GENE CONVENE GLOBAL COLLABORATIVE
Advancing Best Practices in Genetic Biocontrol Technology

FNIH
Foundation for the National Institutes of Health

Regulation of Gene Drive Mosquitos- International and National Framewords

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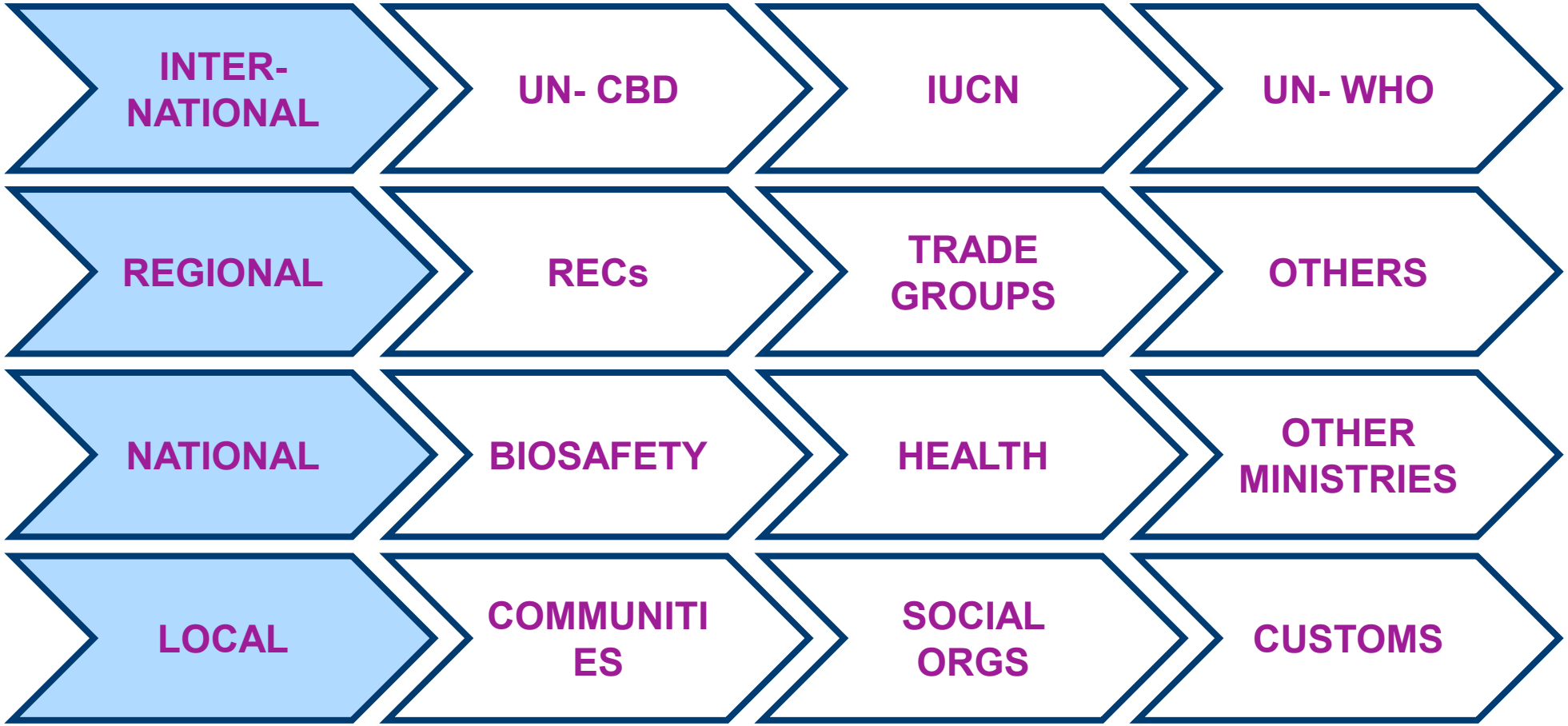
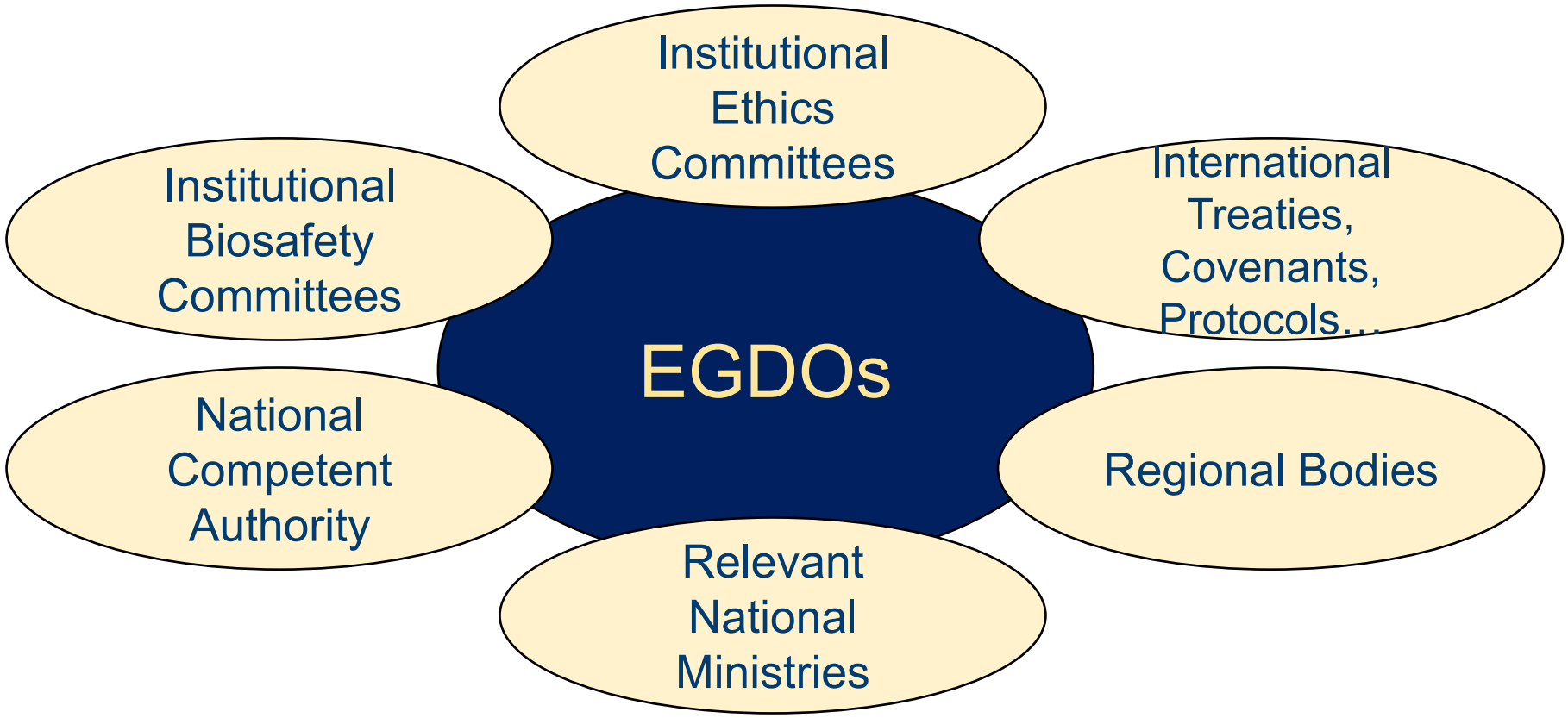
Why is governance critical?

- At all levels- local, national, regional, and international
- Transparency
- Clearly defined requirements
- Level field
- Safe and effective development
- Bring new tools to market

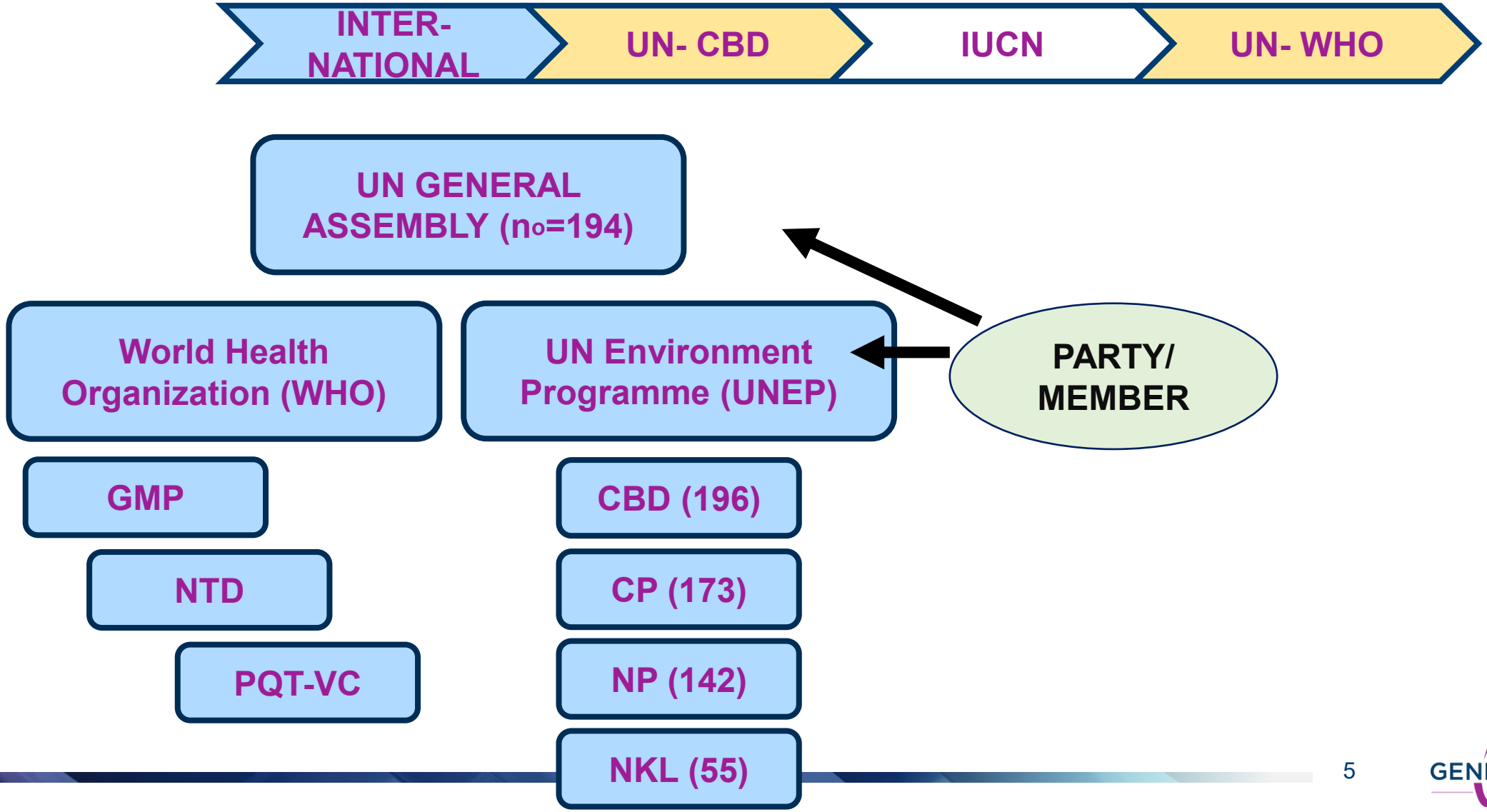
GOVERNANCE


INTER-NATIONAL
UN- CBD
IUCN
UN- WHO
REGIONAL
RECs
TRADE GROUPS
OTHERS
NATIONAL
BIOSAFETY
HEALTH
OTHER MINISTRIES
LOCAL
COMMUNITIES
SOCIAL ORGS
CUSTOMS

Multiple levels of oversight

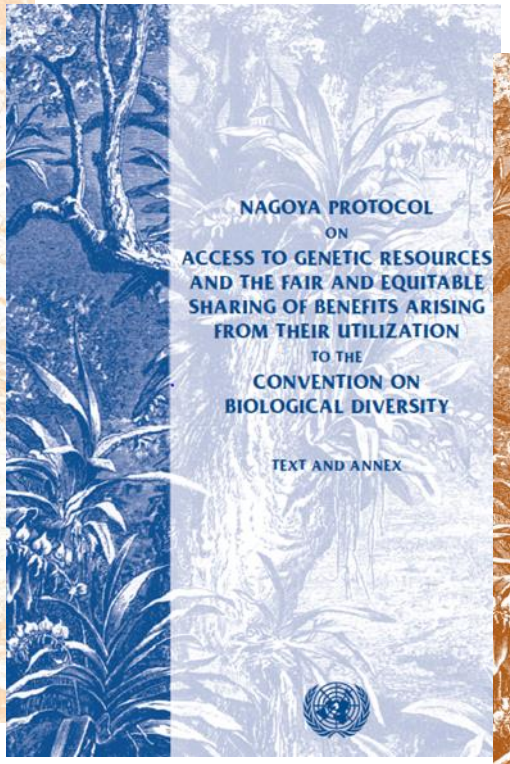


GLOBAL GOVERNANCE

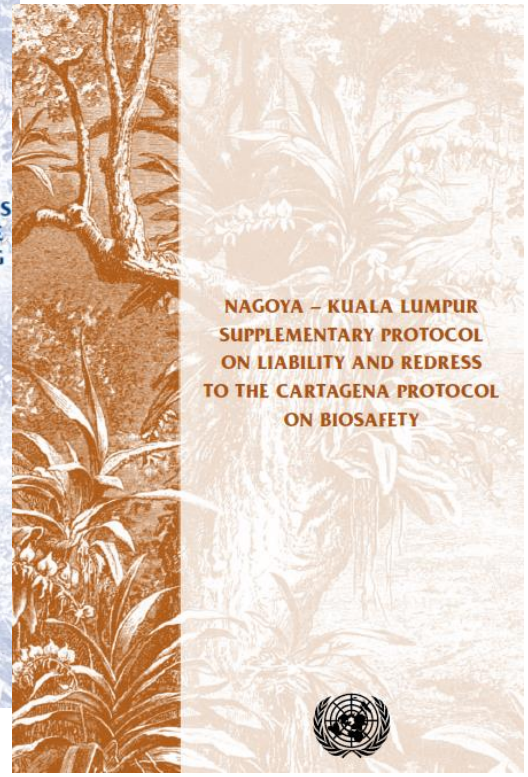


International Consideration- UN Conventions

Living Modified Organism resulting from modern biotechnology



Access to genetic resources and sharing of benefits



Liability and redress related to LMO impacts

Living Modified Organism
- Safe transfer
- Handling
- Use

Adverse effect on conservation **AND** **Sustainable use of biodiversity**

https://bch.cbd.int/protocol/text/; https://bch.cbd.int/protocol/supplementary/

UN CBD- Guidance

Section 1- Objective and scope from previous COPs
Decision 9/13 and 10/10
Section 2- Introduce EGD-LMOs, Precautionary Approach, Context
Section 3- Opportunities, risks, concerns on EGD strategies
Section 4- Risk assessment considerations for EGD-LMOs, introduces problem formulation
Section 5- Risk recommendations- acceptability, risk management strategies
Section 6- Monitoring
Section 7- Issues related to risk assessment- consideration of benefits, IPLC, FPIC, socio-economic, cultural and ethical considerations, transboundary movement, public participation
Annex- Modelling, uncertainty, WHO guidance, mosquito vectors, current EGDO landscape, EGD systems

UN CBD- CP MOP 11 Decision

CP-11/7 Risk assessment and risk management

Taking note of the assessment by the Ad Hoc Technical Expert Group on Risk Assessment of additional issues on which guidance materials on risk assessment may be needed,[4]

1. *Welcomes with appreciation* the outcomes of the meetings of the Ad Hoc Technical Expert Group on Risk Assessment;[5]

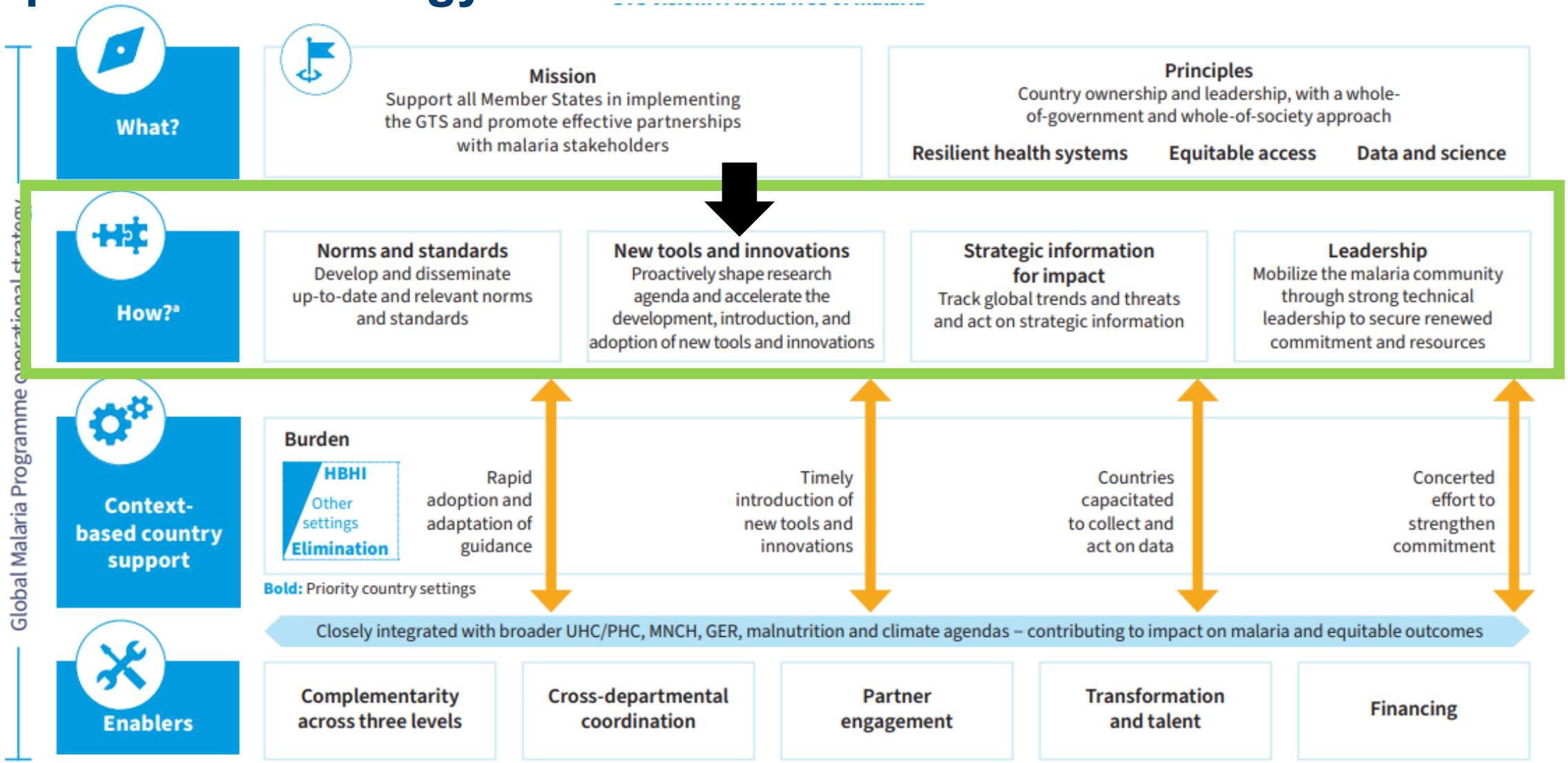
2. *Welcomes* the additional voluntary guidance materials to support the case-by-case risk assessment of living modified organisms containing engineered gene drives;[6]

3. *Invites* Parties, other Governments, indigenous peoples and local communities, women and youth organizations and relevant organizations and stakeholders to make use of the additional voluntary guidance materials in conducting relevant risk assessments and as a tool for capacity-building activities in risk assessment;

4. *Calls for* the consideration of the related issues set out in the additional voluntary guidance materials[7], including traditional knowledge, innovation and practices of indigenous peoples and local communities, in the decision-making process;

World Health Organization- Global Malaria Program

Operational strategy 2024-2030

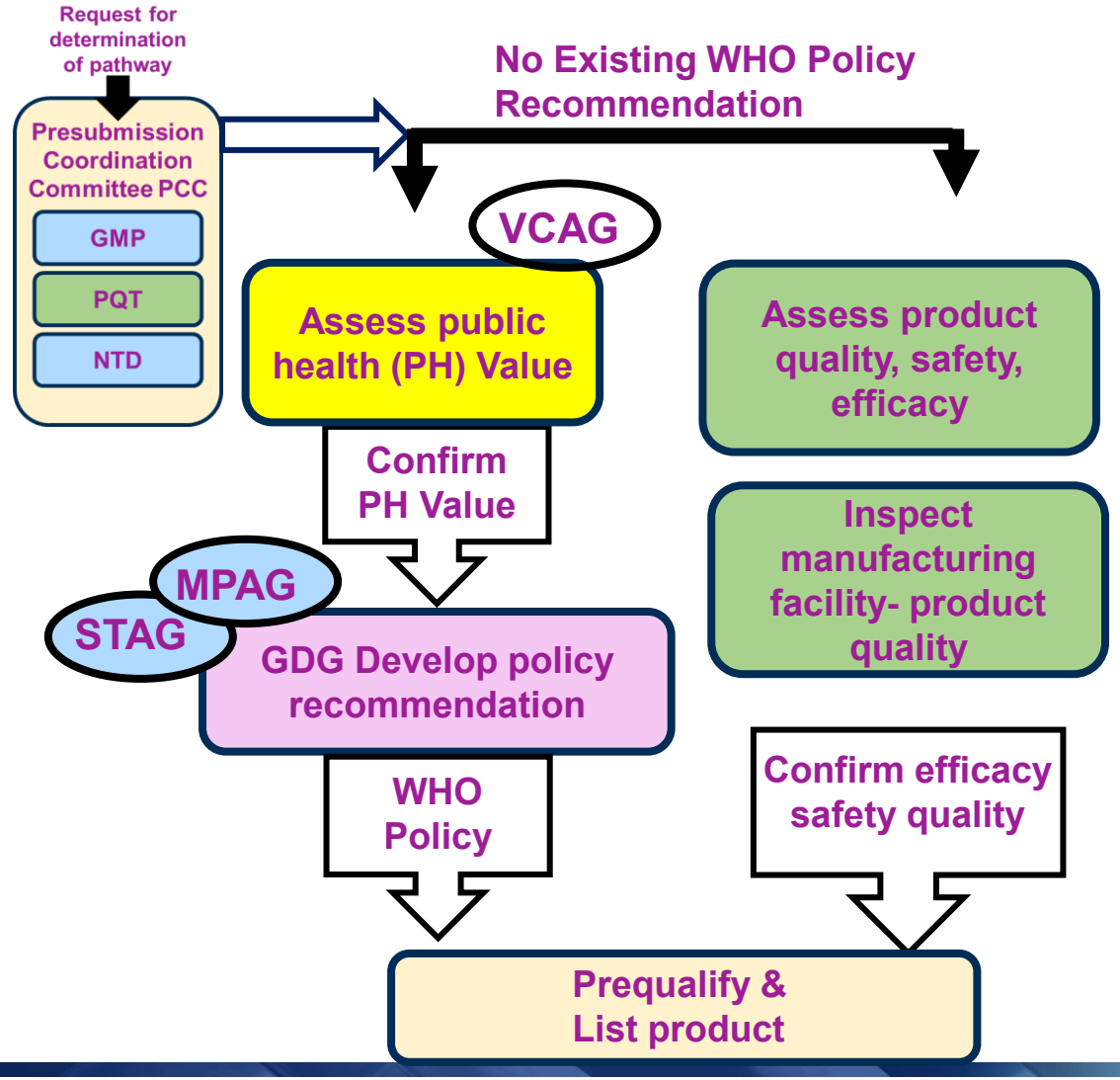


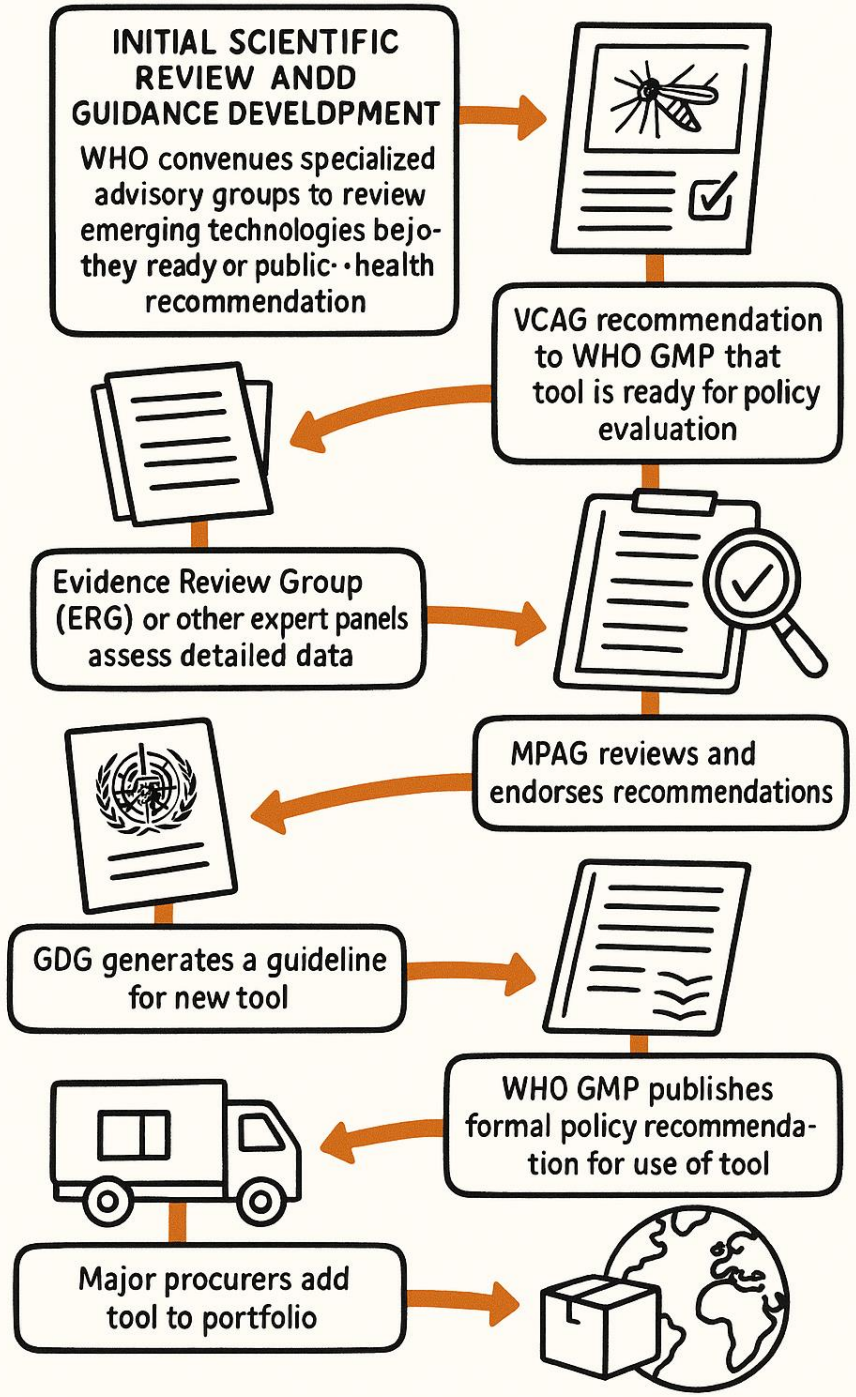
GER: gender, equity, rights; GTS: *Global technical strategy for malaria 2016–2030*; HBHI: High burden to high impact; MNCH: maternal, neonatal and child health; PHC: primary health care; UHC: universal health coverage

[a] Across the following interventions: vector control, immunoprevention, chemoprevention, diagnosis, chemotherapy, surveillance

FNIH

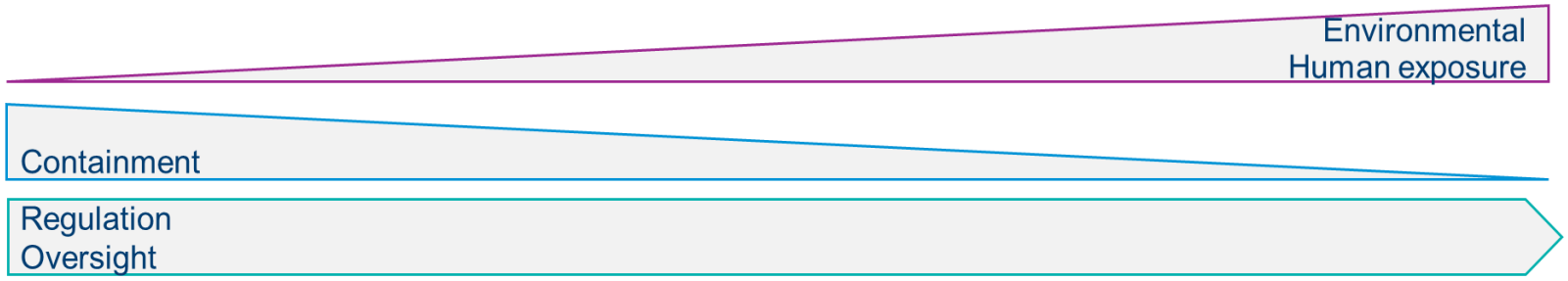
International-
World Health Organization





International

World Health Organization



https://iris.who.int/handle/10665/259688

Regional Consideration- IVM

REGIONAL | RECs | TRADE GROUPS | OTHERS

African Union Development Agency-NEPAD

- IVM platform with a regional focus in Economic Community of West African States (ECOWAS) - WA IVM platform
- WAHO Secretariat
- Biosafety guidelines and capacity strengthening
- IBC training
- Risk Assessment of LMOs
- Dossier evaluations
- Streamlining processes
- Ethics

https://www.nepad.org/news/establishment-of-west-africa-integrated-vector-management-programme

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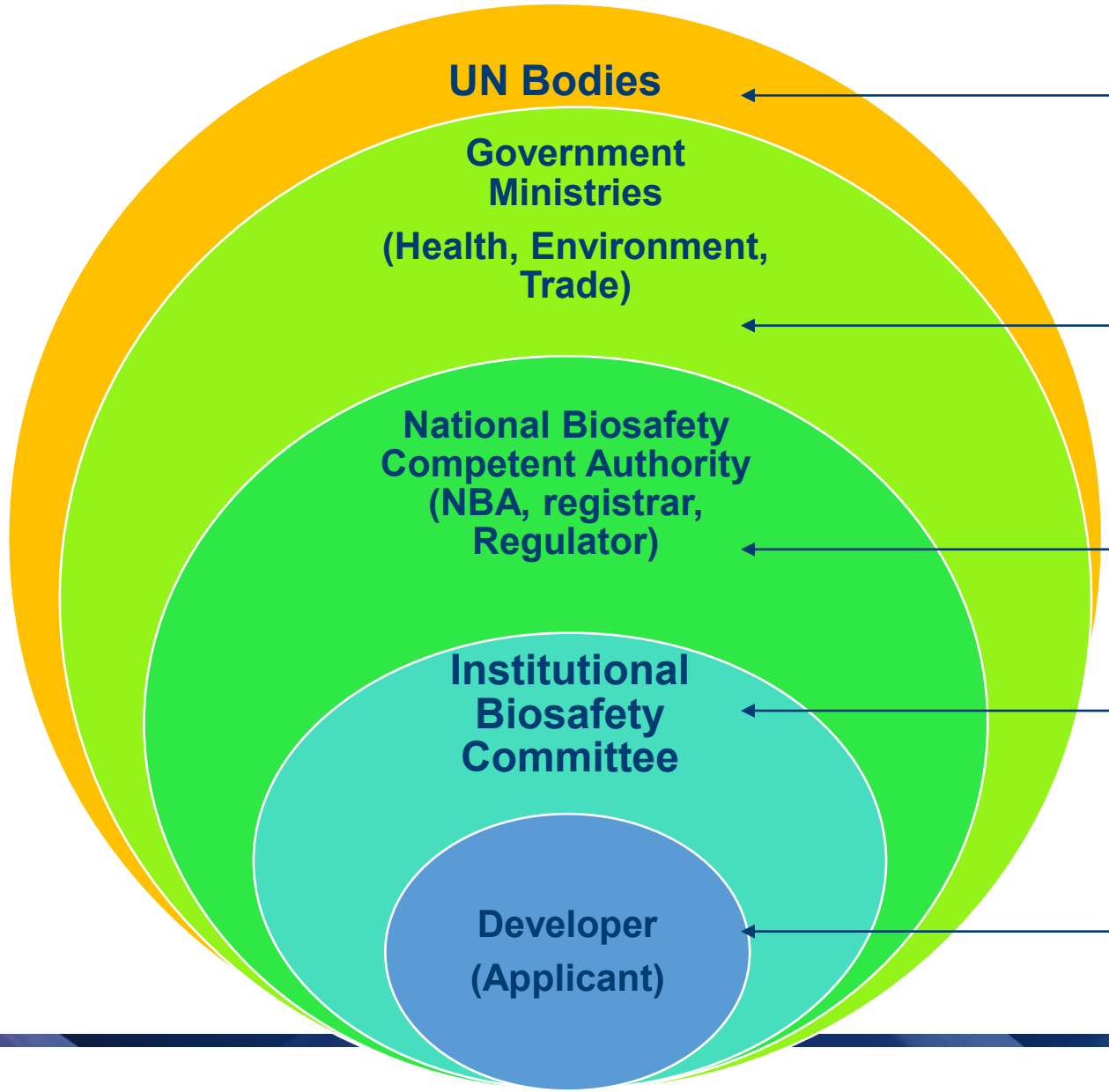
National Consideration



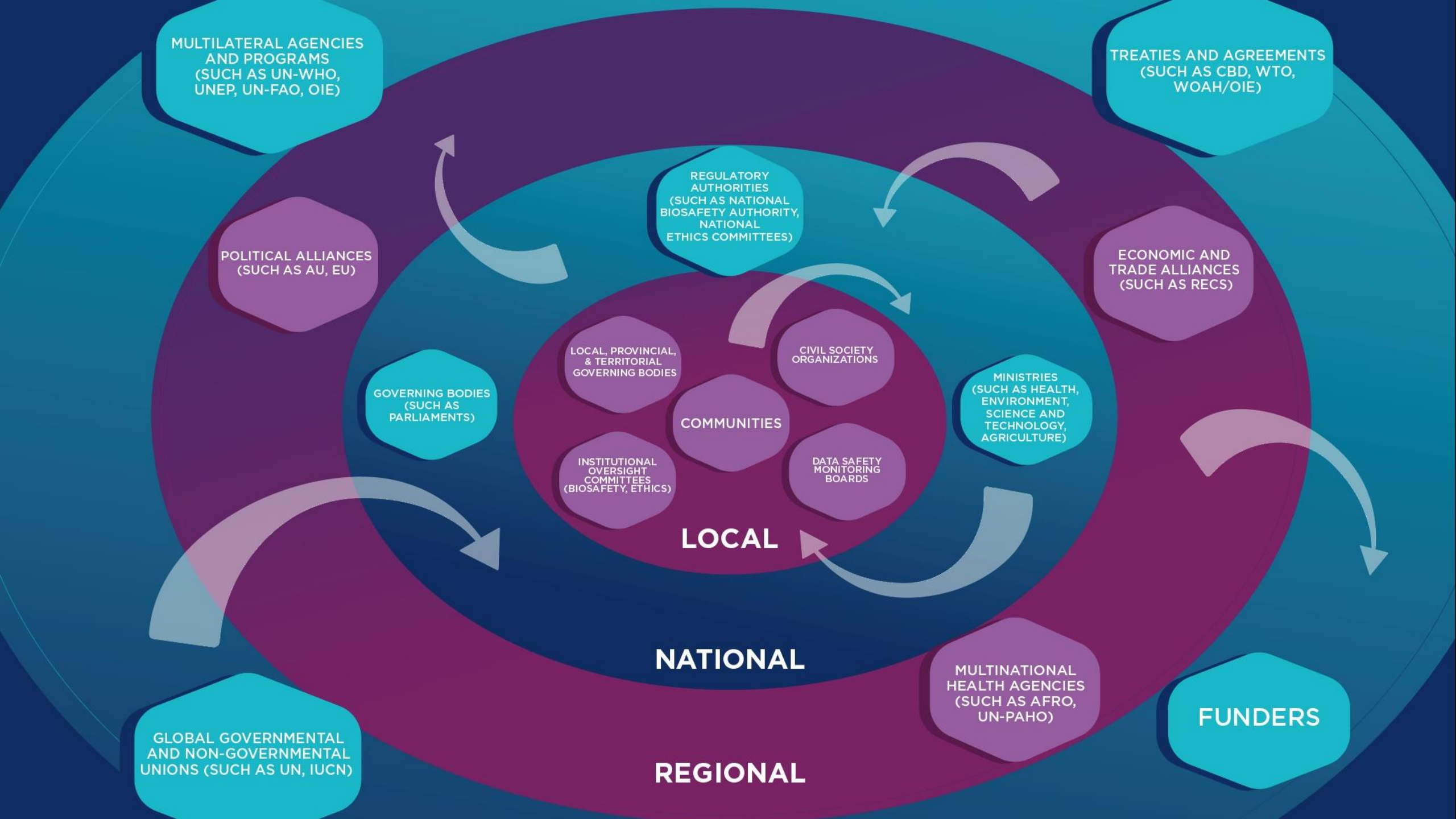
United Nations Convention on Biological Diversity (CBD), as implemented through the Cartagena (CPB) International agreements that aim to ensure safe handling, transport, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on biodiversity and risks to human health.

Ministry (ies): Federal government entity responsible for developing laws and policies, exercises authority and supervisory capacity of the Competent Biosafety Regulatory Authority (NBA)

Federal regulatory agency authorizes applications and ensures responsible trial conduct as per parent Ministry

Group chartered by a research institution responsible for implementing policies and guidelines. Ensures safety of researchers, laboratory workers, research subjects, the public and the environment.

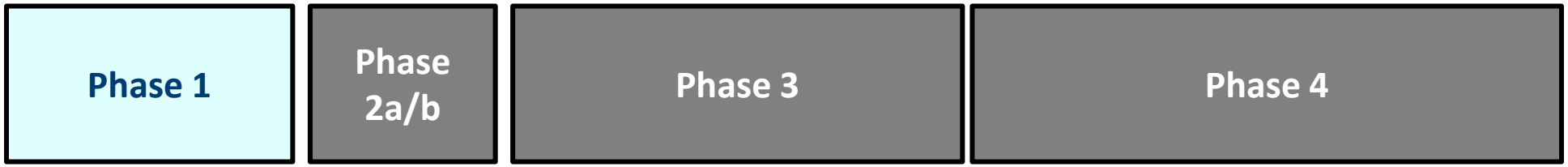
Individual or institution -Seeks authorization to develop and test EGDM


MULTILATERAL AGENCIES AND PROGRAMS (SUCH AS UN-WHO, UNEP, UN-FAO, OIE)
TREATIES AND AGREEMENTS (SUCH AS CBD, WTO, WOAH/OIE)
REGULATORY AUTHORITIES (SUCH AS NATIONAL BIOSAFETY AUTHORITY, NATIONAL ETHICS COMMITTEES)
POLITICAL ALLIANCES (SUCH AS AU, EU)
ECONOMIC AND TRADE ALLIANCES (SUCH AS RECS)
LOCAL, PROVINCIAL, & TERRITORIAL GOVERNING BODIES
CIVIL SOCIETY ORGANIZATIONS
GOVERNING BODIES (SUCH AS PARLIAMENTS)
MINISTRIES (SUCH AS HEALTH, ENVIRONMENT, SCIENCE AND TECHNOLOGY, AGRICULTURE)
COMMUNITIES
INSTITUTIONAL OVERSIGHT COMMITTEES (BIOSAFETY, ETHICS)
DATA SAFETY MONITORING BOARDS
LOCAL
NATIONAL
MULTINATIONAL HEALTH AGENCIES (SUCH AS AFRO, UN-PAHO)
FUNDERS
GLOBAL GOVERNMENTAL AND NON-GOVERNMENTAL UNIONS (SUCH AS UN, IUCN)
REGIONAL

WHO WE ARE

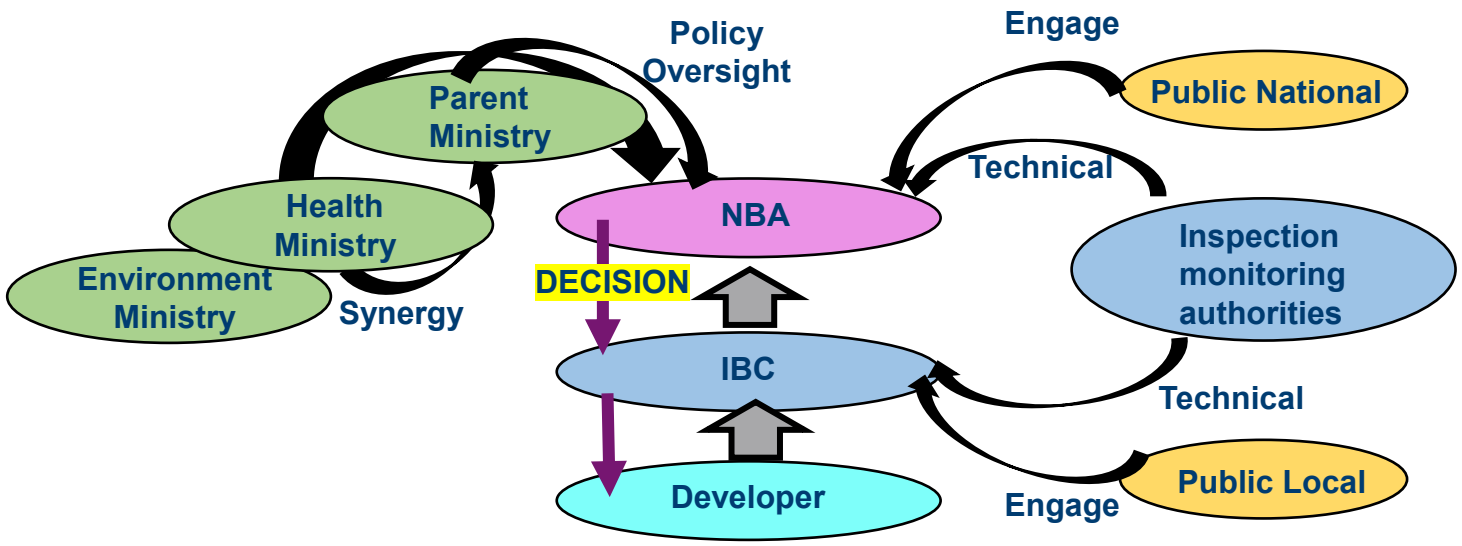
Partner with stakeholders

EGDO Development- Phase 1

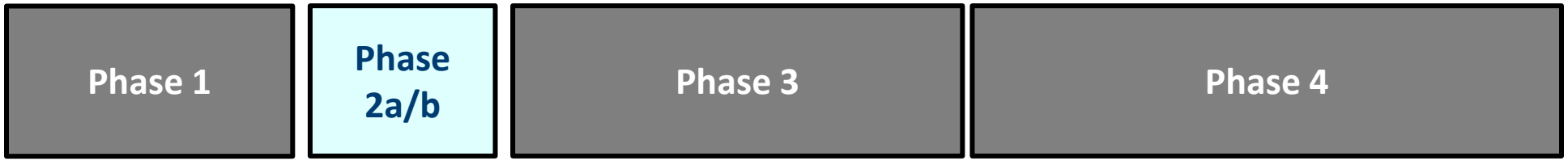


BIOSAFETY

- Engage IBC
- Import permit
- Inspection of facility, validation of containment
- Dossier for proposed work
- Monitoring plan (for EGDO)
- Detection method (validated)
- Remediation options/ plan
- Environmental Risk Assessment-ERA
- Stakeholder engagement
- Research permit and terms
- Public engagement

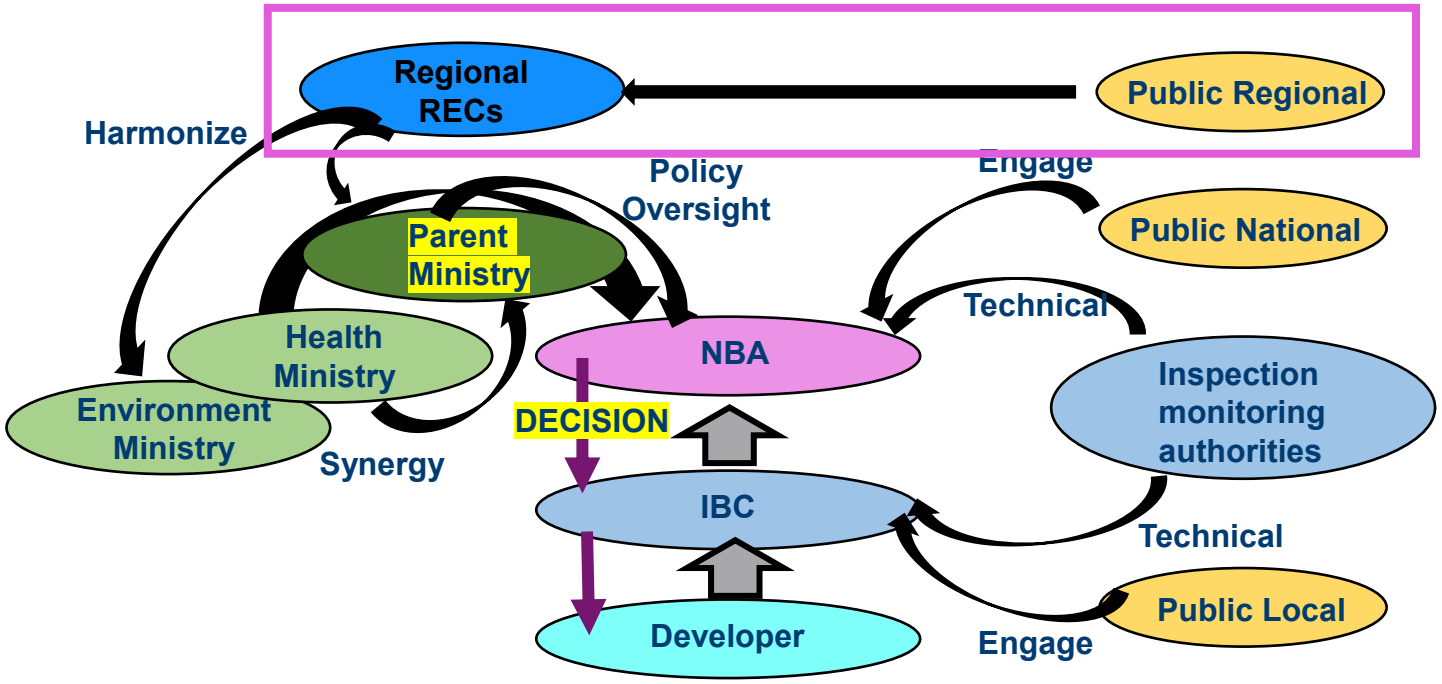


EGDO Development- Phase 2

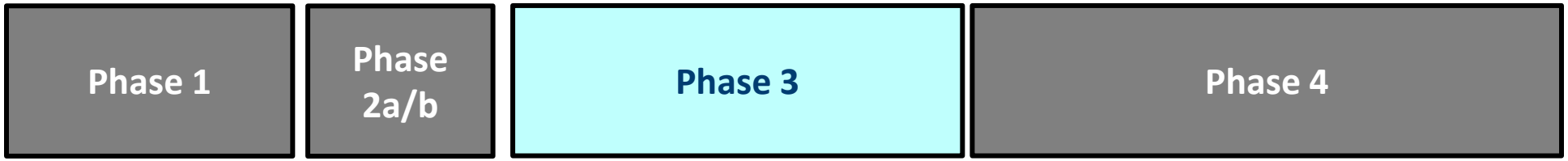


EFFICACY (entomological)

- Engage IBCs, NBAs
- Multiple ministries- Environment, Health, Biocontrol
- Facility Inspection- Quality Stds.
- Dossier for proposed work
- Monitoring plan (for EGDO & **Environment**)
- Remediation options/ plan; recall
- Environmental Risk Assessment
- **ESHIA**
- Stakeholder engagement
- Research permit and terms ⟹ Scale up
- Public engagement/ communication
- **Transboundary effects-** Regional

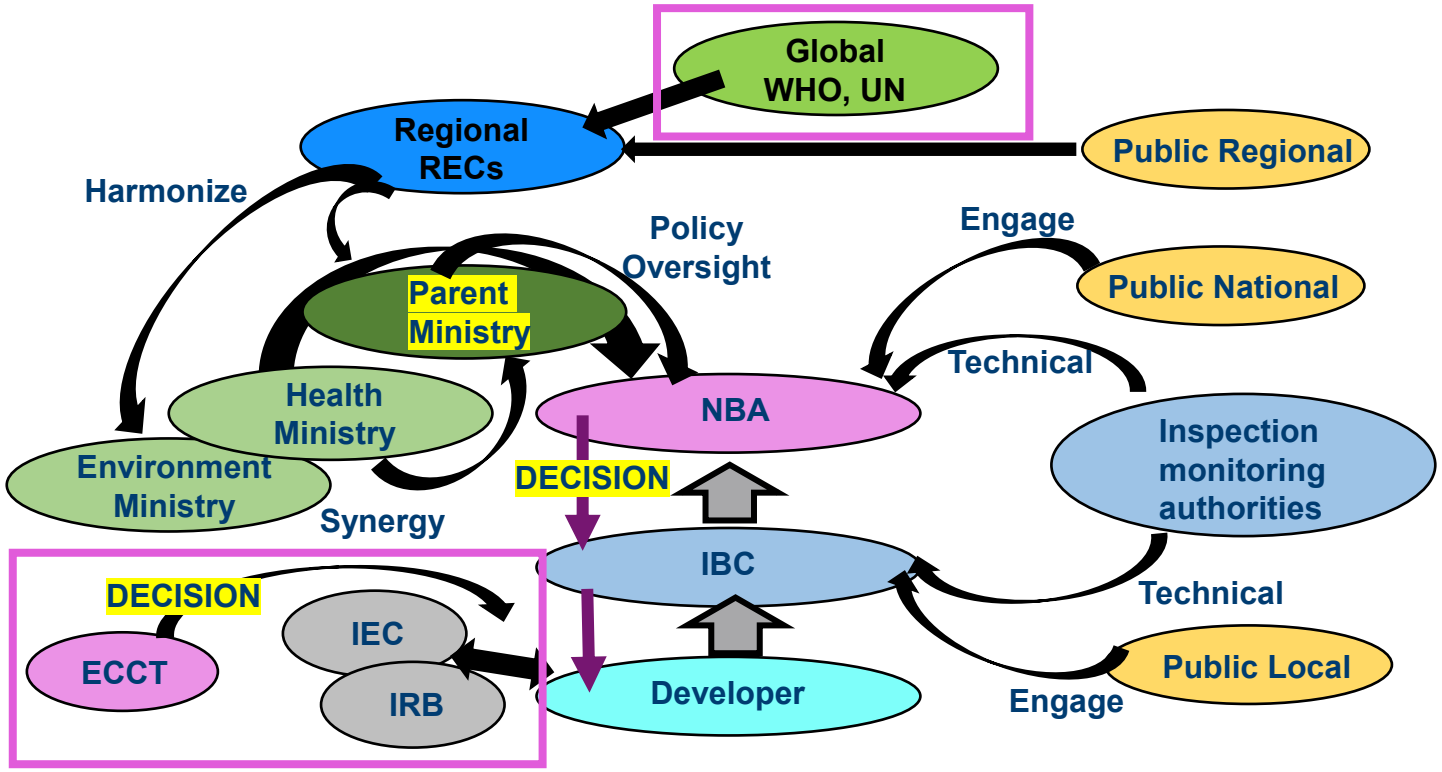


EGDO Development- Phase 3

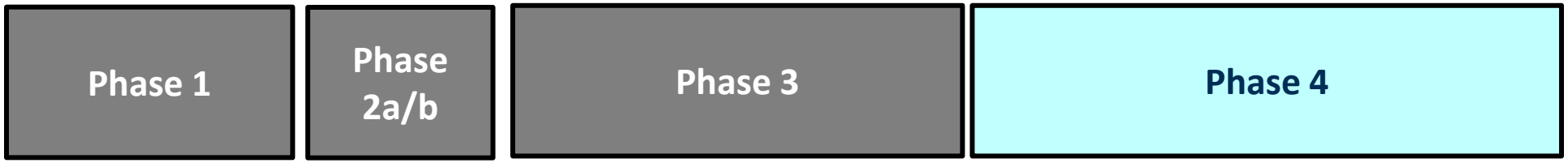


EFFICACY (epidemiological)

- Engage **IEC, IRB, ECCT, DSMB**
- **Health ministry**- national, regional
- **Facility Inspection-** GCP, GMP
- Clinical **trial design, registration**
- Monitoring plan (for EGDO, Environment, **Public Health**)
- Remediation options/ plan, standard of care
- Environmental Risk Assessment, ESHIA
- Stakeholder engagement, Consent
- **Trial terms** → Scale up
- Public engagement/ communication
- Transboundary effects, liability- Regional
- **WHO, REC-MRH**
- **TPP, Cost analysis**

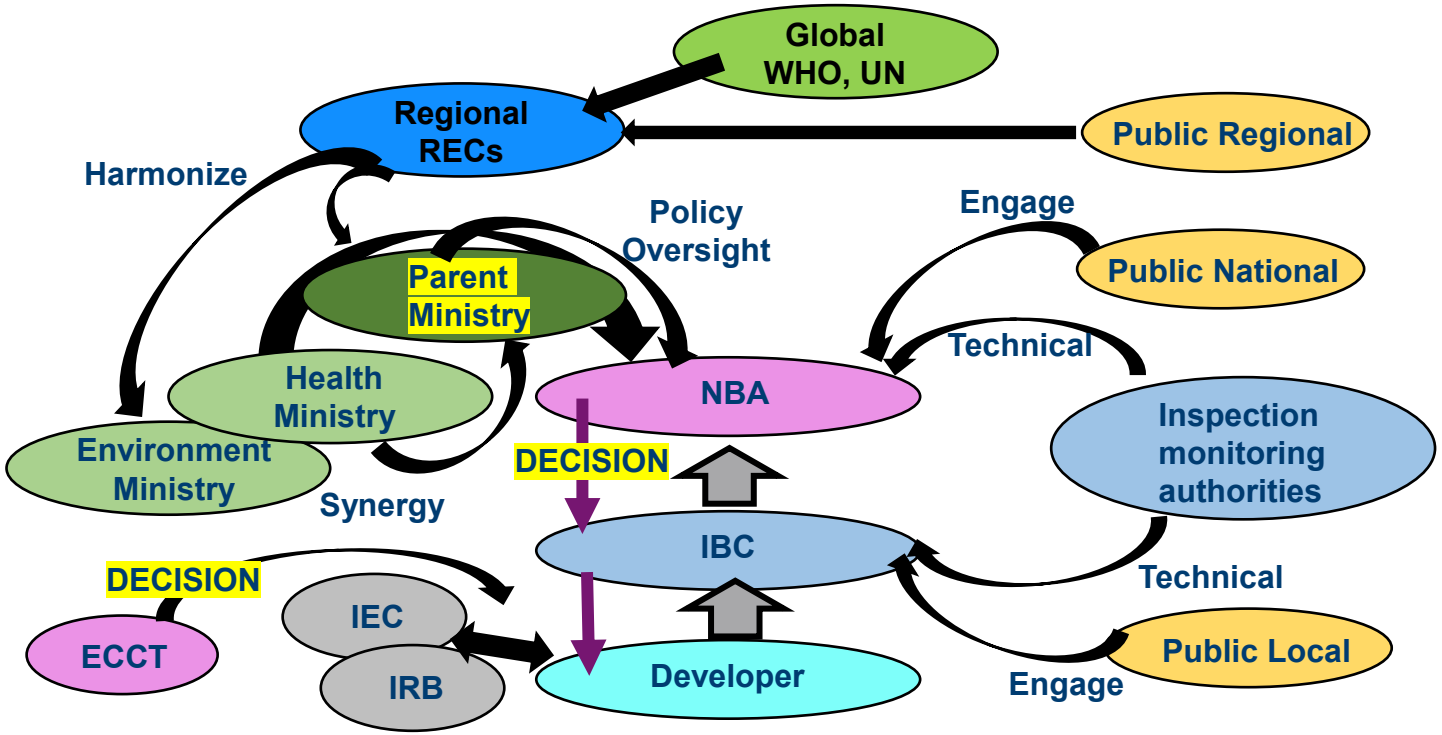


EGDO Development- Phase 4



Post-market Performance & Monitoring

- Monitoring plan (for EGDO, Environment, Public Health)
- Surveillance for AEs
- Remediation options/ plan, standard of care
- Stakeholder engagement
- Public engagement/ communication
- Transboundary effects, liability- Regional
- WHO, REC-MRH-Product registration
- Follow-on product interaction



EGDO Development

Stage 1 Identify Needs & Design	Stage 2 Begin Research & Development	Stage 3 Plan for Introduction	Stage 4 Introduce & Scale
Define problems & design requirements	Evaluate market feasib. & potential for scale	Develop & execute operational launch plan	Monitor execution and optimize

DRUG

							Phase 4		
Problem definition & vision	Design	Discovery Pre-clinical	Phase 1	Phase 2a/b	Phase 3	Regis-tration	Launch	Uptake	Market matures

GMM (WHO)

IMPORTANT TERMS

- **LAWS (basis; Act, Bill, Law)**
  - rules or code of action that are binding and enforced by a controlling authority

- **REGULATIONS (implementation; order, decree, rule, regulation, ordinance)**
  - legal interpretation of enacted legislation
  - Translates law into action

- **POLICY & GUIDANCE (non-binding; guidelines)**
  - More detailed information on requirements that allow regulations to be met