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Environmental risk assessment of veterinary medicinal products – a new concept for a plant test with more realistic exposure scenario

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The poster presents the regulatory need and the background of a special more realistic terrestrial plant testing approach for veterinary pharmaceuticals. Environmental effects of veterinary medicines are assessed according to the guidelines of the European Medicines Agency (EMA) and the VICH GL 38 (ECOTOXICITY PHASE II). According to the guideline a terrestrial plant test in phase II is required because residues of pharmaceuticals release with dung and manure from treated animals on agriculture land. The terrestrial plant test is conducted using the standardised test protocoll OECD 208 (Seedling Emergence and Seedling Growth Test).

The current regulations take into account only the parent compound but do not consider transformation products and NER (Non Extrectable Residues). This might result in incorrect estimation of risk in case of substances applied on agricultural soils with manure. Therefore, the German Federal Environmental Agency (UBA) has initiated a research project to develop a special terrestrial plant test with a more realistic exposure scenario. The test substance is applied in manure and stored over a defined period prior testing. Then this mixture is tested in a standard terrestrial plant test according to OECD 208 in order to evaluate the potential phytotoxicity of transformation products and NER. This new approach is currently developed with different plant species, different manures and storing periods by two research partners: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) Schmallenberg and ECT Oekotoxikologie GmbH Flörsheim.