

Read-across Assessment Guidance

Korea Chemicals
Management Association



KCMA

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Korea Chemicals Management Association

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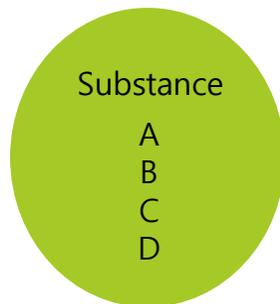


1. Background and Definition

Read-across guidance background

- Read-across method has been used in OECD HPV substance evaluation, US, EU and etc. for the assessment of existing and new chemical substances
- Read-across approach has been used as one of alternative ways of animal test to minimize vertebrate tests, especially in EU REACH.
- The guidance is provided for the reduction of cost and time on generating test data during the registration under ARECs
- A chemical substance can be registered by utilizing the test data of its similar chemical (Article 13 sub-paragraph 4 of enforcement decree of ARECs)

Grouping



"Toxicity test data of substance A"

Read-across approach

"Utilization of the data for the registration dossier of Substance B, C, D"

Reduction of

- **Animal Test**
- **Registration Cost**

<Similar structure and characteristics>

| Applicable Condition

- **Alternate source of test data must be adequate and reliable for the purpose of classification & labelling and/or risk assessment**
 - Should provide reliable dose descriptor so that the data can be used for the risk assessment defined under ARECs
 - Should follow internationally adequate and reliable test method and cover an exposure duration comparable or longer than the corresponding method

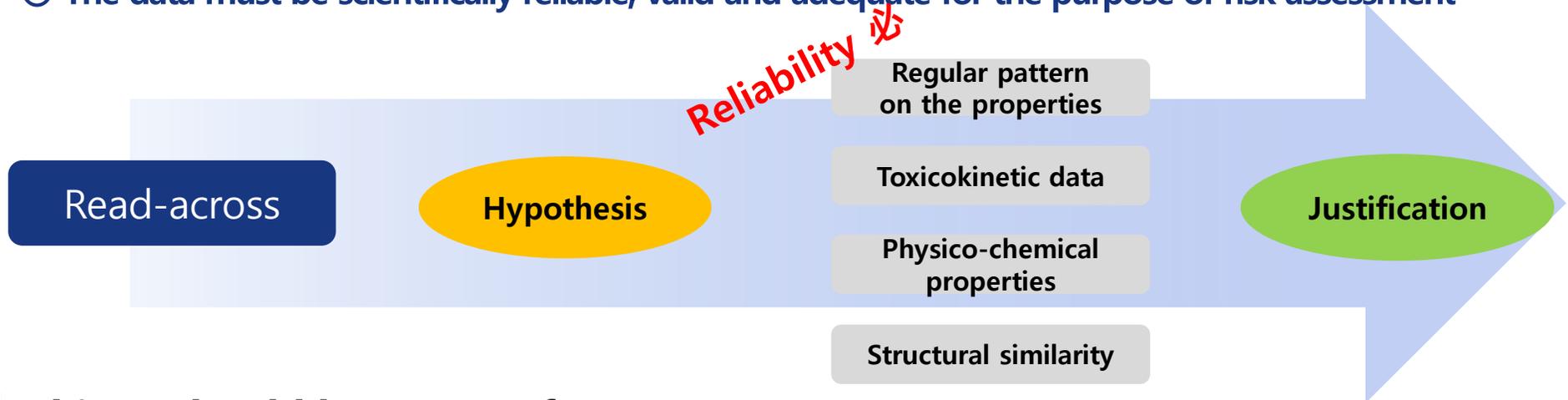
- **Read-across approach must be documented thoroughly for its independent assessment of appropriateness and scientific justification**
 - Read-across Hypothesis
 - Read-across Justification
 - List of all chemical substances included in Read-across
 - Identification of all substances included in Read-across
 - List of tests applied to Read-across approach
 - Data matrix
 - Conclusion on applicability

Requirements

- Assessment on structural similarity of reference substance and target substance
- Toxicokinetics and metabolism
 - When similarity of substance is based on in vivo studies of metabolic process, the existence of metabolic pathway must be substantiated
- Physicochemical properties
 - Molecular weight, log Kow, water solubility, vapor pressure, granulometry, dissociation constant
- Reference and supporting evidence
 - Supporting evidence such as scientific reference (existing available data) and (Q)SAR estimated data for read-across justification

Conclusion

- Data utilization of reference substance is necessary in the aspect of animal protection and cost reduction
- The data must be scientifically reliable, valid and adequate for the purpose of risk assessment



Things should be aware of

- Read-across utilization does not mean that the test data, cost or time for the registration is not required
- Establishment and justification of hypothesis may cost a lot of money and require experts' analysis
- Read-across assessment may be rejected or require additional data depending on the NIER's judgement

Thank you

