

ORDER
NO 1/DPL/PBSCH/2021
of the President of the Bureau for Chemical Substances
of 7 January 2021

on conduct of the inspection and verification of compliance with the Principles of Good Laboratory Practice in the remote system

Pursuant to Article 5 and Article 16(3)(7) of the Act of 25 February 2011 on the chemical substances and their mixtures¹, hereinafter referred to as the “Act”, it is hereby provided as follows:

§ 1

1. In view of the risks associated with the spread of the SARS-CoV-2 coronavirus and in order to ensure the continuity of the functioning of the National Good Laboratory Practice Compliance Monitoring Programme the inspection and verification of compliance with the Principles of Good Laboratory Practice by organisational entities testing substances and their mixtures, hereinafter referred to as the “test facilities”, in order to confirm if they comply or do not comply with the Principles of Good Laboratory Practice may be performed remotely.
2. The President of the Bureau for Chemical Substances shall decide if the inspection and verification of compliance with the Principles of Good Laboratory Practice by the test facilities can be performed remotely.
3. The remote inspection and verification of compliance with the Principles of Good Laboratory Practice by the test facilities shall be performed in accordance with Article 16(9) of the Act on the chemical substances and their mixtures, based on a written authorisation issued by the President of the Bureau for Chemical Substances.
4. The remote inspection and verification of compliance with the Principles of Good Laboratory Practice by the test facilities shall be performed using the Cisco Webex Meetings communicator available to the Bureau of Chemical Substances, which allows to conduct HD video-conferences in real time.
5. Provisions of Article 16 of the Act and provisions of Regulation of the Minister of Health of 22 May 2013 on Good Laboratory Practice and performance of studies in compliance with the Principles of Good Laboratory Practice² shall be applied for the remote inspection and verification of compliance with the Principles of Good Laboratory Practice by the test facilities.

§ 2

In order to enable the Good Laboratory Practice inspectors to carry out the remote inspection and verification of compliance with the Principles of Good Laboratory Practice by the test

¹ Act of 25 February 2011 on the chemical substances and their mixtures (i.e. of 18 November 2020; Dz. U. of 2020 item 2289)

² Regulation of the Minister of Health of 22 May 2013 on Good Laboratory Practice and performance of studies in compliance with the Principles of Good Laboratory Practice (Dz. U. of 2013 item 665)

facilities, the inspected test facility shall send the following electronic documents to the Bureau for Chemical Substances:

- 1) Master schedule of the test facility or certified test facility;
- 2) Organisation chart of the test facility;
- 3) Copies of floor plans depicting premises where studies requiring compliance with the principles of Good Laboratory Practice are conducted;
- 4) Standard operating procedures used in the test facility;
- 5) Records of periodical inspection, cleaning, maintenance, calibration, validation and verification of measuring apparatus and validation of computerised systems;
- 6) Details of individuals responsible for the quality assurance programme, and details confirming their qualifications;
- 7) Details of study personnel and details confirming their qualifications;
- 8) Documentation (study plan, study report, raw data) for selected completed studies in the test facility after the last inspection and verification of compliance with the Principles of Good Laboratory Practice;
- 9) Documentation (study plan, raw data) for selected on-going studies.

§ 3

During the remote inspection and verification of compliance with the Principles of Good Laboratory Practice by the test facilities:

- 1) The management structure and operating procedures are inspected;
- 2) Interviews with the personnel are delivered;
- 3) The integrity of data generated in the test facility is evaluated;
- 4) The degree of compliance with the Principles of Good Laboratory Practice is evaluated;
- 5) Completed or on-going studies are audited.

§ 4

The Director of the Department for Good Laboratory Practice shall oversee execution of this Order.

§ 5

The Order shall enter into force on the date of signature.