



Your ref.: 1545/B-Hu/II/2/2012.

Our ref.: 04.2/2814-5/2012.

18 June 2012

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

**At the request of the BIOTEK Agriculture Hungary Kft. (H-2013 Pomáz, Mártírok útja 1-3.), I, acting as the food chain control body of first instance, make the following**

#### DECISION.

I hereby renew the Good Experimental Practice (GEP) certification of the **BIOTEK Agriculture Hungary Kft. (H-2013 Pomáz, Mártírok útja 1-3.)**. According to it the above testing facility may carry out efficacy trials of authorization in the following categories of products and cultivation in Hungary:

- product categories:** herbicides, fungicides, bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamental plants, forest, public place, others.

**This certificate is valid for 5 years from its entry into force.**

No further complaint shall be lodged against the present decision through state administration. With reference to infringement of law, judicial review of the decision may be requested. Within 30 days of the communication of the decision a complaint may be lodged against it, addressed to the Budapest Court but submitted to the authority having issued the decision of first instance (National Food Chain Safety Office Directorate of Plant Protection, Soil Conservation and Agri-environment) or sent to the same body by registered mail.

Submission of the complaint has no delaying force on the implementation of this decision.

#### J U S T I F I C A T I O N

The BIOTEK Agriculture Hungary Kft. got GEP certification on 30 March 2010, and asked the renewal of it on 21 May 2012. Pursuant to the application, on 1 June 2012 the National Food Chain Safety Office Directorate of Plant Protection, Soil Conservation and Agri-environment made an official inspection in the above testing facility at Pomáz, Mártírok útja 1-3., and concluded that the BIOTEK Agriculture Hungary Kft. did not meet the requirements concerning the efficacy trials specified in the *paragraph 22 of Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the*

*packaging, labelling, storage and transport of plant protection products (hereinafter: Ministerial Decree).* Statements made during the local inspection and the judgement for suppletory are reported in the protocol No. 04.2/2660-3/2012. BIOTEK Agriculture Hungary Kft. eliminated the deficiencies, and reported it to the National Food Chain Safety Office Directorate of Plant Protection, Soil Conservation and Agri-environment in the letter of 13 June 2012. According to it BIOTEK Agriculture Hungary Kft.meets the requirements concerning the efficacy trials specified in the paragraph 22 of Ministerial Decree.

Validity of this certificate is determined according to paragraph 22 (6) of the Ministerial Decree.

I call your attention that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the obligation for obtaining them.

Furthermore I call your attention that you are obliged to notify the National Food Chain Safety Office, within 15 days, about any important changes concerning the certified activity of the testing facility.

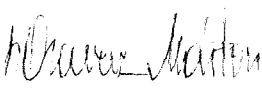
Respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority according to paragraph 22 (9) of the Ministerial Decree.

If during the official inspection it is found that the testing facility does not respect the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is found that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing details, from those that may be accepted for authorization.

My competence and scope of authority are determined according to paragraphs 3 and 22 (1) of the Ministerial Decree, and in Article 5 paragraph 5 (c) and Article 3 paragraph 3 (1) of *Government Decree 22/2012 (II. 29.) concerning the establishment and operation of the National Food Chain Safety Office.*

I made this decision in compliance with paragraph 71 (1) and paragraph 72 (1) of *Act 140 of 2004 on general rules of administrative official procedure and service (hereinafter: Act 140/2004).*

I provided the possibility of judicial review in compliance with paragraph 109 (1) of Act 140/2004 and paragraph 330 (2) of Act III of 1952 on Civil Procedure.

  
Dr. Márton Oravecz  
president  
