Amendments to Regulation on Biocidal Products are Introduced

11 Mar 2022

The Regulation Amending the Regulation on Biocidal Products (the "**Amendment Regulation**"), effective as of 30 December 2021, were published in Official Gazette numbered 31705 of even date. The Amendment Regulation aims to align the Regulation on Biocidal Products closer with the European Union legislation and practice, and to increase the efficiency of market surveillance and control activities.

The Amendment Regulation provides, in relevant part, as follows:

- The pre-application and sealed sampling process is abolished.
- The tests, other than toxicological and ecotoxicological tests presented in the application files of active substances and biocidal products, can be carried out by organizations whose compatibility in accordance with the Regulation on Principles of Good Laboratory Practices, Harmonization of Test Units, Inspection of Good Laboratory Practices and Studies has been documented or accredited in the test method or who have completed validation/verification studies.
- Biological effectiveness analyzes of pest control products will be carried out by authorized laboratories. With the Amendment Regulation, this authorization is granted by Ministry of Health ("**Ministry**").
- In the preparation and evaluation of the application files, the guide documents published by the European Chemicals Agency (ECHA) and in cases where these are not sufficient, the guide documents published by other international organizations will be taken into consideration. Thus, harmonization with the European Union legislation was aimed.
- The Ministry also has the right to request the content of the license application file physically.
- All information in the label sample approved by the Ministry is now required to be on the label on the manufactured product. Claims and statements that do not fall within the scope of the Regulation on Biocidal Products will not be included in the label sample approved by the Ministry.
- In order to ensure the monitorability of the license and the label approved by the Ministry, a data matrix will be placed on the biocidal product label.
- A product that has been granted a new license or whose license has been renewed will be inspected at least once until the expiration date of the license, by taking samples and performing physical and chemical analyzes.

Please see this link for the full text of the Amendment Regulation (only available in Turkish).

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