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Proposed criteria for the evaluation of the scientific quality of mandatory rat and mouse feeding trials with whole food/feed derived from genetically modified plants

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In recent years, animal feeding trials conducted with whole food/feed have been a focal issue in the controversy on the safety assessment of genetically modified (GM) plants and derived food/feed. Within the scientific community and among stakeholders, quite different views have been expressed on how these studies should be conducted, analysed and interpreted, what they might add in terms of information relevant to safety and whether 90-day rodent feeding trials should be mandatory. In the context of the ongoing debate on GMO risk assessment in Europe, it is crucial to investigate: Criteria for evaluating the scientific quality of subchronic, chronic toxicity and carcinogenicity studies with whole food/feed in rats and mice. This will help risk assessors in evaluating this type of studies when provided in the course of a pre-market risk assessment and will create a basis for further general debate. This talk specifically addresses the question on how to evaluate whole GM food/feed feeding trials. It does so by proposing a list of key quality criteria for the evaluation of 90-day and extended feeding trials with whole food/feed derived from GM plants. The proposed quality criteria should be taken into account when evaluating a feeding trial in the frame of an application to regulatory bodies and are not intended to be applied in other cases in which a feeding trial is performed to answer a specific open question in basic research.

Biography

Kerstin Schmidt completed her University degree in Mathematics with specialisation in Statistics and Probability Theory. In 1990, she established her own company BioMath, an internationally operating consultancy for research institutions and industrial partners in statistics and informatics, especially in the life sciences. She has been accompanying more than 100 projects in Toxicology, several of them joint/ international projects. She works as a Lecturer for Statistics and Experimental Design at the University of Rostock. In April 2016, she submitted her Doctoral thesis entitled "Statistical aspects and methods of the risk assessment and post-market environmental monitoring of genetically modified plants".

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