12th meeting of FCM Network | 21-23 Oct 2025

GUIDANCE ON THE USE OF READ-ACROSS FOR CHEMICAL SAFETY ASSESSMENT IN FOOD AND FEED

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EUROPEAN FOOD SAFETY AUTHORITY

Context and background information

CONTEXT

Self-task mandate of EFSA's Scientific Committee:

- Guidance (EFSA-Q-2020-00413)
- Public consultation (EFSA-Q-2020-00414)
- Procurement contract (EFSA-Q-2020-00415)
- Workshop (EFSA-Q-2020-00416)

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SCIENTIFIC OPINION | Open Access

Guidance on the use of read-across for chemical safety assessment in food and feed

EFSA Scientific Committee, Susanne Hougaard Bennekou, Ana Allende, Angela Bearth, Josep Casacuberta, Laurence Castle, Tamara Coja, Amélie Crépet, Thorhallur Halldorsson, Laurentius (Ron) Hoogenboom, Pikka Jokelainen, Helle Knutsen, Konstantinos Koutsoumanis, Claude Lambré, Søren Nielsen, Dominique Turck, Antonio Vicent Civera, Roberto Edoardo Villa, Holger Zorn, Emilio Benfenati, Romualdo Benigni, Qasim Chaudhry, Lucian Farcal, George Kass, Alexis Nathanail, Alicia Paini, Rositsa Serafimova ... See fewer authors

First published: 28 July 2025 | https://doi.org/10.2903/j.efsa.2025.9586 | Citations: 1

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European Food Safety Authority (EFSA)

First published: 28 July 2025 | https://doi.org/10.2903/sp.efsa.2025.EN-9569

Event report | Open Access

Workshop on read-across: role and guidance in chemical risk assessment

European Food Safety Authority (EFSA)

First published: 28 July 2025 | https://doi.org/10.2903/sp.efsa.2025.EN-9521

External scientific report | Open Access

Read-Across Application for Food or Feed Ingredients

Jenny Irwan, Nelly Simetska, Matthias Wehr, Rupert Kellner, Sylvia E. Escher

First published: 11 July 2024 | https://doi.org/10.2903/sp.efsa.2024.EN-8811 | Citations: 2

CONTEXT

Why 

- **Address data gaps** in risk assessment
- **Ensure scientific robustness** and regulatory consistency across EFSA Panels and Units
- **Reduce reliance on in vivo animal data** and integrate new approach methodologies (NAMs)

How 

- **The guidance explains key steps** in the read-across workflow to support chemical risk assessment
- **Provides context and requirements** from EFSA, linking to existing frameworks like ECHA and OECD
- **Promotes the use of NAMs** to strengthen evidence and reduce uncertainty

BACKGROUND

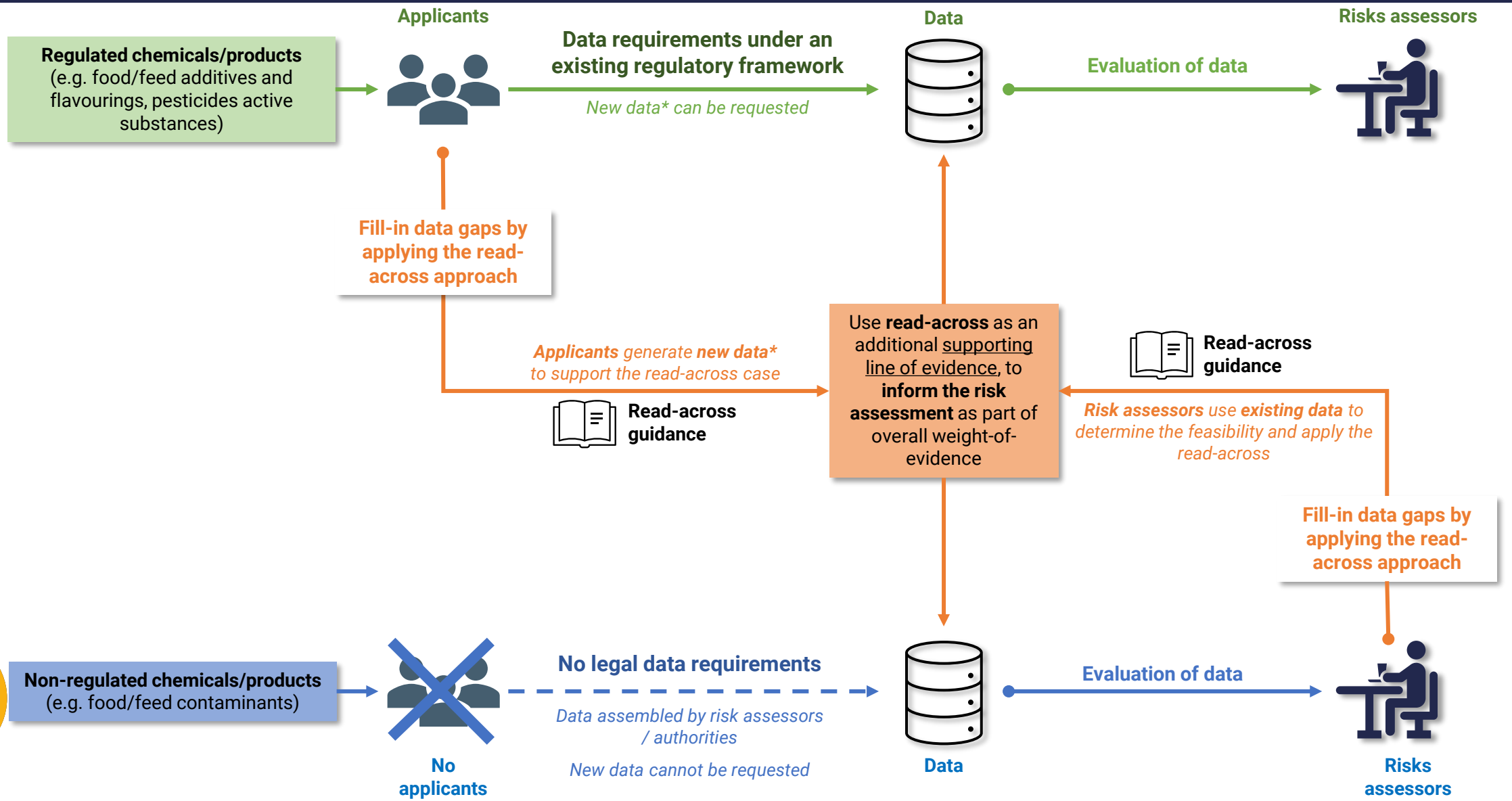
Scope The guidance is specifically applicable to individual substances, including those that are part of a mixture.

Use It is intended to be complementary and inform the risk assessment and used as part of a weight-of-evidence (WoE) approach (not as a substitute of the whole risk assessment process).

Degree of obligation Read-across and the application of this guidance does not supersede already specified data requirements under existing regulatory frameworks. Nevertheless, a case can be made to use read-across as an additional supporting line of evidence in some situations.

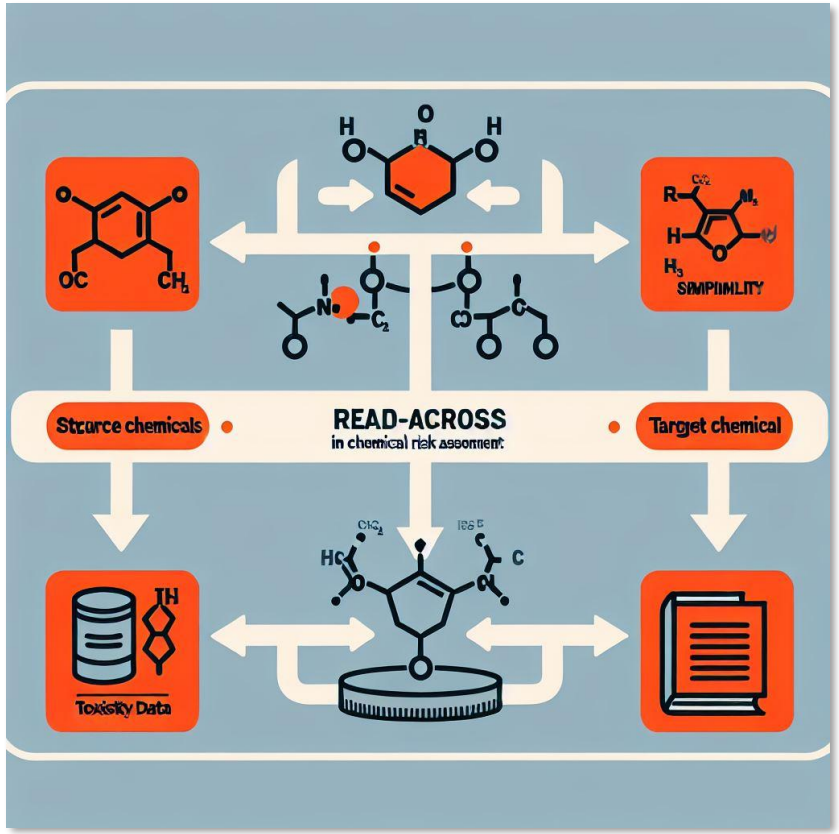
Regulatory acceptance The acceptance of read-across depends on the context of use, the endpoint, and the acceptable level of uncertainty.

BACKGROUND | TARGET AUDIENCE AND INTENDED APPLICATION



BACKGROUND

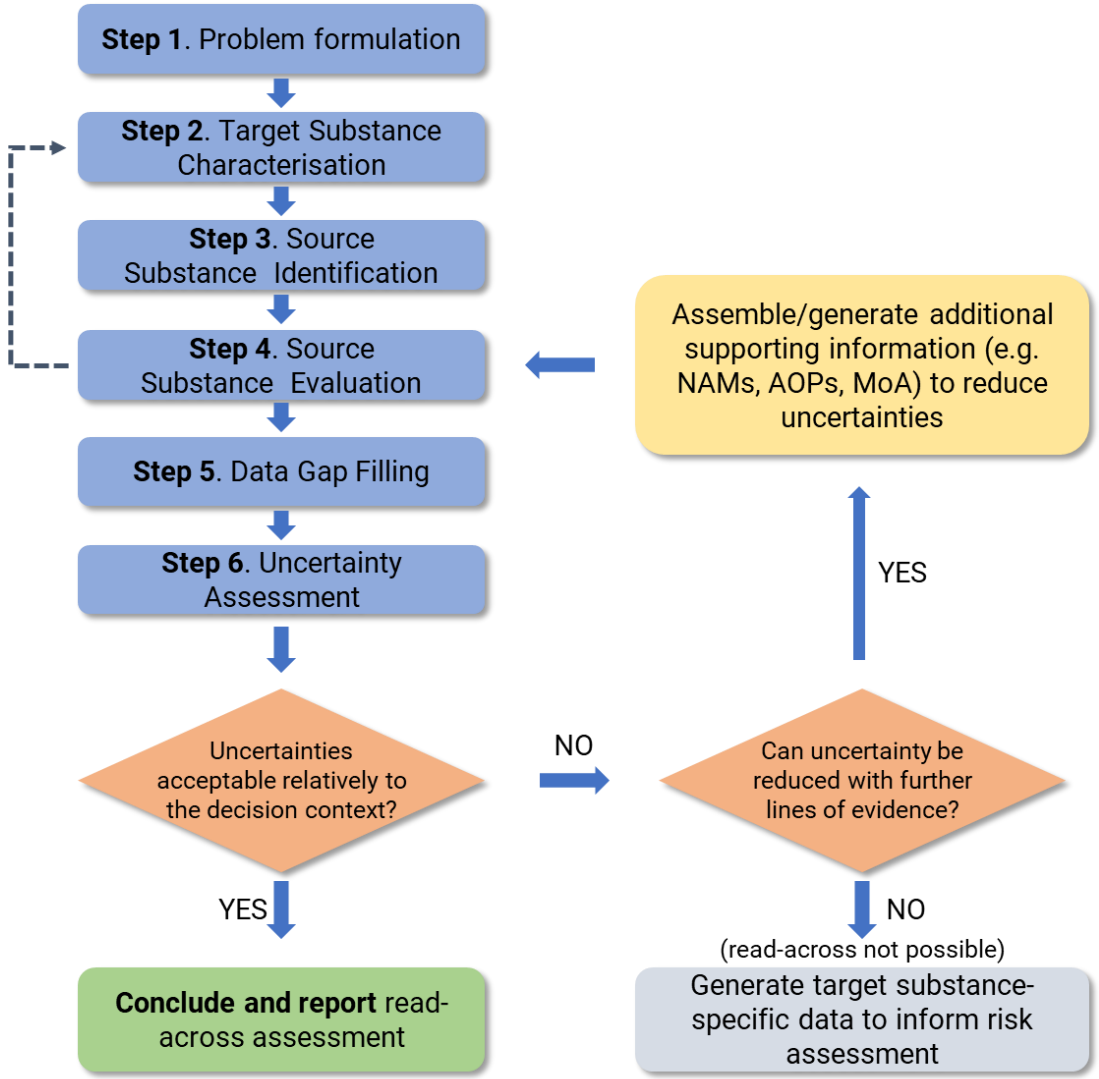
- Read-across is a method used in chemical risk assessment to predict the toxicological properties of a **data-poor substance (target)** by using known information from one or more **data-rich substances (source)** that are structurally and mechanistically similar.
- **Read-across is endpoint-specific**, meaning predictions are made for a defined property relevant to the assessment.
- **Read-across workflow involves several steps**, each with some uncertainty, which must be handled transparently and objectively to ensure scientifically sound and reliable conclusions.



Visual generated by AI (Microsoft Copilot)

Read-across workflow

READ-ACROSS WORKFLOW



The guidance provides detailed explanation of the key aspects that need to be considered at each step of read-across approach, as a support tool to the overall risk assessment process:

1. **Problem Formulation**
2. **Target Substance Characterisation**
3. **Source Substance Identification**
4. **Source Substance Evaluation**
5. **Data Gap Filling**
6. **Uncertainty Assessment**

→ **Conclusion of the assessment**

READ-ACROSS WORKFLOW | STEPS 1-4

Step	Aim	Outcome	Uncertainties with major impact (examples)
1. **Problem formulation**	Define the regulatory context, data gaps, and acceptable uncertainty.	Clear identification of the endpoint and scope of the read-across.	Unclear purpose, unclear substance identity, undefined uncertainty acceptability.
2. **Target Substance Characterisation**	Gather hazard data and define the read-across hypothesis.	A strategy for identifying suitable source substances.	No relevant data found, unclear scope of the data gaps, MoA insufficiently understood.
3. **Source Substance Identification**	Find analogues with structural or functional similarity.	A list of candidate source substances.	Poorly defined similarity rationale, no information on the quality of the databases.
4. **Source Substance Evaluation**	Assess relevance and quality of source substances.	Selection of suitable analogues for read-across.	Lack of toxicokinetic/dynamic similarity, poor data quality.

READ-ACROSS WORKFLOW | STEPS 5-6 AND REPORTING

Step	Aim	Outcome	Uncertainties with major impact (examples)
5. Data Gap Filling	Use source data to fill gaps for the target substance.	Evidence supporting hazard prediction.	Weak integration with other data to complete the overall WoE.
6. Uncertainty Assessment	Evaluate if the read-across is scientifically justified.	Decision on acceptability or need for refinement.	
Conclusion and reporting	Provide a structured and transparent documentation of the read-across process, clearly stating the conclusion and associated uncertainties for the intended regulatory purpose.	Conclusion of the read-across and description of uncertainties. Scientific rationale and strategy, search criteria and sources used. Use of reporting tools (e.g. OECD QSAR Toolbox, IUCLID templates).	

Guidance implementation

GUIDANCE IMPLEMENTATION | INTERNAL MANDATE & WG

Purpose: methodological support for implementing the guidance on the use of read-across for chemical safety assessment in food and feed.

Objectives: promote consistency and harmonisation in the application of the guidance across EFSA activities.

- Offer scientific advice: assist EFSA Units and Panels in addressing methodological questions and challenges that may arise during implementation
- Provide training: ensure a clear understanding of the guidance and its practical application by the business operators and risk assessors

Mandate: M-2025-00103

EFSA-Q-2025-00556
https://open.efsa.europa.eu/questions/EFSA-Q-2025-00556

Deadline: 1 Jan 2029

WG/U/MESE/2025/03 - WG Read-Across
https://open.efsa.europa.eu/working-group/300000068856964

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