Case Study on Biosafety System in Moldova and the Updated Outcomes of the CBD Expertise for SynBio

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Biosafety in Moldova

- Ratification of the Cartagena protocol on Biosafety of the CBD, 2000.
- National Law on Biosafety, 2001.
- NCA – Ministry MADRE, 2003.
- National Biosafety Commission, 2003.

- Ratification of Aarhus Convention on public access to information and decision making, 1999.
- Ratification of Amendment to the Aarhus Convention (Almaty, 2005) on public access to decision making in the field of Biosafety, 2008.
- National BCH website and database.
- BCH system of the Cartagena Protocol on Biosafety, updated information.
- New law on GMOs, elaborated in accordance with the Association Agreement Moldova-EU, 2016 (in Parliament).

NATIONAL BIOSAFETY FRAMEWORK

National Biosafety Committee

Ministry Ecology and Natural Resources

Center Testing and Risk Assessment

Technical Group of the NBC

Ministries and Departments

Agriculture

Health Care

Academy of Sciences

Technical Biosafety Committees of the Ministries

Monitoring, Inspection, Control

Ecological Inspection

Agriculture Inspections

Health Care Inspections

Customs Inspection

Dep. Exceptional Situations

Dep. Metrology and Standards

BCH and GMO Register

Stakeholders and Public

Business, Farmers, Local Administration, NGOs, Communities

Activities GMOs

Production
Import
Export
Uses

AUTHORIZATION

Key points of the NBF

- National Competent Authority and NFP
- Notification
- Risk assessment
- Scientific opinion – National Biosafety Commission
- Public information and consultation
- Transparent Decision making/authorisation
- Monitoring and control
- Labelling
- BCH

Reference Lab for LMO detection

- 2015 **- Laboratory of Molecular Biology** (LMB) of the Central Phytosanitary Laboratory, **National Agency for Food Security** (ANSA).
- Specific testing equipment for PCR method Uniplex, Classic Multiplex and Real-Time.
- 2016 - LMB **accredited** to provide GMO testing, and in 2017 - for testing of Flavescence golden phytoplasm, the accreditation is in accordance with **ISO 17025**.
- 2018 - the laboratory performed **42 tests** for the detection of GMOs (37 for soy and products containing soy and 5 for maize),
- 2019 so far **21 tests** were performed at GMOs (10 for soybeans and 11 for maize), the samples in particular coming from the State Monitoring Plans.

- The laboratory is able currently to carry out tests for GMO detection of *soy, corn and rape* products.

Moldova's case study. Public information and participation at national level

- **Art.39 of the Law on Biosafety** require application pf principle of transparency during the procedures of notification and authorization of deliberative release of LMOs to the environment and placing to the market. The transparency in case of contained use of GMOs is a responsibility of National Biosafety Committee
- Art. 24.p.C provision on **labelling** for LMOs products and seeds (1%, 0,3%)
- **National Biosafety Committee** is represented by governmental bodies, academia, education **and NGOs**
- **Special Guidelines** is developed to ensure Mechanism for Public information and PP /confidential information
- **BCH system** involving stakeholders network and website available for public and strengthen capacities of Biosafety Committee
- **National Register** for interested public

Finding Information
- National Contacts
- Laws and Regulations
- Country's Decisions and other Communications
- Submissions
- Risk Assessments
- Roster of Experts
- LMOs, Genes or Organisms
- National Reports
- Capacity-Building
- Organizations
- The BCH Virtual Library

Survey on indicators (2014)

Compiled Information
- National Contacts
- LMO Registry
- Organism Registry
- Gene Registry

Go to record ID [ ] Go

Search results

Group records by [ ]
Sort records by [ ]

Display Type [Listing]
Results per page [25]

Export results to CSV file
Subscribe to RSS feed updates for this search

ID	Description		
3 record(s) found			
109126	**Republic of Moldova** Approval of the import/use of the LMO(s) with conditions	MON-89788-1 Soya bean, Soya, Soybean, SOYBN	
109127	**Republic of Moldova** Approval of the import/use of the LMO(s) with conditions	MON-877Ø1-2 Soya bean, Soya, Soybean, SOYBN	
109128	**Republic of Moldova** Approval of the import/use of the LMO(s) with conditions	MON-Ø4Ø32-6 Soya bean, Soya, Soybean, SOYBN	

BIOSECURITATEA ÎN MOLDOVA

CBD

Ministerul Ecologiei şi Resurselor Naturale

- căutare in site - OK

ro | en | ru

- **BIOSECURITATE GENERAL**
  - Protocolul de la Cartagena
  - Cadrul Național de Biosecuritate
  - Legea privind Biosecuritatea
- **BCH - MANAGEMENT CENTER**
  - BCH - Portalul central
  - BCH - Reteaua Națională
  - BCH - Training site
  - **Registering data**
- **LOCALIZARE INFORMAȚIE**
  - **Contacte naționale**
  - **Legi şi regulamente**
  - **Decizii şi autorizații**
  - **Capacități instituționale**
  - Registru de experți
  - Registrul Național pentru OMG
- **CENTRUL DE RESURSE**
  - **Testarea OMG**
  - **Cercetări biotehnologice**
  - **Publicații**
  - **Resurse publice**

Convention on Biological Diversity

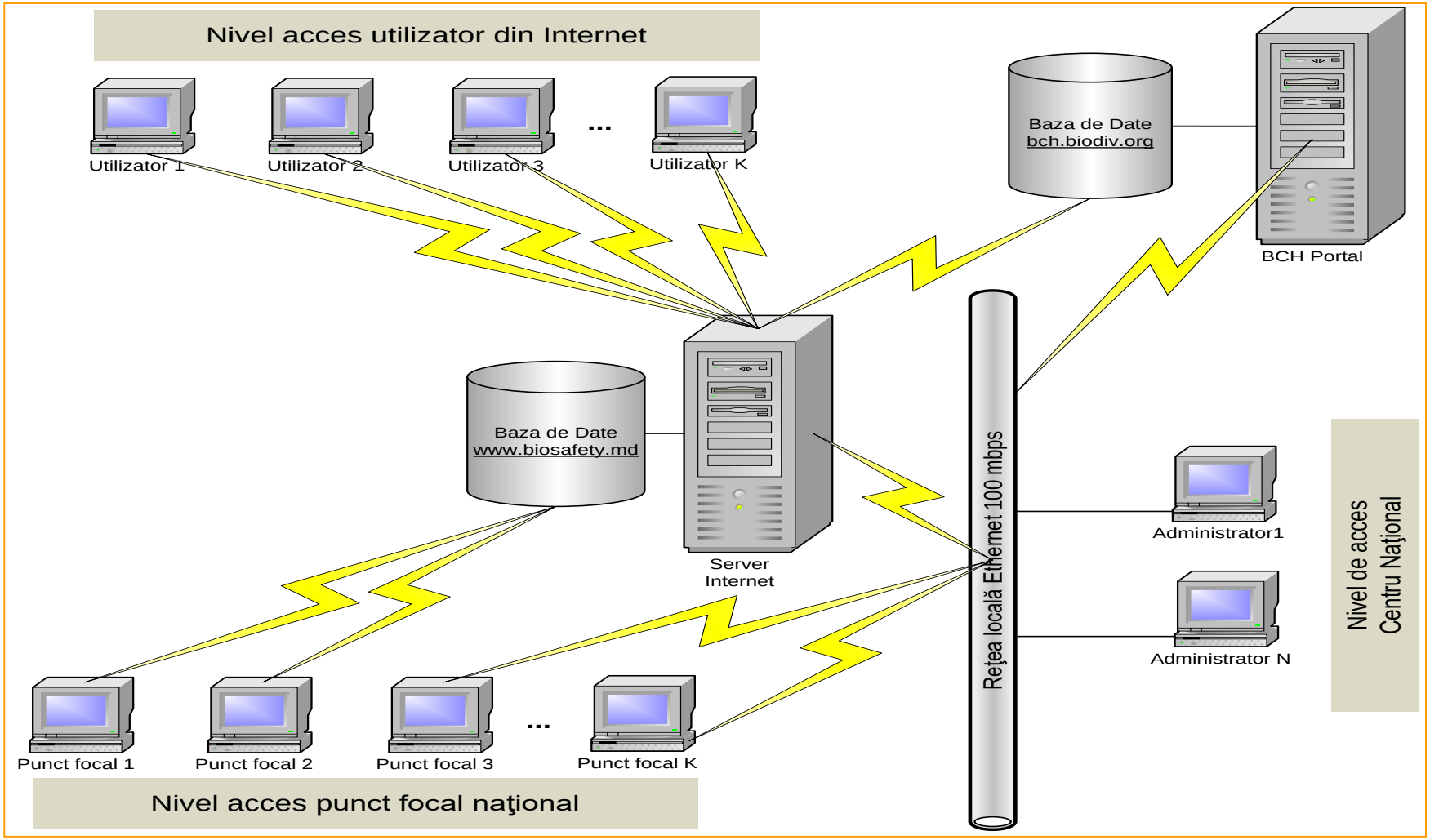
Global Environment Facility

United Nations Environment Programme

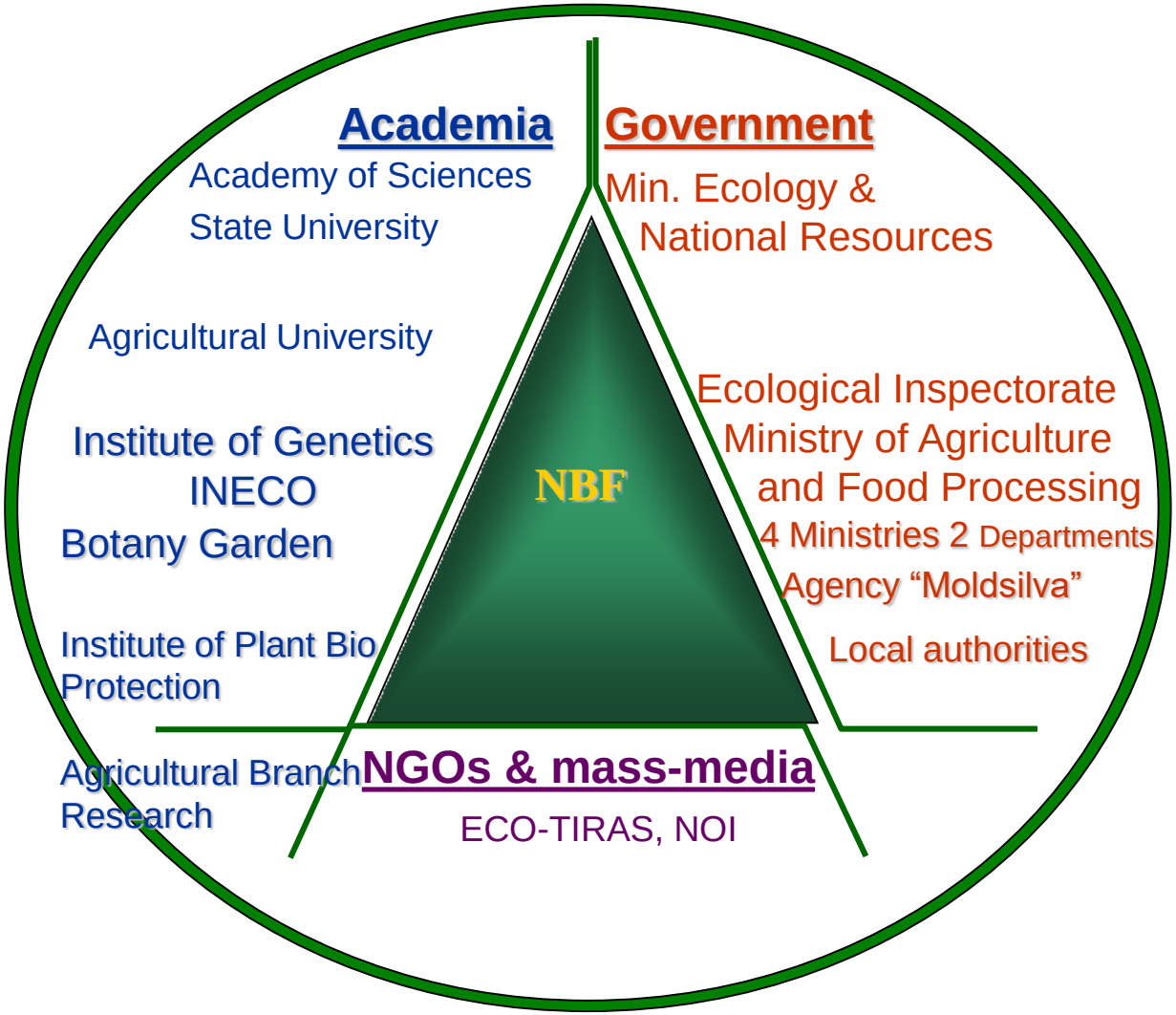
Ministry of Ecology and Natural Resources

La 29 ianuarie 2000 la o întâlnire extraordinară a **Conferinței Părților la Convenția privind diversitatea biologică** (Montreal, Canada), a fost adoptat Protocolul de la Cartagena privind Biosecuritatea. Acest document la nivel global reglementează activitățile legate de asigurarea unui nivel adecvat de protecție pentru siguranța transferului, manipulării şi utilizării organismelor modificate genetic rezultate din biotehnologiile moderne şi care pot avea efecte imprevizibile asupra conservării şi utilizării durabile a diversității biologice, ținând de asemenea cont de riscurile pentru sănătatea umană şi concentrându-se în special asupra mişcării lor transfrontaliere. Semnarea Protocolului a fost calificată drept un pas semnificativ prin faptul că el asigură cadrul internațional de reglementare pentru reconcilierea necesităților respective de comerț şi protecție a mediului în privința industriei biotehnologice. Astfel, Protocolul creează un mediu favorabil pentru aplicarea ecologică a biotehnologiei moderne, ceea ce permite utilizarea echitabilă a beneficiilor din potențialul oferit de biotehnologie, minimizând în acelaşi timp riscurile pentru mediu şi sănătatea umană.

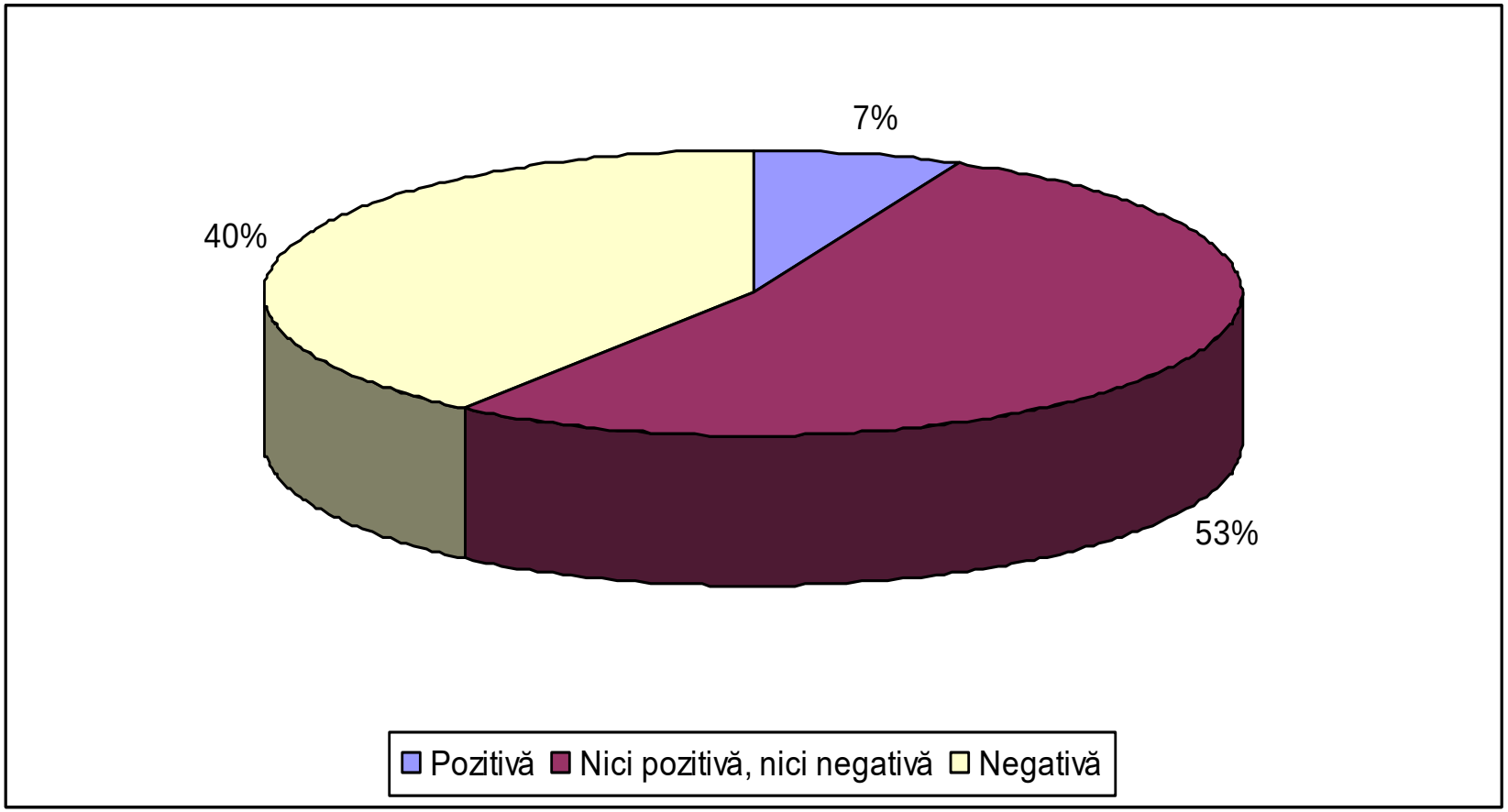
Architecture of the BCH system in Moldova
General scheme



Stakeholders' partnership



What is your attitude regarding perspectives of GMOs use in Moldova?



The Cartagena Protocol
What's new
About the Protocol
Text of the Cartagena Protocol
Strategic Plan
Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress
Key Protocol Issues
Assessment and Review
Capacity Building
Compliance
Financial Mechanism
Mainstreaming
Handling, Transport, Packaging and Identification
Information sharing
Monitoring and Reporting
Public Awareness and Participation
Risk Assessment
Risk Management
Roster of Experts
Socio-economic Considerations
Transit and Contained Use
Unintentional Transboundary Movements
Post-2020
Background
Global Biodiversity Framework and biosafety
Implementation Plan for the Protocol
Action Plan for Capacity Building
Liaison Group
Submissions
Parties
List of Parties
Becoming a Party
National Contacts

Home | The Cartagena Protocol | Parties | List of Parties | Country Profile

Country Profile

Profile information and status	
Country	**Republic of Moldova**
Date of signature	2001-02-14
Date of ratification	2003-03-04
Date of entry into force	2003-09-11
Profile revision	-
Profile status	Published
Profile last updated on	-

Type of document	Number of records	Date of last update
Biosafety Expert	1	2019-02-21
Capacity Building Needs and Priorities	1	2010-05-18
Competent National Authority	2	2018-03-05
Country's Decision or any other Communication	3	2015-11-03
Law, Regulation or Guideline	5	2015-11-02
National Database or Website	1	2018-03-05
National Focal Point	2	2019-06-07
News	5	2016-09-22
Report on Assignment	0	-
Risk Assessment	1	2015-11-03
Reports on Implementation of the Protocol	3	2015-10-31
Total number of records	**24**	

Notes

Link to this country's profile under the FAO GM Foods Platform: http://www.fao.org/food/food-safety-quality/gm-foods-platform/browse-information-by/country/country-page/en/?cty=MDA

AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

Montreal, June, 2019

AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

At its fourteenth meeting, the Conference of the Parties to the Convention on Biological Diversity adopted **decision 14/19** on synthetic biology:

- *New technological developments* in synthetic biology.
- Synthetic biology applications that are in *early stages of research* and development, vis-à-vis the **three objectives of the Convention.**
- Synthetic biology organisms that *may fall outside the definition of living modified* organisms as per the Cartagena Protocol.
- The *state of knowledge on the potential environmental impacts* of applications of synthetic biology, including those applications that involve organisms containing engineered gene drives.
- Options for ***regular horizon scanning, monitoring and assessing*** of developments.

I. NEW TECHNOLOGICAL DEVELOPMENTS IN SYNTHETIC BIOLOGY

- Increased ***field testing*** of organisms, components and products derived from new developments in synthetic biology;
- Increased development of technologies that genetically modify organisms ***directly in the field***;
- A shift to the development of synthetic biology for ***environmental, conservation, agricultural and health uses;***
- Increasing sophistication of methods, including, for example, new ***genome editing techniques, more complex metabolic engineering, the recoding of genomes, and the use of artificial intelligence/machine learning*** for the redesign of biological systems;
- The use of ***transient modification of organisms***, including, for example, through the use *of synthetic double-stranded RNA molecules, nano-particles and genetically modified viruses*;
- Ability to produce new synthetic biomolecules using ***non-canonical nucleotides and amino acids***;
- The use of synthetic biology for ***non-biological purposes***, for example in data storage.

II. SYNTHETIC BIOLOGY APPLICATIONS THAT ARE IN EARLY STAGES OF RESEARCH AND DEVELOPMENT, VIS-À-VIS THE THREE OBJECTIVES OF THE CONVENTION

– Applications intended for use in the *environment in managed and wild populations*:
  - Genetically engineered ***nitrogen-fixing bacteria*** and other genetically engineered bacteria/viruses for agriculture;
  - Genetically ***engineered bacteria*** for such environmental applications as *bioremediation, biodegradation and biomining*;
  - ***Engineered gene drive system in mice*** for conservation purposes, control of *vector-borne disease* and agricultural pests, medical research;
  - ***Engineered gene drives in a few mosquito*** species for potential control of vector-borne diseases;
  - ***Engineered gene drive for an agricultural pest*** (spotted wing *Drosophila*);
  - Genetically engineered sorghum to ***produce a new synthetic protein*** (for food and feed);
  - ***Insect delivery of modified viruses*** for the modification of crops (for biodefense, agriculture);
  - ***Improving the resilience*** of wild animal and plant populations (corals);
  - ***Transient modification*** of agricultural plants (**non-living biopesticide**);
  - ***Cyanobacteria production*** platforms (*fuels and fine chemicals*).

II. SYNTHETIC BIOLOGY APPLICATIONS THAT ARE IN EARLY STAGES OF RESEARCH AND DEVELOPMENT, VIS-À-VIS THE THREE OBJECTIVES OF THE CONVENTION

- Applications intended for use in the *laboratory:*
  - Development of ***protocells and minimal cells*** for basic research;
  - Applications ***to produce non-native nucleotides and amino acids*** inside the cell (novel engineered synthetic pathways) for basic research and production of pharmaceuticals;
  - Development of ***synthetic virus-like assemblies for drug delivery and vaccine applications*** (synthetic nucleocapsids) for human health and perhaps animal health;
  - ***Re-creation of an extinct infectious horsepox virus*** from chemically synthesized DNA fragments, for the purpose of creating a smallpox vaccine;
- Applications with intended use in *both the environment and the laboratory:*
  - Genetically engineered ***bio-containment systems*** within the cell;
  - ***Biofoundries (***i.e., highly automated service laboratories) that engineer microbes for a variety of purposes;
  - Genetically engineered plants to ***produce recombinant polyclonal antibodies*** against *snake venom toxins*.

III. SYNTHETIC BIOLOGY ORGANISMS THAT MAY FALL OUTSIDE THE DEFINITION OF LIVING MODIFIED ORGANISMS AS PER THE CARTAGENA PROTOCOL

- It was acknowledged that both **virus-like macromolecular assemblies** and **protocells** were not living organisms.
- Views differed on whether organisms whose **genomes had been edited without the use of nucleic acids** using only protein reagents introduced into the cell;
- The AHTEG considered that it was unclear whether some **transiently modified organisms** fall within or outside the definition of “living modified organism”.

- It was noted, however, that the Convention contains a **definition of “biotechnology”** which is broader than the definition of “**modern biotechnology”** in the Cartagena Protocol.

IV. THE CURRENT STATE OF KNOWLEDGE BY ANALYSING ON THE POTENTIAL POSITIVE AND NEGATIVE ENVIRONMENTAL IMPACTS OF SYNTHETIC BIOLOGY, INCLUDING ENGINEERED GENE DRIVES, TAKING INTO ACCOUNT HUMAN HEALTH, CULTURAL AND SOCIOECONOMIC IMPACTS, INDIGENOUS PEOPLES AND LOCAL COMMUNITIES

- Assessing the current state of knowledge, including environmental, human heath, cultural, socioeconomic and ethical dimensions as well as the implications for indigenous peoples and local communities:
  - Information on the **potential receiving environment** and **its interaction** with some organisms, products and components of synthetic biology intended for release into the environment;
  - Analytical tools to **detect, identify and monitor** some organisms, products and components of synthetic biology;
  - Tools to **complement risk assessment methods**, e.g. regarding assessment of ethical, cultural and socioeconomic factors, including potential benefits, in addition to environmental and human health factors.

Potential adverse effects identified by the AHTEG

- (a) An engineered fitness advantage ***may lead to invasiveness***;
- (b) Enhanced gene flow that ***leads to loss of biodiversity***;
- (c) An increased ***pathogenic potential***;
- (d) Increased levels of ***toxic substances***;
- (e) Negative effects on ***non-target organisms***, such as pollinators;
- (g) Applications that are aimed at ***altering and replacing natural populations*** (for example, gene drive systems) may have adverse effects at the ecosystem level;
- (j) Gene flow may lead to ***adverse effects on agrobiodiversity***;
- (k) *Loss of market* share and income by ***indigenous and local communities***;
- (m) Inappropriate access ***without benefit-sharing*** due to the use of sequenced data without material transfer agreements under the Nagoya Protocol.

Additional potential adverse effects

- (a) Misuse of synthetic biology technology to create and develop ***bio-weapons for use in bioterrorism***;
- (b) The potential integration of ***cell-free components*** and circuits into living cells;
- (f) *Gene drive applications* could be highly invasive at small release numbers and could result in **unintentional transboundary movements**;
- (g) The removal of a specie from the environment ***using a gene drive*** could facilitate the introduction of a ***new disease vector*** though environmental filling;
- (h) Unexpected outcomes of *gene drives* could ***detrimentally affect biodiversity*** (e.g. recombination to produce more invasive, self-sustaining drive;
- (i) *Gene editing* could have the potential to ***produce CRISPR-resistant viruses*** through evolution;
- (j) *Gene editing* could produce unknown or unexpected results through ***on- or off-target mutagenesis*** or through accidental RNA editing by a DNA editor.

Risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology

- The *general principles and methodologies for risk assessment* under the Cartagena Protocol and existing national biosafety frameworks, as well as **voluntary guidance on RA**, could provide a good basis for risk assessment of organisms developed through synthetic biology and should be updated as followed:
- (a) The **lack of suitable comparators** in cases whereby organisms developed through techniques of synthetic biology;
- (b) Knowledge gaps in assessing **unintended effects** that might result from complex changes and novel traits;
- (c) Knowledge gaps in assessing **interactions of combinatorial and cumulative effects** of multiple organisms developed through synthetic biology being released in the same environment;
- (d) Lack of experience with the introduction of **organisms containing engineered gene drives** into natural populations.
- Current strategies for risk management and monitoring of LMOs might provide a good basis for managing the risks and monitoring potential impacts of organisms developed through synthetic biology.

V. OPTIONS FOR REGULAR HORIZON SCANNING, MONITORING AND ASSESSMENT

- Decision 14/19, paragraph 3, agreed that broad and **regular horizon scanning, monitoring and assessment** of the most recent technological developments was needed for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the **three objectives** of the Convention and those of the Cartagena Protocol and Nagoya Protocol:
- (a) Information gathering; Biosafety Clearing House (BCH);
- (b) Compilation, organization and synthesis of information;
- (c) Assessment;
- (d) Reporting on outcomes.
- Reporting on outcomes should be undertaken primarily by a *multidisciplinary technical expert group*, and approved by *SBSTTA* - the Subsidiary Body on Scientific, Technical and Technological Advice under the CBD.
- All of the information compiled and synthesized **could be made available**, including through the clearing-house mechanism.


THANK YOU FOR YOUR ATTENTION!