

# Ministry of Health

Department of Prevention and Communication  
General Management of Preventive Healthcare  
Office VI – Biotechnologies and Secondary Prevention  
Viale Giorgio Ribotta, 5 – 00144 Rome



BIOTECNOLOGIE B.T. S.r.l.  
Frazione Pantalla di Todi  
06050 TODI (PG)

RE: Despatch of the Certificate of Conformity of the Assay Centre to Good Laboratory Practice Standards, issued on 28.09.2010.

We attach the Certificate of Conformity of the Assay Centre to Good Laboratory Practice, as per Legislative Decree N°50 of 2nd March 2007.

Director of Office VI  
Dr. Grazia Ballacci

# Ministry of Health

Department of Prevention and Communication  
General Management of Preventive Healthcare  
Office VI

## CERTIFICATE OF CONFORMITY OF THE ASSAY CENTRE TO GOOD LABORATORY PRACTICE STANDARDS

(Legislative Decree N°50 of 2nd March 2007 – Directive 2004/9/CE)

Rome, 28/09/2010

Certification: 119/2010

As per Article 4, Para. 1 of Legislative Decree N°50 of 2nd March 2007 and of Article 5 of the Ministerial Decree of 4th July 1997, and taking into account the positive outcome of the inspection carried out between 14th and 16th December 2009,

### IT IS HEREBY CERTIFIED

that the Assay Centre:

**BIOTECNOLOGIE B.T. S.r.l.**  
Frazione Pantalla – 06050 Todi (PG)

is qualified under Good Laboratory Practice Standards to carry out the procedures contained in Enclosure II of the above-mentioned legislative decree:

## 1] Physico-Chemical Tests

- Standard waters
- Appearance
- Wettability
- Sampling of a granular product
- Dispersion in water of WG formulates
- Determination of pH
- Acidity/Alkalinity
- Suspension of wettable powders
- Suspending ability of concentrated aqueous suspensions
- Stability of the suspension of water-dispersible granules
- Wet sieve test of an aqueous suspension, Viscosity
- Density of products in concentrated suspension
- Fluidity, pourability
- Persistent foam
- Accelerated storage tests
- Spontaneity of dispersion
- Suspending ability of formulates in aqueous suspensions
- Wet sieve test
- Wet sieve test in water recirculation/recycling
- Storage tests at different temperatures
- Implementation and validation of analytical methods for identification and quantification of active ingredients using HPLC with detector, UV-VIS, DAD and mass spectrometer.

## 4] Environmental toxicity studies on aquatic and terrestrial organisms

### Acute toxicity and reproduction

- Studies on earthworms, bees, beneficial arthropods and *Daphnia magna*

AGRONOMICAL TESTS:

**In the laboratory:**

- Determination of the toxicity of a sample of *Bacillus thuringiensis* in Lepidoptera larvae through bio-assay with surface application on the diet.
- Determination of the toxicity of a sample of *Bacillus thuringiensis* in Lepidoptera larvae through bio-assay with product incorporation in the diet.
- Determination of the toxicity of a sample of *Bacillus thuringiensis* var. israelensis (BTI) in *Culex pipiens pipiens* larvae.
- Determination of the toxicity of a chemical insecticide in Lepidoptera larvae through bio-assay with surface application on the diet.
- Determination of the toxicity of a sample of a chemical insecticide to Lepidoptera larvae, through bio-assay with product incorporation in the diet.
- Bio-assay on insect and mite egg, larval and adult phases.



#### **In the greenhouse:**

- Test assessments for the efficacy evaluation of plant protection products (EPPO-PP 1/152).
- Preliminary screenings of pathogens, lithophages and xenobiotics on cultivated plants.

#### **5] Studies on behaviour in water, earth and air: bio-accumulation**

- Determination of Cry 1Ab/1Ac by ELISA immunological method
- Determination of soil respiration, carbon transformation test.
- Determination of nitrates in the soil, nitrogen turn-over test
- Effects of a test substance on the inhibition of activated sludge respiration
- Phototransformation of a microorganism on the soil surface
- Biodegradation tests
- Determination of mycotoxins by ELISA immunological method

#### **9] Others**

##### **Microbiological characterization**

- Quantification of delta endotoxin content in technical powder, in concentrate and in fermentation broth of *Bacillus thuringiensis* through the use of denatured polyacrylamide gel with sodium dodecyl sulphate and through densitometric analysis
- Extraction of DNA from bacterial cells
- Bacterial and fungal DNA sequencing using Microseq 516 S rDNA kit for molecular identification

- Determination of bacterial and fungal load by direct count of cells at the optical microscope and by direct count of cells forming colonies (CFU).
- Study of the proteinaceous profile and analysis of the molecular weight of a bacterial strain through the use of denatured polyacrylamide gel with sodium dodecyl sulphate.
- Molecular characterization of microbial strains using AFLP.
- Antibiotic assay of GRAM+ and GRAM- bacteria.
- Analytic methods to determine pathogenic micro-organisms in microbial formulates.

**This Certificate is valid for 24 months from the date of issue.**

This Certification will not be renewed after its natural expiry date unless a request for renewal of the same, complete with the updated summary form, is presented **at least 90 days before the expiry date**, as per Para 2 of Article 4 of Ministerial Decree of 4th July 1997 (published in the Official Gazette N°229 of 1/10/1997).



THE DIRECTOR OF OFFICE VI  
Dr. Grazia Ballacci



*Dr. A. Ballacci*



# TRIBUNALE DI PERUGIA



Cron. 14857

R. Mod. 17 206

Verbale di giuramento di TRADUZIONE.

Oggi, 12/04/2021 davanti al sottoscritto, è personalmente comparso

ENRICA AGNELLO identificato a mezzo di  
\_\_\_\_\_ /personalmente conosciuto il quale

ha chiesto di poter asseverare con giuramento l'unita traduzione,  
nell'interesse di Sig. BIOLOGIE B.T.S.K.L.

Io sottoscritto, previe le ammonizioni di legge ha deferito al traduttore il  
giuramento di rito che egli presta dicendo: "Giuro di avere bene e  
fedelmente adempiuto alle funzioni affidatemi al solo scopo di far  
conoscere a chiunque la verità."

Letto, confermato e sottoscritto.

IL TRADUTTORE

in Acqui

