

Agricultural BioTech Regulatory Network

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Agricultural BioTech Regulatory Network Expert Sets Safety Assessment Process for Nanotechnology in Food

The Agricultural BioTech Regulatory Network (ABTR Network) proudly announces a new publication co-authored by Dr Andrew Cockburn (Toxicological Consulting Ltd).

Approaches to the Safety Assessment of Engineered Nanomaterials (ENM) in Food describes a systematic approach to assess the safety of these new ingredients for human consumption. Using a tiered approach, the ENM is first compared to its non-nano form counterpart to determine if ENM-specific assessment is required. Of highest concern from a toxicological perspective are ENMs, which have potential for systemic translocation, are insoluble or only partially soluble over time, or are particulate and bio-persistent. Where ENM-specific assessment is triggered, Tier 1 screening considers the potential for translocation across biological barriers, cytotoxicity, generation of reactive oxygen species, inflammatory response, genotoxicity and general toxicity. *In silico* and *in vitro* studies, together with a sub-acute repeat-dose rodent study, can also be considered for this phase. Tier 2 hazard characterization is based on a sentinel 90-day rodent study with an extended range of endpoints, additional parameters being investigated case-by-case. Physicochemical characterization should be performed in a range of food and biological matrices. A default assumption of 100% bioavailability of the ENM provides a 'worst case' exposure scenario, which can be refined as additional data become available. The safety testing strategy is considered applicable to variations in ENM size within the nanoscale and to new generations of ENM. Contact Prof Andrew Cockburn at andrew_cockburn@btinternet.com or Alessandro Chiodini at ILSI Europe achiodini@ilsieurope.be for a copy of the publication.

Andrew Cockburn, Roberta Bradford, Neil Buck, Anne Constable, Gareth Edwards, Bernd Haber, Paul Hepburn, John Howlett, Frans Kampers, Christoph Klein, Marek Radomski, Hermann Stamm, Susan Wijnhoven & Tanja Wildemann (2012) Approaches to the safety assessment of engineered nanomaterials (ENM) in food. *Food and Chemical Toxicology* 50: 2224-2242.

Established in 2006, the ABTR Network is a unique global network of independent regulatory affairs managers/services serving the agricultural biotechnology industry from product conception through commercialization.

Services cover the entire range of regulatory support required for Ag Biotech projects, including project management, project evaluation, risk assessments, contained/confined use permits; field trial permits / notifications; regulatory files; commercial permits; movement of biological materials; compliance audits; compliance systems; training; quality control; study design; documentation systems; regulatory strategies; regulatory management; issue management; communication; emergency response & public advocacy.

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