Guidance Document for the agronomic and phenotypic characterisation of GM plants

Meeting with applicants
26 November 2015, Parma

efsa
European Food Safety Authority

www.efsa.europa.eu

BACKGROUND

On the 24 June the EFSA guidance on agro/pheno, along with its technical report were published.

European Food Safety Authority

EFSA Journal 2015;13(6):4128

SCIENTIFIC OPINION

Guidance on the agronomic and phenotypic characterisation of genetically modified plants[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This document provides guidance for the agronomic and phenotypic characterisation of genetically modified (GM) plants and clarifies the EFSA GMO Panel's view on how agronomic and phenotypic data support the risk assessment of GM plants. Specific recommendations are given on (1) the selection of sites and test materials; (2) the quality and design of field trials; (3) the selection of relevant agronomic and phenotypic endpoints; and (4) data analysis. The guidance proposes a comprehensive and harmonised approach for the agronomic and phenotypic characterisation of GM plants, which should ensure the best use of agronomic and phenotypic data for the comparative analysis of GM plants and derived food and feed products, and for their food and feed and environmental risk assessment.

KEY WORDS

comparative analysis, field trials design, invasiveness, persistence, receiving environments, representativeness, unintended effects

European Food Safety Authority

EFSA supporting publication 2015:EN-829

TECHNICAL REPORT

Outcome of the public consultation on the draft guidance on the agronomic and phenotypic characterisation of genetically modified plants[1]

European Food Safety Authority[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A public consultation on the draft guidance on the agronomic and phenotypic characterisation of genetically modified plants, endorsed by the Panel on Genetically Modified Organisms of the European Food Safety Authority, was launched on 25 September 2014 and continued until 6 November 2014. The European Food Safety Authority received 263 comments on the draft guidance from 23 interested parties. On 18–19 December 2014, the European Food Safety Authority held a specific workshop during which received comments were discussed and clarified with stakeholders, so as to have an open dialogue on the areas of divergence and to exchange relevant scientific information in an interactive manner. Through its dedicated working group on the agronomic and phenotypic characterisation of genetically modified plants, the Panel on Genetically Modified Organisms scrutinised and assessed all received comments and provided clarifications, falling within the remit of the European Food Safety Authority. When appropriate and necessary, the draft guidance was revised to take into account relevant comments. This technical report summarises the most relevant comments received through the public consultation, and outlines how those were taken into account in the final document.

KEY WORDS

comparative analysis, field trial design, invasiveness, persistence, receiving environments, representativeness, unintended effects

BACKGROUND

Scope of the guidance

- the guidance is designed to assist applicants in generation, analysis and interpretation of the agronomic and phenotypic dataset submitted as part of their GM plant applications under Dir. 2001/18/EC or Reg. 1829/2003

- it supplements general recommendations outlined in previous EFSA GMO Panel guidelines and Imp. Reg. 503/2013

BACKGROUND

Aim of the agro/pheno field trials

(1) To detect and measure differences between the GM plant and its CC

(2) To assess to what extent the environmental and agricultural conditions under which the GM plant is to be grown affect these differences

(3) To confirm that good agronomic practices have been followed for the generation of the compositional data

(4) To support the risk characterisation of GM plants.

TECHNICAL CHAPTERS

Specific recommendations are given on:

(1) The selection of test materials and sites (Ch2)

(2) The quality and design of field trials (Ch3)

(3) The selection of relevant agronomic and phenotypic endpoints (Ch4)

(4) Data analysis (Ch5)

CHAPTER 2 – SELECTION OF SITES/TEST MATERIALS

Protocol for site and test material selection

- to perform field trials, applicants need to select suitable test materials and representative sites
- the selection of other test materials and sites is closely related to the characteristics of the selected variety or line(s) harbouring the GM event
- need to capture appropriately the variability that may exist across potential REs for the GM line in order to be representative
- a strategy is proposed

CHAPTER 2 – SELECTION OF SITES/TEST MATERIALS

Applicants need to **make and justify** two critical choices:

1) Selection of **suitable test materials**

- ability of the GM line to be adapted to a range of typical receiving environments for the GM event
- non-GM comparator as close as possible to the GM line
- non-GM reference varieties appropriate to the areas in which the GM line can be grown

CHAPTER 2 – SELECTION OF SITES/TEST MATERIALS

Applicants need to **make and justify** two critical choices:

2) Selection of **representative site** locations and management systems to carry out field trials

- capture as much variability in REs as possible
- some sites outside the most typical area for the GM line

The two choices are closely related and interdependent

CHAPTER 3 – TEST MATERIALS

Description of starting material and receiving environment (RE)

- to guarantee the production of reliable agronomic and phenotypic datasets, the guidance provides recommendations on:
  - the quality of the testing materials
    - to ensure that differences are not related to factors other than the genetic transformation
  - description of the RE
    - agrometeorological data and soil characteristics
    - management systems
    - to demonstrate representativeness of selected sites
    - on a case-by-case basis to support interpretation of the outcomes of the data analysis

CHAPTER 3 – TEST MATERIALS

Applicants need to provide information on the quality of the selected test materials

- GM and CC:
  - similar seed production conditions requested
  - identity of the starting materials demonstrated
  - comparative test of seed germination
  - assessment of health and vigour
- non-GM reference varieties:
  - seed certification of quality
  - in case uncertified seed is used same tests as for GM and CC should be provided

CHAPTER 3 – DESCRIPTION OF REs

Applicants need to provide information on the characteristics of each REs

- location of the REs
- agrometeorological conditions throughout the cropping period
  - mean and SE on a weekly basis for average air temperature and precipitation
  - to report exceptional weather conditions
- soil characteristics
  - soil texture, organic carbon, pH and soil bulk density

CHAPTER 3 – DESCRIPTION OF REs

Applicants need to provide detailed information on the management system at each REs:

- crop management
  - tillage, seedbed preparation, sowing, crop maintenance, harvest and specific intervention
  - Herbicide regimes applied in case of GM HT crops
- field trial design
  - plot size, inter plot distance and buffer rows

CHAPTER 4 – AGRO/PHENO ENDPOINTS

The selection of relevant agronomic and phenotypic endpoints

- the choice of the endpoints is based on
  - the biology of crop species
  - the scope of GM plant application
- focuses simultaneously on
  - the familiarity
  - the ability to predict harm
  - the ability to identify unintended differences between the GM plant and its comparator

CHAPTER 4 – AGRO/PHENO ENDPOINTS

- **Generic** endpoints allow
  - a proper characterisation and description of the plant's biology and performance under different REs
  - to identify differences between the GM plant and other test materials

  Generic endpoints should always be measured according to scope of application

- **Case-specific** endpoints (crop- or trait-related)
  - Trait-specific endpoints
  - Endpoints related to potential unintended effects
  - Endpoints related to persistence and invasiveness

CHAPTER 4 – AGRO/PHENO ENDPOINTS

Generic endpoints for soybean, maize, cotton and oilseed rape

Phase	Endpoint	I&P	CULT	Growth stages (BBCH)
Vegetative	Early stand count	✓	✓	11-13
	Crop development	Opt	✓	31-39
Reproductive	Days to flowering	✓	✓	61-69
	Flowering duration	Opt	✓	61-69
Maturity	Lodging	✓	✓	80-89
	Final stand count	✓	✓	31-99
	Plant height	✓	✓	71-89
	Days to maturity	✓	✓	87-89
	Seed loss	Opt	✓	89
	Fruit/ear count	✓	✓	89
Harvest	Seed moisture	✓	✓	99
	Seed weight	✓	✓	99
	Yield	✓	✓	99
After plant emergence	Biotic interactions	✓	ERA GD	-
	Abiotic interactions	✓	ERA GD	-

CHAPTER 5 – DATA ANALYSIS

This section provides clarifications and specifies requirements for data analysis

- how to submit analysed datasets
  - raw data and supporting files for statistical analysis
- how to conduct statistical analyses
  - zero or low variance between non-GM reference varieties
  - consideration on outcome '*type 8*'
- GxE interactions and per-site analysis
  - when to be conducted
- when to discuss correlated endpoints

IMPLEMENTATION OF THE GUIDANCE

From 24 June 2015

- a rationale for the selection of test materials
- a description of seed production conditions
- location of field trials
- a description of crop management practices
  - Including pesticides, herbicide regime, fertilisers and description of the agricultural practices
- a description of the field trial design
  - Including plot size, presence of buffer rows and/or inter plot distance
- a rationale for the selection of additional endpoints

IMPLEMENTATION OF THE GUIDANCE

From 24 June 2017

- production of starting material in line with the guidance
  - seed identity check, seed germination, health and vigour
- to apply an adequate strategy for the site and test materials selection
- description of the agrometereological conditions
  - weekly mean for air temperature and precipitation and to report exceptional conditions
- description of soil type
  - texture, organic matter, pH and soil density
- generic agro/pheno endpoints
  - to be collected and reported in line with the new requirements
- additional agro/pheno endpoints
  - discussion for inclusion or exclusion of additional endpoints

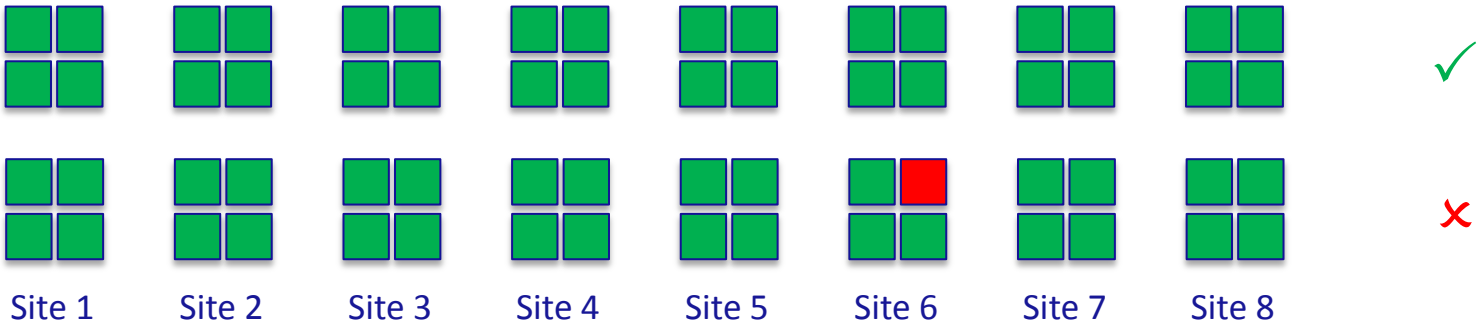
ADDITIONAL CLARIFICATIONS

ADDITIONAL CLARIFICATIONS

MISSING VALUES

Acceptability of data when a plot or a small number of plots are missing

If the dataset has less than 32 values for one of the generic endpoints

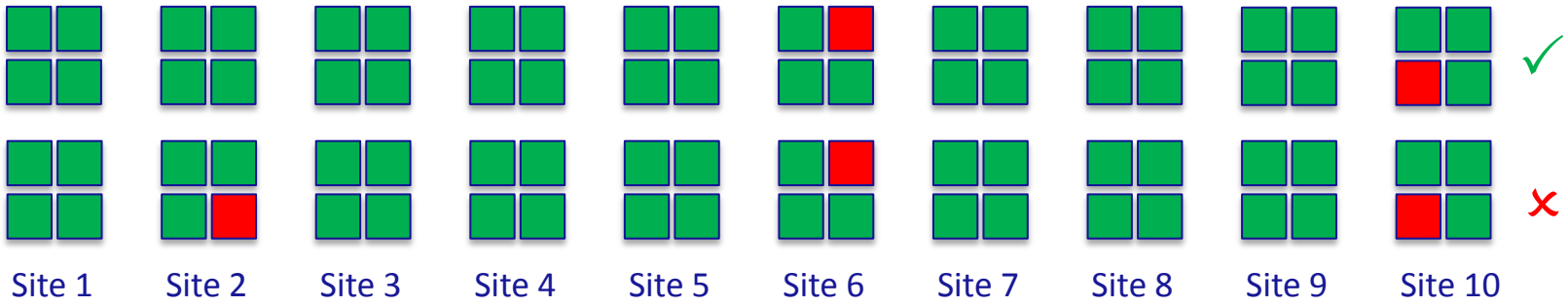


The second dataset will not be considered in line with EFSA guidance documents and with the Imp. Reg. 503/2013 '*The replication at each site is the number of results obtained for each test material; the replication should never be less than four at any site'.*

MISSING VALUES

Acceptability of data when a plot or a small number of plots are missing

If for a given endpoint **≥32** values have been obtained combining **≥8**sites x **≥2**reps rather than 8 sites x 4 reps



The second dataset will not be considered in line with EFSA guidance documents and with the Imp. Reg. 503/2013

RESPONSES TO ABIOTIC AND BIOTIC STRESSORS

Responses to stressors

EFSA considers appropriate to collect in a qualitative manner response to a/biotic stressors (arthropods, diseases and abiotic factors) and to present and compare ranges associated with observed categories per individual sites and summarize findings across sites.

Remarks:

- if a statistical test can be conducted on the collected stressors, this should be presented
- if the intended trait confers tolerance/resistance to a/biotic stress this should be in any case monitored across all sites

CERTIFIED SEEDS FOR REFERENCE VARIETIES

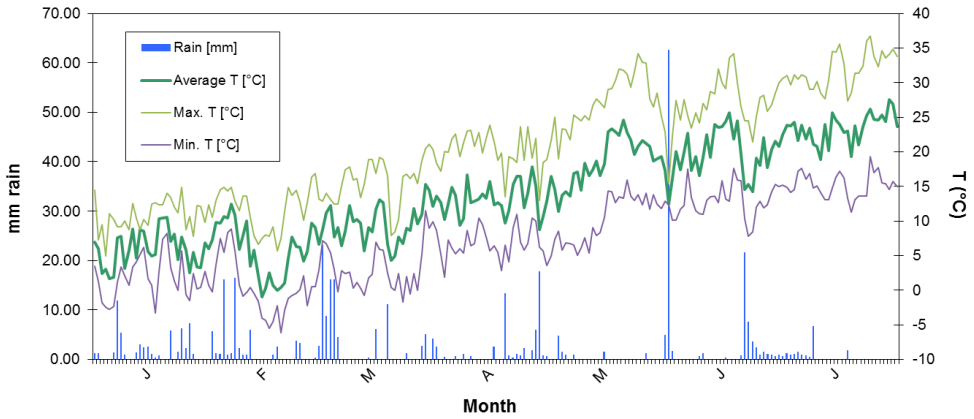
Quality of the seed source for the reference varieties

In the case in which the seed for the non-GM reference varieties has been obtained from countries where the certification system allows for the commercialisation only on the basis of label information, EFSA will consider this information acceptable. If such information is not available, applicants should verify the quality of non-GM reference varieties.

ADDITIONAL METEOROLOGICAL DATA

Agrometeorological data

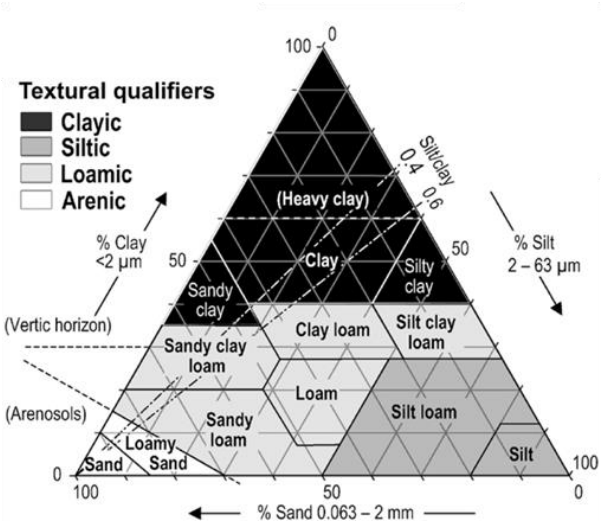
EFSA considers the additional parameters, that can be requested on a case-by-case basis, relevant in specific situations. For example for the representativeness of selected sites, or when phytotoxic effects are observed, or in case of unexpected results. The additional data can also support the outcome of the response to a/biotic stress and occurrence of extreme weather conditions.



SOIL TEXTURE CLAY – SILT – SAND

Soil characteristics

EFSA identifies a mistake in the guidance since the *loam* was reported erroneously instead of *sand* in the proposed categorisation system. The use of the clay, silt and sand soil texture categorisation will be certainly accepted.



PREVIOUS CROPS AND CROP MANAGEMENT PRACTICES

Cropping history

EFSA is interested to know the specific management in the year of the field trials. Only the crops and major changes in management practices occurred during the previous three years should be reported (e.g. a change from plough to no-tillage, or a shift from conventional control to IPM).

Crop management

EFSA considers acceptable to express adjuvant rate as a percentage because sufficient information will be gathered combining the percentage with the sprayed volume.

HARVESTING OILSEED RAPE

Generic agro/pheno endpoints

EFSA considers appropriate to extend the window for collecting the maturity endpoints of oilseed rape. In any case applicants are requested to indicate the growth stage when the endpoints are collected.

Phase	Endpoint	I&P	CULT	Growth stages (BBCH)
Maturity	Days to maturity	✓	✓	86-89
	Seed loss	Opt	✓	86-89
	Fruit/ear count	✓	✓	86-89

POOR QUALITY DATA

Data submission

EFSA considers that the partial disruption of a site reduce the quality of the data obtained after the disruptive event, however the ones collected before the event should be of high quality and of relevance for the RA. Poor quality data should not be used.