

CABINET OF MINISTERS OF UKRAINE

RESOLUTION
No. 734, of 20 August 2008
Kyiv

To approve the Procedure of Issuing Permit on Importation of Unregistered Genetically Modified Organisms into the Customs Territory of Ukraine for Scientific Research or State Approval (Testing) Purposes

Having regard to Article 16 of the Law of Ukraine on State System of Biosafety at Creating Testing, Transporting and Using Genetically Modified Organisms ([1103-16](#)), the Cabinet of Ministers of Ukraine
HEREBY RESOLVES TO:

1. Approve the Procedure of Issuing Permit on Importation of Unregistered Genetically Modified Organisms into the Customs Territory of Ukraine for Scientific Research or State Approval (Testing) Purposes (enclosed).
2. Request the ministries and other central bodies of the Executive to bring their legal regulations in line with this Resolution within three-month term.
3. This Resolution shall come into effect as of 1 January 2009.

YU. TYMOSHENKO,
Prime Minister of Ukraine

Ref No. 28

APPROVED

By Cabinet of Ministers of Ukraine Resolution

No. 734, of 20 August 2008

PROCEDURE
of Issuing Permit on Importation of Unregistered
Genetically Modified Organisms into the Customs
Territory of Ukraine for Scientific Research or State
Approval (Testing) Purposes

1. This Procedure sets forth the procedure of issuing permit on importation of unregistered modified organisms into the customs territory of Ukraine for purposes of scientific research or state approvals (testing) in open and closed systems (hereinafter, 'Permits').

Terms and definitions used throughout this Procedure shall have the meaning provided in the Law of Ukraine on State System of Biosafety at Creating Testing, Transporting and Using Genetically Modified Organisms ([1103-16](#)).

2. The Permit shall be issued to legal entities and natural persons (hereinafter, 'Regulation Entities') for each genetically modified organism (hereinafter, 'Modified Organism') free of charge per Sample Form in Annex 1 on the basis of State scientific and technical expert opinion and with due regard to recommendations issued by the Interdepartmental Commission for Biosafety established with the MES.

3. The Permit shall be valid for the duration of scientific research works and state approvals (testing) but not in excess of five years. Modified organisms may be imported into the customs territory of Ukraine within the validity period of the Permit in numbers necessary for the conduct of such works and approvals (testing).

4. To obtain a Permit, the Regulation Entity must submit to the MES the application as per the Standard Form in Annex 2.

5. The Regulation Entity may submit a substantiated proposal to classify certain information as confidential at the time of applying for permit.

6. The Permit shall be issued:

1) Within 45 working days as of the date of application received by the MES whenever:

Scientific research works or state approvals (testing) held in closed system conditions;

Scientific research works or state approvals (testing) held in open system conditions have been recognised by MES decision as posing no threat to human health or natural environment;

2) Within 90 working days as of the date of application received by the MES whenever such scientific research works or state approvals (testing) held in open system conditions have been recognised by MES decision as posing no threat to human health or natural environment pending certain preventive measures taken;

3) Within 270 working days as of the date of application received by the MES whenever such scientific research works or state approvals (testing) held in open system conditions but for a decision on the granting of permit on be made additional materials are necessary that the Regulation Entity submits within 20 working days as of the date of receiving request to the above effect from the MES.

7. The Permit shall be issued to the Regulation Entity in two original copies. The hard and the electronic copy of the Permit shall be mailed within 10 working days as of the date of permit granting by the Ministry for Natural Environment Protection and the MES also to the address of the State Customs Service to inform the customs authorities in the order established by the State Customs Service and the MES.

8. The Regulation Entity may be refused from the granting of the Permit in the event of receiving scientifically validated information on the harmfulness of such modified organisms to human health and natural environment in the event of their intended use.

9. The MES may cancel the Permit in cases expressly provided for by law.

The information on Permit cancellation shall be forwarded to the Regulation Entity, the Ministry for Natural Environment Protection and the Ministry of Public Health Protection, as well as to the State Customs Services to inform the customs authorities in the order established by the State Customs Service and the MES within 10 working days as of the date of relevant decision adoption by the MES.

10. The decision to decline the granting of the Permit or its cancellation may be appealed against by the Regulation Entity within 30 working days under the established procedure.

11. The permit granting or cancellation notice shall be published on the MES web site.

12. After the expiry of the Permit, the latter shall be returned to the MES together with information on measures taken to dispose of remaining biological matter of the modified organism after termination of scientific research works and/or state approvals (testing).

13. The MES shall not regard as confidential the information related to:

Particular biological features of modified organisms;

Methods of monitoring modified organisms and measures envisaged for out-of-order situations;

Potential negative impact of modified organisms on human health and natural environment.

Annex 1
to the Procedure

State Coat of Arms of Ukraine

MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE

PERMIT

on importation of unregistered modified organisms into the customs
territory of Ukraine for purposes of scientific research or state approvals
(testing) _____
(Please specify the applicable system)

(Registration number) (dd/mm/yy)

Issued to _____
(Name of legal entity or first, second names and patronymic of the
natural person – Regulation Entity)

(Registered address of the legal entity or residential address of the
natural person)

(Phone) (E-mail address)

Valid until _____
(dd/mm/yy)

Name of supplier and country; Registered address (also e-mail address),
phone and fax numbers _____

(Name of genetically modified organism; Code under UCCFEA)

(Scientific name of the genetically modified organism in Ukrainian and
Latin)

(Genetic modification of the genetically modified organism)

(Genetically modified organism lot volume/weight (in SI measurement units))

(Number of lots imported, per annum)

(Name of the enterprise, institution or organisation that/who intends to carry out scientific research works or state approvals (testing))

From _____ to _____
(dd/mm/yy) (dd/mm/yy)

Risk level of the scientific research works and/or state approvals (testing)

Additional terms and conditions _____

(dd/mm/yy)

Authorised office _____

MES (Signature) (Second name and initials)

SEAL

Annex 2
to the Procedure

MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE

APPLICATION

on the Issue of Permit on importation of unregistered modified organisms into the customs territory of Ukraine for purposes of scientific research or state approvals (testing)

Of _____ No. _____
(dd/mm/yy)

(Name of legal entity or first, second names and patronymic of the natural person – Regulation Entity)

(Registered address of the legal entity or residential address of the natural person; phone/fax; e-mail address)

Hereby applies for the Permit on n importation of unregistered modified organisms into the customs territory of Ukraine for purposes of scientific research or state approvals (testing)

(Please specify the applicable system)

(Name of genetically modified organism)

Name of legal entity or natural person that/who intends to carry out scientific research works or state approvals (testing)

(Registered or residential address, phone/fax; e-mail address)

Duration of scientific research works or state approvals (testing): from _____ to _____

Term of disposal after the termination of the above works or approvals (testing):

from _____ to _____

Submitted enclosures:

Notarised copy of the license to genetic engineering activities within the closed system (for the granting of permit on importation of unregistered modified organisms into the customs territory of Ukraine for scientific research or state approvals (testing) purposes;

Copies of documents on official registration, health and disease control and environmental clearance for Ukraine, as well as permits on the using of genetically modified organism in other countries (if applicable);

Information about the genetically modified organism intended for importation into the customs territory of Ukraine in accordance with the Annex to the Application;

Written confirmation of the existence of insurance coverage of activities related to the importation of the genetically modified organism into the customs territory of Ukraine, its transportation, storage, use, and disposal;

The description of the route of genetically modified organisms transportation on the territory of Ukraine and of the scope of measures for preventing their uncontrolled release during transportation;

Sample primers of the transgenic organisms and information about methods of identification of genetic constructs components of modified genes of the genetically modified organism for the purpose of their lab inspection and control (on MES' request);

Written confirmation of authenticity of the submitted documents (materials) authenticated by the Regulation Entity and affirmed by its seal under the established procedure.

SEAL

(Date) (Signature)

Annex to Application Form

1. Information about the genetically modified plant (hereinafter, 'the modified plant') meant for importation into the customs territory of Ukraine shall include:

- 1) Systematic name of the original form of the modified plant in Ukrainian and Latin;
- 2) Taxonomic data of the original form in Ukrainian and Latin: family, genus, species, subspecies, cultivar, line;
- 3) Information on biological aspects of reproduction of the original form: reproduction method and its specific factors; ability to develop structures able to either survive or enter the dormant period; pollen transport ways; top-crossing frequency; interspecific and intergeneric hybridisation capacity (frequency of hybridisation with cultivated and wild kins and hybrid viability); ways of seed material reproduction.
- 4) Possible interaction between the modified plant and other organisms (symbiots, pests etc.) in ecosystems;
- 5) Plant's area; information on the centre of origin and centres of genetic diversity of the original form; optimal natural environment conditions;
- 6) List of genus types deemed weed plants in Ukraine to which modified plants belong;
- 7) Description of added or modified characters;
- 8) Vegetative and/or genesic organs of the modified plant that express the new character characteristic of the functioning of the given genetic construct; the development phase at which the above character is expressed;
- 9) Difference between the modified plant and its original form at the phenotype level, also between reproduction rates, pollen transfer, dormant periods, survivability, and synthesis of toxins;

10) Selection benefits offered by the transgenic sort (hybrid, line) compared against the original form;

11) Taxonomic status; usual name; collection area and production source; biological features characteristic of the donor organism as related to biosafety requirements;

12) Detailed description of the genetic construct transferred:

Genus (genes) name(s);

Description of the donor organism(s);

Genus (genes) origin;

Transformation method;

Vector description;

Description and origin of marker genes, gene promoters and terminators components of the modified plant's genetic construct;

Genetic construct localisation within the plant cell (chromosomes, plastids, mitochondria, non-integrated form);

Genetic stability of the genetic construct;

Replicable ways and methods of such genetic construct identification;

13) Proposals regarding the carrying out of scientific research works or state approvals (testing):

Out-of-order measures (in the event of modified plant accidental release);

Measures on disposal or elimination of the remaining biological material of the modified plant after scientific research works or state approvals (testing) termination.

2. Information about the genetically modified animal (hereinafter, 'the modified animal') meant for importation into the customs territory of Ukraine shall include:

- 1) Systematic name of the original form of the modified animal in Ukrainian and Latin;
- 2) Taxonomic data of the original form in Ukrainian and Latin: family, genus, species, subspecies, cultivar, line;
- 3) Information on biological aspects of the original form reproduction: reproduction method and its specific factors; top-crossing frequency; interspecific and intergeneric hybridisation capacity (frequency of hybridisation with cultivated and wild kins and hybrid viability);
- 4) Possible interaction between the modified animal and other organisms (symbiots, pests etc.) in natural ecosystems;
- 5) Animal's area; information on the centre of origin and centres of genetic diversity of the original form;
- 6) List of genus types deemed pests in Ukraine to which modified animals belong;
- 7) Description of added or modified characters;
- 8) Phase of modified animal development at which the gene and the above character are expressed;
- 9) Difference between the modified animal and its original form at the phenotype level, also between reproduction and survivability rates;
- 10) Selection benefits offered by the transgenic breed (hybrid, line) compared against the original form;
- 11) Detailed description of the genetic construct transferred:
 - Genus (genes) name(s);
 - Description of the donor organism(s);
 - Genus (genes) origin;
 - Transformation method;
 - Vector description;

Description and origin of marker genes, gene promoters and terminators components of the modified animal's genetic construct;

Genetic construct localisation within the animal cell (chromosomes, mitochondria, non-integrated form);

Genetic stability of the genetic construct;

Replicable ways and methods of such genetic construct identification;

12) Proposals regarding the carrying out of scientific research works:

Out-of-order measures (in the event of modified animal accidental release);

Measures on disposal or elimination of the remaining biological material of the modified animal after scientific research works termination.

3. Information about the genetically modified micro organism (hereinafter, 'the modified micro organism') meant for importation into the customs territory of Ukraine shall include:

1) Systematic name of the original form of the modified micro organism in Ukrainian and Latin;

2) Taxonomic data of the original form in Ukrainian and Latin: family, genus, species, subspecies, strain, line;

3) Information on biological aspects of the original form reproduction: reproduction method and its specific factors; ability to make structures capable of surviving or entering the dormant period; interspecific and intergeneric hybridisation, as well as conjugation, transformation and transduction capacities;

4) Possible interaction between the modified micro organism and other organisms in natural ecosystems;

5) Modified micro organism habitation area; information on centres of origin and centres of genetic diversity of the original form;

6) List of genus types deemed pathogens in Ukraine to which modified micro organisms belong;

7) Description of added or modified characters;

8) Difference between the modified micro organisms and their original forms at the phenotype level, also per reproductive rate, dormant period duration, survivability and toxin production rates;

9) Selection benefits offered by the transgenic strain (line) compared against the original form;

10) Detailed description of the genetic construct transferred:
Genus (genes) name(s);

Description of the donor organism(s);

Genus (genes) origin;

Transformation method;

Vector description;

Description and origin of marker genes, gene promoters and terminators components of the modified micro organism's genetic construct;

Genetic construct localisation within the micro organism (chromosomes, mini chromosomes, plastids, mitochondria, plasmids, non-integrated form);

Genetic stability of the genetic construct;

Replicable ways and methods of such genetic construct identification;

11) Proposals regarding the carrying out of scientific research works or state approvals (testing):

Special measures of preventing the proliferation of modified micro organisms able to survive and replicate;

Out-of-order measures (in the event of modified micro organism accidental release);

Measures on disposal or elimination of the remaining biological material of the modified micro organism after scientific research works or state approvals (testing) termination.

