

Bioethics in the Field of DNA Testing, Biosafety, Conservation and Sustainable Use of Genetic Resources

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**INTERFERENCE OF SCIENTISTS IN THE GENOME
STRUCTURE CAUSES SERIOUS BIOETHICAL CONCERNS**

ETHICAL ISSUE

BIOENGINEERING

Is it always
necessary to do
whatever can be
done in the field of
gene technologies?



**BIOMEDICAL
ENGINEERING**

**GENETIC
ENGINEERING**

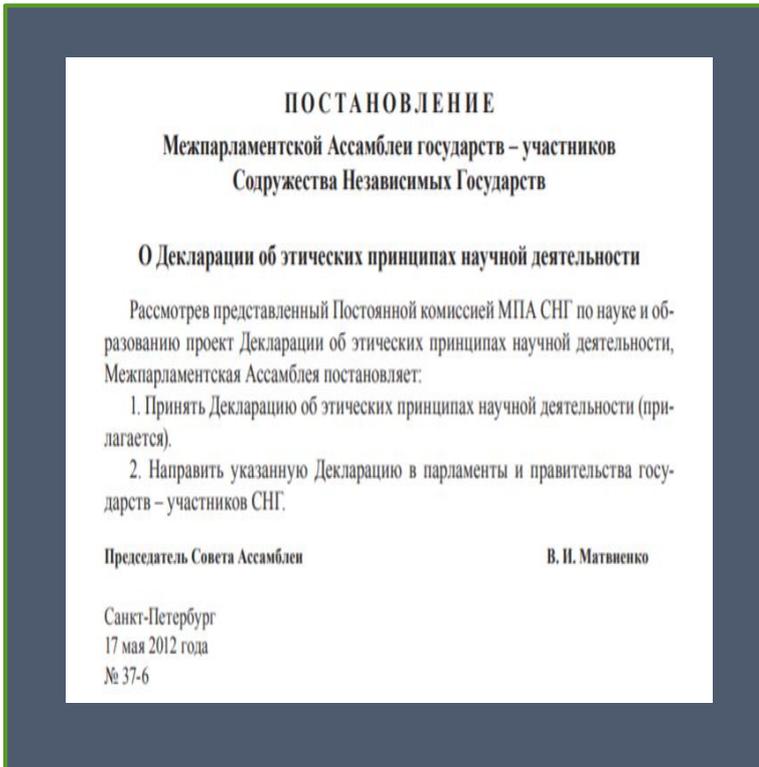
**SYNTHETIC
BIOLOGY**

**CRISPR-CAS
TECHNOLOGIES**

**GENOME
EDITING**

IMPLICATIONS ARE NOT PREDICTED AT THE PROPER LEVEL

DECLARATION ON THE ETHICAL PRINCIPLES IN SCIENTIFIC ACTIVITIES



In 2012, the Interparliamentary Assembly of the CIS Member States adopted the Declaration on the Ethical Principles in Scientific Activities

The Declaration proclaims a standard of ethically grounded scientific activities as a foundation of both its own organization and the public policy to ensure and support it. *The Declaration seeks to proclaim the priority of social responsibility in the activity.*

Article 8

Responsibilities of scientists shall involve:

- a) Precaution with regard to likely adverse humanitarian, social and environmental consequences of scientific activities
- b) Ensured transparency of the methodology and research results for the scientific community and the general public
- c) Openness in relation to intradisciplinary and interdisciplinary intellectual communication
- d) Promoting the dissemination of scientific and technical knowledge for the benefit of society

Pursuant to the order of the Council of Ministers of the Republic of Belarus of July 26, 2005 No. 05/137-143 to exercise public control over the observance of ethical standards and rules when performing activities related to the use of humans and animals as objects of experimental and clinical research to comply with human rights and freedoms when modern scientific advances are applied to him or her and in performing of educational, medical, preventive and other activities, **the National Bioethics Committee was established at the Ministry of Health of the Republic of Belarus as an Advisory Body.**



Areas falling under the scope of Bioethics Committees

- *In the area of scientific research*

These are ethical aspects related to experimental studies on laboratory animals, clinical and experimental use of stem cells, **genetic research**, cell and tissue transplantation, cloning, etc.

- *In the area of clinical tests and registration of new drugs and medical technologies*

Biomedical ethics-related issues during clinical tests of medicines; **the problems related to the use of products containing genetically modified organisms**, etc.;

- *Nature management*

Biosphere aspect, **biotechnology in modern animal breeding**, **ecological ethics and the safety of agricultural products**, **transgenic organisms**, etc.

Bioethics Committee



Bioethics Committee is an independent collegial body that conducts an ethical review of planned or ongoing tests.

Each research project must receive a conclusion – the Bioethics Committee approval.

In 2019, the Bioethics Committee was established at the Institute of Genetics and Cytology, NAS of Belarus.

PREDICTIVE DNA TESTING

MAIN BIOETHICAL PRINCIPLES APPLIED TO PREDICTIVE DNA TESTING VOLUNTARINESS, CONFIDENTIALITY, AWARENESS

BASED ON THE MOLECULAR-GENETIC ANALYSIS, THE RISK OF MULTIFACTORIAL DISEASES IS IDENTIFIED

- **CARDIOVASCULAR**
- **VENOUS THROMBOSIS**
- **OSTEOPOROSIS**
- **METABOLIC SYNDROME**
- **TYPE 2 DIABETES**
- **MISCARRIAGE**
- **HEREDITARY LOSS OF HEARING**
- **EFFICIENT USE OF MEDICINES, etc.**

A **DNA CERTIFICATE** IS DESIGNED BASED ON THE TESTING PERFORMED — INFORMATION ON GENE VARIANTS ALLOWING FOR TARGETED PREVENTIVE ACTIONS WITH REGARD TO THE POSSIBLE DISEASE DEVELOPMENT OF A CONCRETE INDIVIDUAL.



PREDICTIVE DNA TESTING



KEY BIOETHICAL ISSUES

- Results are quite difficult to interpret and they are of indicative (stochastic) nature
- The concepts of “good” or “bad” genes should be avoided
- A person being examined should be fully aware that accurate prediction is impossible
- In cases where the health of relatives of a person under testing is in real danger, which can be prevented, information about high genetic risk can be provided to relatives directly

REPUBLICAN DNA BANK



NGS - NEXT GENERATION SEQUENCING

Overdiagnosis

At the moment, WHO allows testing for genetic predisposition, provided that a voluntary principle is met and based on informed consent.

Three levels of informed consent:

- a. I want to know only what I have ordered.**
- b. I want to know what I have ordered and some of what you have found.**
- c. I want to know everything about myself.**

Streamlined storage of files (the format, how long to store, store for a patient and/or for researchers), should files be given to patients?





PRECAUTIONARY PRINCIPLE

Precautionary principle is based on the assertion that if any kind of activity can potentially cause significant harm, then appropriate measures must be taken to prevent or limit it, even though scientific data do not allow for an accurate assessment of a risk level.

National Coordination Biosafety Centre

It was established in 1998 to ensure effective participation of the Republic of Belarus in addressing a global issue related to the conservation of biological diversity and coordination of activities related to the safe use of modern biotechnology advances under the UN Convention on Biological Diversity and the Cartagena Protocol on Biosafety..



Key directions of its activities:

- Collection, analysis and systematization of information on biosafety legislation and scientific research, field trials, import/export, commercial use of genetically modified organisms (GMO);
- Organization of scientific expertise of GMO safety and products based on them, the testing or use of which is expected in the Republic of Belarus;
- Providing biosafety information to stakeholders;
- Information exchange with Biosafety Centers of other countries and international organizations.

BIOSAFETY BIOETHICS

NATIONAL BIOSAFETY SYSTEM, which includes legislative and normative statutory components to regulate safety in genetic engineering activity, was established in the Republic of Belarus

Law
“ON SAFETY IN GENETIC ENGINEERING ACTIVITY”
of January 9, 2006 No. 96-3

and

the consumer right to obtain information on food product ingredients is entrenched in the **Law**

“On the Quality and Safety of Food Raw Materials and Food Products for Human Life and Health”

And in the **Law “On the Consumer Rights Protection”**



BIODIVERSITY and GENETIC RESOURCES



The last two and a half decades have been characterized by a rapid increase in the utilization of biological (genetic) resources in various fields of production activity.

Genetic resources have become not only an object of commercial interest, but also a reason for intensified “bioprospecting” and “biopiracy.”

The latter has necessitated the adoption of the **UN Convention on Biological Diversity** to **conserve** biological diversity, **sustainably use its components** and **fair and equitably share benefits arising from the utilization of genetic resources** by providing appropriate access to them and transferring appropriate technologies, taking into account all rights over such resources and to technologies, as well as by due financing of such activities.

BIOPROSPECTING BIOPIRACY



BIOPROSPECTING AIMS TO DETECT BIOLOGICAL (GENETIC) RESOURCES AND TRADITIONAL KNOWLEDGE OF A COMMERCIAL VALUE.

BIOPIRACY INCLUDES ACQUIRING, PATENTING AND UTILIZATION FOR COMMERCIAL PURPOSES WITHOUT ANY PERMIT AND COMPENSATORY PAYMENT WITH REGARD TO BIOLOGICAL (GENETIC) RESOURCES AND KNOWLEDGE OF THEIR PROPERTIES – TRADITIONAL KNOWLEDGE OF INDIGENOUS CULTURES.



Catharanthus roseus



Catharanthus roseus contains more than 80 alkaloids derived from indole, including those of an antitumor activity. The raw material to develop an antitumor drug is a plant leaf.



3/4 of the components used today in medications have fallen into the attention of researchers due to their successful utilization in traditional medicine.

Зарегистрировано в Национальном реестре правовых актов
Республики Беларусь 26 мая 2014 г. N 1/15028

УКАЗ ПРЕЗИДЕНТА РЕСПУБЛИКИ БЕЛАРУСЬ

22 мая 2014 г. N 235

О ПРИСОЕДИНЕНИИ РЕСПУБЛИКИ БЕЛАРУСЬ К МЕЖДУНАРОДНОМУ ДОГОВОРУ

1. Присоединиться к Нагойскому протоколу регулирования доступа к генетическим ресурсам и совместного использования на справедливой и равной основе выгод от их применения к Конвенции о биологическом разнообразии, принятому в г. Нагойе 29 октября 2010 года.

Определить Министерство природных ресурсов и охраны окружающей среды органом, ответственным за выполнение обязательств, принятых Республикой Беларусь по указанному международному договору.

2. Совету Министров Республики Беларусь в шестимесячный срок принять необходимые меры по выполнению настоящего Указа.

3. Настоящий Указ вступает в силу со дня его подписания.

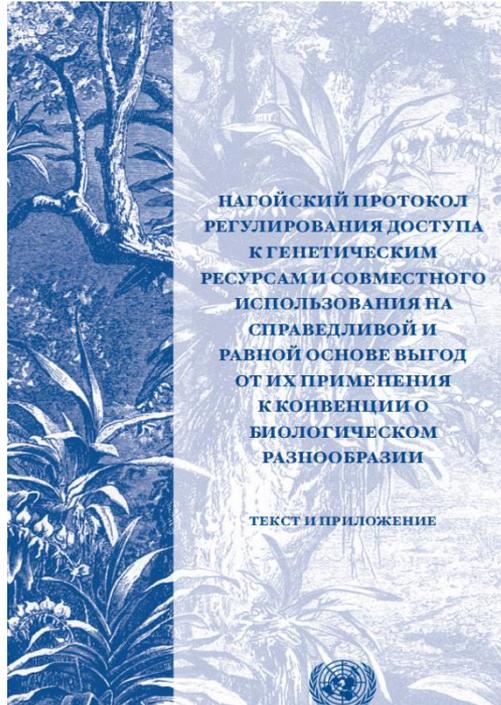
Президент Республики Беларусь

А.Лукашенко



**Holders of genetic resources of
the Republic of Belarus, e.g.
scientific institutions of the
National Academy of Sciences of
Belarus, educational institutions,
National Parks and Reserves,
private organizations, etc.
shall strictly comply with the
Nagoya Protocol Provisions**

Nagoya Protocol to the Convention on Biological Diversity



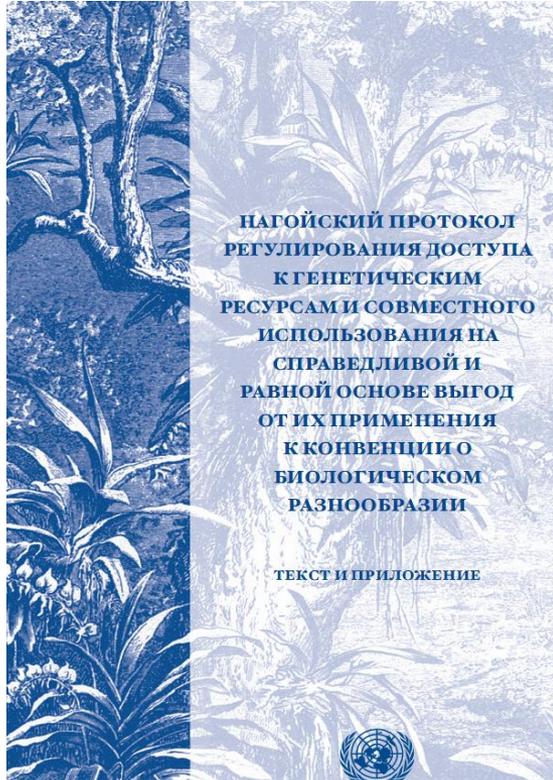
[http:// abs.igc.by](http://abs.igc.by)

The Protocol provides for the legal basis ensuring greater certainty and transparency in the communication of countries providing genetic resources and transferring biotechnologies and countries that utilize them

The Republic of Belarus acceded to the Nagoya Protocol to the Convention on Biological Diversity in May 2014

The National Coordination Centre on Access to Genetic Resources and Benefit-sharing was established at the Institute of Genetics and Cytology, NAS of Belarus

Nagoya Protocol to the Convention on Biological Diversity



Article 20. Codes of Conduct, Guidelines and Best Practices and/or Standards

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation of access and benefit-sharing.



UNDP-GEF “Strengthening of human resources, legal frameworks and institutional capacities to implement the Nagoya Protocol in the Republic of Belarus”

The global goal of the Code of Ethics in the field of building trust between providers and users of genetic resources and related traditional knowledge: **sustainable development of a society is impossible without a moral attitude of a human being to the environment; it is necessary to abandon any actions that could undermine the possibility of existence of future generations or their interests**

The standard part of the Code of Ethics under development contains standards of conduct for providers and users of genetic resources

Key ethical principles remain the principles of **trust, voluntariness and communication based on prior consent**



Thank you for your attention!