Agro/Pheno GD - Overview of comments received during the public consultation

EFSA Info Session on Applications - GMO -

Technical meeting with stakeholders on agronomic and phenotypic characterisation of GM plants
Parma, Italy
18-19 December 2014

efsa
European Food Safety Authority

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Disclaimer

The presentation has been prepared by the EFSA GMO Unit to provide a brief overview of the comments received during the public consultation. This presentation is not designed to compile all received comments, or to review in detail each single comment. EFSA assumes no responsibility or liability for any errors or inaccuracies that may appear.

THE STRUCTURE OF THE DRAFT GUIDANCE

1. Introduction

- Objective • Scope

2. Selection of sites and test materials

- Representativeness & suitability • Spatial & temporal representativeness

3. Quality of test materials used as test materials

- Seed production • Seed purity • Seed health and germination capacity

4. Design of field trials

- Description of the receiving environment • Crop management (herbicide regime) • Experimental design

5. Agro&pheno endpoints

- Mandatory endpoints • Additional endpoints

6. Data analysis

- Data submission • Statistical analysis •G*E interactions •Correlated endpoints

7. Relevance of agro&pheno data for ERA

- Persistence and invasiveness • decision tree • data requirements for SD, SD+ and SD++

Appendix A

- Life cycle •Population growth • Model

AGRO/PHENO WG COMPOSITION

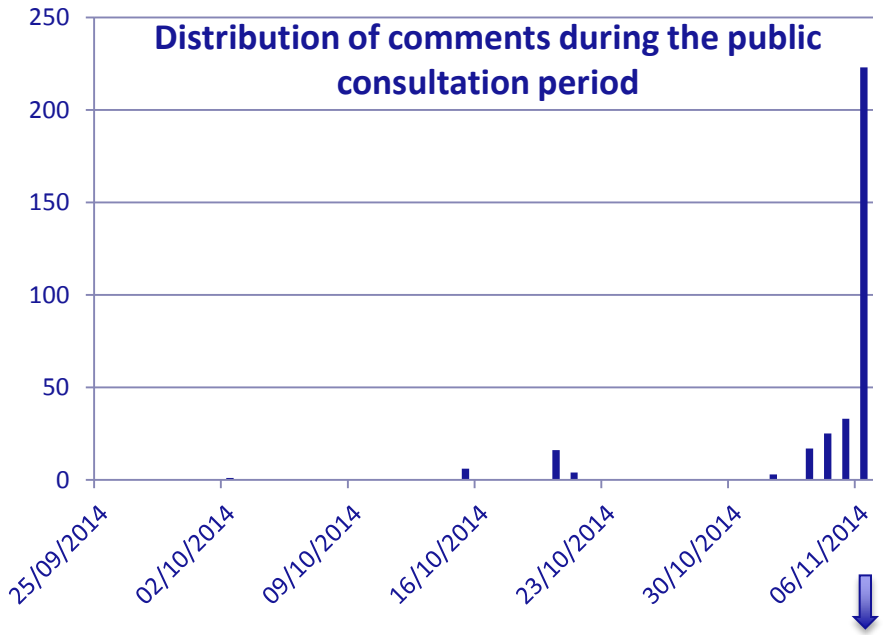
Experts:

- Hans Christer Andersson
- Salvatore Arpaia
- Paolo Bàrberi
- Lammert Bastiaans
- Tom de Jong
- Thomas Frenzel
- Jürgen Gropp
- Huw Jones
- Antoine Messéan (Chair)
- Joe Perry
- Angelo Porta Puglia
- Geoffrey Squire
- Jeremy Sweet (hearing)

EFSA:

- Hermann Broll (FF team)
- Yann Devos (ENV team)
- Andrea Gennaro (ENV team – lead)
- Claudia Paoletti (FF team)

PUBLIC CONSULTATION



Total submitted comments **263**

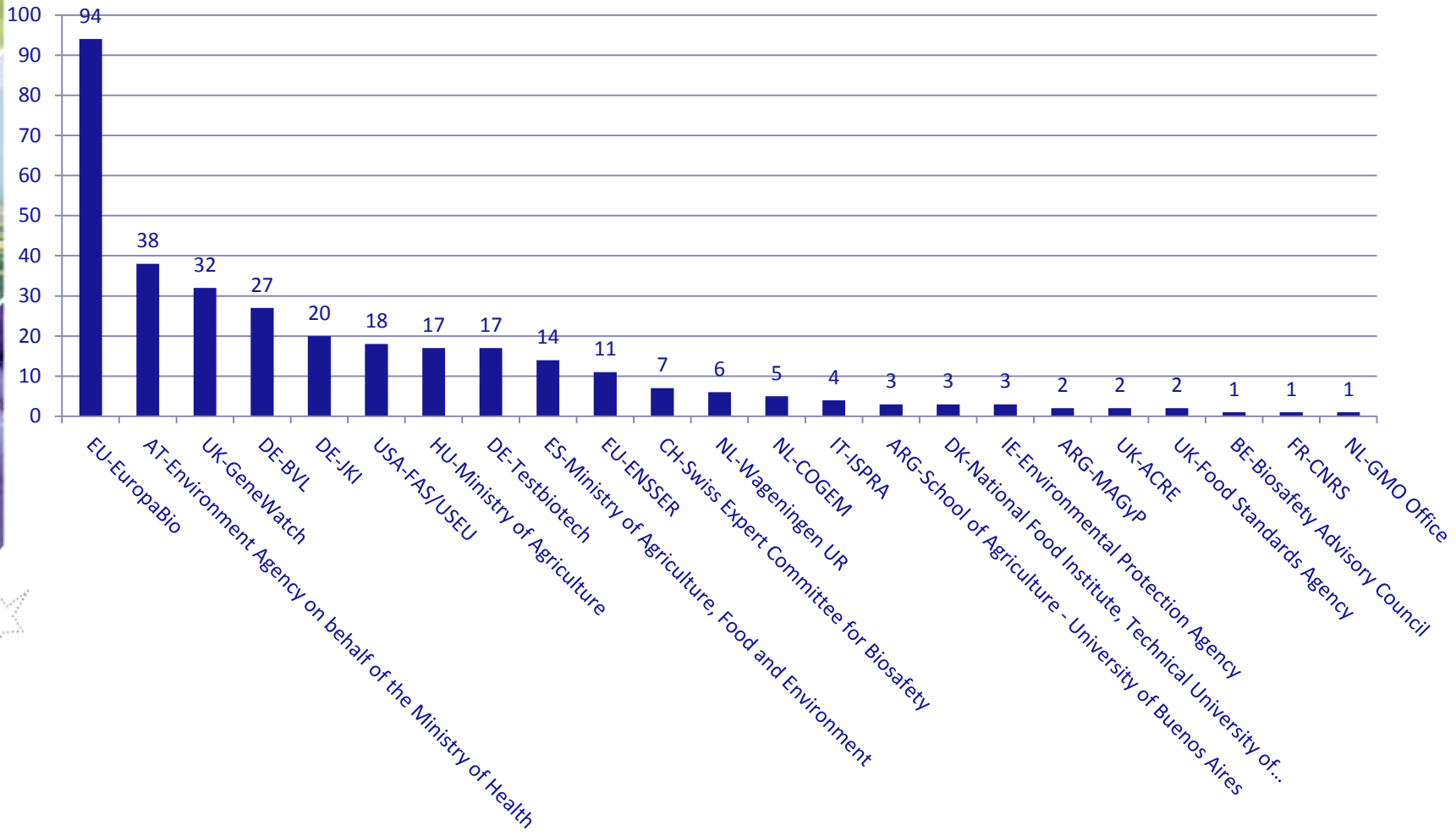
Unique ID # assigned

70 duplications were identified

Complex comments were divided (#a, #b, #c, etc.)

328 comments

NUMBER OF COMMENTS/ORGANISATION



Values based on the restructured list of comments (duplication + simplification)

NUMBER OF COMMENTS/CHAPTER (#/%)

0. Abstract / Background / Terms of reference	17/5.2
1. Introduction	38/11.6
•Objective • Scope	
2. Selection of sites and test materials	47/14.3
•Representativeness & suitability • Spatial & temporal representativeness	
3. Quality of test materials used as test materials	23/7
•Seed production • Seed purity • Seed health and germination capacity	
4. Design of field trials	42/12.8
•Description of the receiving environment • Crop management (herbicide regime) • Experimental design	
5. Agro/pheno endpoints	71/21.6
•Mandatory endpoints • Additional endpoints	
6. Data analysis	23/7
•Data submission • Statistical analysis •G*E interactions •Correlated endpoints	
7. Relevance of Agro/Pheno data for ERA	43/13.1
•Persistence and invasiveness • Decision tree • Data requirements for SD, SD+ and SD++	
8. Documentation provided to EFSA	2/0.6
9. References	4/1.2
Appendix A	18/5.5
•Life cycle •Population growth • Model	

1. Introduction

• Objective • Scope

Content of draft Agro/Pheno guidance document

- Comparative analysis
  - Agro/Pheno data
    - Detection of intended and unintended changes
    - Overall quality of the field trials
    - To inform the ERA (invasiveness & persistence)
- Objectives
  - Comprehensive and harmonised approach
- Scope
  - The GD covers I&P and cultivation APs
  - Limited to common crops
  - Possible implementation in the future (trees, phenotyping, sampling)

1. Introduction (including background and ToR as provided by EFSA)

• Objective • Scope

Summary of the 55 received comments

Mostly general comments

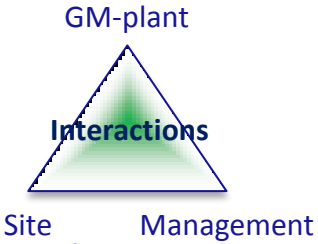
- No need to further clarify existing guidance documents
- To distinguish requirements for I&P and cultivation APs
- Agro/Pheno field trials have a limited relevance for I&P APs
- No rationale for endpoints selection
- 'Nice to know' vs 'Need to know'
- Agro/Pheno field trials should also cover impact on TO, NTO and altered management practices
- Not clear how Agro/Pheno datasets can support FF RA
- To focus on long-term effects
- To request pre-assessment under controlled conditions
- To differentiate between single and stacked events

2. Selection of sites and test materials

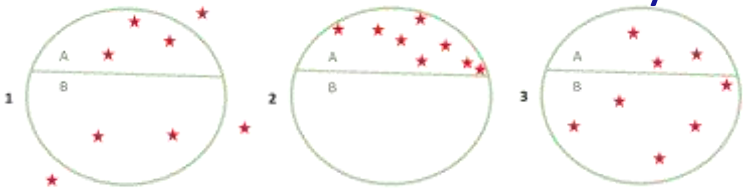
• Representativeness & suitability • Spatial & temporal representativeness

Content of draft Agro/Pheno guidance document

- Selection of sites and test materials
  - Suitability and representativeness (Imp.Reg. 503/2013)
  - Receiving environments



  - Extent of receiving environments
    - RE-plant
    - RE-event
    - RE-line
  - Assessment of site suitability



  - Assessment of site representativeness
  - Assessment of non-GM reference varieties suitability
- Spatial and temporal representativeness

2. Selection of sites and test materials

• Representativeness & suitability • Spatial & temporal representativeness

Summary of the 47 received comments

Statements and requests for clarification:

- The proposed approach is too theoretical
- Definitions of RE are not clear
- Misunderstanding of the concept of representativeness
- Implementation of the proposed approach is unclear
- Spatial limit of site representativeness

Issues covered in other guidance documents \ out of scope:

- Concerns about the minimal number of sites requested in order to be representative of the possible RE where the GM plant might be grown
- To increase number of sites
- To perform field trials where seed may be spilled
- Difficulties in the identification of representative non-GM reference varieties
- Multiple years of testing

3. Quality of test materials used as test materials

• Seed production • Seed purity • Seed health and germination capacity

Content of draft Agro/Pheno guidance document

- Quality of starting materials used as test materials
  - Seed production conditions
    - Similar production conditions for GM-line and CC
    - Same pre-treatments
    - Ideally also for reference varieties
    - Indications for control of seed-borne diseases during seed production
  - Seed purity
    - Seed purity of GM line and CC verified
      - Visually and with molecular methods (PCR, qPCR, ELISA)
      - To verify presence of the event in the CC and of GM events cultivated in the vicinity of seed production area in the CC and GM line
- Seed health and germination capacity
  - In accordance to ISTA (2014) rules or other testing approach with detailed description

3. Quality of test materials used as test materials

• Seed production • Seed purity • Seed health and germination capacity

Summary of the 23 received comments

Impracticability of the proposed protocol:

- GM line available in small amount; not possible to multiply under similar condition as CC
- OECD standards are inappropriate for small scale seed production
- Seed purity of reference varieties (impossible to guarantee \ illegal to re-analyse in US)

Requests for clarification:

- Technical seed purity vs. varietal purity

More flexibility vs. less:

- Same seed pre-treatments between GM, CC and the reference varieties not feasible:
  - Remove this requirement vs. deny the possibility to use pre-treatments on GM and CC
- Any kind of adventitious presence is unacceptable in GM CC and non-GM reference varieties

4. Design of field trials

• Description of the receiving environment • Crop management (herbicide regime) • Experimental design

Content of draft Agro/Pheno guidance document

- Design of field trials
  - Data generation for the characterisation of GM plants

Recommendation to use same field trials for Agro/Pheno, compo and protein expression data

  - Description of receiving environments of field trials (Imp. Reg. 503/2013)
    - Location
    - Agrometeorological data
    - Soil type and soil characteristics
    - Cropping history
    - Post-harvest conditions
  - Crop management
  - Herbicide regimes for GMHT crops
    - Herbicide regimes (Imp.Reg. 503/2013, 3 test materials)
    - Recommendations for GMHT single or stacks treated with intended herbicide/s
  - Experimental design
    - Plot size and shape
    - Inter-plot distance and buffer/guard rows

4. Design of field trials

• Description of the receiving environment • Crop management (herbicide regime) • Experimental design

Summary of the 42 received comments

Requests for clarification:

- Detailed agrometeorological data are considered useless for the RA
- Use of imprecise recommendations *appropriate number, representative number*
- How can crop management inform the RA?
- Clarifications on possible HT regimes
- Minimum plot size ($25m^2$) is not justified

More flexibility vs. less:

- Generation of protein expression data in the same field trials used for Agro/Pheno and compo is not feasible
- It should be up to applicants to decide whether meteorological data should be submitted
- Soil characteristics data (not needed\not relevant for ERA)
- No need to provide cropping history of the sites

5. Agro&pheno endpoints

• Mandatory endpoints • Additional endpoints

Content of draft Agro/Pheno guidance document

- Agro/pheno endpoints (why, how, when, unit, recommendations)
- Mandatory agronomic and phenotypic endpoints

Phenologic phase	Endpoint	Measure[a]	Unit	Soybean	Maize	Cotton	Oilseed rape
				Growth stages[b]			
Pre-sowing	See Section 3.3	-	-	00-08			
Establishment	Early stand count	M	m^{-2}	12-13	11-14	11-13	11-13
	Ground cover I	V	%	2x	16-18	23-25	23-25
	Herbicide injury	V	%	After each HT			
Reproductive	10% flowering[c]	V	Days	61			
	50% flowering[d]	V	Days	65			
	Ground cover II	V	%	65	36-38	65	65
	End of flowering[e]	V	Days	69	67	69	69
	Lodging[f]	V	#/%	89	89	89	80-89
	Final stand count	M	m^{-2}	89	87-89	89	89
Maturity	Plant height	M	cm	89	36-38	69-89	71-89
	Days to maturity	V	Days	89	87	89	89
	Seed loss[g]	M	#	89			
	Fruit count[h]	M	#	89			
	Seed per fruit[i]	M	#	99			
Harvest	Seed moisture	M	%	99			
	100/1000 seed weight	M	g	99			
	Yield	M	$g\ ^{m-2}$	99			
All phases after plant emergence	Biotic interactions	V	-	11-99			
	Abiotic interaction	V	-	11-99			

- Additional endpoints to be considered on a case-by-case basis
  - Pollen characteristics
  - Seed characteristics

5. Agro&pheno endpoints

• Mandatory endpoints • Additional endpoints

Summary of the 71 received comments

Statements and requests for clarification:

- Clear distinction between I&P and cult APs
- Selection of proposed endpoints poorly justified
- Limited significance of selected endpoints for ERA
- To specify minimal number of plant per endpoints to be sampled
- EFSA mandatory endpoints are not in line with those proposed by Codex Guidelines, other RA bodies or used for typical agronomic evaluation

More flexibility vs. less:

- Flexibility in sampling needed
- To expand the list to better cover biotic and abiotic interactions
- Additional endpoints only necessary for cultivation APs
- Additional endpoints should always be measured

6. Data analysis

• Data submission • Statistical analysis •G*E interactions •Correlated endpoints

Content of the draft guidance

- **Data analysis**

Specific clarifications are given in EFSA (2010 Statistical, 2011 FF)

- **Data submission**
  - Raw data
  - Single values for endpoints assessed collecting multiple measurements
  - Data formatted for EFSA stat software
  - Minimal number of sites and reps in line with EFSA (2010, 2011) and Imp.Reg 503/2013
  - Submission of incomplete datasets
- **Statistical analysis**
  - Uncategorised endpoints (due to zero variance in ref. varieties)
  - "*Type 8*" (no difference between GM and CC and not equivalent to ref. varieties)
- **Analysis of GxE interactions**
  - In case of GxE interaction ---> per site analysis
- **Correlated endpoints**

6. Data analysis

• Data submission • Statistical analysis •G*E interactions •Correlated endpoints

Summary of the 21 received comments

Requests for clarification:

- Minimal requirements for number of sites and plots
- Consequences of possible differences in the results obtained with EFSA GMO statistical software and other software
- Multiple vs. single value; how will this be used by EFSA?
- Zero variance (several uncorrelated endpoints)
- GxE interaction to be assessed on a case-by-case basis or not?

More flexibility vs. less:

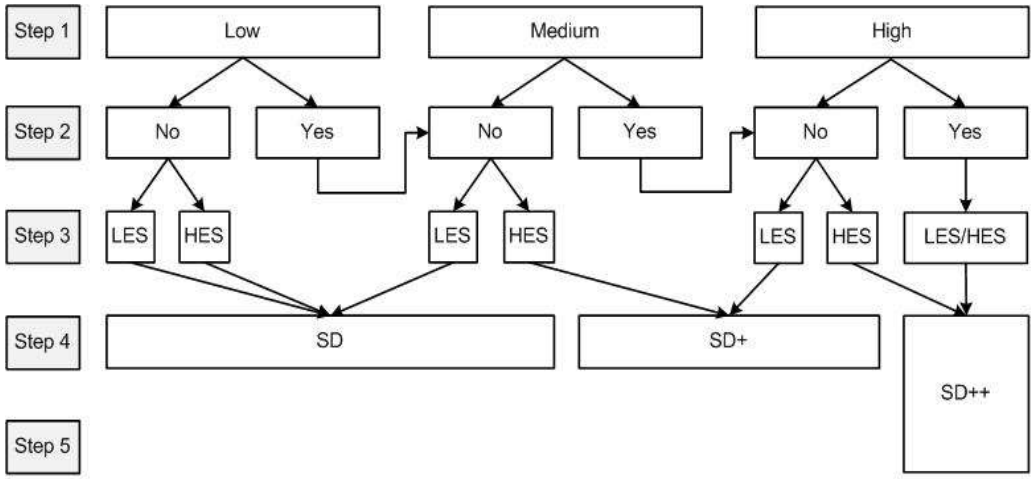
- '*Type 8*' (to consider inclusion of GM reference varieties)
- To always request GxE interaction assessment
- To expand the number of sites in order to better asses GxE interactions
- Discarded values should not be submitted

7. Relevance of agro&pheno data for ERA

• Persistence and invasiveness • decision tree • data requirements for SD, SD+ and SD++

Content of draft Agro/Pheno guidance document

- Relevance of Agro/Pheno data for ERA
  - Relevant for invasiveness and persistence
  - Limited value for TO and NTO
- Persistence and invasiveness of the GM plant
  - Decision tree



Legend:
Step 1 – Estimation of the persistence/invasiveness potential of the parental plant (low, medium or high category)
Step 2 – Assessment of whether the novel trait may increase persistence and invasiveness (yes or no)
Step 3 – Consideration of the level of exposure (LES or HES)
Step 4 – Selection of additional agronomic and phenotypic characteristics
Step 5 – Selection of additional experiments

- Data requirements for SD+ and SD++

7. Relevance of agro&pheno data for ERA

• Persistence and invasiveness • decision tree • data requirements for SD, SD+ and SD++

Summary of the 43 received comments

Statements and requests for clarification:

- Disagreement about the limited usefulness of Agro/Pheno data for ERA
- To expand the above statement also to the impact on management practices
- Clarifications on different steps of the decision tree

More flexibility vs. less:

- To make a clear distinction between I&P and cultivation APs
- To move in the decision tree step 3 to step 1
- To use the decision tree to reduce data requirements
- To expand the description of data requirements

NEXT STEPS

- Today's technical meeting to gather further input from you

45 registered experts:
- 15 Applicants
- 11 GMO Network
- 8 Researchers
- 7 EU Competent Authorities
- 2 EuropaBio
- 1 NGO
- 1 EU

- 1 physical meeting and 2 telemeetings before possible adoption of the final GD by the EFSA GMO Panel in spring 2015