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TECHNICAL WORKING PARTY ON AUTOMATION AND COMPUTER PROGRAMS

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REVISION OF DOCUMENT TGP/8: PART II:
NEW SECTION: GUIDANCE OF DATA ANALYSIS FOR BLIND RANDOMIZED TRIALS

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1. The purpose of this document is to present draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8.

2. The following abbreviations are used in this document:

TC:	Technical Committee
TC-EDC:	Enlarged Editorial Committee
TWA:	Technical Working Party for Agricultural Crops
TWC:	Technical Working Party on Automation and Computer Programs
TWF:	Technical Working Party for Fruit Crops
TWO:	Technical Working Party for Ornamental Plants and Forest Trees
TWPs:	Technical Working Parties
TWV:	Technical Working Party for Vegetables

3. The structure of this document is as follows:

BACKGROUND 1
COMMENTS BY THE TECHNICAL WORKING PARTIES IN 2012 2
COMMENTS BY THE ENLARGED EDITORIAL COMMITTEE IN 2013 2
COMMENTS BY THE TECHNICAL COMMITTEE IN 2013 3

ANNEX I: Extract from document TGP/8/1: Part I: DUS trial design and data analysis: Section 1.5.3.4 “Blind Randomized Trials”
ANNEX II: Draft guidance of data analysis for blind randomized trials conducted by the applicant or under their responsibility

BACKGROUND

4. The Technical Committee (TC), at its forty-eighth session, held in Geneva from March 26 to 28, 2012, agreed that the experts from France should develop guidance on data analysis for blind randomized trials from their experience, including their use of blind randomized trials for disease resistance and other examples (see document TC/48/22 “Report on conclusions”, paragraph 60).

5. Annex I of this document presents an extract from document TGP/8, Part I: DUS Trial Design and Data Analysis, Section 1: DUS Trial Design, with specific guidance on trial layout for blind randomized trials.

COMMENTS BY THE TECHNICAL WORKING PARTIES IN 2012

6. At their sessions in 2012, the TWA, TWV, TWC, TWF and TWO considered documents TWA/41/17, TWV/46/17, TWC/30/17, TWF/43/17 and TWO/45/17 respectively, on guidance of data analysis for blind randomized trials and commented as follows:

General	The TWA considered document TWA/41/17. The TWA noted the information contained in document TWA/41/17 and the presentation received by the expert from France on guidance of data analysis for blind randomized trials. Remarks by the TWA expressed the importance of these blind randomized trials for the breeders and mentioned the contribution they made to the system. The TWA recommended that the work on that guidance should be continued on the basis of that document (see document TWA/41/34 “Report”, paragraphs 23 and 24).	TWA
	The TWV considered document TWV/46/17 and agreed with the comments of the TWA expressing the importance of these blind randomized trials for the breeders and the contribution they made to the system and recommending that the work on that guidance should be continued on the basis of that document (see document TWV/46/41 “Report”, paragraph 23).	TWV
	The TWC agreed with the further development of the document and recommended that it should be made more general so as to apply to all possible users, e.g. to remove the mention to GEVES. The TWC requested that further clarifications be provided for paragraphs 2, 4 and 5. Further guidance provided by the document should include information on the number of replications to ensure that correct labeling of the variety by chance would not be likely (see document TWC/30/41 “Report”, paragraph 45).	TWC
	The TWF considered document TWF/43/17. The TWF requested experts to provide more examples of the use of data analysis for blind randomized trials, which would be considered in the development of guidance. The TWF agreed that the guidance should provide more precise explanation concerning cases in which this method is appropriate and how the use of this technique would assist in DUS examination (see document TWF/43/38 “Report”, paragraphs 32 to 34).	TWF
	The TWO proposed that examples of use of blind randomized trials for other crop types, such as ornamentals, be included in the further development of the guidance (see document TWO/45/37 “Report”, paragraph 33).	TWO

COMMENTS BY THE ENLARGED EDITORIAL COMMITTEE IN 2013

7. The TC-EDC, at its meeting on January 9 and 10, 2013, considered document TC-EDC/Jan13/17 and made the following proposals:

General remark	to add an introduction to explain the role of blind randomized trials.
Annex: Background Paragraph 1 Second bullet	to read: “check some genetic diseases resistance not officially tested ~~by le Groupe d'étude et de contrôle des variétés et des semences (GEVES)~~ the authority in ~~charge of DUS examination~~.”
Annex: Paragraph 2 Preparation of the Trial: first bullet	- to read: “The applicant has the choice to accept ~~or not~~ this possibility or not; - to clarify that the trial could also be conducted at an official site; - to add a possibility for blind randomized trials for vegetatively propagated varieties.

COMMENTS BY THE TECHNICAL COMMITTEE IN 2013

8. The TC, at its forty-ninth session held in Geneva from March 18 to 20, 2013, agreed to the preparation of a new draft for a new Section on “Guidance for Data Analysis for Blind Randomized Trials” by an expert from France, on the basis of the Annex to document TC/49/30 and the comments by the TWPs at their sessions in 2012, and the TC-EDC at its meeting in 2013, for consideration by the TWPs at their sessions in 2013 (see document TC/49/41 “Report on the Conclusions”, paragraphs 67 and 68).

9. The Annex II to this document contains draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8, as prepared by experts from France, on the basis of the comments made by the TWPs at their sessions in 2012 and the TC-EDC, at its meeting in January, 2013. The amendments to the text considered by the TWPs at their sessions in 2012 and the TC-EDC, at its meeting in January, 2013, are indicated by highlighting and strikethrough for deletions and highlighting and underlining for additions.

10. The TWC is invited to consider the draft new Section on “Guidance for Data Analysis for Blind Randomized Trials”, on the basis of the Annex to this document and the comments by the TWPs, the TC-EDC and the TC, as set out in paragraphs 6 to 8 of this document.

[Annexes follow]

ANNEX I

EXTRACT FROM DOCUMENT TGP/8

PART I: DUS TRIAL DESIGN AND DATA ANALYSIS

1. DUS TRIAL DESIGN
[…]

1.5 Test Design
[…]

1.5.3 Trial layout
[…]

"1.5.3.4 Blind Randomized Trials

1.5.3.4.1 Part of a trial may consist of plots sown specifically for randomized "blind" testing, such as plots containing plants of both the varieties to be distinguished between, with the plants sown in a random but known order, or alternatively a mixture of pots with the two varieties in a greenhouse. The two varieties comprise the candidate plus the variety with which the distinctness of the candidate is in dispute. The principle of randomized "blind" testing is that a judge, sometimes the breeder, is presented with the plants and is asked to tell plant by plant which is the candidate, and which is the other variety.

1.5.3.4.2 To allow this, the plants must be presented or sown in a random order but such that the tester knows which is which variety, the judge judges each plant, and the tester counts the number of times the different varieties are correctly identified. In order to reinforce the blindness of the test, a different number of plants from each of the two varieties are presented, for instance 51 of the candidate and 69 of the other, rather than 60 of each. As differences may occur at different stages of growth, the judge can assess the plants on more than one occasion."

[Annex II follows]

ANNEX II

DRAFT GUIDANCE OF DATA ANALYSIS FOR BLIND RANDOMIZED TRIALS CONDUCTED BY THE APPLICANT OR UNDER THEIR RESPONSIBILITY

Introduction:
[To be provided]

Background:

1. The blind randomized trials have been used in France for many years in order to:

- confirm some characteristics announced by the applicant;
- check some genetic diseases resistances not officially tested ~~by le Groupe d'étude et de contrôle des variétés et des semences (GEVES)~~ ~~the authority in charge of DUS examination~~.

2. In cases of difficulties with distinctness after one or two growing cycles, the blind randomized trials have been used to take account of specific adaptations in DUS test (regional, climatic, etc.).

Preparation of the trial:

- The applicant has the choice to accept ~~or not~~ this possibility or not;
- Seeds are sent to the applicant under code A, B, C, D, E … (variety in DUS test + closed reference variety + mixture);
- The trial is conducted in the applicant's facilities on the basis of at least two replications;
- The number of plants observed must be at least the number recommended in the guideline;
- The applicant must inform ~~GEVES~~ the authority ~~of~~ on the progress of the trial for an eventual visit.

3. In the case of a problem of distinctness, a blind test may be planted in ~~GEVES~~ the authority's facilities to avoid identification by other methods (e.g. DNA profiling). The applicant is invited to visit this trial. The protocol of the test is not compulsory but ~~GEVES~~ the authority could ask him and some recommendations are made to the applicant; (number of ~~replications~~ plants to be observed).

Transmission of results:

4. The results are transmitted to ~~GEVES~~ the authority by the applicant as below:

A = Candidate variety
B = Reference variety
C = Mixture
D = Candidate variety
E = Reference variety

5. The fact that the applicant gives good results is a very important point, but not enough. The final decision is always taken ~~by GEVES~~ after analysis of all results. In the case of a distinctness problem, the characteristics used by the applicant to distinguish the varieties must be more or less the same as those observed ~~by GEVES~~ during official cycles.

6. This approach amounts to formalize the results obtained through a non-official test.

[End of Annex II and of document]