Data Transportability of CFT in Argentina

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Confined Field Trials (CFT)

- Wich studies are involved in CFT?

Environmental risk assessment (ERA)

- Agrophenotypic caracterization.
- NTO studies (Tier 3 and 4).
- Efficacy of the technology.
- Expression levels of the introduced sequences.

Data transportability of CFT

Questions about studies performed in other countries :

- Can we considered CFT performed in other countries?
- Can we adopt the same criteria for all studies?
- What information is necessary to accept the CFT?
- It is necessary that the agro-climatic or agro-ecological conditions from the CFT match with the regions or country where the crop will be planted?
- What we transport, data or conclusions?

What we rely on to answer these questions?

Problem Formulation

Agrophenotypic Studies

Objectives to be evaluated

Respond to the risk hypotheses developed from the problem formulation (hypotheses formulated with respect to possible expected effects).

Evaluate unexpected effects caused by the insertion and / or the interaction of the product / s of expression with the biological processes of the plant.

Sustancial equivalence between the GM crop and the conventional counterpart.

Is it necessary to transport the data of the agrophenotypic study?

It depends on the objective

Respond to the risk hypotheses (formulated with respect to the introduced characteristic).

Evaluate unexpected effects caused by the insertion and / or the interaction of the product / s of expression with the biological processes of the plant.

Sustancial equivalence between the GM and the conventional counterpart.

It depends on the risk hypotheses.

We consider that is sufficient to **Transport the Conclusions**.

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For those cases in which the risk hypothesis to be answered requires a test in a particular site, you can use the **Data Transportability** or perform the CFT at the site of interest.

Characteristics that the agrophenotypic studies must have to transport the conclutions

The agrophenotypic study must be performed in a wide range of environments. The sites must differ in:

Climatic variables
- Temperatures
- Rainfall
- Solar radiation

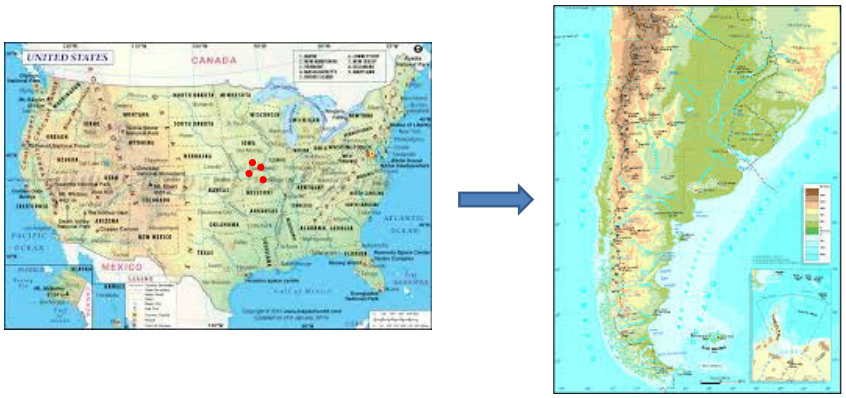
Edaphic conditions

Latitude

Ensures GM crop interaction with different environments (Phenotype = Genotype x Environment)

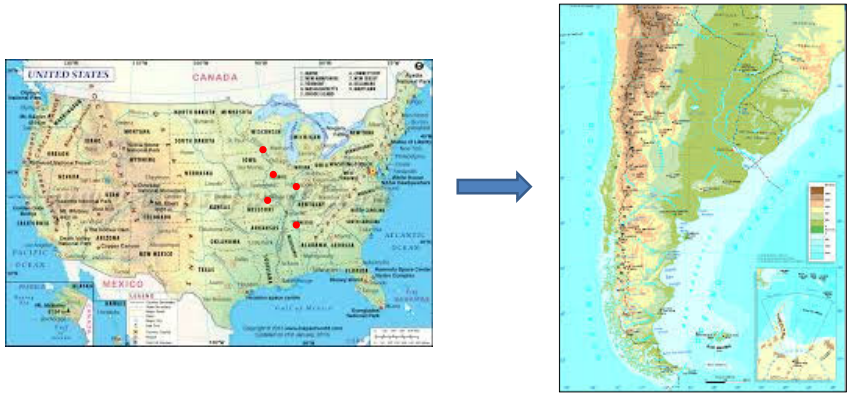
Environmental range of the agrophenothypic study

Narrow environments interaction



Environmental range of the agrophenothypic study

Medium environment interaction

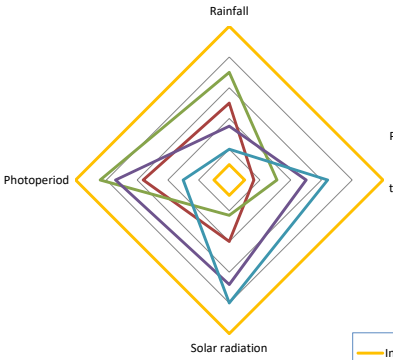


Environmental range of the agrophenothypic study

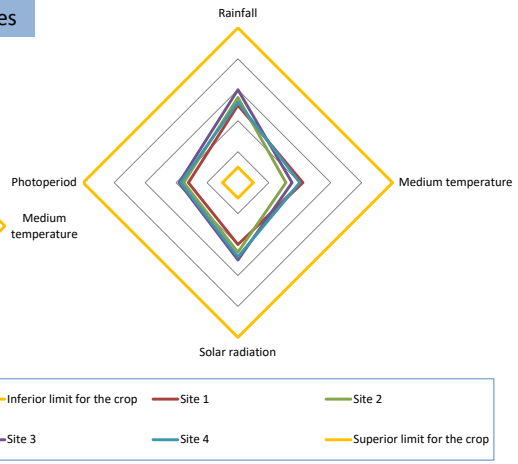
Wide environment interaction

Environmental range of the agrophenothypic study

Wide range of climatics variables

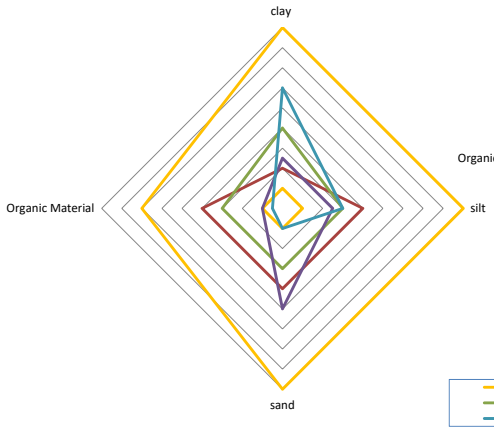


Narrow range of climatic variables

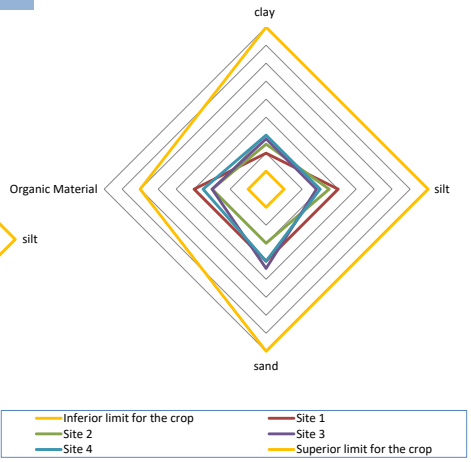


Environmental range of the agrophenothypic study

Wide range of edaphics conditions

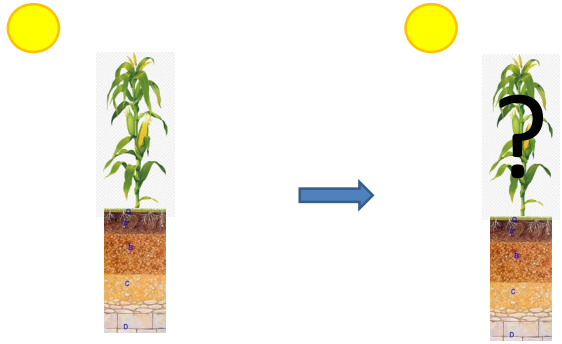


Narrow range efedaphics conditions



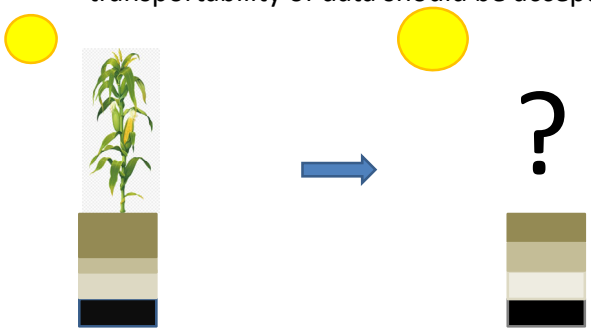
Is the data from the agrophenotypic study transportable?

If a comparison of environments is made and it is concluded that they are equivalent, we consider that the data of the agrophenotypic study is transportable.



Is the data from the agrophenotypic study transportable?

If there are differences in any of the environmental characteristics requested for the transportability, we analyze it influence on the assessment endpoint. If the difference influences, the data shouldn´t be transportable. If not, the transportability of data should be accepted.



What information is necessary to support data/conclusions transportability?

- Latitude
- Rainfall
- Temperatures
- Edaphic conditions

Informative Map

- Agronomic and cultural practices

- Both the experimental design and the presentation of the documented information from the CFT must fulfill the requirements of the technical-scientific bases and local regulatory entity (methodology, statistical analysis, treatments and specific considerations of it).

- Specific abnormalities of the study: drought, flood, etc.

NTO – Problem Formulation

Basic information

Arthropods that are in interaction with the crop.

Bibliography of the country or region.

Study of arthropods abundance.

Arthropods are categorized into functional groups and taxa.

- Is there any protected or valued insect-arthropod in our country ?
- Is this insect exposed to the GM crop?
- Has this insect been considered in the assessment?
- Is it phylogenetically related to any of the evaluated arthropods?
- Would it be necessary to perform a particular study on the insect?

Problem Formulation

Problem Formulation: NTO

Risk hypothesis testing

Theoretical

Pathway to harm

Risk = Hazard x Exposure

Experimental

Speficic studies of NTO

Tier approach - NTO

TIER 1: Lab with purifird protein

Elevated doses . Controlled conditions -

TIER 2: Lab, with plant tissue

"Real" doses . Controlled conditions -

TIER 3: Semi- field

Real doses . Controlled conditions-

TIER 4: Field

Real doses, real field conditions –

NTO

LAB studies

If the assessed insect is relevant for the receiving enviroment, the data is transportable because the conditions are controlled (independent from agroclimatic variables) and replicated. Moreover, these standardized assays can be easily reproduced.

NTO

Semi field studies

(3° steps of tear approach)

Could be transported if:

- Insect (s) are interest (relevant) to the receiving country /environment
- We have to analyse the similarity of agroclimatic conditions in order to conclude about the expression levels of the new protein and/or comparing the expression levels in the local conditions and in the remote country can be also considered.

NTO

Fiels studies

(4° steps of tear approach)

Could be transported if:

- Insect (s) are interest (relevant) to the receiving country /environment
- We have to analyse the similarity of agroclimatic conditions in order to conclude about the expression levels of the new protein and/or comparing the expression levels in the local conditions and in the remote country can be also considered.
- Similarity of biotic interactions (Example: Weeds in interaction with the NTO, Parasitoids and so on).

Efficacy of the technology

Herbicide tolerance

Field studies from other countries are accepted. It´s important to use the same or higher herbicide dose in the country that the data pretends to be transported.

Insect Resistance

Field studies are accepted in those cases in which the evaluated species are the same. They are complementary to the laboratory study that demonstrates the effectiveness of the protein. It is necesarily to analyce a wide range of environments.

Expression levels and pattern

Study endpoints:

- Analyze expression in different tissues.
- Formulate risk hypotheses (pathway to harm).
- Interaction between expression products in stacked GM crops

The **Data Transportability** is only requested in those cases in which there is a risk hypothesis that suggests that there are expression levels that may adversely affect on the agroecosystem. If warranted, the local study will be performed.

If there isn´t a risk hypothesis we **Transport the Conclutions**. It is necesarily to analyce a wide range of environments.

Data Transportability

Uncertainty is reduced as a wider diversity of environments is tested where unexpected differences that can have an adverse effect are not observed.

Thank you!!!

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