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P78 : IMPLEMENTATION OF GOOD LABORATORY PRACTICES

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Purpose
In this study, Good laboratory Practices (GLP) in European Union and Turkey and the relation between GLP and Biocidal Products are assessed.

Method
In this study, national and international legislation and practices in the countries of the European Union are reviewed.

Findings
From the concept of Good Laboratory Practice (GLP), it is understood that GLP is specific documents from consensus by members of the Organization of Economic Cooperation and Development (OECD). GLP is a a quality system concerned planning, carrying out, monitoring and recording of non-clinical health and environmental safety studies and the organization. The scope of GLP activities are physical-chemical, the toxicological and Eco toxicological tests of cosmetic pesticides, biocides, human and veterinary medicinal products, food additives, feed additives and industrial chemicals and also substance or organisms of biological origin. GLP principles are a system consisting activity to be carried out (projects, research, analysis and testing, etc.) and rules on before, during and after working processes. ISO 17025 is defined as a quality system of a laboratory (requirements). It is focused on sampling, measurement uncertainty, traceability, calibration and some issues effecting results of tests or analysis. Fundamental difference between ISO 17025 Standard and OECD-GLP is concerned with difference types of projects they are interested. There are similar and difference subjects between the two quality systems. In relation to the management and organization, common subjects in both quality systems are definitions of responsibilities, standard operating procedures of maintenance and repair, calibration, equipment using, procedures on taking, registration and preservation of samples and test items, training of the staff, keeping the materials, the use of the validated methods, reports of analysis and working. In both systems, chemical, analytical and microbiological tests are carried out. Differences between both systems arise from the differences aims and handling time. Specific subjects belonging to OECD-GLP can be summarized as animal care, access to the work plan, all master's programs of all studies and archiving issues and monitoring all the processes. Specific subjects belonging to ISO 17025 system can be summarized as the evaluation of the complaints, estimating the measurement uncertainty, service to customer, preventive measures, participation in international benchmarks proficiency testing such as proficiency testing, PT, uncertainties in measurements, monitoring and customer analysis. Both systems are almost identical documentation burden. However, ISO 17025 is customer-oriented, but the OECD-GLP is focused on project, research and analysis. Nationally on good laboratory practice, there is By-Law on Principles of Good Laboratory Practices, Harmonization of Test Units and Inspections of Good Laboratory Practices, Internationally, European Union has two Directives on GLP inspection of 2004/9 / EC and on necessary measures for laboratories of 2004/10 / EC. Some issues taken from the European Union on good laboratory practices are being only one original copy with some exceptions, permitting electronic archives in third countries provided that assurance on compliance of GLP principles is given by testing facility administration, electronic signatures on final reports which can be acceptable in a very strict conditions and mutual protection of data. As there is no laboratory with GLP certificate to perform analysis and tests in the scope Annex -VI to By-Law on Biocidal Products in Turkey, these tests to be performed have been postponed one, postponed until 31.12.2021. That shows an example on absence of laboratory with GLP in Turkey. OECD's decision on "the mutual acceptance of data" is an important decision on this issue.

Result
There are the similarities and differences between the ISO 17025 standard and the OECD principles of GLP.A laboratory with e similarities and differences between the OECD principles of GLP. If a laboratory with ISO 17025 accreditation wants to extend their activities according to the OECD-GLP, it may have much more advantageous position. Therefore it may be not necessary for the laboratory to have both certificates. But a laboratory may unit both system by the advantages of overlapping issues. It is very important in terms of human and environmental health to investigate OECD's decision on
the mutual acceptance of data and to promote GLP implementation in Turkey.
Keywords: GLP, biocidal products, tests of physical-chemical, toxicological and ecotoxicological.