Requirements in the scope of documentation necessary for the process of attestation for biopreparations and biocidal products

BIOPREPARATIONS

1. chemical quantitative and qualitative composition of the products (full chemical name of the substance),
2. composition of microorganisms: types of microorganisms (preferably the name of the species),
3. the manner of biopreparation application (product data sheet, instructions),
4. label design,
5. REACH data sheet/product data sheet/SDS/MSDS – if available
6. manufacturer’s declaration, that the preparation **does not contain genetically modified microorganisms**
7. manufacturer’s declaration, that the preparation does not contain pathogenic microorganisms in accordance with the classification pursuant to:

* DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work
* Regulation of the Minister of Health of 22 April 2005, regarding biological agents harmful for health in a workplace and protection of health of workers occupationally exposed to the agents (Dz. U. [Journal of Laws] 2005, no. 81, item 716, as amended)

1. tests conducted in an independent laboratory for detecting the presence of bacteria: *Escherichia coli****,*** *Salmonella spenterococci, Pseudomonas aeruginosa*, in the sample of biopreparation of 10 ml or 10 g, where the scope of the marked parameters may change. Tests on biopreparations conducted in order to obtain a hygienic attestation should be conducted in a laboratory with a documented management system. All markings should be made according to relevant (if possible, standardised) research methods.

BIOCIDAL PRODUCTS

1. precisely specified scope of product application,
2. exact chemical composition of the product,
3. full identification of all active substances applied,
4. the content of product package leaflet,
5. confirmation of fulfilment of requirements of the Regulation (EU) no. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products,
6. valid and up-to-date product marketing authorisation within the territory of the Republic of Poland issued by the Ministry of Health via The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products,
7. in the case of lack of the above authorisation – the manufacturer should present the test results confirming the effectiveness of the preparation/product made according to up-to-date, standardised methods in accordance with the scope of its application.