Utilizing High-Content Imaging Tools Toward Pathways-Based Safety Assessments: A Consumer Product Industry Perspective

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Eliminating the need to use animal data in the safety assessment of new ingredients intended for use in consumer products has been a long and deep set ambition for Unilever. The biggest challenge is posed by the traditional use of animals for systemic (internal organ based) toxicology testing which is embedded in regulatory guidelines worldwide. Since 2007 and the inspiration of the US National Academy of Science’s report ‘Toxicity Testing in the 21st Century: a Vision and a Strategy’, Unilever safety scientists have been seeking not to replicate each animal test with an ‘alternative’ but to capitalize on the recent revolution in biomedical sciences in order characterize toxicological pathway changes in human biological systems. The use of high content imaging (HCI) tools is at the heart of this work and our focus is now on exploiting new mechanistic understanding to craft bespoke exposure-led safety assessments for new ingredients using *in vitro* and *in silico* methods: establishing whether a new agent has the potential (or not) to perturb cellular homeostasis and stress networks beyond their normal restorative capacity. Our work, with various partners in this space, has encompassed a number of areas including adaption/adversity decision-making on DNA damaging agents, on androgen receptor effects, lung fibrosis and as a general tool for early MIE definition. This work fits into our larger strategy of working towards using these tools as part of a TT21C safety assessment. Developing the models and tools to reliably achieve these aims is an on-going odyssey that has grown as new scientific partners from the EU, USA and China have joined to engage regulators with these new approaches to safety assessment while assuring the highest standard of safety for our consumers, workers and the environment.