



**Toxys and Unilever enter agreement to further validate and expand ReproTracker® for animal-free developmental toxicity assessment**

*Toxys and Unilever will start a collaborative R&D project to further validate and develop the ReproTracker assay, a human cell assay for in vitro teratogenicity testing.*

**LEIDEN, The Netherlands and Bedford, UK, April 28, 2021** – Toxys and Unilever Safety and Environmental Assurance Centre (SEAC) have entered into an agreement to further validate and expand the ReproTracker assay.

Testing for developmental toxicity according to the current international guidelines requires large numbers of animals, making these tests very resource-intensive and time-consuming as well as raising ethical concerns. The current ReproTracker *in vitro* teratogenicity assay has been available to clients since 2020 and monitors the differentiation of stem cells into functional heart, liver and neural tissues. The assay has been validated using various reference compound libraries and has shown a high predictivity for the detection of *in vivo* teratogenic compounds. Consequently, ReproTracker allows a much more rapid and cost-effective developmental toxicity hazard identification for novel and existing drugs, chemicals, and many other substances.

In this collaborative project between Toxys and Unilever, the ReproTracker assay will be further validated with various classes of reference compounds. Importantly, quantitative dose-response models will be developed for the ReproTracker biomarkers to define the developmental toxicity of test agents at doses that are relevant for human exposure. Furthermore, optimised and validated protocols will be developed for human induced pluripotent stem cell (hiPSC) differentiation into bone cells (osteoblasts) as a new and valuable endpoint within ReproTracker to cover skeletal developmental toxicity.

The intent of the collaboration with Unilever is to extend and further validate ReproTracker in order to design a teratogenicity strategy in line with the next generation risk assessment (NGRA) framework that integrates new approach methodologies (NAMs) to ensure product safety without generating animal data. Through this Unilever collaboration, and by adding in validated biomarkers for skeletal development, ReproTracker will be even better positioned to improve developmental toxicity testing without the use of animals.

“We are very happy to be starting this new initiative with Toxys to further build the ReproTracker capability for exposure-led *in vitro* developmental toxicity testing in NGRA. In recent times, Toxys have stood out as a developer and provider of data from innovative NAMs that underpin human-focused bioactivity point-of-departure determinations without pathology in animals. We anticipate a great synergy from our combined efforts to raise the bar in non-animal based safety assessments”.

- *Professor Paul Carmichael, Unilever SEAC*

“We are very excited about the collaboration with Unilever to further validate and extend ReproTracker and further support the non-animal safety testing of novel chemicals, cosmetics and consumer products. Toxys is continuously looking for opportunities to expand and improve its portfolio of unique animal-free assays for chemical safety testing. With its long-standing expertise in non-animal human safety testing, Unilever SEAC is an ideal collaborator for Toxys.”

- Dr. Giel Hendriks, CEO of Toxys

### **About Toxys**

[Toxys](#) is a Dutch biotech company that offers a broad spectrum of innovative *in vitro* toxicology solutions. Toxys was founded in 2014 as a spin-off from the Leiden University Medical Center and has its state-of-the-art laboratory facilities located at the Leiden Bio Science Park. Toxys is expert in toxicological research with a mission to improve animal-free safety testing by creating mechanistic *in vitro* chemical safety tests to meet the needs for safer medicines, chemicals and cosmetics. Toxys has developed the unique ToxTracker<sup>®</sup>, ReproTracker<sup>®</sup> and ToxProfiler<sup>™</sup> assays. ToxTracker is a high-throughput stem cell-based reporter suite of assays that allows reliable identification of genotoxic carcinogens. ReproTracker is an animal-free test to identify compounds that are toxic to human embryonic development. ToxProfiler is a human cell assay for mechanistic toxicity testing. Toxys is currently working with seven of the top ten global Pharma companies and several major chemical, cosmetics and food multinationals and is highly valued for its scientific expertise, high-quality results and responsiveness.

### **About Unilever SEAC**

See <https://www.unilever.com/brands/innovation/safety-and-environment/> for information on Unilever SEAC

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