

Background

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

3. Read-across is a method used in chemical risk assessment for screening, classification, prioritisation and hazard assessment of data-poor target substances based on toxicological data from one or more data-rich source substances that are structurally and mechanistically similar. It is one of the most

common alternatives to animal testing.

4. The read-across prediction can be applied through two ways of chemical groupings, known as the analogue and category approaches. An analogue approach compares the properties of a target substance with a limited number of closely related source substances, whereas a category approach is based on the premise that structural similarity among several source substances can predict the target substance's properties.

5. Read-across involves a number of steps (i.e. problem formulation, data gap analysis, source substance identification and evaluation, data gap filling and uncertainty assessment), each of which may carry a certain level of uncertainty. Therefore, it needs to be carried out in as transparent, standardised and unbiased a manner as possible to make the overall conclusions scientifically justified and reliable.

6. A number of read-across frameworks have been proposed, such as the OECD's Guidance on Grouping of Chemicals (OECD, 2014), and ECHA's Read-Across Assessment Framework (ECHA, 2017). Moreover, EFSA has previously considered the use of read-across in specific risk assessments, including those for smoke flavourings, feed additives, and pesticide active substances, and has drawn on related guidance documents that refer to its application (EFSA FAF Panel, 2021; EFSA SC, 2019 and ECHA/EFSA, 2023). However, these documents mention read-across only as a supporting line of evidence, without offering detailed guidance on its implementation. Therefore, EFSA argues that a generic and flexible framework, together with a standardised workflow that provide a scientific basis for the use of read-across for applicants and risk assessors is needed.

7. The present EFSA guidance outlines a stepwise approach for applying read-across to fill data gaps in the chemical safety assessments of individual substances in food and feed. The guidance also explains how to integrate different types of New Approach Methodologies (NAMs) data at relevant steps to support the read-across. In addition, it provides guidance on performing a thorough analysis of the uncertainties pertaining to each step of the read-across and assessing the overall uncertainty, along with a discussion on the applicability domain of read-across.