

Conclusions

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This is a paper for discussion. It does not reflect the views of the Committee and should not be cited.

39. The concept of read-across is based on the principle that structurally or mechanistically similar molecules tend to exhibit similar properties. This methodology involves identifying data-rich source substances that closely resemble a data-poor target substance and using their toxicological data to estimate the potential toxicity of the target.

40. EFSA's guidance provides a structured framework for applying read-across to assess the toxicological hazard of a chemical substance, supporting safety evaluations within the food and feed chain. However, EFSA emphasises that read-across is not a substitute for a full risk assessment. Instead, it serves as a supporting line of evidence within hazard assessment, which itself is a key component of risk assessment. Like other structure-activity relationship-based approaches, read-across alone is generally insufficient for regulatory conclusions—particularly when asserting the absence of toxicity for a specific endpoint. Such evidence is more robust when integrated into a WoE analysis alongside other data sources.

41. The guidance outlines the key steps in conducting a read-across: problem formulation, target substance characterisation, source substance identification and evaluation, data gap filling, and uncertainty analysis. Each step may introduce varying degrees of uncertainty, which collectively determine the overall uncertainty level—low, moderate, or high. Whether this level is acceptable depends on the context of the risk assessment. Therefore, the risk assessor must define a tolerable level of uncertainty during the initial problem formulation. The guidance also addresses strategies to manage and minimise uncertainty throughout the process.

42. While expert judgement is necessary at certain stages, EFSA stresses that read-across must be conducted transparently, using standardised and unbiased procedures. Scientific justification should be clearly provided to support the overall conclusions.