APPROVED

by Resolution No. 114 of the Cabinet of Ministers

of Ukraine as of February 18, 2009

PROCEDURE

for the State Registration of Genetically Modified Organisms of Food Source, Food Products and Medicinal Agents Containing Those Organisms or Derived Therefrom

1. This Procedure describes the process of state registration of genetically modified organisms of food source, food products, cosmetic and medicinal agents containing those organisms or derived therefrom (hereinafter referred to as the "Products").

2. The terms and definitions used herein shall have the meaning set forth in the Law of Ukraine "On the State System of Bio-Security in the creation, testing, transportation and use of genetically modified organisms".

3. State registration of the Products is carried out by the Ministry of Health.

4. For the purpose of state registration, a legal entity or an individual (hereinafter referred to as the "Applicant") shall file an application with the Ministry of Health providing the following:

Generally accepted name of the products;

Commercial name of genetically modified organisms in the language of the producer country, English and Ukrainian;

Designation, types and modes of the Products application;

Name/family name, surname and patronymic of an Applicant, his location, place of residence, phone number, fax and e-mail; in case of a foreign Applicant – registration number, in case of a local Applicant — USREOU code;

Name/family name, surname and patronymic of the Products producer, his location, place of residence, phone number, fax and e-mail; in case of a foreign producer – registration number, in case of a local producer — USREOU code.

To be attached to an Application:

Opinion of the State Sanitary and Epidemiological Expertise and State Ecological Expertise if the Products contain genetically modified organisms or their parts are capable of self regeneration or hereditary factor transfer;

Data related to the findings of the expert appraisal of registration materials (registration file) of a medicinal agent and its quality control carried out in compliance with the procedure set by the Ministry of Health.

The Applicant shall be liable for the reliability of the documents above.

No documents shall be requested from an Applicant other than those above.

If relevant documents have been executed in inappropriate form or in case of a lack of any of them, the Ministry of Health rejects those documents and notifies an Applicant thereof within a 10-day period of their receipt and specifies the reason of such rejection.

The Applicant shall be entitled to re-file duly executed documents.

5. An application for state registration may be rejected on the basis of:

A negative opinion of the state ecological and/or sanitary and epidemiological expertise of the Products;

Negative findings of the expert appraisal of registration materials (registration file) of a medicinal agent and its quality control;

The availability of scientifically based information that the Products may be dangerous for human health and the environment in case of their suitable application.

The time period for considering the documents filed for state registration shall not exceed 120 days from their receipt, including the time period required to carry out a state ecological and/or sanitary and epidemiological expertise.

6. State registration is carried out free of charge for a five-year period through the entry of the Products in the State Register of Genetically Modified Organisms of Food Source, Food Products, Cosmetic and Medicinal Agents Containing Genetically Modified Organisms or Derived Therefrom (hereinafter referred to as the "Register").

Re-registration of the Products shall be carried out according to the registration procedure.

7. Information set forth in documents filed for the state registration of the Products shall be deemed confidential and may not be disclosed to or used for the benefit of a third party unless an Applicant gives its consent.

8. The Register shall be kept in the form approved by the Ministry of Health.

9. Data kept in the Register is available on the official website of the Ministry of Health, systematically published in mass media and provided free of charge upon requests from legal entities and individuals.

10. If the state ecological and/or sanitary and epidemiological monitoring and control reveals any properties of the Products that have not been known before and which are dangerous for human health and/or environmental biological objects, the Ministry of Health and Ministry for Environmental Protection shall decide within 10 days and within the limits of their powers on a repeat state ecological and/or sanitary and ecological expertise of the Products. Such a decision shall also be made in case of the receipt of information set forth in clause 5 hereof.

In case of a negative opinion of a repeat expertise, the Ministry of Health shall decide to cancel the state registration of the Products and on their removal from the Register and must notify an Applicant thereof in writing within a 10-day period.

That decision may be appealed in accordance with the applicable procedure.