



Summary of discussions on the proposed way forward on the revision of the draft guidelines on the agronomic and phenotypic characterisation of genetically modified (GM) plants

AGRO/PHENO Working Group

SCENE SETTING

Disclaimer

The presentation has been prepared by the EFSA GMO Unit to provide a summary of the discussion points raised during the Info Session. The views or positions expressed in the presentation reflect those of the participants, and do not necessarily represent those of EFSA. EFSA assumes no responsibility or liability for any errors or inaccuracies that may appear.

- Summary of discussion points raised by participants during the workshop

SCENE SETTING

Overall comments

- **Relevance of (draft) AGRO/PHENO GD**
 - No consensus
 - Diverse views
 - Little relevance
 - Focus on endpoints only
 - No added values to refer to good practices as they should be adhered to anyhow when conducting studies and analysing data
 - Step in good direction
 - Consensus
 - Further improvements needed

SCENE SETTING

Overall comments

■ Requirements

- To be **proportionate** to scope of AP
 - Requirements disproportionate for I&P APs
- To be justified by **RA-based rationale**
 - Bucket vs. searchlight
 - Problem formulation – pathway to harm – hypothesis/hazard-driven assessment
 - Case-by-case
- To be in-tune with **international practices**
 - Harmonise (OECD – Codex Alimentarius)
 - Learn from experience gained outside EU

TOPIC 1 (AGENDA ITEM 4)

Objectives of AGRO/PHENO characterisation

- **Detection of unintended effects**
 - Some participants agreed that AGRO/PHENO data can help to detect unintended effects
 - No common view on required efforts to achieve this goal
 - **To reduce:**
 - AGRO/PHENO data of limited value to capture unintended differences
 - Unintended effects are eliminated during plant breeding process
 - Case-by-case
 - Not applicable to I&P APs – grain import

TOPIC 1 (AGENDA ITEM 4)

Objectives of AGRO/PHENO characterisation

- **Detection of unintended effects**

- No common view on required efforts to achieve this goal

- **To optimise:**

- Prioritise endpoints fulfilling multiple uses/objectives (ERA link)

- **To expand:**

- Difficult to predict; PF not applicable
 - Generic set of endpoints
- Stress tests
- Phenotyping platforms

TOPIC 1 (AGENDA ITEM 4)

Objectives of AGRO/PHENO characterisation

- **To assess to which extent environmental and agricultural conditions under which the GM plant may be grown affect these differences**
 - Sufficient to cover different REs
 - No need to specifically look for environmental and agricultural effects?
- **To confirm that good agronomic practices have been followed in COMPO field trials**
 - Not discussed



TOPIC 1 (AGENDA ITEM 4)

Objectives of AGRO/PHENO characterisation

- **To deliver data that can inform ERA**
 - Inform PF phase (hazard identification)
 - Inform P&I (fitness) assessment



TOPIC 4 (AGENDA ITEM 5)

Suitability and representativeness

- **Representativeness of sites**
 - Proposed guidance considered unclear
 - *Field trials should not be performed in all possible REs, but RE info should be accounted for when selecting representative sites*
 - Requirement “sites to be distributed proportionally” considered problematic
 - Overall agreement that the choice of selected sites should be justified
 - How?
 - No concrete alternative suggestions offered
 - Simplify concept

TOPIC 2 (AGENDA ITEM 7)

AGRO/PHENO endpoints

- **Objectives (WHY's)**
 - Specifying the WHY's is key as it connects to the question under test and thus the objective
 - Account for
 - Scope of AP
 - Pathway to harm



TOPIC 2 (AGENDA ITEM 7)

AGRO/PHENO endpoints

■ Generic endpoints

- Relevance of generic endpoints for ERA was questioned by some stakeholders
 - Hypothesis under test not clear
 - Endpoints serving as indicators of change challenged by some stakeholders
 - Linkage to harm necessary
 - Exercise part of the problem formulation or not? (*Yes; hazard identification*)
 - To characterise entire plant or only imported material?

TOPIC 2 (AGENDA ITEM 7)

AGRO/PHENO endpoints

- **Case-specific endpoints**
 - Supported as the way forward as clear hypothesis serving as driver
 - Case-by-case
 - Not relevant: starch composition is not likely to affect frost tolerance
 - Ensure proportionality



TOPIC 2 (AGENDA ITEM 7)

AGRO/PHENO endpoints

- **Alternative/additional endpoints**
 - Photosynthetic performance
 - Substitute currently proposed endpoints by photosynthetic performance
 - Seed characteristics
 - Primary dormancy (*see testing of starting material*)
 - Secondary dormancy (*see assessment of P&I*)



TOPIC 2 (AGENDA ITEM 7)

AGRO/PHENO endpoints

- **Less endpoints**
 - Applicants' perspective
 - Only select typical endpoints used by plant breeders
 - To be excluded or made optional
 - Ground cover
 - Flowering duration
 - Seed per fruit (as captured by yield)
 - Fruit count (for I&P APs)
 - A/biotic interactions (for I&P APs)



TOPIC 2 (AGENDA ITEM 7)

AGRO/PHENO endpoints

- **Single vs. stacked events**
 - *De novo* AGRO/PHENO characterisation needed?
 - No consensus on whether data requirements should be relaxed or not
 - Pros (relaxing)
 - RA event-specific – singles starting point
 - Focus on assessment of interactions
 - Cons (no relaxing)
 - Potential occurrence of unintended effects independent of the combination of events
 - Rationale needed if AGRO/PHENO characterisation requested

TOPIC 3 (AGENDA ITEM 7)

Field trial design / data analysis

- **Field trial design**
 - Field size
 - Details to be reported
 - RE descriptors
 - Relevance was challenged
 - Not all proposed descriptors are considered relevant
 - Focus on relevant ones



TOPIC 3 (AGENDA ITEM 7)

Field trial design / data analysis

■ Field trial design

■ Herbicide treatments

■ GMHT plants in AGRO/PHENO field trials

- To be treated with all relevant herbicides to which it is tolerant
- To be treated with single herbicide

■ Crop protection

- IPM suggestion is considered confusing and open for interpretation
 - Thresholds unclear
 - Clarifications required



TOPIC 3 (AGENDA ITEM 7)

Field trial design / data analysis

- **Data analysis**
 - Concerns raised about missing data/plots
 - Unexpected loss of single data/plots
 - Scientific integrity of the entire study not necessarily jeopardised



TOPIC 5 (AGENDA ITEM 8)

Persistence and invasiveness (P&I) assessment

■ Remit

- P&I is outside the scope of the AGRO/PHENO GD and only relevant for ERA
 - Valuable approach but out of scope
 - Do not mix objectives for clarity purposes



TOPIC 5 (AGENDA ITEM 8)

Persistence and invasiveness (P&I) assessment

- **Case-specific endpoints**
 - Reasoned + case-by-case approach welcomed
 - Requirements should be proportional to the level of risk
 - Are case-specific endpoints mandatory or not? (*they are not*)
 - Seed characteristics should be mandatory
 - Pollen characteristics missing



TOPIC 5 (AGENDA ITEM 8)

Persistence and invasiveness (P&I) assessment

- **Decision tree**
 - Risk categories of the parental species to be fine-tuned
 - To adjust the order of parameters
 - To account for uncertainties



ACKNOWLEDGEMENT

Thank you very much for your input

- **We take note of your suggestions/comments**
 - Received input will be considered further

