

Opportunities for Data Sharing Under EFSA's Latest Read-Across Guidance

In 2025, the European Food Safety Authority (EFSA) published the Guidance on the use of read-across for chemical safety assessment for food and feed.¹ The read-across approach itself is not new; it has been formally recognised by the European Chemicals Agency (ECHA) since the introduction of REACH² in 2007. While REACH defines the legally binding framework for read-across, the EFSA guidance provides a practical assessment approach in a different regulatory context. Both authorities agree that 'read-across (...) is one of the most common alternatives to animal testing.' This article highlights the animal welfare perspective and explores the data-sharing opportunities arising from the new EFSA guidance.

The preparation and submission of an application for regulated products as assessed by ECHA or EFSA such as chemicals, novel foods, feed additives or pesticides is widely recognised as a time- and resource-intensive process, requiring comprehensive compliance with regulatory guidance and a robust demonstration of safety under the intended conditions of use. In this context, the recent EFSA guidance on the use of read-across provides a valuable, non-legally binding, opportunity to streamline dossier preparation while simultaneously supporting the reduction of animal testing. By enabling the use of existing data, the guidance has the potential to reduce both development costs, developmental risks and the need for additional toxicological studies. To assess this potential, it is essential to examine the underlying principles of the read-across approach as described by EFSA.

Read-across allows for the prediction of toxicological properties of a data-poor target substance based on relevant information from one or more structurally and mechanistically similar, data-rich source substances. Consistent with the approach established by ECHA, EFSA distinguishes two principal read-across strategies:

- (i) The analogue approach, which compares the target substance with a limited number of closely related source substances.
- (ii) The category approach, which relies on structural similarity and, where applicable, observed trends or patterns across multiple source substances to predict the properties of the target substance.¹

Irrespective of whether an analogue or a category approach is applied, both follow a common, structured workflow comprising problem formulation, data gap analysis, identification and evaluation of suitable source substances or analogues, data gap filling and uncertainty assessment. A critical final step in establishing confidence in the application of the read-across approach is the provision of structured, transparent and sufficiently detailed documentation.

EFSA has beautifully illustrated an overview of those steps formulated in this read-across guidance document – including further potential approaches to reduce animal testing such as using NAMs (new approach methodologies), assessing AOPs (Adverse Outcome Pathways) or comparing mode of actions (MoA).

The EFSA guidance on the use of read-across for chemical safety assessment describes a structured workflow in which Step 4 plays a pivotal role in evaluating the plausibility of the read-across hypothesis. In Step 4, once relevant source substances have been identified (Step 3), the assembled or generated data are organised in a data matrix. EFSA emphasises that the final decision on source substance evaluation requires expert judgement, since conclusions cannot reliably be derived solely from automated systems or structural alerts. The outcome of Step 4 is therefore a decision either to proceed with data gap filling in Step 5 or to refine the read-across hypothesis through further information gathering in a new iteration. This step is critical for the subsequent uncertainty assessment, as it determines the strength of the supporting evidence and whether additional data are necessary to confirm the proposed read-across.

EFSA's emphasis on expert judgement in Step 4 reflects the guidance's central focus on uncertainty analysis. Uncertainty assessment is essential for a scientifically robust read-across and can be reduced through improved mechanistic understanding between source and target substances. As EFSA highlights, the reliability of read-across depends on high-quality experimental data and either a shared mode of action or clear, consistent trends within a category that support endpoint prediction.

While the EFSA guidance¹ does not explicitly specify the origin of data used for read-across, clearer direction is provided by the REACH Regulation.² Under REACH, data sharing is mandatory (Article 30) and the generation of new *in vivo* data is considered a last resort, to be undertaken only when existing information is insufficient to perform a risk assessment (Article 25).

This raises the practical question of where and how suitable data for read-across can be obtained.

Importantly, data contained in previously submitted dossiers that have become publicly accessible following the introduction of EFSA's Transparency Regulation³ cannot be freely reused. EFSA explicitly states in its Intellectual Property Rights Notice⁴ that: 'the reproduction, distribution, or further use of information and data made available on EFSA's website may be subject to intellectual property protection and that their use without prior permission of the rights holder may constitute a legal violation.'

The same holds true for ECHA chemical data,⁵ where every user of the ECHA database must consider that: 'The reproduction, distribution or further use of information, documents and data contained in the ECHA website and/or in ECHA's databases may be subject to protection under intellectual property rights and other rights and their utilisation without obtaining the prior permission from the rightholders(s) of the respective information, documents and data might violate the rights of the rightholder(s).'

Consequently, when relevant data are neither available in the open literature nor owned by the applicant (e.g. from previous registrations), alternative routes like contract data sharing must be considered. One option is to directly approach

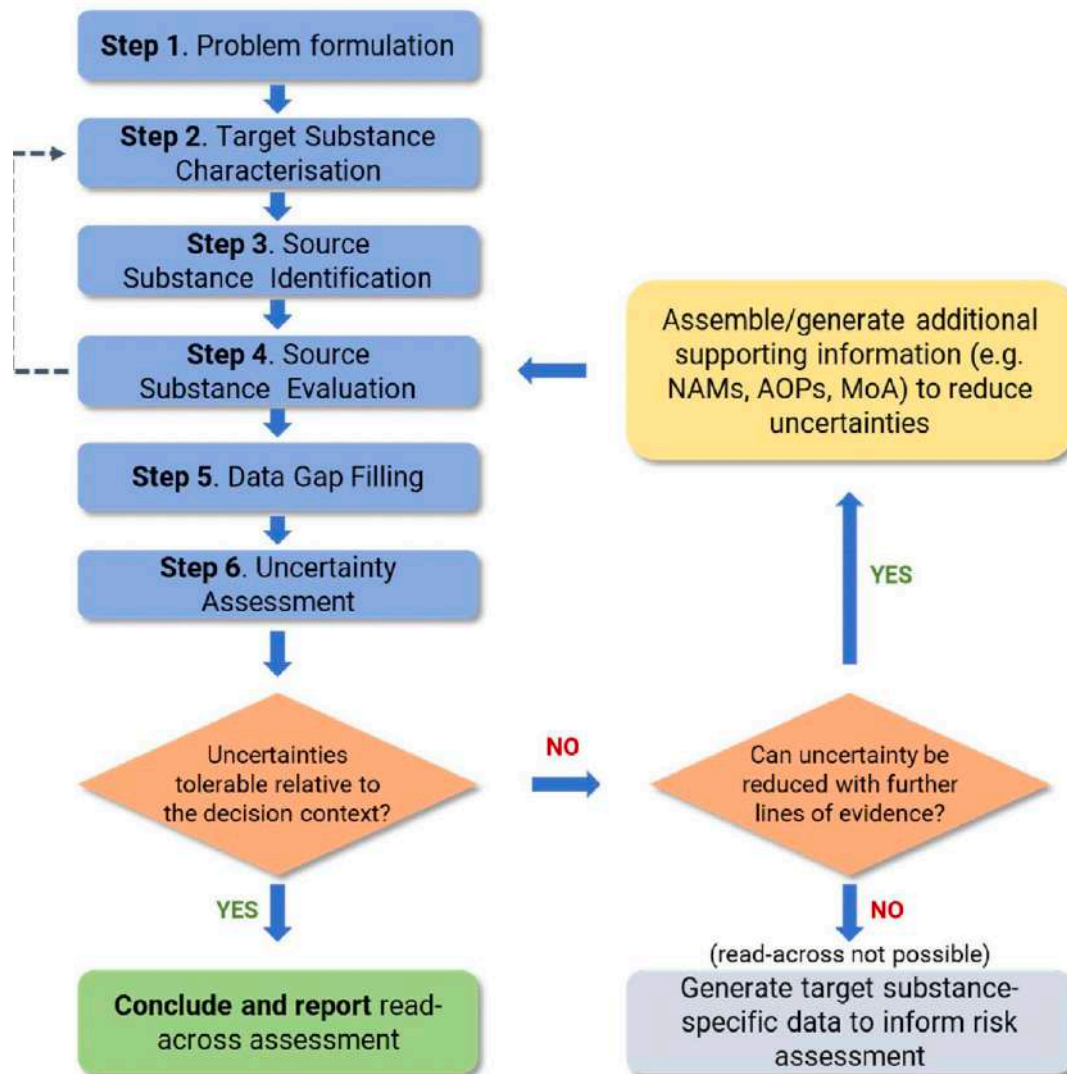


Figure 1: Structured workflow on read-across from the EFSA Guidance on the use of read-across for chemical safety assessment in food and feed. EFSA Journal, 23:2025. <https://doi.org/10.2903/j.efsa.2025.9586>

companies holding the relevant data and negotiate 'letters of access,' or complete copy rights. In practice, this is often challenging – due to the need to keep new product pipelines as confidential as possible, or simply due to difficulties in identifying appropriate contact persons. As an alternative, specialised data brokers, such as 4ReValue GmbH,⁶ have emerged that focus specifically on facilitating access to toxicological study data. This service includes:

- Anonymised presentation of the data sets available for sale and/or of required data sets.
- Independent scientific rating of data quality.
- Assistance with pricing and contract drafting for both parties.
- Service charge only in case of concluded data-sharing contract as brokerage fee.

A match can help save laboratory animals lives, re-capitalise the assets of the data provider and save time and money for the data customer (including risk reduction – as the experimental outcome is clear).

Evidence on how frequently read-across has been applied under REACH is provided by Roe *et al.* (2024),⁷ who evaluated ECHA dossiers submitted between 2008 and 2023 against multiple criteria. Approximately 23% of submitted dossiers included read-across adaptations and nearly half of these (49%) were ultimately accepted. Notably, category-

based read-across approaches were more successful than analogue approaches. It remains to be seen how frequently read-across will be submitted to and accepted by EFSA in the context of food and feed safety assessments.

Beyond data sharing, EFSA's read-across guidance is also characterised by a strong animal welfare perspective. Compared with the REACH framework and the 2017 Read-Across Assessment Framework (RAAF), a notable feature of the EFSA guidance is its explicit emphasis on the integration of new approach methodologies (NAMs). These include *in vitro* methods and *in silico* models, which can be used to support and strengthen mechanistic plausibility and thereby increase confidence in read-across justifications. Importantly, NAMs are not excluded under the RAAF, which is method-neutral and allows NAM-derived evidence provided it is relevant, robust and transparently documented. In this respect, EFSA's guidance complements the REACH/RAAF framework by explicitly promoting the use of NAMs in a food and feed safety context and by clarifying their role in reducing uncertainty.

However, despite this regulatory momentum, the translation of NAMs into routine assessment practice remains uneven. It is striking that a substantial proportion of current EU research funding is directed towards the development of NAMs (Table 1: not exhaustive but illustrative), highlighting a potential gap between methodological innovation and its systematic regulatory uptake.

Call	Status (January 2026)	Deadline / Timeframe
Translating Disruptive NAMs into Practice (EIC-AIC-02)	OPEN	Until 02/26/2026
Integrating NAMs to advance research (HLTH-01-TOOL-03)	OPEN	Until 04/16/2026
Support to European Research Area (ERA) Action on accelerating NAMs (HLTH-01-TOOL-06)	OPEN / ONGOING	Until 04/16/2026
NAM experience & regulatory confidence (HLTH-2024-IND-06-09)	CLOSED	Until 04/11/2024
Alternative methods to animal testing (BMFTR*)	OPEN / ONGOING	Until 03/15/2026
Animal Welfare Research Award (BMLEH**)	OPEN / ONGOING	Until 03/31/2026
Felix-Wankel Animal Welfare Research Award	OPEN / ONGOING	Until 09/30/2026

*BMFTR: Bundesministerium für Bildung, Forschung, Technologie und Raumfahrt (German Federal Ministry of Education, Research, Technology, and Space)
 **BMLEH: Bundesministerium für Landwirtschaft, Ernährung und Heimat (German Federal Ministry of Agriculture, Food, and Rural Affairs)

Table 1: EU research funds for NAM projects

A notable precursor to current NAM-focused research was the SEURAT-1 (Safety Evaluation Ultimately Replacing Animal Testing) program, launched on 1 January 2011 and running for approximately five years until 2016, represents an example of early efforts to bridge this gap. SEURAT-1⁸ was a European public-private research consortium aimed at advancing animal-free testing strategies while maintaining a high level of consumer protection. Although its long-term vision was the development of an initial toxicity predictions based on a comprehensive mechanistic understanding, the initiative explicitly acknowledged that, in the nearer term, data generated from innovative testing methods would be used to support read-across arguments. This approach was illustrated through case studies that integrated *in vitro* assays, computational models and mechanistic information to strengthen read-across justifications. The resulting conceptual framework for an integrated assessment strategy has since informed international developments in the use of alternative approaches and 21st-century tools for chemical safety evaluation.

In summary, EFSA's new read-across guidance aligns with the conceptual framework established by ECHA, while placing explicit emphasis on reducing animal testing, accepting alternative methodologies, and recognising data sharing as a legitimate means of assembling evidence to support read-across justifications. The extent to which these provisions will be adopted in future regulatory practice remains to be determined and will ultimately depend on their practical implementation and the generation of sufficient confidence in NAM-based evidence. Practical solutions for data-sharing are offered by specialised contract research data brokers like the 4ReValue GmbH.

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Dr. Regina Ohlmann

The veterinarian Dr. Regina Ohlmann recognized the strong potential of read-across approaches to efficiently close data gaps in the preparation of authorisation dossiers for food and feed applications. Together with Dr. Schreiner, she founded 4ReValue GmbH to enable structured data sharing and provide solutions for missing data, while actively contributing to the global reduction of animal testing.

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Dr. med. Vet. Regine Schreiner founded Feed and Additives GmbH in 2014. Her experience in the approval of feed additives led to the idea of initiating the data sharing portal, 4ReValue GmbH, in May 2023 with Dr. Ohlmann. 4ReValue GmbH stands for reducing animal studies in contract research by sharing data and initiating calls for common sponsorships.

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