENE CONVENE GLOBAL COLLABORATIVE

FNIH Foundation for the National Institutes of Health

What the decision means for gene drive organisms

No new gene drive-specific obligations – but the guidance is now being tested in practice

BTS7 stays the reference

Guidance welcomed in 2024 is unchanged. Capacity-building is to draw “in particular” on its approaches (para. 3).

Experience is being collected

Parties and others invited to report on BTS7's applicability and usefulness; the Secretariat compiles experiences on the BCH (paras. 6, 15(g)).

The method becomes the template

New LM fish guidance is to follow Annex III and the BTS7 methodology (para. 2) – BTS7 now forms baseline RA method, shapes guidance for other LMOs.

Next decision point: 2028

Further topics considered at CP-MOP 13 (Quito) through the CP-9/13 process, after SBSTTA review (paras. 10, 16).

For regulators today

- No new gene drive-specific obligations.
- BTS7 Section 4 – protection goals → pathways to harm → testable risk hypotheses – can be used now, inside existing national frameworks.
- Report what works: submissions on BTS7 experience feed the next cycle.
- Watch for CBD notifications calling for submissions and forum input.

Elsewhere in Yerevan: synthetic biology and biosafety

Decisions that shape the wider environment for new GM & biotechnology tools

COP-17 · Synthetic biology (item 16)

- **Thematic action plan adopted** – capacity-building, technology transfer, knowledge-sharing; voluntary and complementary
- **Precautionary approach** "as provided in Principle 15 of the Rio Declaration", with science-based, case-by-case assessment for environmental release
- **Anticipatory approaches** recognised – horizon scanning; a monitoring mechanism to be developed for COP-18
- **Online forum and submissions** on new developments and their potential positive and negative impacts
- **Stocktake** of CBD synthetic biology work since 2010; need for a new expert group decided afterwards

CP-MOP 12 · Other biosafety decisions

- **Detection and identification:** update the training manual chapter on novel detection technologies, incl. digital PCR
- **Socio-economic considerations:** keep sharing experiences; regional capacity-building on the voluntary guidance
- **New developments in modern biotechnology:** Parties invited to share national laws, regulations and guidelines via the BCH
- **Liability and redress:** first effectiveness review; Parties encouraged to put financial security (Art. 10) and civil liability rules (Art. 12) in place

Next: COP-18 · CP-MOP 13 · NP-MOP 7 – Quito, Ecuador, last quarter of 2028

From global floor to national decision

Treaties and guidance inform; national authorities decide – phase by phase

Phase 1
Laboratory & population cages

Phase 2
Confined field trials

Phase 3
Staged open-field releases

Phase 4
Post-implementation surveillance

Containment decreases → exposure and scrutiny increase · go/no-go decision and a new authorisation at each step

Gene drive (malaria): contained studies

Self-limiting GM mosquitoes: open releases underway

Who does what at national level

Applicant / developer

Dossier: risk assessment, monitoring plan, detection method, remediation options; communication

Institutional committees

Biosafety and ethics review; containment and study protocols; stakeholder and public engagement

National Biosafety Authority

Assesses, decides, sets permit conditions – and can withdraw them, community engagement/ public participation

Ministries, public & neighbours

Health and environment mandates; public participation; cross-border notification

Key takeaways and the road to 2028

1

Governance is layered

A binding treaty floor, voluntary global guidance and regional harmonisation – decisions are national.

2

Gene drive organisms are LMOs

Annex III applies; BTS7 adds operational detail, not new obligations.

3

Yerevan chose implementation

One new guidance (LM fish), more capacity-building, BTS7 as the method anchor.

4

Synthetic biology: precaution plus foresight

Precautionary, science-based, case-by-case – with horizon scanning and a monitoring mechanism for COP-18.

Road to Quito

2027 (expected)

Submissions and online forums on risk assessment and synthetic biology

Before CP-MOP 13

New risk assessment AHTEG: ≥2 meetings – LM fish guidance and process efficiency

Then

SBSTTA reviews expert group outputs, peer-reviewed topics and the synthetic biology stocktake

Q4 2028

COP-18 · CP-MOP 13 · NP-MOP 7 in Quito, Ecuador

WHO WE ARE



Partner with stakeholders

GENE CONVENE
GLOBAL COLLABORATIVE
Advancing Best Practices in Genetic Biocontrol Technology

FNIH
Foundation for the National Institutes of Health

Thank you

Questions and discussion

Gene drive risk assessment guidance (BTS7): bch.cbd.int

Yerevan meeting documents: cbd.int/meetings/CP-MOP-12

GeneConvene Global Collaborative: geneconvenevi.org

Outreach Network for Gene Drive Research: genedrivenetwork.org

bdass@fnih.org









