



2 years after full implementation of the agro/pheno guidance: what went well and what can be improved

Ad hoc meeting with industry representatives,
23-24 October, Parma

Trusted science for safe food

- How the GMO Unit appraises the reports in support of agro/pheno comparative analysis (**rapid assessment**)
- what went well and what can be further improved after 2 years of the full implementation of the agro/pheno guidance



- WHEN

before first discussion in the CompERA WG

- WHY

early identification of issues

■ WHAT

- Genetic similarity between GM and CC
breeding tree, molecular data
- Suitability of the test materials
year of registration, characteristics
- Description of seed production conditions
and seed purity
when, where, how, PCR
- Seed germination of the starting materials
applied protocol, summary statistics

■ WHAT

- Representativeness of the selected sites
Optimal and sub-optimal conditions
- Applied crop management practices
special attention to the intended herbicides
(replacement, over the top), plant protection
products, sowing and harvesting
- Description of the field trial
size, plot shape, inter-plot distances, map
- Description of the experimental design
reps, sites

■ WHAT

- Check of mandatory agro/pheno endpoints
agro/pheno guidance list, plotting GMO analysis
- Inclusion of *ad-hoc* agro/pheno endpoints
trait dependent endpoints
- Discussion of the correlated endpoints
when two or more endpoints show differences
and/or lack of equivalence
- Presence of missing values in the
agro/pheno and compo datasets
minimal requirements for each endpoints (8x4)



- a major issue is identified
- some minor issues are identified
- no issues identified

- Description of GM production and similarity with the CC
- Description of the reference varieties

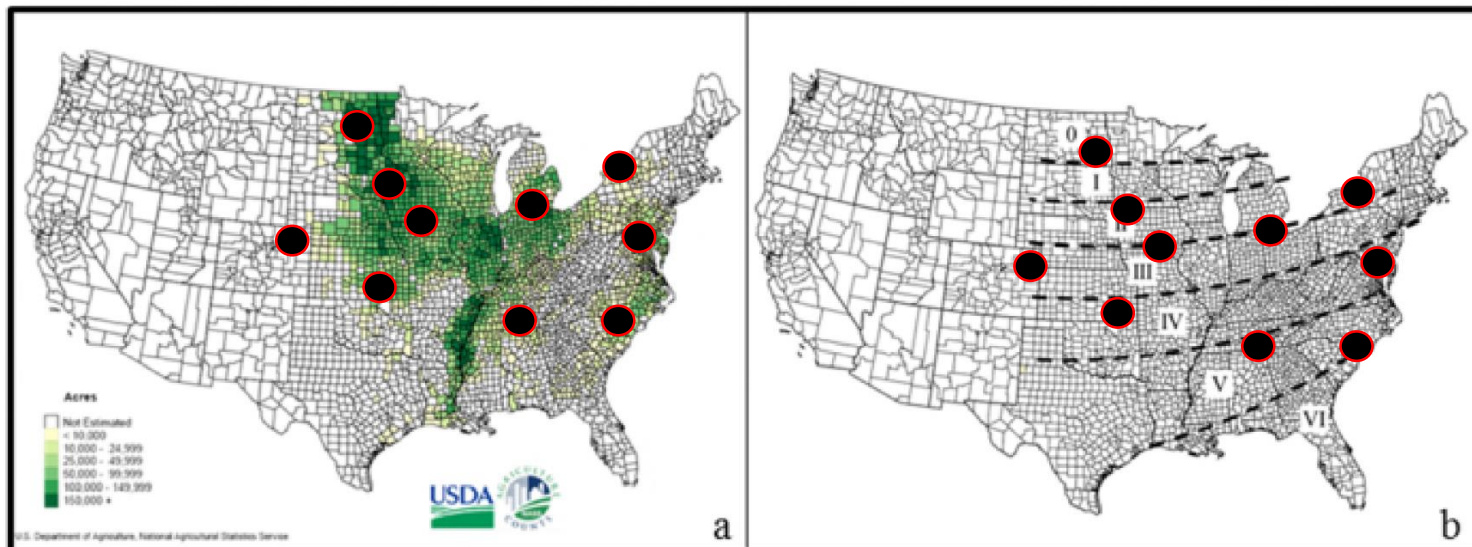
Table 10. A summary table including information on the selected non-GM reference varieties and their main characteristics.

Variety name	Breeder	Variety code in the application	Maturity ⁷	Information on the variety ⁸
Variety Comparator A	Company Institution Organization name	GB A	105/520	e.g. year of registration -year of introduction of the variety -uptake of the variety in the countries where is commercialised - -technological application - etc.
Variety Comparator B	...	GB B	110/590	...
Variety 1	...	Var1	104/500	...
Variety 2	...	Var2	107/550	...
Variety 3	...	Var3	108/560	...
Variety 4	...	Var4	111/600	...
...
Variety 12	...	Var6	111/600	...

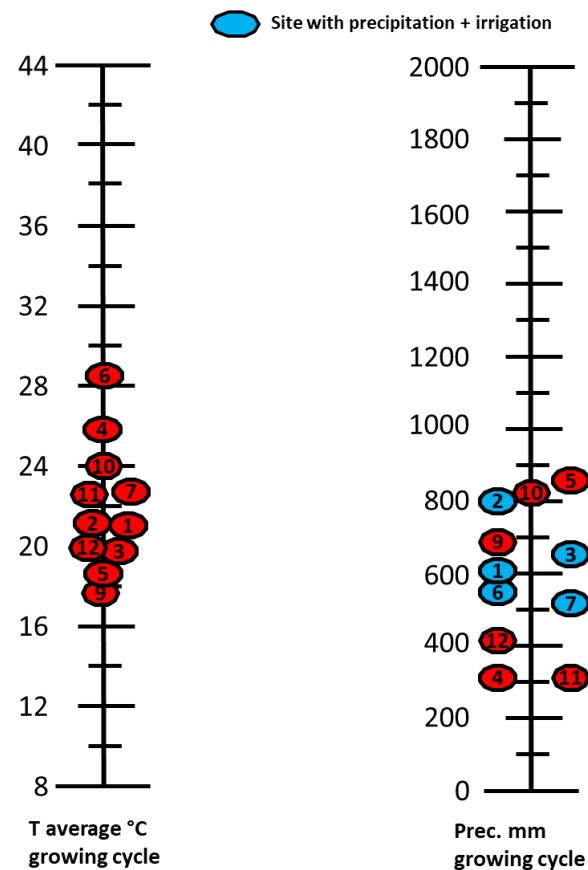
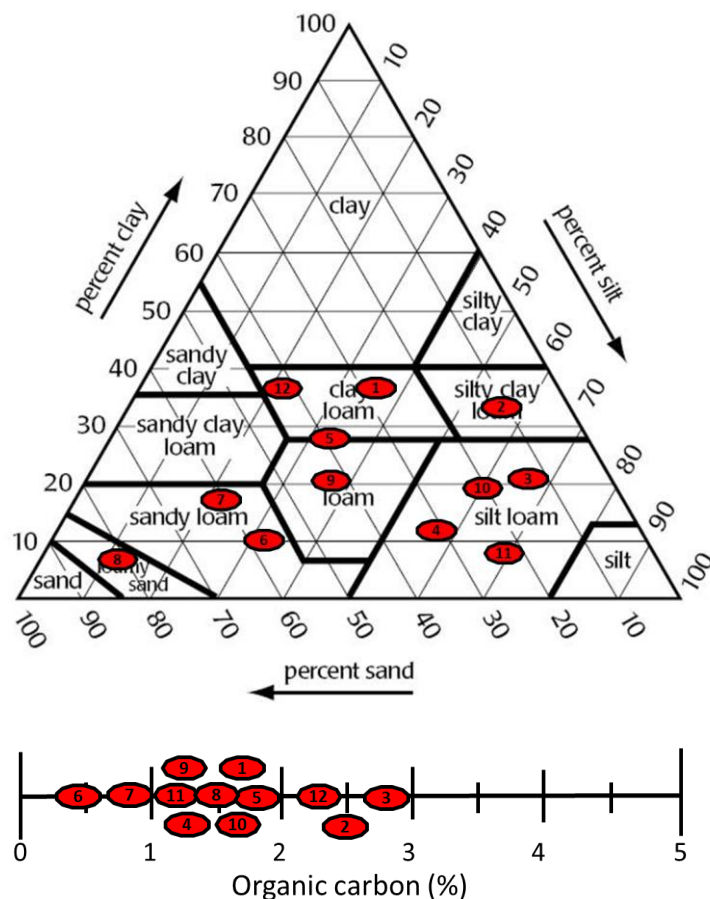
- Justification for the selection of the field trial sites

locations of sites (coordinates) against
crop harvested areas and often crop
maturity areas

variability of the stable characteristics
(historical meteo and soil)

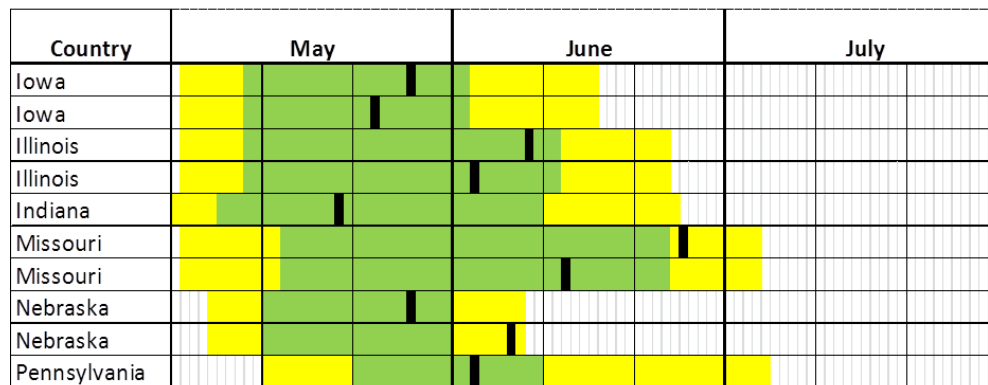


- Some dossier included figures to show the variability of the agrometeorological conditions of the field trials



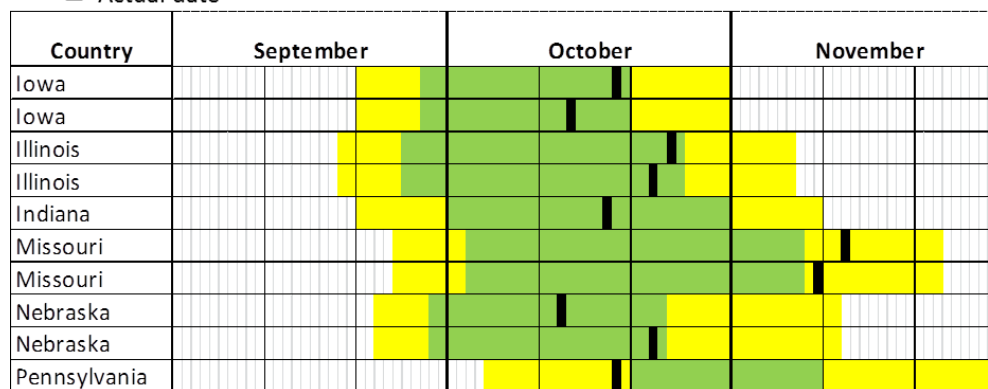
■ Better timing for sowing and harvesting

Soybean usual dates for planting



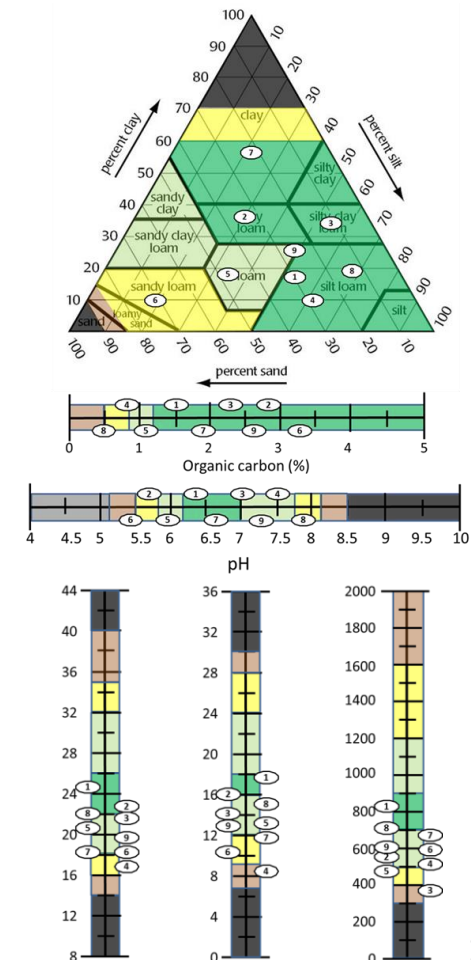
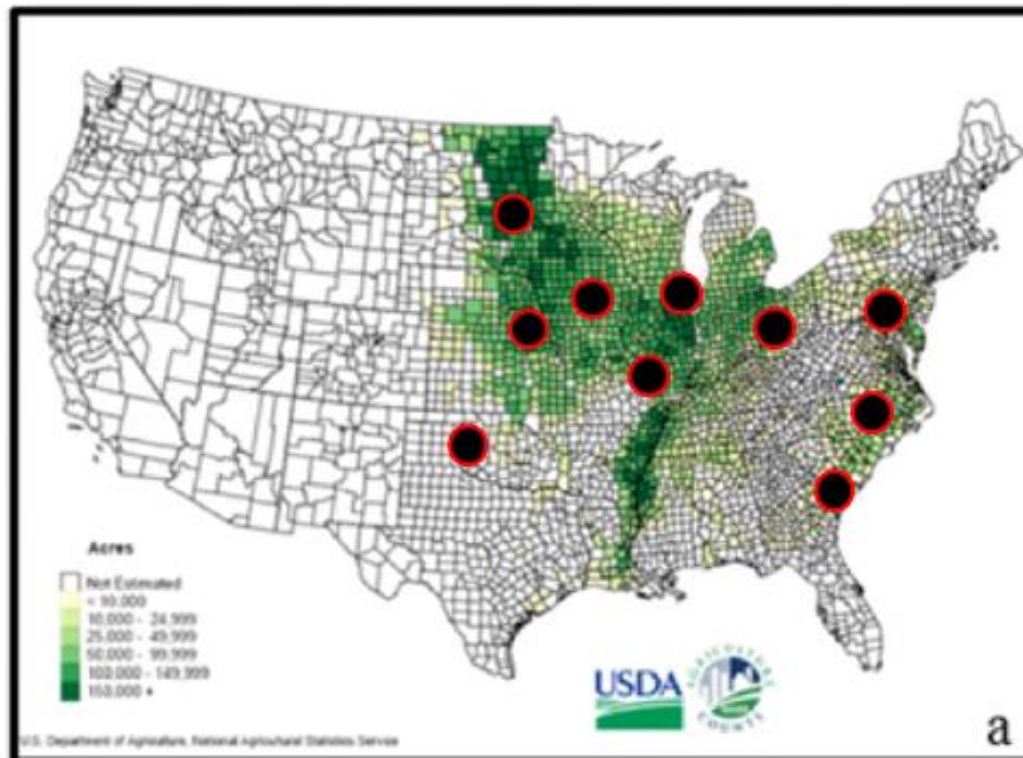
Most active dates
 Less active dates
 Actual date

Soybean usual date for harvesting



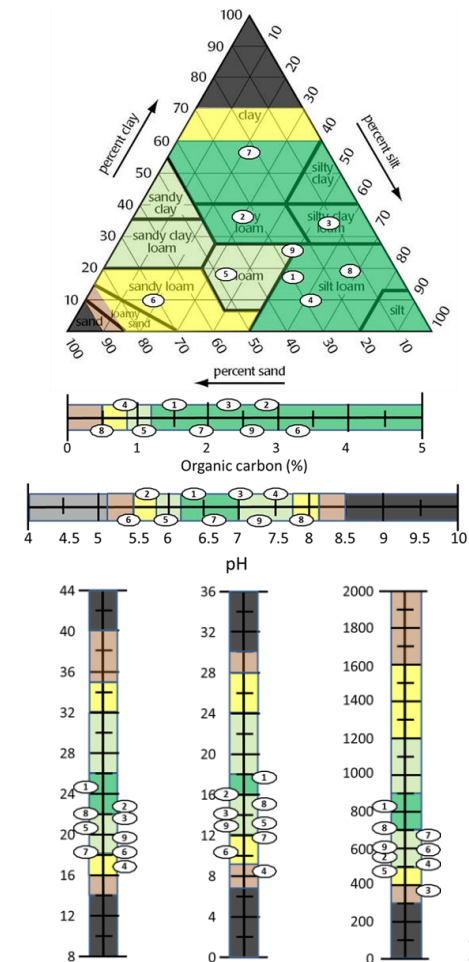
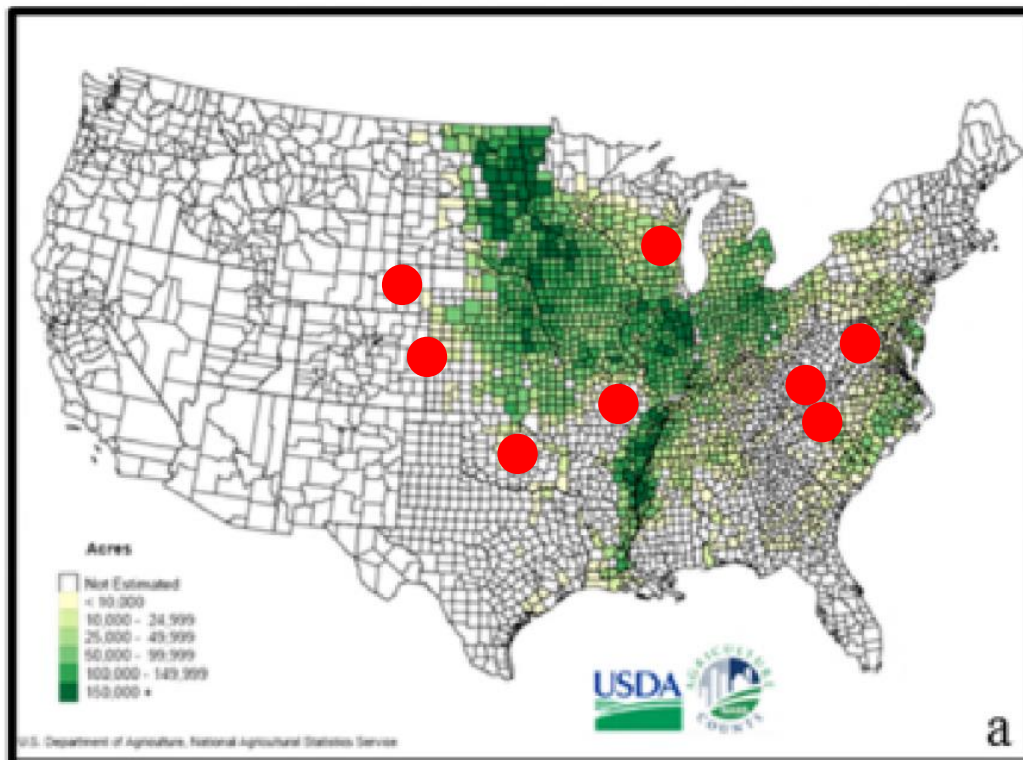
What can be improved

- Figures of site representativeness
Sys et al., 1993 implemented (submission GD)



What can be improved

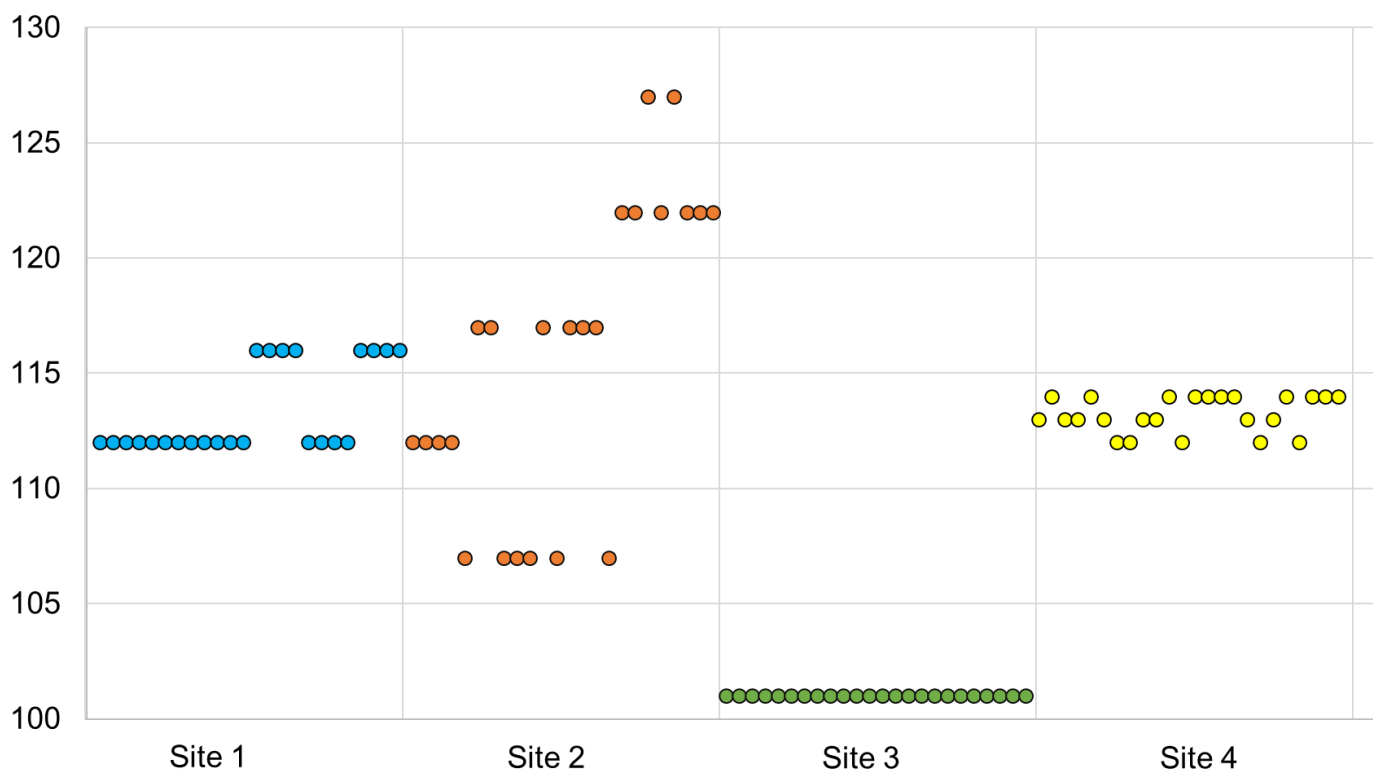
- Figures of site representativeness
Sys et al., 1993 implemented (submission GD)



- Site exclusion criteria
justifications and partial data collected
- Daily meteorological data
excel file
- Historical weather data
series of 20-30 years during specific crop
growing seasons (harmonisation across sites is
advisable)

- Justification of the herbicides applied
Special attention to intended herbicides (typical timing and rates for HT crops)
 - Thinning (not recommended)
 - Unusual plant population
(e.g. maize)
- Not representative of the farm conditions

- Information on the sample frequency and consistency across sites
(e.g. maturity dates)



- Missing endpoints
days to maturity in cotton, ear count in maize
- Internal Quality Check
Data transcription
(field trial notebook → reports → xls)
- Completeness of the replies to our requests of clarifications
EFSA cannot reiterate questions

- No new requirements
- The overall quality of the field trials is increasing in APs submitted under the full implementation of the agropheno GD
- Further increase on the quality of the field trials would speed up the assessment of the agro/pheno comparative analysis (less questions to be asked to applicants)



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