



Your ref.: -

Our ref :: 04.2/6149-7/2016

7 October 2016

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

Having received the application submitted by the Anadiag Hungary Mczőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary), the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (hereinafter: GEP), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for earrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation: •product categories: herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives:

•cultivation categories: field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you 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 client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet 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 particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.



ANADIAG HUNGARY Kft.

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REPORT

HUA-17-012

JUSTIFICATION

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the 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: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure. (8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet 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 established 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 data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250,000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

> on behalf of dr. Márton Oravecz president

Der László Jordán director A