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CONSIDERATION OF POSSIBLE REORGANIZATION OF TGP/8: A PROPOSAL FROM CHINA

Document prepared by an expert from China

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1. Document TGP/8 “Trial Design and Techniques Used in the Examination of Distinctness, Uniformity and Stability” is a very important document for practical guidance on DUS testing. Currently, document TGP/8 has plenty of useful guidance including two parts in 17 chapters. However, there are two small problems that affect its practical value. First, the chapters are not at the same level and are not in an ideal order, for example, distinctness has a chapter on selection of methods but uniformity does not. Second, many examples do not provide raw data and relationship with previous chapters. This document is intended to initiate a discussion on reorganizing document TGP/8.

2. Annex I to this document contains a copy of a proposal for consideration of a possible reorganization of TGP/8 at its thirty-fifth session of the Technical Working Party on Automation and Computer Programs (TWC). Annex II to this document contains a copy of the current table of contents of TGP/8.

Yang Kun, Deputy Director, Beijing Station of Plant Variety Tests, Ministry of Agriculture, China

[Annexes follow]

NEW TABLE OF CONTENTS

Note: Underlined chapters are new chapters proposed by China

INTRODUCTION

INTRODUCTION

PART 1: DUS TRIAL DESIGN

1. DUS TRIAL DESIGN

1.1 Introduction

1.1 Introduction

1.2 Growing cycles

1.2 Growing cycles

1.2.1 Introduction

1.2.2 Independent growing cycles

1.3 Testing locations

1.3 Testing Place

1.3.1 Conditions for conducting the examination

1.4 Conditions for conducting the examination

1.3.2 Purpose

1.3.1 Purpose

(a) Minimizing the overall testing period

(b) Reserve Trial

(c) Different agro-climatic conditions

1.3.3 Use of information from multiple locations

1.3.2 Use of information from multiple locations

(a) Additional tests

(b) DUS examined on the basis of data for the same characteristics examined at different locations

1.4 Replicates and plots

1.5 Test Design

1.5.1 Introduction

1.5.3 Trial layout

1.5.3.1 Introduction

1.5.3.2 Single plots

1.5.3.3 Replicate plots (statistical analysis)

1.5.3.3.1 Introduction

1.5.3.3.2 Replicate plots for statistical analysis of individual plant data

1.5.3.3.3 Randomization

1.5.3.3.4 Randomized incomplete block designs

1.5.3.3.5 Design for pair-wise comparisons between particular varieties

1.5.3.3.7 Trial elements when statistical analysis is used

1.5.3.3.7.1 Introduction

1.5.3.3.7.2 Plots and blocks

1.5.3.3.7.3 Allocation of varieties to plots

1.5.3.3.7.4 Plot size, shape and configuration

1.5.3.3.7.5 Independence of plots

1.5.3.3.7.6 The arrangement of the plants within the plot/ Type of plot for observation

1.5.3.4 Blind Randomized Trials

1.5 Optimal sample size for DUS examination

1.5.2 Number of Plants in the trial

1.5.3.3.6 Further statistical aspects of trial design

1.5.3.3.6.1 Introduction

1.5.3.3.6.2 The hypotheses under test

1.5.3.3.6.3 Determining optimal sample size

1.6 Changing Methods
1.6 Changing Methods

PART 2: DATA RECORDING AND PROBABILITY DISTRIBUTION

2.1 Different levels to look at a characteristic
2.4 Different levels to look at a characteristic

2.2 DATA TO BE RECORDED
2. DATA TO BE RECORDED

- 2.1 Introduction
- 2.2 Types of expression of characteristics
- 2.3 Types of scales of data
 - 2.3.1 Data from qualitative characteristics
 - 2.3.2 Data from quantitative characteristics
 - (a) Ratio scale
 - (b) Interval scale
 - (c) Ordinal scale
 - 2.3.3 Data from pseudo-qualitative characteristics
 - 2.3.4 Summary of the different types of scales
 - 2.3.5 Scale levels for variety description
 - 2.3.6 Relation between types of expression of characteristics and scale levels of data
 - 2.3.7 Relation between method of observation of characteristics, scale levels of data and recommended statistical procedures

2.3 Probability Distribution

Binomial distribution, Poisson distribution, Normal distribution, t distribution, χ^2 distribution, F distribution

PART 3: VALIDATION OF DATA AND ASSUMPTIONS

3. VALIDATION OF DATA AND ASSUMPTIONS

3.1 Introduction
3.1 Introduction

3.2 Validation of data
3.2 Validation of data
(3.2.5 Box graph should include original data)

3.3 Assumptions for statistical analysis and the validation of these assumptions
3.3 Assumptions for statistical analysis and the validation of these assumptions

3.3.1 Introduction

3.3.1 Assumptions for statistical analysis involving analysis of variance

3.3.1.1 Introduction

3.3.2 Independent observations

3.3.1.2 Independent observations (the example should include original data)

3.3.3 Variance homogeneity

3.3.1.3 Variance homogeneity

3.3.4 Normal distributed observations

3.3.1.4 Normal distributed observations

3.3.1.5 Additivity of block and variety effects (move to new 3.3.2)

3.3.2 Validation of assumptions for statistical analysis

3.3.2.1 Introduction (move to new 3.3.1 Introduction)

3.3.2.2 Looking through the data (move to new 3.3.1 Introduction)

3.3.2.3 Using figures (3.3.2.3.2 move to new 3.3.2, 3.3.2.3.4 move to new 3.3.3, 3.3.2.3.5 move to new

3.3.2, 3.3.2.3.7 move to new 3.3.4)

PART 4: CHOICE OF STATISTICAL METHODS FOR EXAMINING DISTINCTNESS

4. CHOICE OF STATISTICAL METHODS FOR EXAMINING DISTINCTNESS

4.1 Introduction

4.2 Statistical methods for use with two or more independent growing cycles

4.2.1 Introduction

4.3 Summary of selected statistical methods for examining distinctness

4.4 Requirements for statistical methods for distinctness assessment

4.1 THE COMBINED OVER-YEARS CRITERIA FOR DISTINCTNESS (COYD)

3. THE COMBINED OVER-YEARS CRITERIA FOR DISTINCTNESS (COYD)

3.1 Summary of requirements for application of method

3.2 Summary

3.3 Introduction

3.4 The COYD method

3.5 Use of COYD

3.6 Adapting COYD to special circumstances

3.6.1 Differences between years in the range of expression of a characteristic

3.6.2 Small numbers of varieties in trials: Long-Term COYD

3.6.3 Crops with grouping characteristics

3.7 Implementing COYD

3.8 References

3.9 COYD statistical methods

3.9.1 Analysis of variance

3.9.2 Modified joint regression analysis (MJRA)

3.9.3 Comparison of COYD with other criteria

3.10 COYD software

3.11 Schemes used for the application of COYD

4.2 t test by 2X1%

4.2 X1% METHOD

4.1 Requirements for application of method

4.2 The 2x1% Criterion (Method)

4.3 PEARSON'S CHI-SQUARE TEST APPLIED TO CONTINGENCY TABLES

5. PEARSON'S CHI-SQUARE TEST APPLIED TO CONTINGENCY TABLES

4.4 FISHER'S EXACT TEST

6. FISHER'S EXACT TEST

6.1 Assessment of Distinctness

4.5MATCH APPROACH

7. MATCH APPROACH

7.1 Requirements for application of method

7.2 Match Method

PART5: CHOICE OF STATISTICAL METHODS FOR EXAMINING UNIFORMITY

5.1 THE METHOD OF UNIFORMITY ASSESSMENT ON THE BASIS OF OFF-TYPES

8. THE METHOD OF UNIFORMITY ASSESSMENT ON THE BASIS OF OFF-TYPES

8.1 Fixed Population Standard

8.1.1 Introduction

8.1.2 Using the approach to assess uniformity in a crop

8.1.3 Issues to be considered when deciding on the use of the method

8.1.4 Examples

8.1.5 Introduction to the tables and figures

8.1.6 Method for one single test

8.1.7 Method for more than one single test (year)

8.1.7.1 Introduction

8.1.7.2 Combined test

8.1.7.3 Two-stage test

8.1.7.4 Sequential tests

8.1.8 Note on balancing the Type I and Type II errors

- 8.1.9 Definition of statistical terms and symbols
- 8.1.10 Tables and figures

5.2 THE COMBINED-OVER-YEARS UNIFORMITY CRITERION (COYU)

9. THE COMBINED-OVER-YEARS UNIFORMITY CRITERION (COYU)

- 9.1 Summary of requirements for application of method
- 9.2 Summary
- 9.3 Introduction
- 9.4 The COYU Criterion
- 9.5 Use of COYU
- 9.6 Mathematical details
- 9.7 Early decisions for a three-year test
- 9.8 Example of COYU calculations
- 9.9 Implementing COYU
- 9.10 COYU software
 - 9.10.1 DUST computer program
- 9.11 Schemes used for the application of COYU

5.3 UNIFORMITY ASSESSMENT ON THE BASIS OF THE RELATIVE VARIANCE METHOD

10. UNIFORMITY ASSESSMENT ON THE BASIS OF THE RELATIVE VARIANCE METHOD

- 10.1 Use of the relative variance method
- 10.2 Thresholds for different sample sizes
- 10.3 The relative variance test in practice
- 10.4 Example of relative variance method
- 10.5 Relationship between relative variance and relative standard deviation

PART6: CYCLIC PLANTING OF VARIETIES FROM THE VARIETY COLLECTION TO REDUCE TRIAL SIZE

5. CYCLIC PLANTING OF VARIETIES FROM THE VARIETY COLLECTION TO REDUCE TRIAL SIZE

- 5.1 Summary of requirements for application of method
- 5.2 Summary
- 5.3 Cyclic Planting of Established Varieties in Trial
 - 5.3.1 The assessment of distinctness by data compensation
 - 5.3.2 Method of analysis for distinctness assessment
 - 5.3.3 The assessment of uniformity
- 5.4 Comparison of the cyclic planting system with the existing system
- 5.5 Cyclic planting system software
- 5.6 Additional technical detail and example of analysis for distinctness assessment
 - 5.6.1 Example of distinctness assessment
- 5.7 References

PART7: PARENT FORMULA OF HYBRID VARIETIES

2. PARENT FORMULA OF HYBRID VARIETIES

- 2.1 Introduction
- 2.2 Requirements of the method
- 2.3 Assessing the originality of a new parent line
- 2.4 Verification of the formula
- 2.5 Uniformity and stability of parent lines
- 2.6 Description of the hybrid

PART8: METHODS of TRANSFORMING DATA TO NOTE AND SELECTING SIMILAR VARIETIES

8.1 METHODS OF TRANSFORMING DATA TO NOTE

8.2 THE GAIA METHODOLOGY

1. THE GAIA METHODOLOGY

- 1.1 Some reasons to sum and weight observed differences
- 1.2 Computing GAIA phenotypic distance
- 1.3 Detailed information on the GAIA methodology
 - 1.3.1 Weighting of characteristics
 - 1.3.2 Examples of use

- 1.3.2.1 Determining “Distinctness Plus”
- 1.3.2.2 Other examples of use
- 1.3.3 Computing GAIA phenotypic distance
- 1.3.4 GAIA software
- 1.3.5 Example with Zea mays data
 - 1.3.5.1 Introduction
 - 1.3.5.2 Analysis of notes
 - 1.3.5.3 Electrophoresis analysis
 - 1.3.5.4 Analysis of measurements
 - 1.3.5.5 Measurements and 1 to 9 scale on the same characteristic
- 1.3.6 Example of GAIA screen copy

[Annex II follows]

<u>TABLE OF CONTENTS</u>	<u>PAGE</u>
INTRODUCTION.....	5
PART I: DUS TRIAL DESIGN AND DATA ANALYSIS.....	6
1. DUS TRIAL DESIGN	6
1.1 Introduction	6
1.2 Growing cycles.....	6
1.2.1 Introduction.....	6
1.2.2 Independent growing cycles	7
1.3 Testing Place	7
1.3.1 Purpose	7
(a) Minimizing the overall testing period.....	7
(b) Reserve Trial.....	7
(c) Different agro-climatic conditions	8
1.3.2 Use of information from multiple locations.....	8
(a) Additional tests.....	8
(b) DUS examined on the basis of data for the same characteristics examined at different locations	8
1.4 Conditions for conducting the examination	8
1.5 Test Design.....	8
1.5.1 Introduction.....	8
1.5.2 Number of Plants in the trial	9
1.5.3 Trial layout.....	9
1.5.3.1 Introduction	9
1.5.3.2 Single plots	11
1.5.3.3 Replicate plots (statistical analysis).....	11
1.5.3.3.1 Introduction	11
1.5.3.3.2 Replicate plots for statistical analysis of individual plant data	11
1.5.3.3.3 Randomization	11
1.5.3.3.4 Randomized incomplete block designs.....	14
1.5.3.3.5 Design for pair-wise comparisons between particular varieties.....	15
1.5.3.3.6 Further statistical aspects of trial design	15
1.5.3.3.6.1 Introduction.....	15
1.5.3.3.6.2 The hypotheses under test.....	15
1.5.3.3.6.3 Determining optimal sample size.....	17
1.5.3.3.7 Trial elements when statistical analysis is used	17
1.5.3.3.7.1 Introduction.....	17
1.5.3.3.7.2 Plots and blocks	18
1.5.3.3.7.3 Allocation of varieties to plots	18
1.5.3.3.7.4 Plot size, shape and configuration.....	19
1.5.3.3.7.5 Independence of plots	19
1.5.3.3.7.6 The arrangement of the plants within the plot/ Type of plot for observation	19
1.5.3.4 Blind Randomized Trials.....	19
1.6 Changing Methods.....	20
2. DATA TO BE RECORDED	21
2.1 Introduction	21
2.2 Types of expression of characteristics	21
2.3 Types of scales of data	22
2.3.1 Data from qualitative characteristics	22
2.3.2 Data from quantitative characteristics.....	22
(a) Ratio scale	23
(b) Interval scale.....	23
(c) Ordinal scale.....	24
2.3.3 Data from pseudo-qualitative characteristics	24
2.3.4 Summary of the different types of scales.....	25
2.3.5 Scale levels for variety description	25
2.3.6 Relation between types of expression of characteristics and scale levels of data	25
2.3.7 Relation between method of observation of characteristics, scale levels of data and recommended statistical procedures.....	26
2.4 Different levels to look at a characteristic.....	28
3. MINIMIZING THE VARIATION DUE TO DIFFERENT OBSERVERS OF THE SAME TRIAL	32
3.1 Introduction	32
3.2 Training and importance of clear explanations of characteristics and method of observation.....	32
3.3 Testing the calibration.....	32
3.4 Testing the calibration for QN/MG or QN/MS characteristics	32

3.5	<i>Testing the calibration for QN/VS or QN/VG characteristics</i>	33
3.6	<i>Trial design</i>	33
3.7	<i>Example of Cohen's Kappa</i>	34
3.8	<i>References</i>	35
4.	VALIDATION OF DATA AND ASSUMPTIONS	36
4.1	<i>Introduction</i>	36
4.2	<i>Validation of data</i>	36
4.3	<i>Assumptions for statistical analysis and the validation of these assumptions</i>	37
4.3.1	<i>Assumptions for statistical analysis involving analysis of variance</i>	38
4.3.1.1	<i>Introduction</i>	38
4.3.1.2	<i>Independent observations</i>	38
4.3.1.3	<i>Variance homogeneity</i>	38
4.3.1.4	<i>Normal distributed observations</i>	39
4.3.1.5	<i>Additivity of block and variety effects</i>	39
4.3.2	<i>Validation of assumptions for statistical analysis</i>	40
4.3.2.1	<i>Introduction</i>	40
4.3.2.2	<i>Looking through the data</i>	40
4.3.2.3	<i>Using figures</i>	41
5.	CHOICE OF STATISTICAL METHODS FOR EXAMINING DISTINCTNESS	45
5.1	<i>Introduction</i>	45
5.2	<i>Statistical methods for use with two or more independent growing cycles</i>	45
5.2.1	<i>Introduction</i>	45
5.3	<i>Summary of selected statistical methods for examining distinctness</i>	47
5.4	<i>Requirements for statistical methods for distinctness assessment</i>	48
6.	CYCLIC PLANTING OF VARIETIES FROM THE VARIETY COLLECTION TO REDUCE TRIAL SIZE	49
6.1	<i>Summary of requirements for application of method</i>	49
6.2	<i>Summary</i>	49
6.3	<i>Cyclic Planting of Established Varieties in Trial</i>	49
6.3.1	<i>The assessment of distinctness by data compensation</i>	50
6.3.2	<i>Method of analysis for distinctness assessment</i>	51
6.3.3	<i>The assessment of uniformity</i>	51
6.4	<i>Comparison of the cyclic planting system with the existing system</i>	51
6.5	<i>Cyclic planting system software</i>	51
6.6	<i>Additional technical detail and example of analysis for distinctness assessment</i>	51
6.6.1	<i>Example of distinctness assessment</i>	52
6.7	<i>References</i>	53
	PART II: SELECTED TECHNIQUES USED IN DUS EXAMINATION	54
1.	THE GAIA METHODOLOGY	54
1.1	<i>Some reasons to sum and weight observed differences</i>	54
1.2	<i>Computing GAIA phenotypic distance</i>	54
1.3	<i>Detailed information on the GAIA methodology</i>	55
1.3.1	<i>Weighting of characteristics</i>	55
1.3.2	<i>Examples of use</i>	56
1.3.2.1	<i>Determining "Distinctness Plus"</i>	56
1.3.2.2	<i>Other examples of use</i>	57
1.3.3	<i>Computing GAIA phenotypic distance</i>	57
1.3.4	<i>GAIA software</i>	58
1.3.5	<i>Example with Zea mays data</i>	59
1.3.5.1	<i>Introduction</i>	59
1.3.5.2	<i>Analysis of notes</i>	59
1.3.5.3	<i>Electrophoresis analysis</i>	60
1.3.5.4	<i>Analysis of measurements</i>	62
1.3.5.5	<i>Measurements and 1 to 9 scale on the same characteristic</i>	63
1.3.6	<i>Example of GAIA screen copy</i>	64
2.	PARENT FORMULA OF HYBRID VARIETIES	67
2.1	<i>Introduction</i>	67
2.2	<i>Requirements of the method</i>	67
2.3	<i>Assessing the originality of a new parent line</i>	67
2.4	<i>Verification of the formula</i>	68
2.5	<i>Uniformity and stability of parent lines</i>	68
2.6	<i>Description of the hybrid</i>	68
3.	THE COMBINED OVER-YEARS CRITERIA FOR DISTINCTNESS (COYD)	69
3.1	<i>Summary of requirements for application of method</i>	69
3.2	<i>Summary</i>	69
3.3	<i>Introduction</i>	69
3.4	<i>The COYD method</i>	70
3.5	<i>Use of COYD</i>	70
3.6	<i>Adapting COYD to special circumstances</i>	71

3.6.1	<i>Differences between years in the range of expression of a characteristic</i>	71
3.6.2	<i>Small numbers of varieties in trials: Long-Term COYD</i>	72
3.6.3	<i>Crops with grouping characteristics</i>	72
3.7	<i>Implementing COYD</i>	73
3.8	<i>References</i>	73
3.9	<i>COYD statistical methods</i>	76
3.9.1	<i>Analysis of variance</i>	76
3.9.2	<i>Modified joint regression analysis (MJRA)</i>	76
3.9.3	<i>Comparison of COYD with other criteria</i>	77
3.10	<i>COYD software</i>	77
3.11	<i>Schemes used for the application of COYD</i>	84
4.	2X1% METHOD	87
4.1	<i>Requirements for application of method</i>	87
4.2	<i>The 2x1% Criterion (Method)</i>	87
5.	PEARSON'S CHI-SQUARE TEST APPLIED TO CONTINGENCY TABLES	89
6.	FISHER'S EXACT TEST	92
6.1	<i>Assessment of Distinctness</i>	92
7.	MATCH APPROACH	94
7.1	<i>Requirements for application of method</i>	94
7.2	<i>Match Method</i>	94
8.	THE METHOD OF UNIFORMITY ASSESSMENT ON THE BASIS OF OFF TYPES	95
8.1	<i>Fixed Population Standard</i>	95
8.1.1	<i>Introduction</i>	95
8.1.2	<i>Using the approach to assess uniformity in a crop</i>	95
8.1.3	<i>Issues to be considered when deciding on the use of the method</i>	96
8.1.4	<i>Examples</i>	97
8.1.5	<i>Introduction to the tables and figures</i>	100
8.1.6	<i>Method for one single test</i>	101
8.1.7	<i>Method for more than one single test (year)</i>	102
8.1.7.1	<i>Introduction</i>	102
8.1.7.2	<i>Combined test</i>	102
8.1.7.3	<i>Two-stage test</i>	102
8.1.7.4	<i>Sequential tests</i>	103
8.1.8	<i>Note on balancing the Type I and Type II errors</i>	103
8.1.9	<i>Definition of statistical terms and symbols</i>	104
8.1.10	<i>Tables and figures</i>	105
9.	THE COMBINED-OVER-YEARS UNIFORMITY CRITERION (COYU)	112
9.1	<i>Summary of requirements for application of method</i>	112
9.2	<i>Summary</i>	112
9.3	<i>Introduction</i>	113
9.4	<i>The COYU Criterion</i>	113
9.5	<i>Use of COYU</i>	113
9.6	<i>Mathematical details</i>	114
9.7	<i>Early decisions for a three-year test</i>	116
9.8	<i>Example of COYU calculations</i>	117
9.9	<i>Implementing COYU</i>	118
9.10	<i>COYU software</i>	118
9.10.1	<i>DUST computer program</i>	118
9.11	<i>Schemes used for the application of COYU</i>	122
10.	UNIFORMITY ASSESSMENT ON THE BASIS OF THE RELATIVE VARIANCE METHOD	125
10.1	<i>Use of the relative variance method</i>	125
10.2	<i>Thresholds for different sample sizes</i>	125
10.3	<i>The relative variance test in practice</i>	125
10.4	<i>Example of relative variance method</i>	126
10.5	<i>Relationship between relative variance and relative standard deviation</i>	126
11.	EXAMINING CHARACTERISTICS USING IMAGE ANALYSIS	127
11.1	<i>Introduction</i>	127
11.2	<i>Combined characteristics</i>	127
11.3	<i>Image recording: calibration and standardization</i>	127
11.4	<i>Conclusions</i>	129
11.5	<i>References</i>	129