AbstractID: 17
Presentation-Section: Regulatory Toxicology
Status: Review
Presentation-Form: Poster

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Abstract title:

Dermal absorption in regulatory toxicology – new perspectives

Assessment of dermal absorption is an integral part for the risk assessment for plant protection products (PPPs) and biocidal products (BPs). Applicants are hence requested to submit studies for the derivation of dermal absorption values during the authorisation process.

In the course of its regulatory work the German Federal Institute for Risk Assessment (BfR) has set up a database for the respective studies with the aim to further harmonise future estimates for dermal absorption. The database includes studies submitted for authorisation of PPP, BP and active substance evaluations. Data from this database provides the basis for evaluation of the triple pack approach or the determination of the influence of co-formulants on dermal absorption.

The Triple pack is the combination of three study types, that is dermal absorption *in vivo*, *in vitro* (animal) and in human *in vitro* systems. This combination permits refinement of dermal absorption values by correcting for the generally higher permeability of animal skin compared to humans. A total of 115 triple pack studies will be evaluated in order to evaluate if and to which degree dermal absorption studies *in vivo* can be replaced by human *in vitro* studies.

The other project deals with the possible influence of co-formulants on dermal absorption. Both, PPPs as well as BPs usually consist of one or more active substances in conjunction with various co-formulants. Several studies show that the latter can have an impact on dermal absorption. As of today, there are 26 functional classes of co-formulants. Altogether PPPs authorised in Germany currently contain 1815 different co-formulants. The data in the BfR database will be analysed using random forest analysis for parameters with a dominant influence on dermal absorption.

Both projects shall promote the progression of dermal absorption estimation in regulatory toxicology, thus further improving risk assessment.