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Geneva

TECHNICAL WORKING PARTY FOR FRUIT CROPS

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REVISION OF DOCUMENT TGP/8: PART II: SELECTED TECHNIQUES USED IN DUS EXAMINATION,
NEW SECTION: GUIDANCE FOR BLIND RANDOMIZED TRIALS

Document prepared by the Office of the Union

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 The purpose of this document is to present draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8.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

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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 existing guidance on trial layout for blind randomized trials.

COMMENTS BY THE TECHNICAL COMMITTEE IN 2013

6. 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).

COMMENTS BY THE TECHNICAL WORKING PARTIES IN 2013

7. At their sessions in 2013, the TWO, TWF, TWV, TWC and TWA considered documents TWO/46/19, TWF/44/19, TWV/47/19, TWC/31/19 and TWA/42/19, respectively, which contained the draft guidance reproduced in Annex II to this document.

General	The TWO noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on "Guidance for Data Analysis for Blind Randomized Trials" (see document TWO/46/29 "Report", paragraph 44).	TWO
	The TWF noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on "Guidance for Data Analysis for Blind Randomized Trials" (see document TWF/44/31 "Report", paragraph 48). The TWF agreed that the drafter should further develop the guidance as set out in Annex II to document TWF/44/19 on draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8 (see document TWF/44/31 "Report", paragraph 49).	TWF
	The TWV noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on "Guidance for Data Analysis for Blind Randomized Trials" (see document TWV/47/34 "Report", paragraph 48).	TWV
	The TWC considered document TWC/31/19 and noted that the draft guidance should be described in general terms to become suitable for crops tested in plots or as individual plants and for the observation of the different types of characteristics (QN, PQ, QL) (see document TWC/31/32 "Report", paragraph 46).	TWC

	<p>The TWA noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on “Guidance for Data Analysis for Blind Randomized Trials.”</p> <p>The TWA agreed that the drafter should further develop the guidance as set out in Annex II to document TWA/42/19 on draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8.</p> <p>The TWA agreed that blind randomized trials were a useful method for specific circumstances and recalled the role of breeders in identifying their varieties and of DUS experts in the final decision of trials (see document TWA/42/31 “Report”, paragraphs 51 to 53).</p>	TWA
Title	The TWO noted that the draft new section related to the DUS trial design and suggested to change the title to “Draft guidance for blind randomized trials conducted by the authority or a third party” (see document TWO/46/29 “Report”, paragraph 45).	TWO
Introduction	The TWO suggested that the introduction to be provided should be generic and requested the addition of an example for ornamental plants (see document TWO/46/29 “Report”, paragraph 46).	TWO
Origin of the material / Authorization for use of certain reference varieties	The TWV agreed that the drafter should further develop the guidance to include explanations that the origin of the material should not influence the final judgment and that the authorization of the breeder should be obtained for varieties that were the subject of an application, as well as certain parent lines (see document TWV/47/34 “Report”, paragraph 49).	TWV
Preparation of the trial	<p>The TWC agreed that the section describing the method of preparation of the trial should be further developed to clarify the procedure for coding the varieties to be used. The TWC requested an improvement to the example used in paragraph 4 with random allocation of codes and the duplication of all samples used, including “C” (Mixture) (see document TWC/31/32 “Report”, paragraph 47).</p> <p>The TWC agreed that the guidance should include statistical consideration on the design of the trial, such as that the number of replications should be sufficiently large to ensure that there was only a small probability (e.g. <0.05 or 0.01) that the candidate variety was correctly labeled by chance (see document TWC/31/32 “Report”, paragraph 48).</p>	TWC
Analysis of results	The TWC agreed that the draft guidance should provide information about analysis of the results (see document TWC/31/32 “Report”, paragraph 49).	TWC

COMMENTS BY THE TECHNICAL COMMITTEE IN 2014

8. The TC, at its fiftieth session, held in Geneva, from April 7 to 9, 2014, considered document TC/50/26 which contained the draft guidance reproduced in Annex III to this document. The TC agreed to request that experts from France continue the development of the proposed guidance on the basis of the comments by the TWPs, as set out in paragraph 7 of this document, and the following comments by the TC-EDC, at its meeting held in Geneva on January 8 and 9, 2014:

General remarks	- The TC-EDC noted that blind randomized trials were used only very rarely and suggested that the TC review whether it was appropriate to include guidance in TGP/8 on a method that is only used in exceptional circumstances on the basis that its inclusion in TGP/8 might imply that it was a routine method. If it is decided to retain the guidance, it was proposed that it should be clarified that blind randomized trials were a useful means by which authorities could demonstrate to breeders that varieties were
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	not distinct, but which also offered the possibility for breeders to demonstrate differences in relevant characteristics that would have clearly distinguished varieties in the growing trial, with suitable knowledge. The TC-EDC further proposed that the structure of the document be reviewed in order to improve the clarity.
Cover page	to check whether to delete "Data analysis" from the title of the document.

9. The TC agreed that the circumstances under which blind randomized trials would be appropriate should be clarified.

10. The TC agreed that the structure of the document should be reviewed in order to improve clarity and that consideration should be given to including guidance on the use of blind randomized trials without data analysis, which would require deletion of "Data analysis" from the title of document. The TC agreed that the Office of the Union should seek information on the use of blind randomized trials for presentation to the TWPs and the TC (see document TC/50/36 "Report on the conclusions", paragraphs 59 to 61).

11. The expert from France has informed the Office of the Union that, given the need for extensive redrafting of the text, it will not be possible to produce a text for consideration by the TWPs in 2014. It is proposed that a new draft be prepared for consideration by the TC and TWPs in 2015. In order to facilitate the consideration by the TC, at its fifty-first session, it is further proposed that an initial draft be prepared for consideration by the TC-EDC at its meeting in January 7 and 8, 2015

12. *The TWA is invited to:*

(a) provide information on the use of blind randomized trials at the different UPOV members, including the circumstances under which blind randomized trials are used; and

(b) note the proposal from the expert from France to prepare a new draft for consideration by the TC and the TWPs at their sessions in 2015.

[Annexes follow]

EXTRACT FROM DOCUMENT TGP/8/1: PART I: DUS TRIAL DESIGN AND DATA ANALYSIS:
SECTION 1.5.3.4 "BLIND RANDOMIZED TRIALS"

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]

DRAFT GUIDANCE CONSIDERED BY THE TWPS AT THEIR SESSIONS IN 2013

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 disease 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.

[Annex III follows]

DRAFT GUIDANCE FOR BLIND RANDOMIZED TRIALS CONDUCTED BY THE AUTHORITY OR A THIRD PARTY

BACKGROUND

1. The Technical Committee, 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).
2. The blind randomized trials can be used for many crops in order to:
 - Confirm some characteristics announced by the applicant;
 - Check some genetic disease resistances or other characteristics not officially tested by the national authority in charge of DUS examination.

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

Preparation of the trial:

1. The applicant has the choice to accept or not this possibility;
 2. Seeds are sent to the applicant under code A, B, C, D, E... (variety in DUS test + closed reference variety + mixture); In case a closed reference variety is under test or is a parental line, the authorization of the breeder must be obtained before plant material transmission;
 3. The trial is conducted in the applicant's facilities on the base of more than one replication (the number of replications should be sufficiently large to ensure that there was only a small probability that the candidate variety was correctly labeled by chance).
 4. The applicant must inform the national authority 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 the national authority 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 the national authority could ask him and some recommendations are made to the applicant (number of plants to be observed).

Transmission of results:

4. The results are transmitted to the national 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 the national authority 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 during official cycles.
6. This approach amounts to formalize the results obtained through a non official test.

[End of Annex III and of document]