

Summary of Data Transportability Concepts and Presentations

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Explanation of the Presentation

What follows is a short summary

- Attempting to identify key characteristics of each presentation

The purpose is to help inform our discussion of the different ideas and concepts for data transportability

The summaries have been prepared by the organizers, and it is fully recognized that some of the details will be lost in each summary

However, this should still provide a useful starting point for our discussions

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Identifying surrogate environment to facilitate data transportability for ERA

- Provides a scientific rationale for using data produced in other places in support of regulatory risk assessments
- If the trial was conducted in an environment that is relevant for the importing country the data is expected to be the same as a trial conducted in-country
 - Uses agroclimate to identify relevant environments
- Crop and trait independent
 - Although crop specific information can help identify relevant environments

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EU Import Environmental Risk Assessment

Data must come from an environment that is “typical” for the crop being grown

- Regardless of what country the data is generated in
- However, the field trials need to be conducted in multiple environments sufficient to assess the plant under a variety of conditions

Import Assessments include a subset of information taking into account expected exposure

- Persistence and invasiveness
- Gene transfer to microorganisms

Relatively independent of crop and trait

- Problem formulation informs any specific assessment

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CFT Transportability in Argentina

Always considers the problem formulation for a case specific risk assessment

Data will be transportable if:

- The field trials have been conducted in multiple environments sufficient to assess the plant under a variety of conditions
- The trial site is considered the same as a trial site in Argentina, based on a comparison of environments

Does consider the crop and the trait

- But doesn't exclude consideration of transportability outside of specific cases

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Japan Import and Cultivation

Will allow data transportability if:

- The host plant is familiar with low weed potential in Japanese environment (Only Corn is accepted at this moment)
- The trait is familiar and mode of action is well understood (The gene has to be tested in Japan CFT with other GM events previously)

Environments where trials are conducted outside of Japan can be diverse

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ILSI Japan

Data from CFT should be transportable

If sufficient information on no weed potential of the host in the receiving environment is available

If trials have been conducted across a range of environments sufficient to assess the plant under a variety of conditions

This is independent of the trait being tested

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