Experiences with a higher tier test design simulating environmental fate and effect of medical products after the use phase.

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Introduction

Nanomedicine is of growing interest, as the nanoscale materials exhibit new possibilities. Excretion of biomaterials such as nanocarrier drug delivery systems cannot be excluded. With sewage they end up in wastewater treatment plants (WWTP) and released into the environment via effluent or sewage sludge used as fertilizer. Although transformations cannot be excluded, this pathway is not considered in the current risk assessment.

We simulated fate and effect of biomedical products after excretion. AuNPs designed for various medical applications and its dispersant were used as influent for model WWTP (OECD 303A). The effluent was used for aquatic studies. For the terrestrial studies sewage sludge was mixed with soil.

Results

Terrestrial invertebrates and soil microorganisms were suitable test organisms for the soil/sludge mixtures. Effects on the soil microbial population were determined by functional as well as by genomic tests. In more generation-tests with enchytraeids and collembola effects of the medical product were noticeable and not detected using the standard test approach. Earthworms died in accumulation studies when sewage sludge exposure was made via food source. The effluent killed the fish cells, even after exchange of the liquid by cell media. Tests with daphnids revealed no negative acute impact.

Conclusions

A higher tier testing approach simulating fate and effect of biomedical products after their use phase was successfully implemented. Sewage sludge as sole food for earthworms and fish cells require further considerations.

Summary

Excreted and potentially transformed bionanomedical products can enter the environment by the effluent of WWTP and by sorption to sewage sludge used as fertilizer. For a higher tier testing, investigation of sewage sludge/soil mixtures and effluent is recommended as it captures most entry sources and targets. Limitations in the amount of sewage sludge and peculiarities of the test organisms regarding the test conditions must be taken into account.