

THE MINISTRY OF HEALTH AND SOCIAL WELFARE

1866

Pursuant to Article 138, paragraph 4 of the Nature Protection Act (Official Gazette, No 162/03), the Minister for Health and Social Welfare, with the consent of the Minister competent for the protection of nature and the environment and the Minister competent for agriculture and forestry, hereby passes

THE ORDINANCE

ON THE CONDITIONS TO BE FULFILLED BY A LABORATORY FOR TESTING, CONTROL AND MONITORING OF GMOs AND PRODUCTS CONTAINING GMOs

Article 1

This Ordinance establishes the conditions related to the premises, equipment and workers' qualifications, to be fulfilled by laboratories for testing, control and monitoring of genetically modified organisms (hereinafter referred to as: GMOs) and products containing GMOs.

Article 2

Laboratories which conduct testing, control and monitoring of GMOs and products containing GMOs, must have the following premises:

1. a premise for processing and preparing samples, with a minimum surface of 10 m², with a separate ventilation and air conditioning system;
2. a premise for the extraction of nucleic acids (hereinafter referred to as: DNA and RNA), with a minimum surface of 6 m² with a chamber for work under sterile conditions and with a separate ventilation and air conditioning system;
3. a premise for the preparation of polymerase chain reaction (hereinafter referred to as: PCR), with a minimum surface of 6 m² with a chamber for work under sterile conditions and with a separate ventilation and air conditioning system;
4. a premise for PCR and gel electrophoresis, with a minimum surface of 10 m² with a separate ventilation and air conditioning system;
5. a premise for receiving samples for analysis, with a minimum surface of 10 m², with a ventilation and air conditioning system;
6. a premise for conducting administrative activities;
7. an ante-room for keeping working clothes and shoes in decontamination conditions;
8. toilet facilities.

The premises referred to in paragraph 1 items 1 through 8 of this Ordinance must constitute a functional unity.

The premise referred to in Article 2 paragraph 1 item 5 of this Ordinance must have secured entrances to premises referred to in items 1, 2, 3 and 4 of paragraph 1 Article 2 of this Ordinance.

The ante-room referred to in paragraph 1 item 7 of this Article must be connected to the premise referred to in item 5 of this Article.

Article 3

The premises referred to in Article 2 of this Ordinance must have secured warm, cold and de-mineralized water, electric installations and a personal computer network.

The floors, walls and ceiling of the premises must be built in such a manner that hydro and thermo isolation is ensured.

The floors of the premises must be built from firm, non-sliding material, resistant to corrosive substances, with smooth and entirely flat surfaces enabling easy cleaning and maintenance.

The walls of the premises must have smooth and flat surfaces, built from material resistant to corrosive substances, which enables easy cleaning and maintenance.

The ventilation of the premises referred to in Article 2 paragraph 1 of this Article must be located within a closed system.

A constant temperature must be ensured both in summer and in winter (19 – 22 °C) in the premises referred to in paragraph 1 of this Article.

The premises referred to in Article 2 paragraph 1 item 3 of this Ordinance must have secured the entry of clean air through HEPA filters – the expected air class of empty space shall be C or 100,000 and by maintaining the positive pressure of cca 20 Pa when compared to the atmospheric pressure.

The premises referred to in Article 2 paragraph 1 item 4 of this Ordinance must have secured the entry of clean air through HEPA filter – the expected air class of empty space shall be C or 100,000 and by maintaining the negative pressure of cca 20 Pa when compared to the atmospheric pressure or the chamber for work in sterile conditions.

The laboratory referred to in Article 2 of this Ordinance may work with modified live organisms only if it possesses a level of protection and security measures in compliance with a special regulation.

Article 4

In order to perform testing, control and monitoring of GMOs and products containing GMOs, a laboratory must be equipped with the following:

- a real-time polymerase chain reaction machine (real time PCR)
- a thermomixer and a thermoblock;
- a centrifuge with a minimum relative centrifugal force (rcf) 15,000 x g;
- a centrifuge with a cooling system and a rotor;
- a vacuum concentrator;
- a polymerase chain reaction machine;
- a horizontal electrophoresis unit with a power supply (also including a mould for pouring out gels and combs);
- a transilluminator (UV 312 nm) and a camera with the possibility of connecting to a personal computer;
- a spectrophotometer;
- a refrigerator;
- a freezer (-20°C);
- a grinder;

- a mixer;
- a digital scale from 0,1 g to 2000 g;
- an analytical digital scale to 5 decimals, max, 60 g, d=0,1 mg;
- a dishwasher;
- a test tube shaker;
- automatic pipettes with the possibility of adjusting the volume (pipette-0,5-10 mm, pipette 2-20 ml, 10-100 ml, 20-200 ml, 100-1000 ml, 500-5000 ml);
- an automatic pipetor with a charger;
- a chamber for work under sterile conditions;
- a freezer (-80°C);
- a table pH meter with electrodes and 220 V charging;
- a water bath with a temperature range 0-100° C;
- a thermostat;
- an autoclave;
- a homogenizer;
- a magnetic stirrer with heater;
- a crushed ice machine with a minimum capacity of 2 kg/h or > ;
- an ELISA test reader.

Article 5

Laboratories which conduct testing, control and monitoring of GMOs and products containing GMOs must have a minimum number of employees permanently employed , as follows:

1. one person, a college graduate from the Faculty of Science, Department of Molecular Biology,
2. one person, a college graduate from the Faculty of Food Technology and Biotechnology, Department of Biochemical Engineering (a biotechnologist),
3. one person, a technician, with secondary school qualifications or with a two-year degree, in the health-laboratory or sanitary field.

The employees referred to in items 1 and 2 of paragraph 1 of this Article must have specialized training for GMO detection completed in the competent European Union Centre.

Article 6

A Commission comprising a minimum of three members shall determine whether the conditions stipulated by the provisions of this Ordinance have been fulfilled; the Commission shall be established and appointed by the Minister competent for Health with the consent of the Minister competent for Agriculture, Forestry and Water Management.

Article 7

Upon the proposal of the Commission referred to in Article 6 of this Ordinance, the Minister competent for Health shall pass a decision by which a laboratory is granted authorisation for testing, control and monitor GMOs and products containing GMOs.

The authorisation referred to in paragraph 1 of this Article shall be granted for a period of two years.

Article 8

This Ordinance shall enter into force on the eighth day from its publication in the Official Gazette.

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Zagreb, 7 June 2004

The Vice-President of the Government
and the Minister for Health and Social Welfare
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