EUON Publishes Nanopinion on ECETOC’s NanoApp

On May 5, 2020, the European Union (EU) Observatory for Nanomaterials (EUON) published a Nanopinion entitled “NanoApp helps navigate legal obligations under REACH.” Olivier de Matos, Secretary General of the European Center for Ecotoxicology and Toxicology (ECETOC), describes the web-based app that was designed to help registrants follow the European Chemicals Agency’s (ECHA) guidance on sets of nanoforms. According to de Matos, the app primarily covers the “Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification.” The NanoApp has two main tiers:

- Tier 1 asks users to provide basic data required for preparing their registrations in IUCLID about the nanoforms being assessed. Based on transparent similarity algorithms and decision rules, the app then establishes whether two or more of
those nanoforms can be grouped into a single set based on the intrinsic similarity of their basic properties; and

- Tier 2 applies when criteria for Tier 1 grouping are not fulfilled, but the similarity values for the basic properties are still within predefined boundaries. The app then guides users on what data should be generated to support the justification of that potential set of nanoforms. This could be data on dissolution, dispersion stability, or in vitro. When these data are introduced in the app, it gives the result of the final evaluation and concludes whether the set can be justified.

According to de Matos, the app has established criteria and rules that systematically evaluate the similarity between nanoforms, and on that basis, conclude whether a set of nanoforms can be justified. Initiated by ECETOC, the app was developed by a core team of BASF in Germany, Leitait in Spain, and ThinkWorks in the Netherlands. de Matos states that the decision logic, methods, and cut-offs used were all discussed with industry, including members of the ECETOC Nano Task Force and the academic and regulatory partners of the EU-funded Horizon 2020 research project GRACIOUS. ECETOC then gave a demo of the app to ECHA, and ECHA participated in testing the beta version and reviewing the rationales for the methods and the cut-offs it uses. ECETOC is cooperating with the Nanotechnology Industries Association (NIA) to involve its members further and describe the tool and its use. de Matos notes that the methods used to generate data that characterizes nanomaterials and their functionalities, as well as the cut-offs to decide on the similarity of nanoforms, will most likely be amended and refined in the future. The NanoApp is currently in beta testing and is available to anyone interested in testing the app. Once the final version of NanoApp is complete, ECETOC will provide training on how to use it.

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