E

TWO/48/9
ORIGINAL: English
DATE: August 7, 2015

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

TECHNICAL WORKING PARTY FOR ORNAMENTAL PLANTS AND FOREST TREES

Forty-Eighth Session
Cambridge, United Kingdom, September 14 to 18, 2015

REVISION OF DOCUMENT TGP/10: NEW SECTION: ASSESSING UNIFORMITY BY OFF-TYPES ON BASIS OF MORE THAN ONE GROWING CYCLE OR ON THE BASIS OF SUB-SAMPLES

Document prepared by the Office of the Union

Disclaimer: this document does not represent UPOV policies or guidance

EXECUTIVE SUMMARY

1. The purpose of this document is to present a proposal for revision of document TGP/10 "Examining uniformity" to provide guidance on assessing uniformity by off-types on the basis of more than one growing cycle or on the basis of sub-samples.

2. The TWO is invited to consider:

(a) the information on the risks, benefits, cost implications and other relevant aspects in their choice of Approach 1 and 2 when assessing uniformity by off-types on basis of more than one sample or sub-sample, as provided by members and observers; and

(b) the draft guidance for inclusion in a future revision of document TGP/10, as presented in Annexes I and II to this document.

3. The structure of this document is as follows:

4. 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

5. The background to this matter is provided in documents TC/48/14 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample” and TC/50/12 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample” and TWC/32/9 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample”.

DEVELOPMENTS IN 2014

Technical Working Parties

Technical Working Party for Ornamental Plants and Forest Trees

6. The TWO, at its forty-seventy session held in Naivasha, Kenya, from May 19 to 23, 2014, considered document TWO/47/9 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample” and the situations described in the Annexes I to IV as a basis to develop guidance in document TGP/10.

7. The TWO agreed that clarification should be provided on the decision to be taken in Situation B, Alternative (a) “the trial is repeated at both locations for a second year”, in case after repeating a trial for the second year a variety is within the uniformity standard in one growing location but is not within the uniformity standard in the other growing location (see document TWO/47/28 “Report”, paragraphs 61 and 62).

Technical Working Party for Fruit Crops

8. The TWF, at its forty-fifth session held in Marrakesh, Morocco, from May 26 to 30, 2014, considered document TWF/45/9 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample” and the situations described in the Annexes I to IV as a basis to develop guidance in document TGP/10.

9. The TWF agreed with the comment made by the TWO at its forty-seventh session that clarification should be provided on the decision to be taken in Situation B, Alternative (a) “the trial is repeated at both locations for a second year”, in case after repeating a trial for the second year a variety is within the uniformity standard in one growing location or year but is not within the uniformity standard in the other growing location or year.

10. The TWF agreed that the approaches were not relevant for the fruit sector, because vegetatively propagated varieties did not appear to be in the scope of the document (see document TWF/45/32 “Report”, paragraphs 66 to 68).

Technical Working Party on Automation and Computer Programs

11. The TWC, at its thirty-second session held in Helsinki, Finland, from June 3 to 6, 2014, considered document TWC/32/9 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample”.

12. The TWC agreed that the values for type I and type II errors should be included in each of the examples described in situations A and B for the development of guidance in document TGP/10. The type I error is associated with a decision for non-uniformity (rejection of the true null hypothesis) and the type II error is associated with a decision for uniformity (acceptance of the alternative hypothesis).

13. The TWC agreed that the guidance provided in document TGP/10 “Examining Uniformity”, Section 6 “Combining all observations on a variety” was sufficient to address situation C “More than one sample or subsample for a characteristic in the same growing trial”, Annex III to document TWC/32/9. The TWC agreed that the example provided could be considered as a special test and that results of the uniformity assessment should be considered independently.

14. In relation to situation D, the TWC considered the use of a stepwise approach in the off-type procedure within the same growing cycle and the statistical basis for the acceptable number of off-types in the subsample of 20 plants used in the context of a sample size of 100 plants, as provided in Annex V to document TWC/32/9, which was introduced by an expert from Germany.

15. The TWC agreed that the type I and type II errors used in the statistical basis for the acceptable number of off-types in the subsample of 20 plants used in the context of a sample size of 100 plants were comparable to those of the entire sample for the example provided in wheat and barley.

16. The TWC noted that the stepwise approach in the off-type procedure was intended to reduce costs without increasing risks in the uniformity assessment. The TWC agreed to propose the guidance as follows (see document TWC/32/28 “Report”, paragraphs 19 to 24):

> “SITUATION D: ASSESSING SUB-SAMPLES WITHIN A SINGLE TEST/TRIAL
>
> **“Approach: Use of sub-sample as a first step of assessment**
>
> “A variety is considered uniform if the number of off-types does not exceed a predefined lower limit in the sub-sample.
>
> “A variety is considered non-uniform if the number of off-types exceeds a predefined upper limit in the sub-sample.
>
> “If the number of off-types is between the predefined lower and upper limits the whole sample is assessed. The lower and upper limits have to be chosen considering comparable type I and type II errors in the sub-sample and the whole sample.
>
> “Example:
>
> “In a sample size of 100 plants, the acceptable number of off-types is 3 (based on a population standard of 1% and an acceptance probability of at least 95%).
>
> “In a subsample of 20 plants used in the context of the sample size of 100 plants above:
>
> > “A variety is considered uniform if no off-types are observed in the sub-sample.
> >
> > “A variety is considered non–uniform if the number of off-types in the sub-sample exceeds 3.
> >
> > “If the number of off-types is 1 to 3, the whole sample of 100 plants is assessed.
>
> “Annex V to document TWC/32/9 provides a full description of the statistical basis for this approach.”

Technical Working Party for Vegetables

17. The TWV, at its forty-eighth session held in Paestum, Italy, from June 23 to 27, 2014, considered document TWV/48/9 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample” and the situations described in the Annexes I to IV as a basis to develop guidance in document TGP/10.

18. The TWV agreed on the importance of assessing uniformity in each independent growing cycle and was not in favor of combining results from 2 cycles (see document TWV/48/43 “Report”, paragraphs 79 and 80).

Technical Working Party for Agricultural Crops

19. The TWA, at its forty-third session held in Mar del Plata, Argentina, from November 17 to 21, 2014, considered document TWA/43/9 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample”, including Annexes I to IV, as a basis to develop guidance in document TGP/10.

20. The TWA noted that the TWC had been invited to provide an analysis of the consequences of the different approaches presented in the Annexes of document TWA/43/9 and, in particular, whether approach 2 in Situations A and B was appropriate.

21. The TWA agreed with the TWV on the importance of assessing uniformity in each independent growing cycle and was not in favor of combining results from 2 cycles.

22. The TWA agreed that an introduction paragraph should be added to Situation B to explain that years could be replaced by locations of DUS testing trials only when specific requirements are fulfilled such as no significant genotype x location interaction for any of the characteristics used in DUS examination.

23. The TWA agreed with the TWC that the guidance provided in document TGP/10 "Examining Uniformity", Section 6 "Combining all observations on a variety" was sufficient to address situation C "More than one sample or subsample for a characteristic in the same growing trial", Annex III to document TWA/43/9.

24. The TWA agreed with the TWC that guidance in Situation D should read as follows (see document TWA/43/27 "Report", paragraphs 66 to 71):

> "SITUATION D: ASSESSING SUB-SAMPLES WITHIN A SINGLE TEST/TRIAL
>
> **"Approach: Use of sub-sample as a first step of assessment**
>
> "A variety is considered uniform if the number of off-types does not exceed a predefined lower limit in the sub-sample.
>
> "A variety is considered non-uniform if the number of off-types exceeds a predefined upper limit in the sub-sample.
>
> "If the number of off-types is between the predefined lower and upper limits the whole sample is assessed. The lower and upper limits have to be chosen considering comparable type I and type II errors in the sub-sample and the whole sample.
>
> "Example:
>
> "In a sample size of 100 plants, the acceptable number of off-types is 3 (based on a population standard of 1% and an acceptance probability of at least 95%).
>
> "In a subsample of 20 plants used in the context of the sample size of 100 plants above:
>
> > "A variety is considered uniform if no off-types are observed in the sub-sample.
> >
> > "A variety is considered non–uniform if the number of off-types in the sub-sample exceeds 3.
> >
> > "If the number of off-types is 1 to 3, the whole sample of 100 plants is assessed.
>
> "Annex V to document TWC/32/9 provides a full description of the statistical basis for this approach."

DEVELOPMENTS IN 2015

Technical Committee

25. The TC, at its fifty-first session held in Geneva from March 23 to 25, 2015, considered document TC/51/24 "Revision of document TGP/10: New section: Assessing Uniformity by Off-Types on Basis of More than One Sample or Sub-Samples".

26. The TC agreed with the proposals made by the TWPs at their sessions in 2014 and the TC-EDC at its meeting in January 2015, on the draft guidance for inclusion in a future revision of document TGP/10, as presented in Annexes I to IV to document TC/51/24.

27. The TC agreed that the title of the document should be amended to read: "Assessing uniformity by off-types on basis of more than one growing cycle or on the basis of sub-samples";

28. The TC agreed that situations A and B as presented in Annexes I and II to document TC/51/24 should be combined, with an explanation that two independent growing cycles could take place in a single location in different years, or in different locations in the same year, according to document TGP/8 Part I, Sections 1.2 and 1.3

29. The TC agreed to invite members of the Union to present to the TWPs and the TC information on the risks, benefits, cost implications and other relevant aspects in their choice of Approach 1 and 2 when assessing uniformity by off-types on basis of more than one sample or sub-sample, as set out in Annexes I and II to document TC/51/24

30. The TC agreed to clarify the possibility to reject a variety on the basis of a lack of uniformity after a single growing cycle. It further agreed to review the fifth example to be more realistic, given that a variety with 10 off-types in the first growing cycle would probably be rejected after the first growing cycle (see document TC/51/39 “Report”, paragraphs 157 to 162).

31. The TC and TWP members and observers were invited to present information on the risks, benefits, cost implications and other relevant aspects in their choice of Approach 1 and 2 when assessing uniformity by off-types on basis of more than one sample or sub-sample, as set out in Annexes I and II to document TC/51/24, during the TWP sessions (see Circular E-15/108). The presentations received will be provided as an Addendum to this document.

SUMMARY OF APPROACHES

32. Annexes I and II to this document summarize different situations when different samples are combined for the overall assessment of uniformity of a variety in accordance with the conclusions of the TC at its fifty-first session on the basis of the proposals made by the TWPs at their sessions in 2014, as follows:

Annex I: Assessing uniformity by off-types on basis of more than one growing cycle

Approach 1: Third growing cycle in the case of inconsistent results
Approach 2: Combining the results of two growing cycles

Annex II: Assessing sub-samples within a single test/trial

Approach*:* Sub-sample as a first step of assessment

33. The summary in Annexes I and II only relates to situations where more than one sample, or sub-sample, concern the examination of the same characteristic. In the case of different samples, or sub-samples (e.g. special test), to examine a different characteristic there is no requirement to combine the results because a variety is required to be uniform for all relevant characteristics.

34. The TWO is invited to consider:

(a) the information on the risks, benefits, cost implications and other relevant aspects in their choice of Approach 1 and 2 when assessing uniformity by off-types on basis of more than one sample or sub-sample, as presented by members and observers; and

(b) the draft guidance for inclusion in a future revision of document TGP/10, as presented in Annexes I and II to this document.

[Annexes follow]

ANNEX I

ASSESSING UNIFORMITY BY OFF-TYPES ON BASIS OF MORE THAN ONE GROWING CYCLE

Two independent growing cycles could take place in a single location in different years, or in different locations in the same year (see document TGP/8 Part I, Section 1.2)

Approach 1: Third growing cycle in the case of inconsistent results

A variety is considered uniform if it is within the uniformity standard in both of the two growing cycles.

A variety is considered non-uniform if it fails to meet the uniformity standard in both of the two growing cycles.

If at the end of the two growing cycles the variety is within the uniformity standard in one growing cycle but is not within the uniformity standard in the other growing cycle, then uniformity is assessed in a third growing cycle. If in the third growing cycle the variety is within the uniformity standard, the variety is considered uniform. If in the third growing cycle the variety fails to meet the uniformity standard, the variety is considered non-uniform.

Care is needed when considering results that were very different in each of the growing cycles, such as when a type of off-type was observed at a high level in one growing cycle and was absent in another growing cycle.

Furthermore, on the basis of a lack of uniformity, a variety may be rejected after a single growing cycle.

Approach 2: Combining the results of two growing cycles

A variety is considered uniform if it is within the uniformity standard in both of the two growing cycles.

A variety is considered non-uniform if it fails to meet the uniformity standard in both of the two growing cycles.

If at the end of the two growing cycles the variety is within the uniformity standard in one growing cycle but is not within the uniformity standard in the other growing cycle, a variety is considered uniform if the total number of off-types at the end of the two growing cycles does not exceed the number of allowed off-types for the combined sample.

Care is needed when considering results that were very different in each of the growing cycles, such as when a type of off-type was observed at a high level in one growing cycle and was absent in another growing cycle.

Furthermore, on the basis of a lack of uniformity, a variety may be rejected after a single growing cycle.

Example:

Population Standard = 1%

Acceptance Probability ≥ 95%

Sample Size in each of growing cycles 1 and 2 = 50 Maximum number of Off-Types = 2
Sample Size in growing cycles 1 and 2 combined = 100 Maximum number of Off-Types = 3

	Growing cycle		Decision	
	First	Second	Approach 1	Approach 2
Number of Off-Types	2	2	uniform	uniform
	0	3	third growing cycle	uniform
	1	3	third growing cycle	non-uniform
	1	4*	third growing cycle*	non-uniform*
	4	1*	third growing cycle*	non-uniform*

* Care is needed when considering results that were very different in each of the growing cycles, such as when a type of off-type was observed at a high level in one growing cycle and was absent in another growing cycle.

[Annex II follows]

ANNEX II

SITUATION: ASSESSING UNIFORMITY BY OFF-TYPES ON THE BASIS OF SUB-SAMPLES WITHIN A SINGLE TEST/TRIAL

Approach: Use of sub-sample as a first step of assessment

A variety is considered uniform if the number of off-types does not exceed a predefined lower limit in the sub-sample.

A variety is considered non–uniform if the number of off-types exceeds a predefined upper limit in the sub-sample.

If the number of off-types is between the predefined lower and upper limits, the whole sample is assessed. The lower and upper limits have to be chosen considering comparable type I and type II errors in the sub-sample and the whole sample.

Example:

In a sample size of 100 plants, the acceptable number of off-types is 3 (based on a population standard of 1% and an acceptance probability of at least 95%).

In a subsample of 20 plants used in the context of the sample size of 100 plants above:

A variety is considered uniform if no off-types are observed in the sub-sample.

A variety is considered non–uniform if the number of off-types in the sub-sample exceeds 3.

If the number of off-types is 1 to 3, the whole sample of 100 plants is assessed.

If the number of off-types in the sample of 100 plants exceeds 3, the variety is considered non-uniform.

Document TWC/32/9 Annex V provides a full description of the statistical basis for this approach.

[End of Annex II and of document]