



TC/49/30

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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

TECHNICAL COMMITTEE**Forty-Ninth Session
Geneva, March 18 to 20, 2013**

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

Document prepared by the Office of the Union

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 The purpose of this document is to present draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8, as prepared by experts from France and taking into consideration the comments made by the Technical Working Parties (TWPs) at their sessions in 2012 and by the TC-EDC, at its meeting in January, 2013.

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

BACKGROUND

3. 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).

COMMENTS BY THE TECHNICAL WORKING PARTIES IN 2012

4. 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 (TC-EDC) IN 2013

5. 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 <u>or not</u> ; - 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

6. The Annex 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 and taking into consideration the comments made by the TWPs at their sessions in 2012 and by the TC-EDC, at its meeting in 2013. The amendments to the text considered by the TWPs at their sessions in 2012 and by the TC-EDC at its meeting in 2013 are indicated by highlighting and strikethrough for deletions and highlighting and underlining for additions.

7. *The TC is invited to agree to the preparation of a new draft for a 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 and the TC-EDC, as set out in paragraphs 4 and 5 of this document.*

[Annex follows]

GUIDANCE OF DATA ANALYSIS FOR BLIND RANDOMIZED TRIALS

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 base of at least two replications;
 - 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.

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

[End of Annex and of document]