Assessment of the representativeness of the sites and management practices

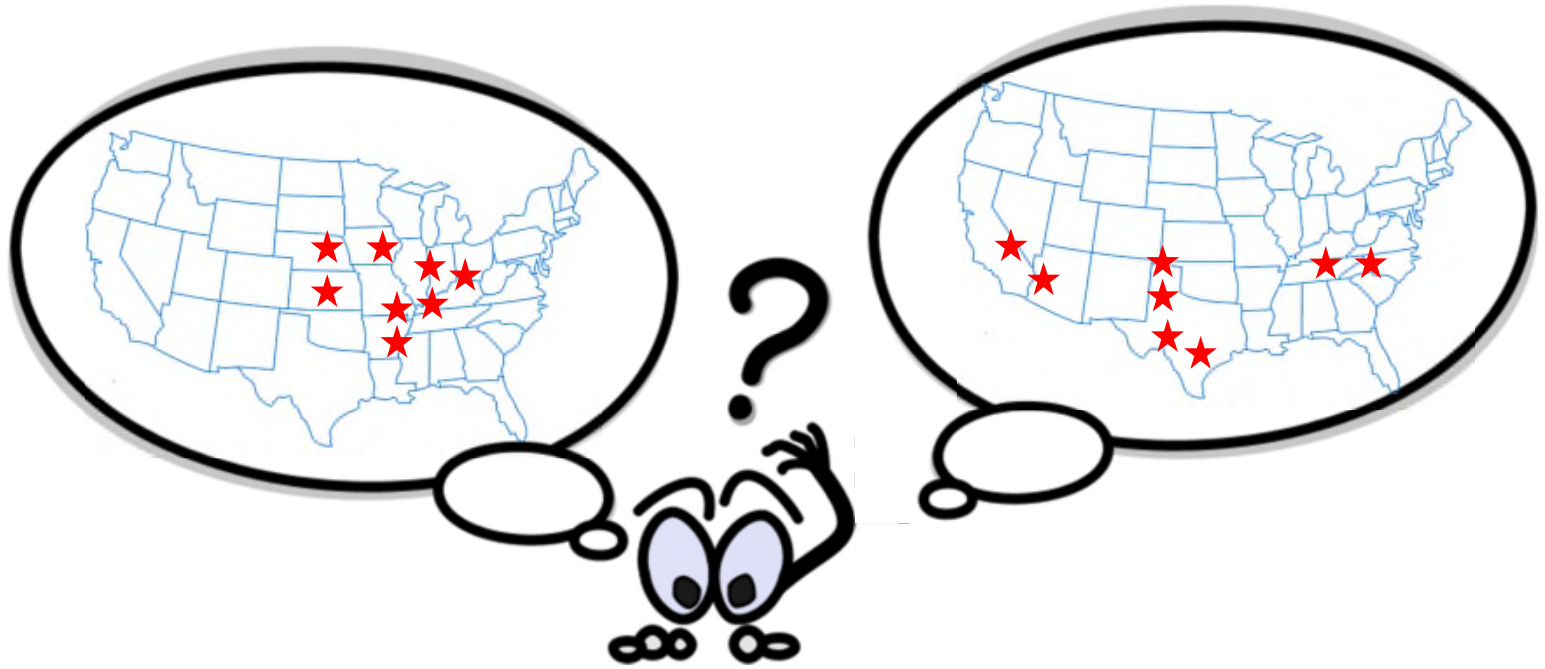
9 November 2017

Ad hoc meeting with applicants

efsa
European Food Safety Authority

OBJECTIVE OF PRESENTATION

To share information on how the representativeness of sites and management practices are assessed by the GMO Panel

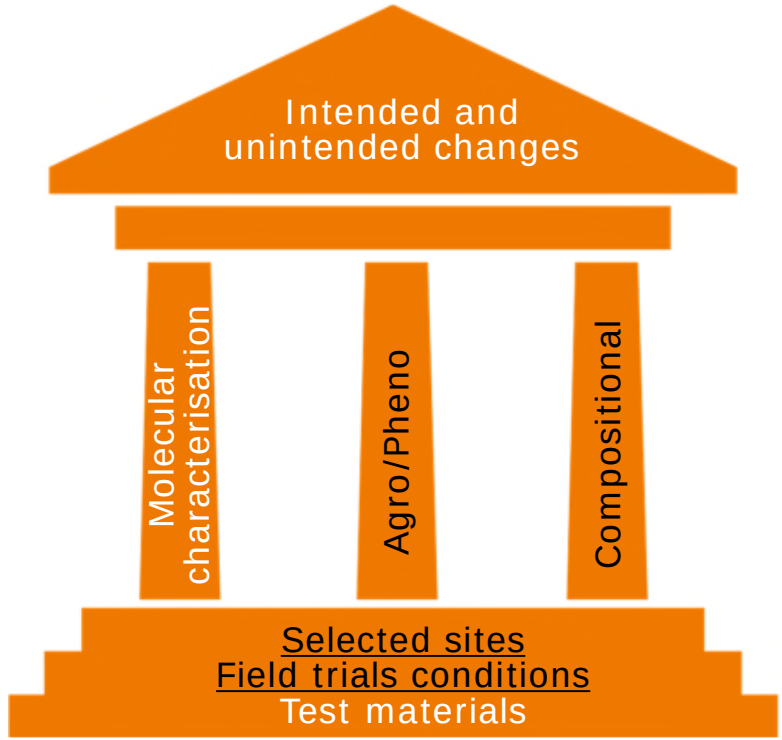


OUTLINE

- Background/context
- Approach
- Examples
- Considerations

WHY DOES SITE REPRESENTATIVENESS MATTER?

Molecular, agronomic/phenotypic and compositional characterisation to identify intended and unintended differences between a GM plant and its conventional counterpart



THE PRINCIPLES OF SITE SELECTION

The different sites selected for field trials shall

EFSA GMO Panel GD on RA of food/feed from GM plants (2011)

- ***be representative of the range of receiving environments where the crop will be grown***, *thereby reflecting relevant meteorological, soil and agronomic conditions;* ***the choice should be explicitly justified***.

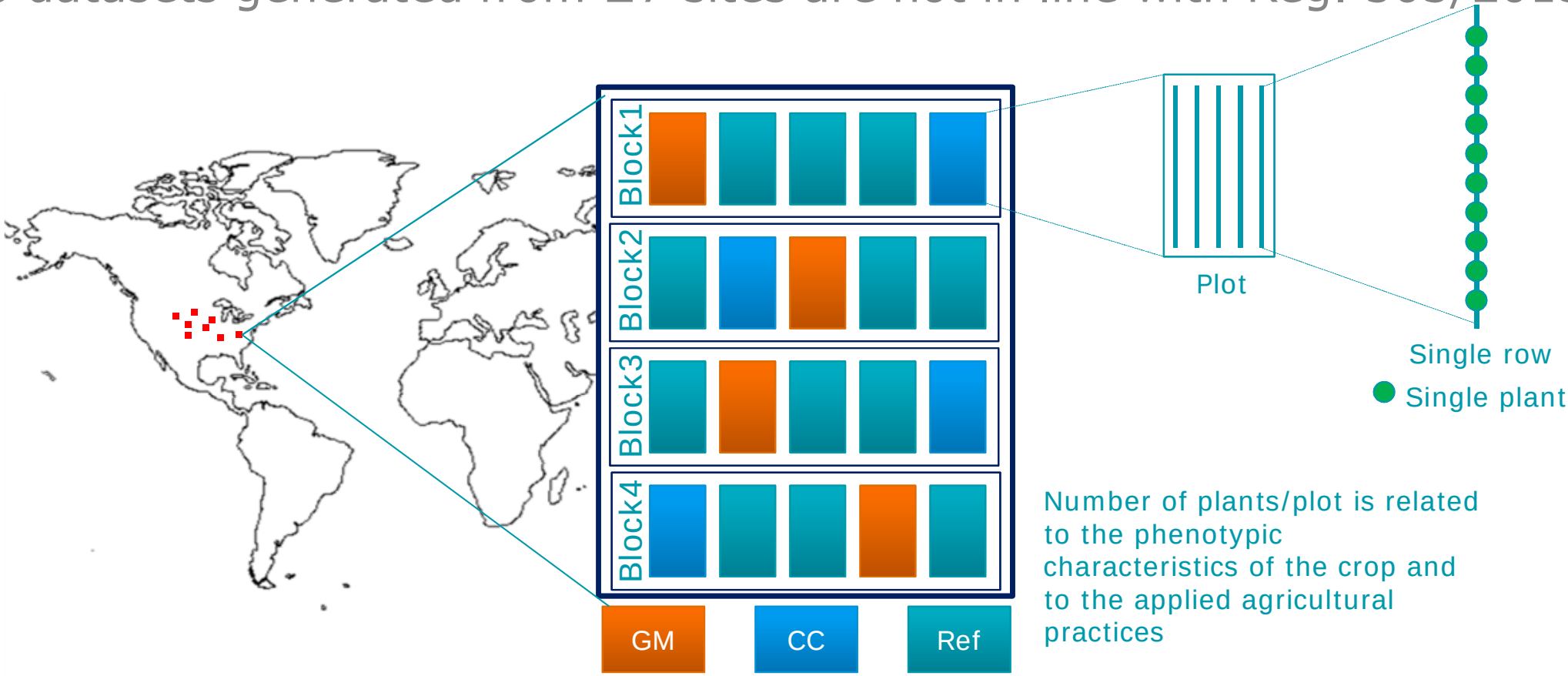
Regulation (EU) 503/2013

- ***reflect the different meteorological and agronomic conditions under which the crop is to be grown***; ***the choice shall be explicitly justified***.

→ Site **selection** and its **rationale** are relevant

EXPERIMENTAL DESIGN: MINIMAL REQUIREMENTS

8 sites, 1 GM plant, 1 comparator, 6 reference varieties (3 per site)
Randomised Block Design
8 datasets generated from ≤7 sites are not in line with Reg. 503/2013



This enables drawing conclusions on materials produced under conditions different from those tested to support the specific application

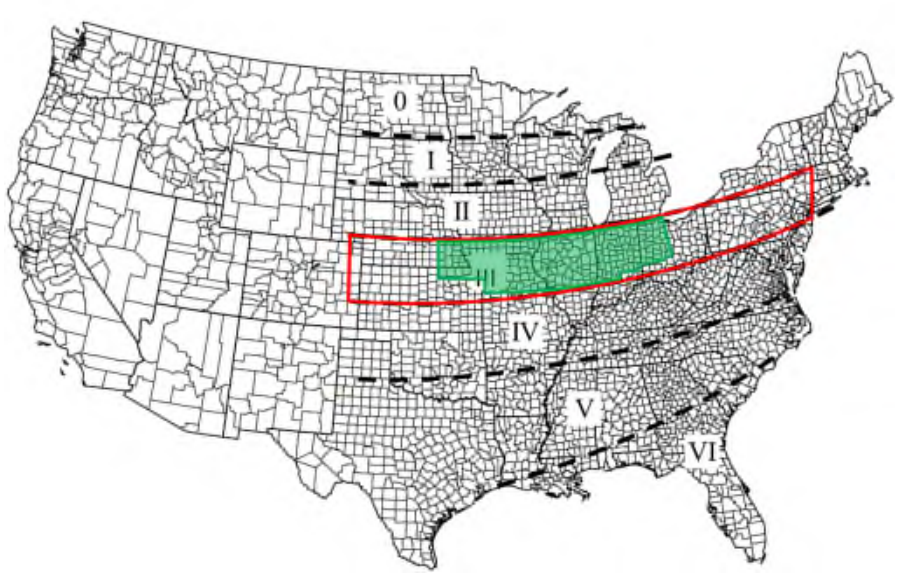
SITE REPRESENTATIVENESS FROM THEORY TO PRACTICE

- The selected field trial sites should capture **enough variability within the set of possible receiving environments** (REs) in which test materials can be grown

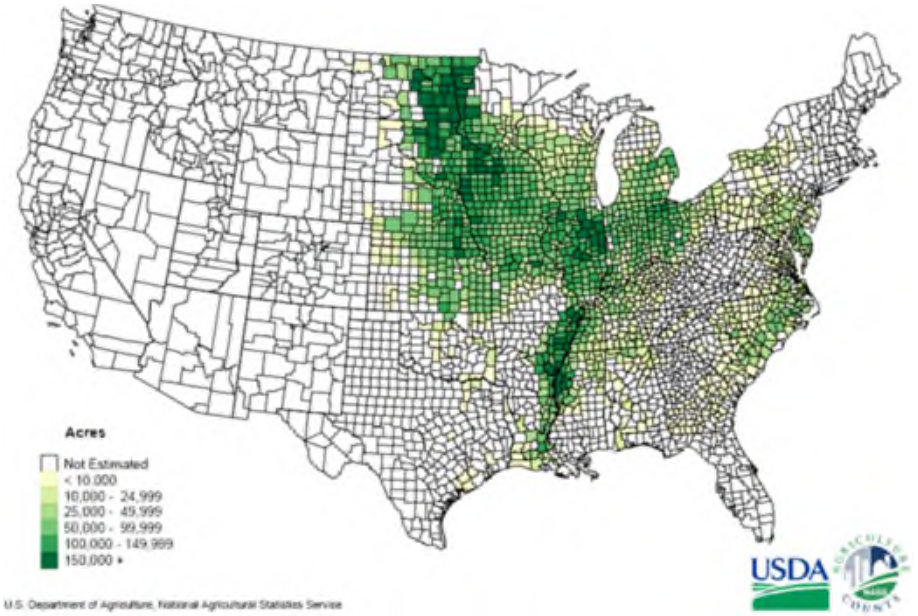
- Each receiving environment is characterised by:
  - more **stable** characteristics
    - adaptability of plant materials
    - geographical distribution of the crop
    - historical agrometeorological characteristics
    - soil characteristics
  - **variable** conditions which are year dependent or under human control
    - specific agrometeorological conditions
    - exceptional weather conditions
    - crop management practices

MATERIALS AND CROP DISTRIBUTION (STABLE)

Plant materials:
A boundary is based on the agronomic characteristics of the GM line and other test materials

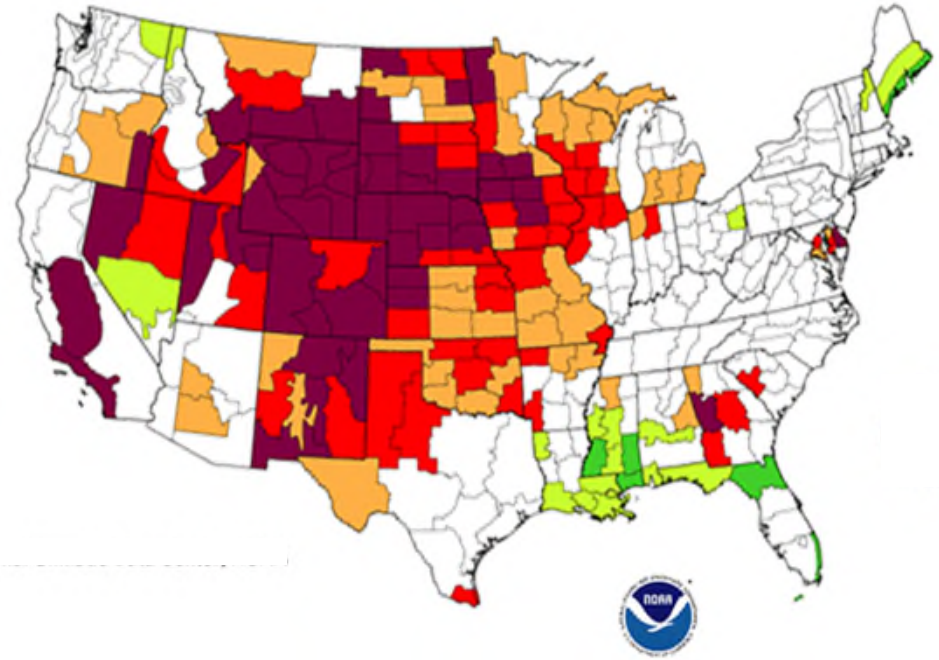


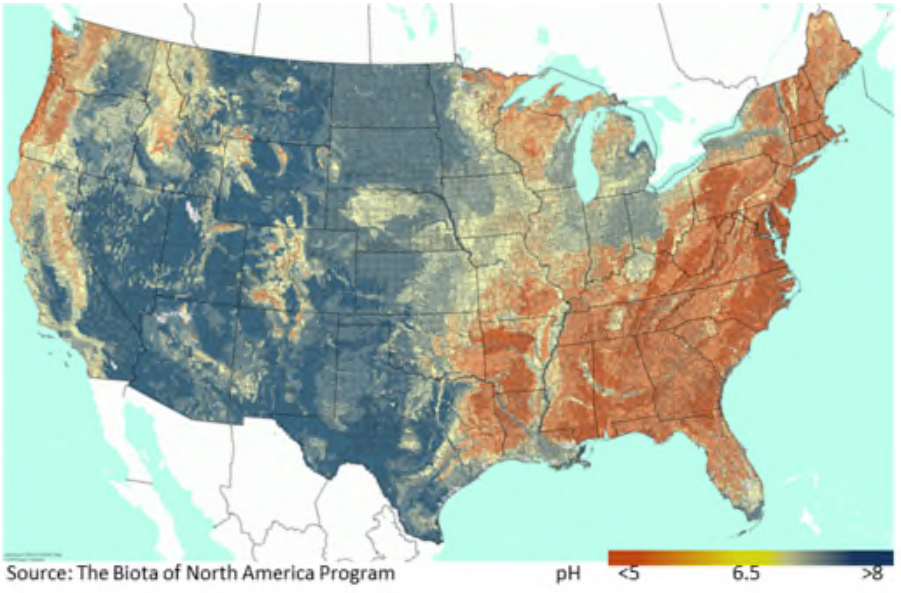
Crop distribution:
To be representative the sites should be within the areas where the crop is typically grown



HISTORICAL AGROMETEOROLOGICAL CONDITIONS (STABLE)

Agrometeorological conditions & soil conditions:
In this case, the diversification is achieved by selecting representative sites in the likely REs, that are variable and inside the limits where the GM will be grown





OUTLINE

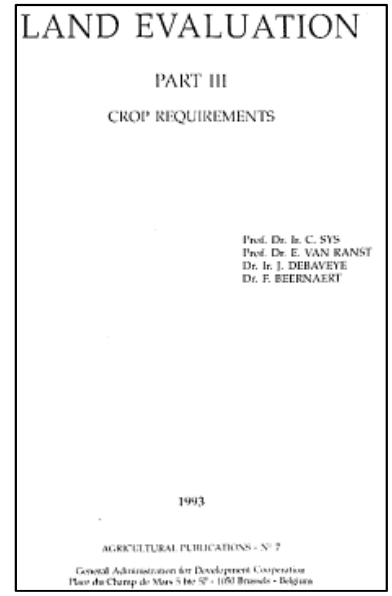
- Background/context
- Approach
- Examples
- Considerations

HOW ARE METEOROLOGICAL CONDITIONS EVALUATED?

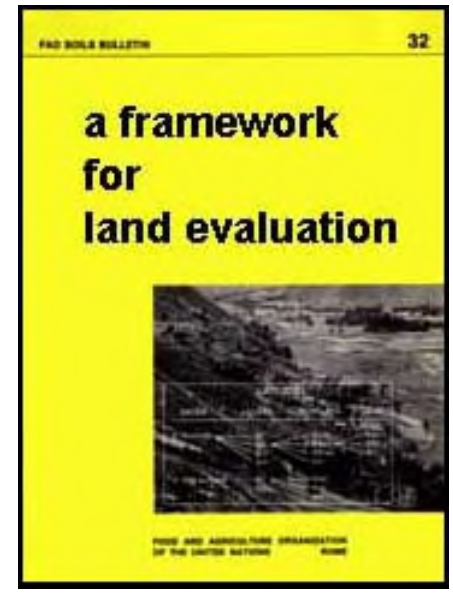
CLIMATIC REQUIREMENTS – MAIZE (growing cycle 90-130 days)

Climatic Characteristics	Class, degree of limitation and rating scale					
	S1 0 (100)	S1 1 (95)	S2 2 (85)	S3 3 (60)	N1 4 (40)	N2 (25) (0)
Precipitation of growing cycle (mm)	750-900 750-600	900-1200 600-500	1200-1600 500-400	> 1600 400-300	- -	- < 300
Precipitation of the 1st month (mm)	175-220 175-125	220-295 125-100	295-400 100-75	400-475 75-60	- -	> 475 < 60
Precipitation of the 2nd month (mm)	200-235 200-175	235-310 175-150	310-400 150-120	400-475 120-70	- -	> 475 < 70
Precipitation of the 3rd month (mm)	200-235 200-175	235-310 175-150	310-400 150-120	400-475 120-70	- -	> 475 < 70
Precipitation of the 4th month (mm)	165-210 165-125	210-285 125-100	285-400 100-80	400-475 60-80	- -	> 475 < 60
Mean temp. of the growing cycle (°C)	24-22 24-26	22-18 26-32	18-16 32-35	16-14 35-40	- -	< 14 > 40
Mean min. temp. of growing cycle (°C)	17-16 17-18	16-12 18-24	12-9 24-28	9-7 28-30	- -	< 7 > 30
Relative humidity of devel. stage (%) (2nd month)	65-50 65-80	50-42 > 80	42-36 -	36-30 -	- -	< 30 -
Relative humidity maturation stage(%)	40-30 40-50	30-24 50-75	24-20 75-90	< 20 > 90	- -	- -
n/N develop. stage (2nd month)	0.55-0.5 0.55-0.6	0.5-0.35 0.6-0.75	< 0.35 > 0.75	- -	- -	- -
n/N maturation stage	> 0.7	0.7-0.5	< 0.5	-	-	-

→ Suitability (classes S1.0; S1.1; S2; S3; N1; N2)



Sys *et al.* 1993 Land evaluation part III crop requirements

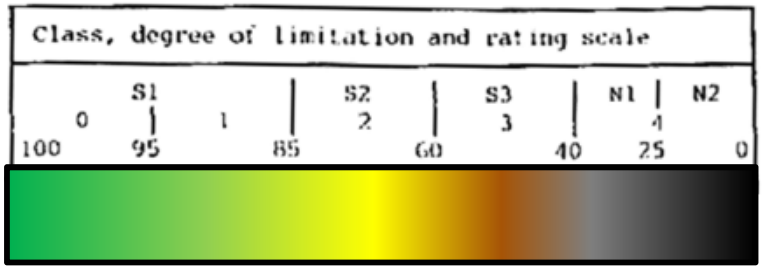


Based on Land suitability classification from FAO (1976)

HOW ARE METEOROLOGICAL CONDITIONS EVALUATED?

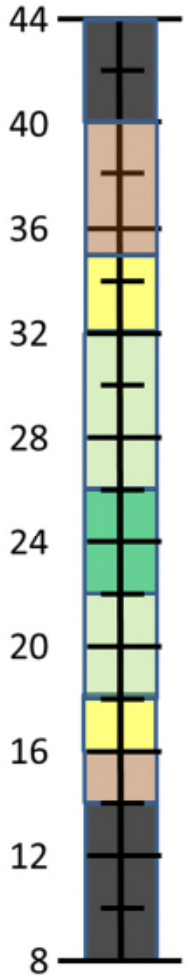
Classes of suitability:

S1.0 optimal areas → **dark green**
S1.1 near optimal areas → **light green**
S2 suboptimal areas → **yellow**
S3 marginal areas → **brown**
N1 not suitable but susceptible to correction → **grey**
N2 not suitable → **black**

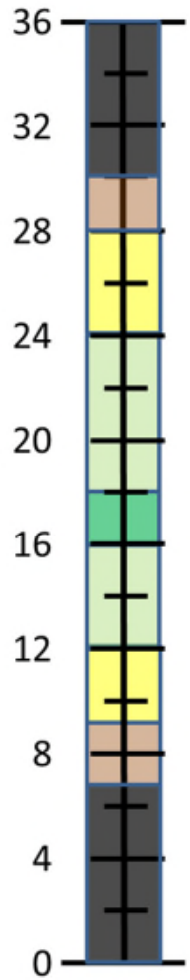


100%
Suitable

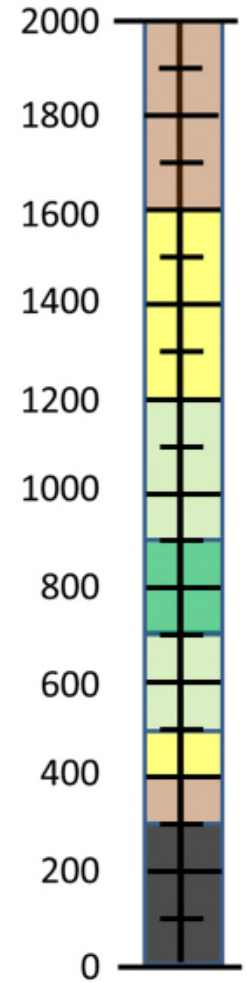
0%
Not suitable



T average °C
growing cycle



T minimum °C
growing cycle



Prec. mm
growing cycle

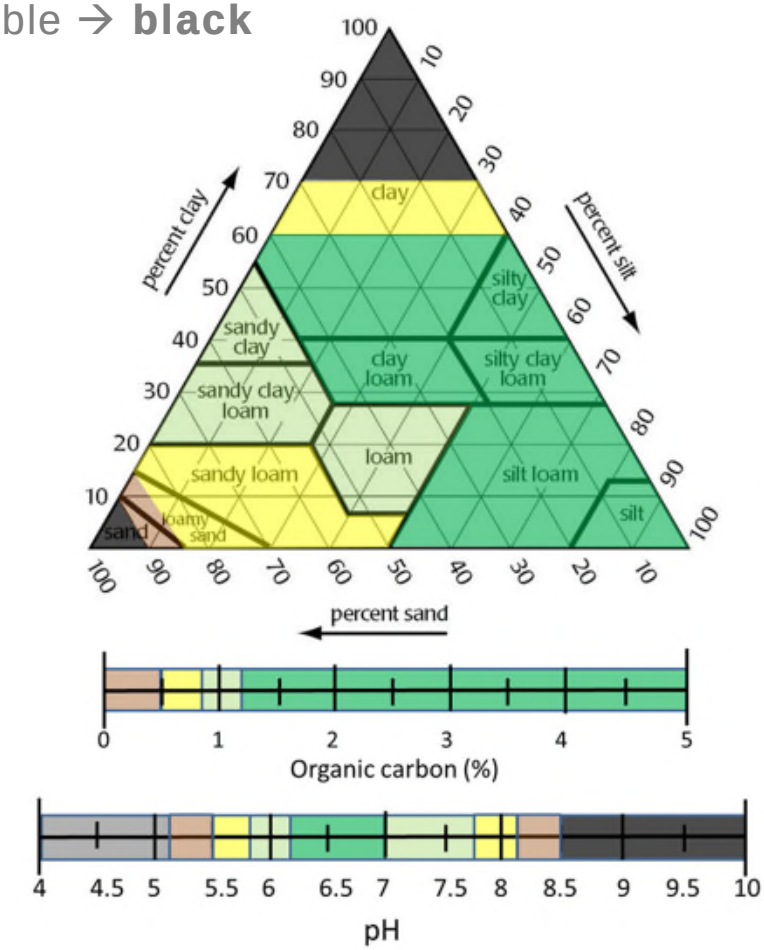
HOW ARE SOIL CONDITIONS EVALUATED?

LANDSCAPE AND SOIL REQUIREMENTS - MAIZE

Land Characteristics	Class, degree of limitation and rating scale.					
	S1 0	S1 1	S2 2	S3 3	N1 4	N2
	100	95	85	60	40	25	0
Topography (t)						
Slope (%) (1)	0-1	1-2	2-4	4-6	-	> 6
(2)	0-2	2-4	4-8	8-16	-	> 16
(3)	0-4	4-8	8-16	16-30	30-50	> 50
Wetness (w)						
Flooding	Fo	-	-	F1	-	F2+
Drainage (4)	good	moderate	imperf.	poor and	poor,	poor,
(5)	imperf.	moderate	good	aeric	but drainab	not drainab
Physical soil characteristics(s)						
Texture/struct.	C<60s,Co, SiC,SiCL, Si,SiL,CL	C<60v,SC C>60s,L SCL	C>60v,SL LfS,LS	fS,S,LcS	-	Cm,SiCm cS
Coarse frag.(vol%)	0-3	3-15	15-35	35-55	-	> 55
Soil depth (cm)	> 100	100-75	75-50	50-20	-	< 20
$CaCO_3$ (%)	0-6	6-15	15-25	25-35	-	> 35
Gypsum (%)	0-2	2-4	4-10	10-20	-	> 20
Soil fertility characteristics(f)						
Apparent CEC (cmol(+)/kg clay)	> 24	24-16	< 16(-)	< 16(+)	-	-
Base saturation(%)	> 80	80-50	50-35	35-20	< 20	-
Sum of basic cations (cmol(+)/kg soil)	> 8	8-5	5-3.5	3.5-2	< 2	-
pH H_2O	6.6-6.2	6.2-5.8	5.8-5.5	5.5-5.2	< 5.2	-
	6.6-7.0	7.0-7.8	7.8-8.2	8.2-8.5	-	> 8.5
Organic carbon(%)						
(6)	> 2.0	2.0-1.2	1.2-0.8	< 0.8	-	-
(7)	> 1.2	1.2-0.8	0.8-0.5	< 0.5	-	-
(8)	> 0.8	0.8-0.4	< 0.4	-	-	-
Salinity and Alkalinity (n)						
ECe (dS/m)	0-2	2-4	4-6	6-8	8-12	> 12
ESP (%)	0-8	8-15	15-20	20-25	-	> 25

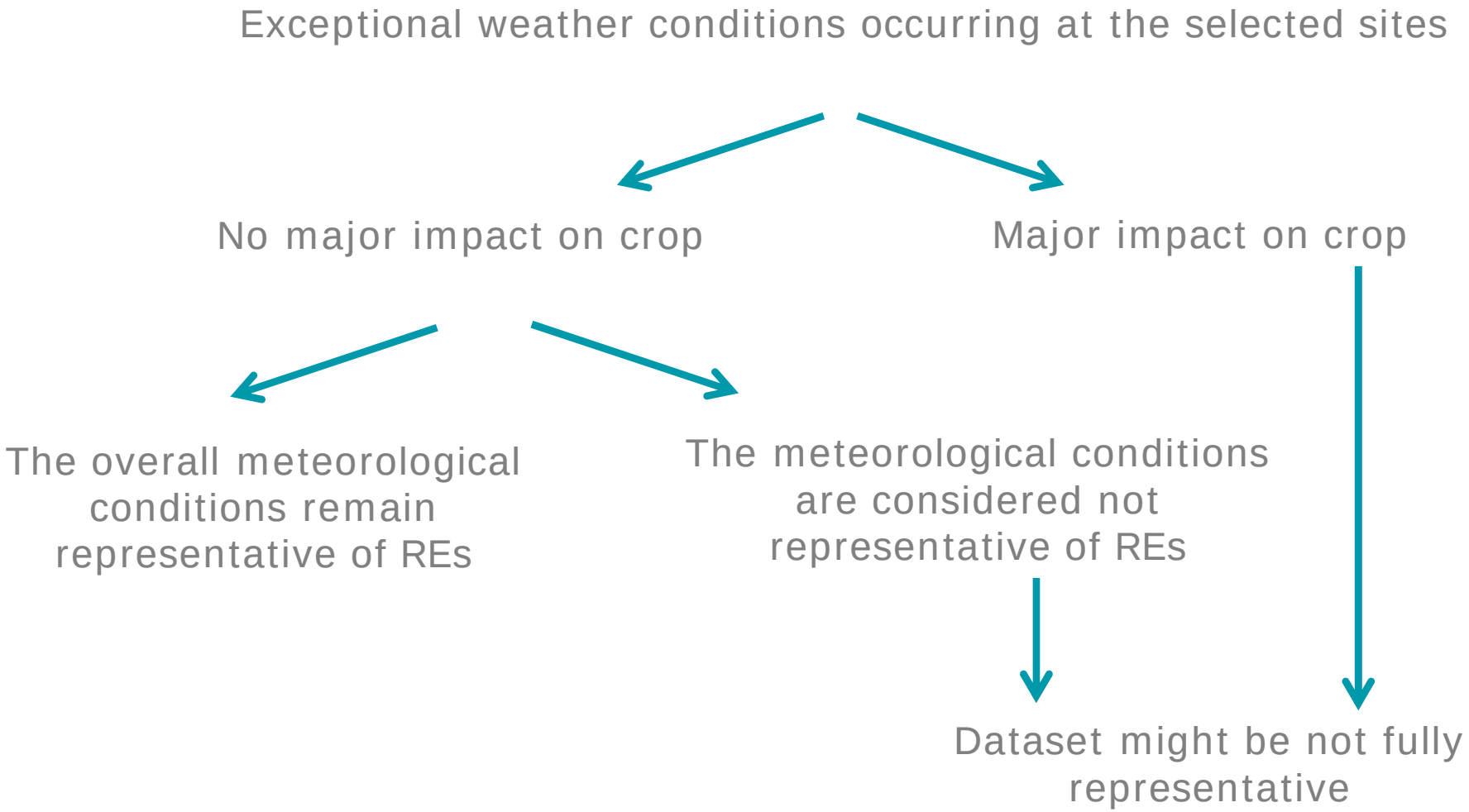
Classes of suitability:

S1.0 optimal areas → **dark green**
S1.1 near optimal areas → **light green**
S2 suboptimal areas → **yellow**
S3 marginal areas → **brown**
N1 not suitable but susceptible to correction → **grey**
N2 not suitable → **black**



EXCEPTIONAL WEATHER CONDITIONS

Applicants should report exceptional weather conditions such as drought, frost, hail or wind storm

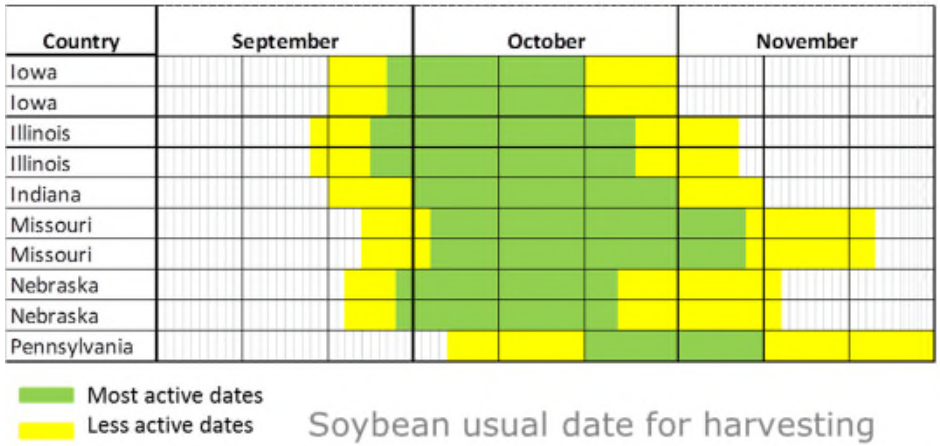


HOW IS CROP MANAGEMENT EVALUATED?

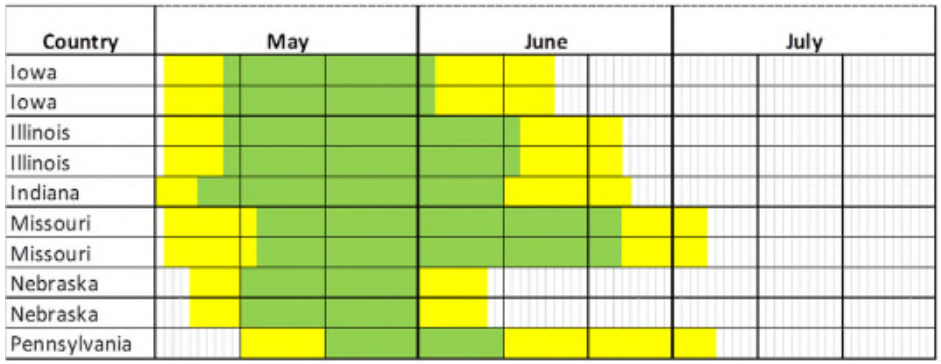
Crop management should be representative of the likely REs:

- Planting and harvesting timing
- Treatments (e.g. herbicide, type and timing)
- Fertilization (amount and timing)
- Irrigation (amount and timing)
- Tillage (type and timing)
- Crop history

Soybean usual dates for planting



Soybean usual date for harvesting



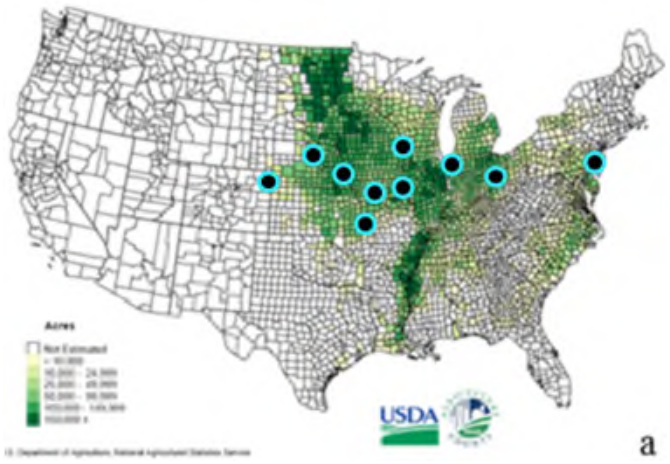
Field crops, usual planting and harvesting dates - USDA report, 2010.

OUTLINE

- Background context
- Approach
- Examples
- Considerations

GEOGRAPHICAL LOCATIONS (STABLE)

3 examples for a soybean (maturity group III)

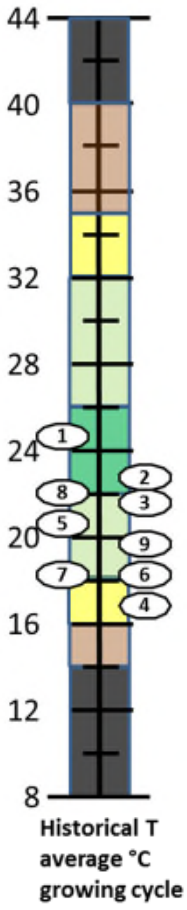


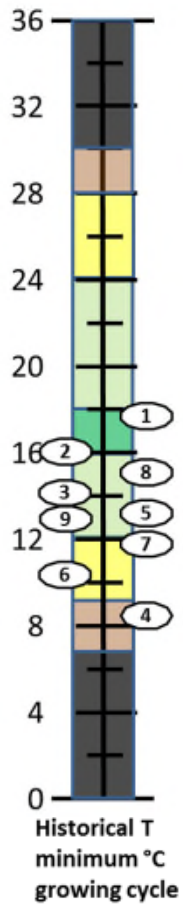
a

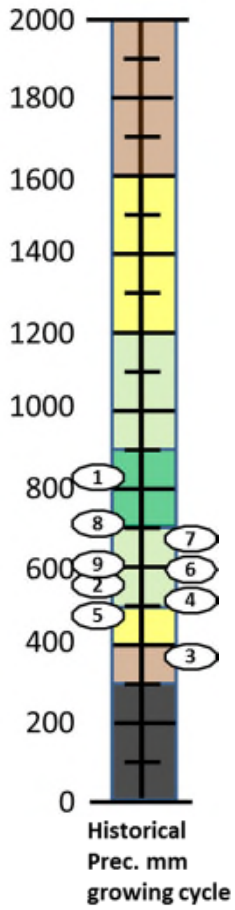
b

	a	b	
Representative	✓	✗	✗
Variable	✓	✓	✗
Appropriate for the GM line	✓	✗	✓

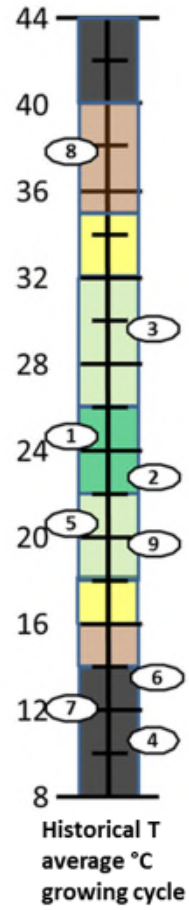
CLIMATIC CHARACTERISTICS (STABLE)

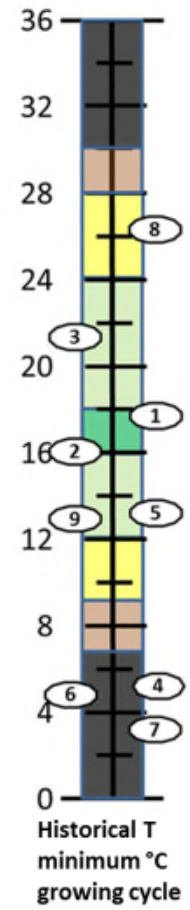


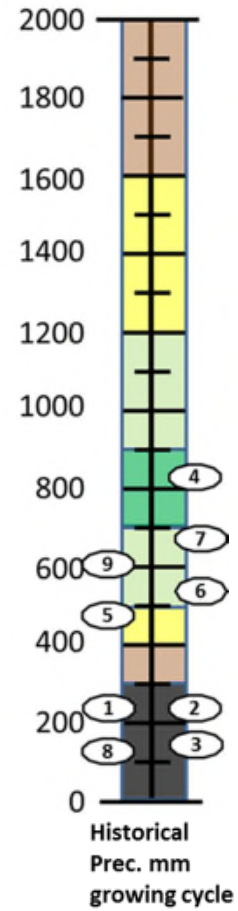




- Representative ✓
- Variable ✓
- Inside the limits where the GM will be grown ✓



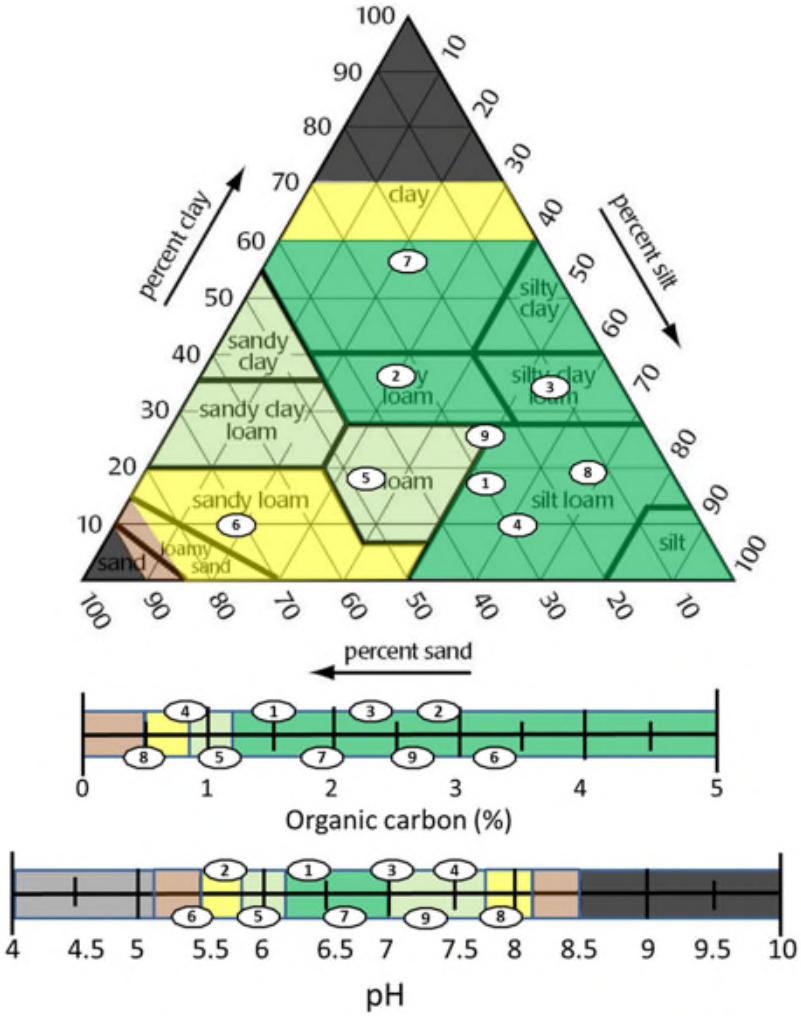




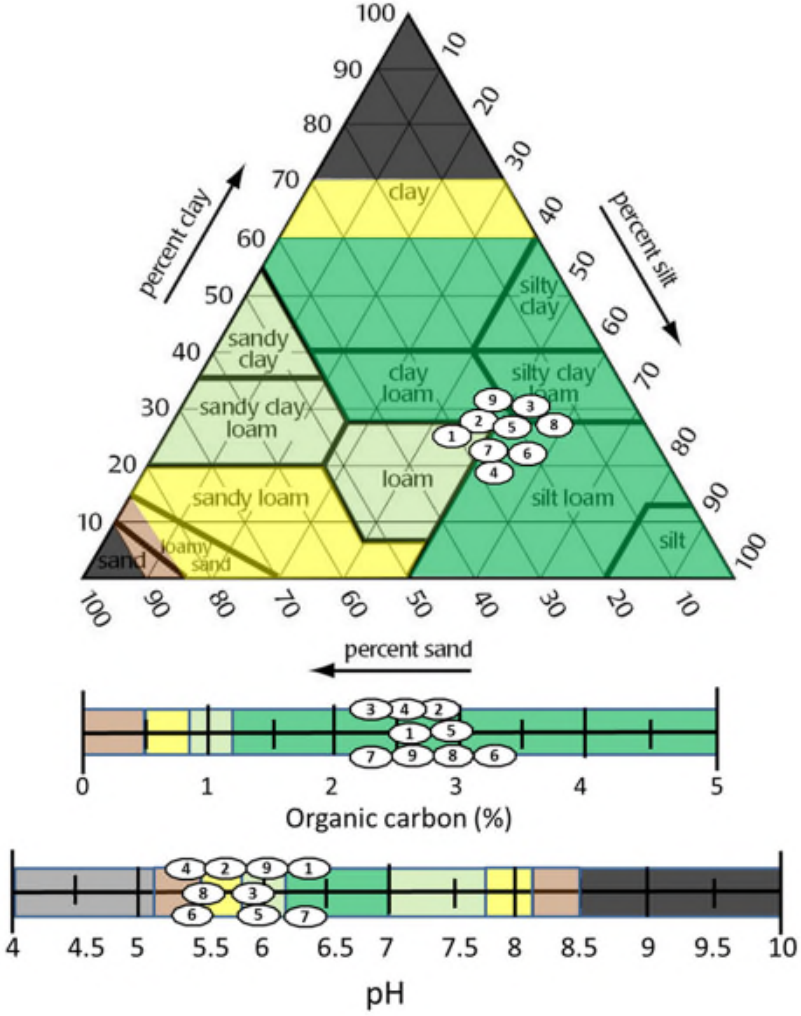
- Representative ✗
- Variable ✓
- Inside the limits where the GM will be grown ✗

Historical climatic conditions (average over 30 years)

SOIL CHARACTERISTICS (STABLE)

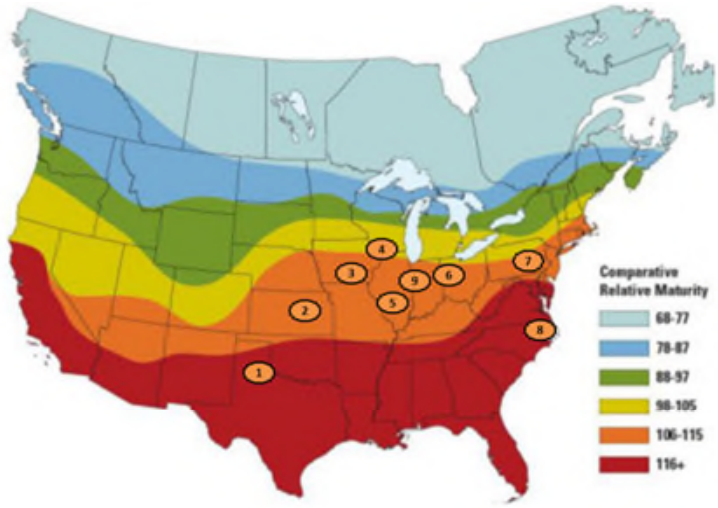


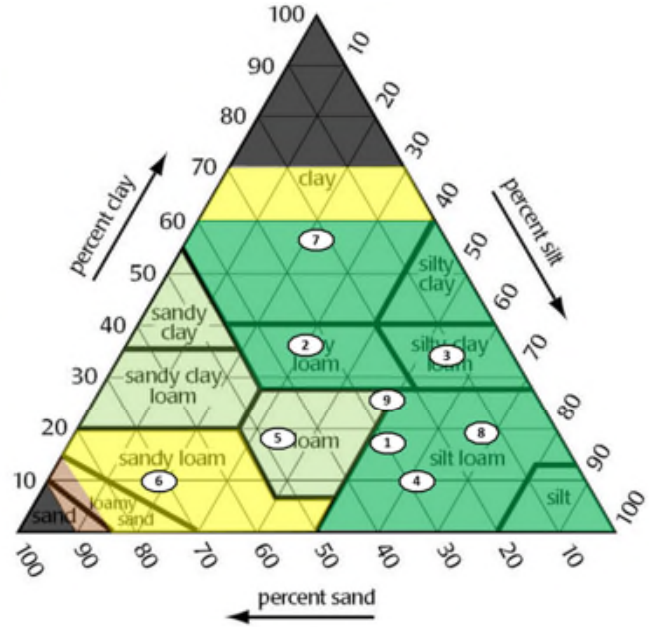
- Representative ✓
- Variable ✓
- Inside the limits where the GM will be grown ✓

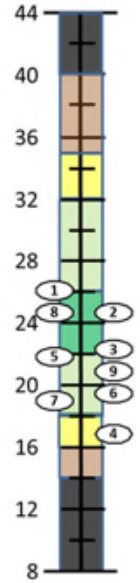


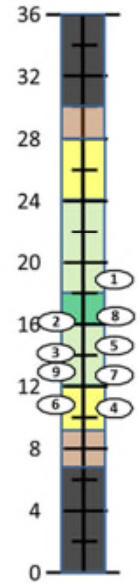
- Representative ✗
- Variable ✗
- Inside the limits where the GM will be grown ✓

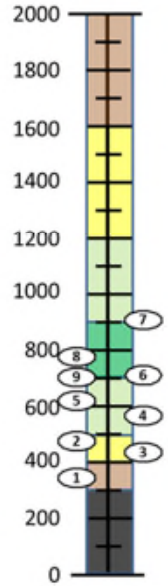
SELECTION OF REPRESENTATIVE SITES STABLE CHARACTERISTICS

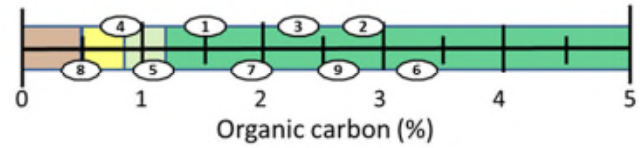


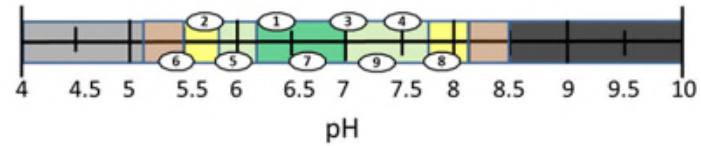








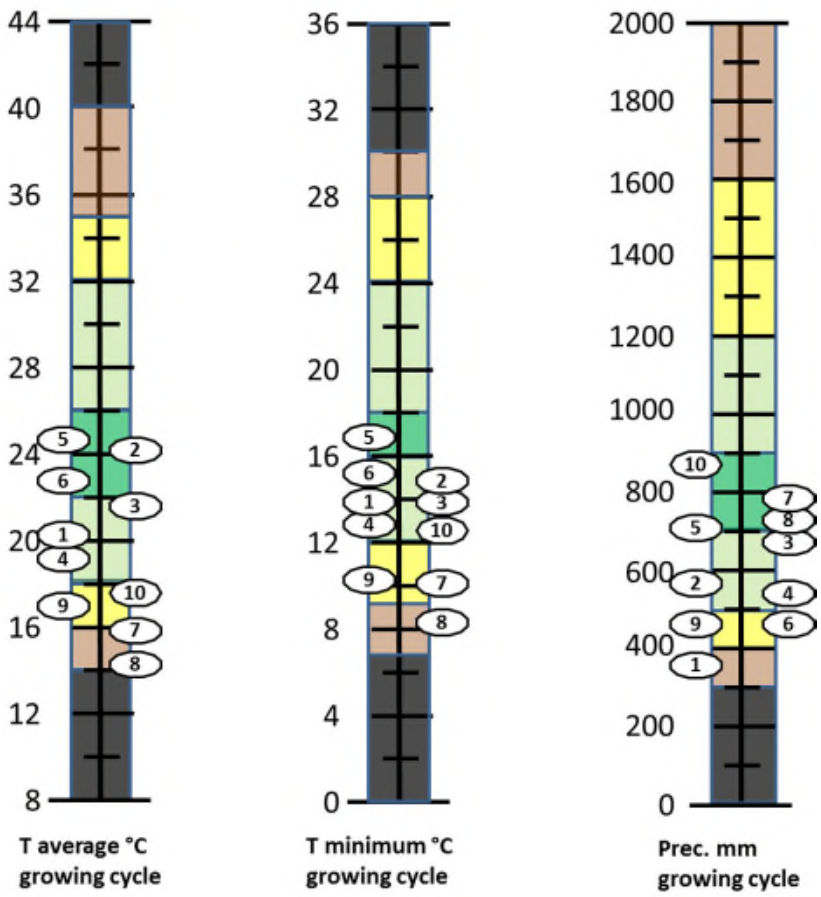


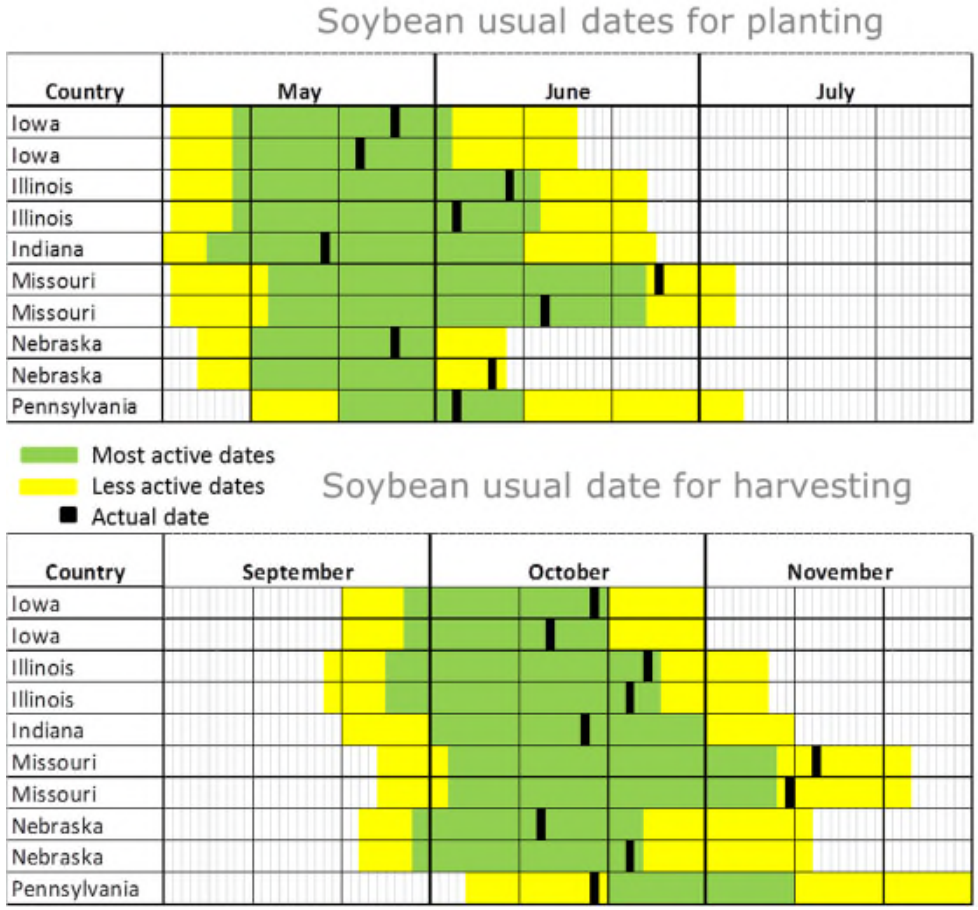


REPRESENTATIVENESS OF THE FIELD TRIALS (VARIABLE CONDITIONS)

Meteorological conditions and crop management applied during the year(s) of field trials

-Normal planting-

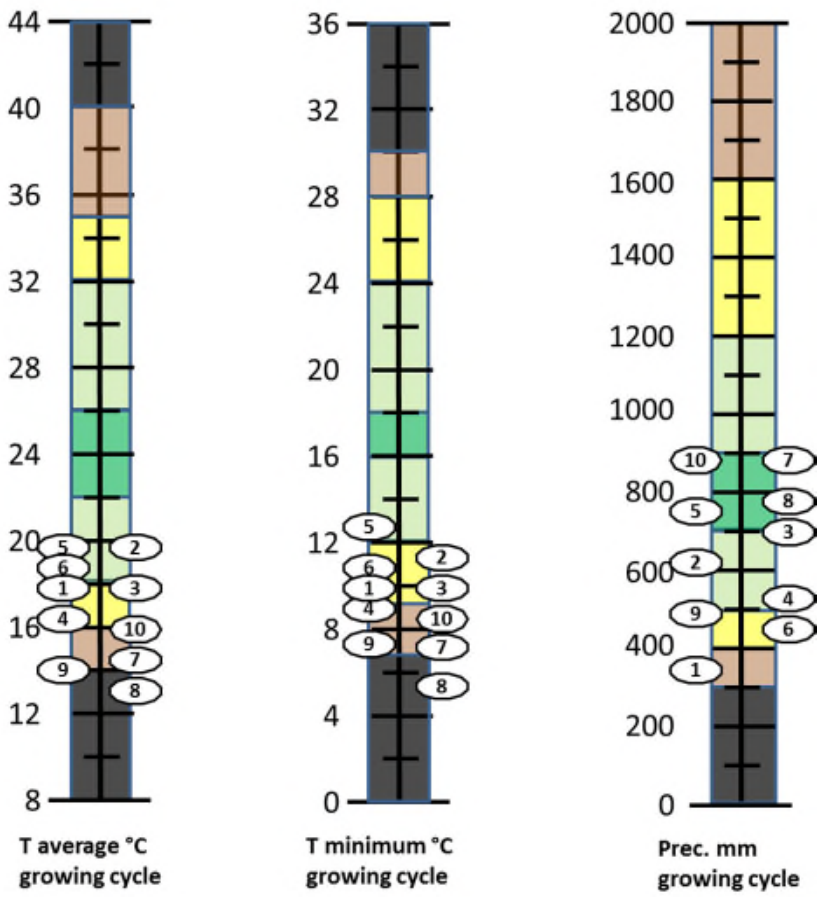


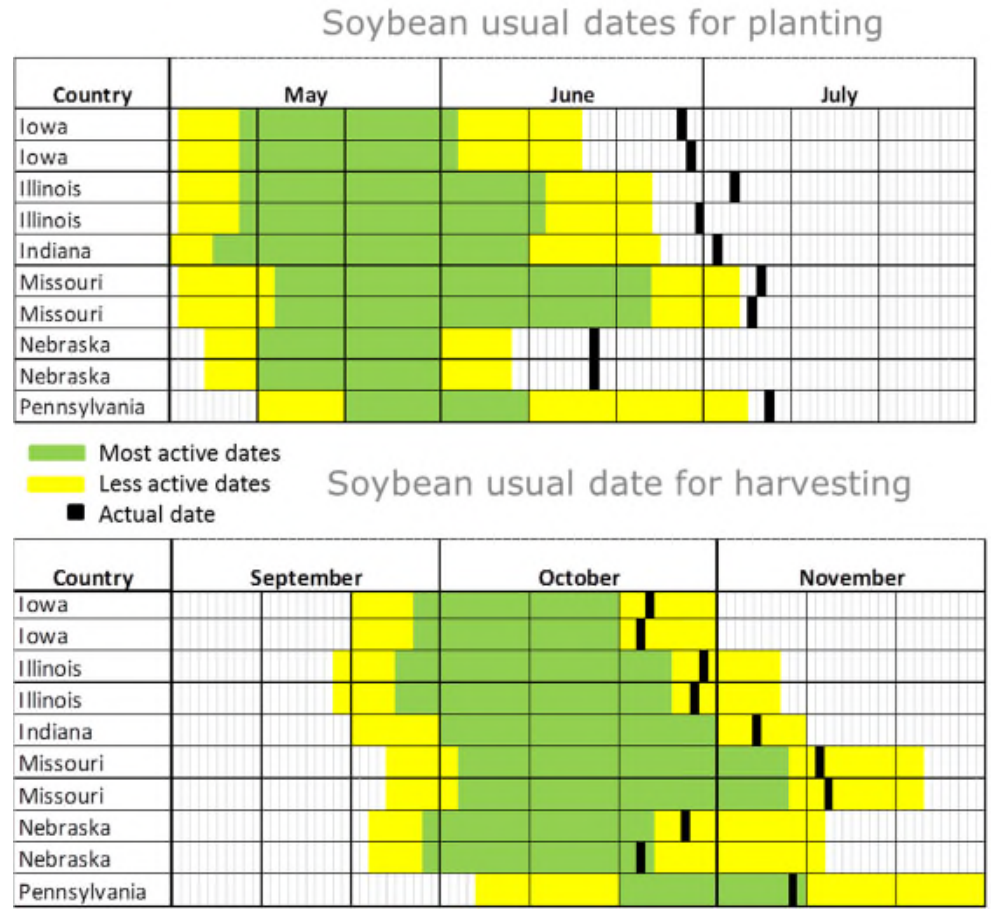


REPRESENTATIVENESS OF THE FIELD TRIALS (VARIABLE CONDITIONS)

Meteorological conditions and crop management applied during the year(s) of field trials

-Late planting-





OUTLINE

- Background context
- Approach
- Examples
- Considerations

CONSIDERATIONS ON SITE REPRESENTATIVENESS 1/2

- Site representativeness is **fundamental** to draw any conclusions on the comparative analysis of GM plants
- Conclusions on site representativeness take **multiple factors** into account
- Graphical tools help to make assessments more **transparent and repeatable**
- Site representativeness requires some level of **expert judgments**

CONSIDERATIONS ON SITE REPRESENTATIVENESS 2 / 2

More **stable** characteristics

- should be exploited by applicant to maximise the representativeness of the selected sites
- should be used by the applicant to build the rationale for site selection

Variable conditions

- the GMO Panel is aware that is not possible to control the year-specific meteorological conditions
- the year-specific meteorological conditions can reduce the representativeness of the selected sites
- the crop management practices can interfere with site representativeness

- Applicants might select **appropriate sites**, but end up with **no representative conditions** → ensure a number of sites beyond the minimal requirement
- Further details about the approach and presented figures will be published in the revised submission GD by the end of this year

THANK YOU FOR YOUR ATTENTION