

## Using read-across data for new substance applications

When you are seeking approval for a chemical pesticide containing new substances and there is no data available on the new substance you are seeking approval for, using read-across data from a similar substance might be an option. The EPA may accept read-across data for all endpoints and where you have specific data gaps.

### Read-across data and your application

Read-across data is most likely to be accepted when an active ingredient of a pesticide is very closely chemically related to an active ingredient for which formulations are already approved, such as a different salt or ester of the same base active ingredient.

In the case where a new salt/ester form is created, a read-across approach may be acceptable. This means your substance can be treated as a Category A application, even if the salt/ester form is new to New Zealand. If the read-across approach is not accepted or you do not have legal access to the data, a Category C application with supporting data may be required.

There are detailed guidance documents that can be used as a reference for developing your read-across justification. These have been developed by the Organisation for Economic Co-operation and Development (OECD), European Chemicals Agency (ECHA), and others and are listed in the *more information* section below. There are also tools, such as the QSAR toolbox, that can help you to define the similarity justification.

### What do you need to provide?

1. Information on the final composition of the active ingredient (that is, after acid/base reaction for instance) must be provided.
2. If you do not own the read-across data, you need a Letter of Access signed by the owner of the relevant data to grant an authorisation to use data in support of a product, the study reports, a European Union draft assessment report or other regulatory review(s).
3. Information on substance identity for each substance included in the category or analog approach, and the similarity justification.

4. The EPA can request additional information on the source substance and the target substance, including:
- identifiers such as the CAS (Chemical Abstracts Service) number and EC (Enzyme Commission) number
  - chemical structures
  - physical/chemical properties, such as physical form, molecular weight, density, pH, water solubility, log Kow, vapour pressure, granulometry, and dissociation constant.<sup>1</sup>

## Definitions

**Analog:** A chemical compound that has a similar structure and similar chemical properties to those of another compound, but differs from it by one or a few atoms or functional groups.

**HSNO Application Category A:** Only a limited information package is required, for example where the components of the substance have been previously classified and the risks of the substance are understood and can be managed by standard controls.

**HNSO Application Category C:** A comprehensive information package is required, for example where one or more of the major hazardous components of the substance have not been previously classified by us and a full hazard and risk evaluation is required.

**Endpoint:** The measure of a biological effect, for example LC<sub>50</sub> or EC<sub>50</sub>. A large number of endpoints are used in regulatory assessments of chemicals. These include lethality, carcinogenicity, immunological responses, organ effects, developmental and reproductive effects.

**Letter of Access (LoA):** A document, signed by the owner (or owners) of relevant data protected under the provisions of a regulation, which states that these data may be used by the EPA for the purpose of assessing a product. In principle the LoA gives permission to refer to a certain study or set of studies, but it does not transfer ownership.

**Log Kow:** Logarithm to the base 10 of the 1-octanol/water partition coefficient.

**Read across:** Endpoint information for one or more chemical (the source chemical(s)) is used to predict the same endpoint for another chemical (the target chemical) that is considered to be “similar” in some way (usually on the basis of structural similarity or having a similar mode or mechanism of action). Sometimes, it is referred to as “data bridging”.

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<sup>1</sup> If a new salt form of an active ingredient is formed, evidence to support the conclusion that it will rapidly dissociate in the environment should be provided.

## For more information on read-across data

European Chemicals Agency (ECHA) Guidance on Information Requirements and Chemical Safety Assessment, chapter R.6: QSARs and grouping of chemicals, May 2008.

[http://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r6\\_en.pdf](http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf)

North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (TWG) (Quantitative) Structure Activity Relationship [(Q)SAR] Guidance Document November, 2012.

<http://www.epa.gov/oppfead1/international/naftatwg/guidance/qsar-guidance.pdf>

Organisation for Economic Co-operation and Development (OECD) Guidance on Grouping of Chemicals, second edition, Series on Testing & Assessment, No. 194, ENV/JM/MONO(2014)4.

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)4&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)

OECD QSAR toolbox – The toolbox is a software application intended to be used by governments, chemical industry and other stakeholders to fill gaps in (eco)toxicity data needed for assessing the hazards of chemicals. The toolbox incorporates information and tools from various sources into a logical workflow.

<http://www.oecd.org/chemicalsafety/risk-assessment/theoecdqsartoolbox.htm>

Read-Across Assessment Framework (RAAF) – RAAF is used by ECHA to assess read-across approaches when encountered in registration dossiers with respect to documentation and scientific justification.

[http://echa.europa.eu/documents/10162/13628/raaf\\_en.pdf](http://echa.europa.eu/documents/10162/13628/raaf_en.pdf)