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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

TECHNICAL COMMITTEE**Fiftieth Session
Geneva, April 7 to 9, 2014****ASSESSING UNIFORMITY BY OFF-TYPES ON BASIS OF MORE THAN ONE SAMPLE
OR SUB-SAMPLES***Document prepared by the Office of the Union**Disclaimer: this document does not represent UPOV policies or guidance*

1. The purpose of this document is to report on developments concerning a summary of approaches used by members of the Union in assessing uniformity by off-types on the basis of more than one sample or sub-sample.

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

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I. BACKGROUND

4. The complete background to this matter is provided in document TC/48/14 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Sample”.

II. DEVELOPMENTS IN 2012

Technical Working Party for Agricultural Crops

5. The TWA, at its forty-first session, held in Angers, France, from May 21 to 25, 2012 considered document TWA/41/9 “Assessing uniformity by off-types on the basis of more than one sample or sub-sample” (see document TWA/41/34 “Report”, paragraph 46).

6. The TWA, at its forty-first session, agreed that clarification should be provided for Situations A and B if the approach combining the results from two growing cycles was considered to correspond to the requirement for “independent” growing cycles (see document TWA/41/34 “Report”, paragraph 47).

7. The TWA, at its forty-first session, noted the explanation from the expert from the Czech Republic that the Apple example should be deleted, because the same approach was used as for other crops (see document TWA/41/34 “Report”, paragraph 48).

8. On the basis of information provided at the meeting on “Situation B: Two growing locations in the same year, Approach: Third growing cycle in case of inconsistent results”, the TWA agreed to revise the text to read as follows:

"[...] If the variety is within the uniformity standard in one growing location but is not within the uniformity standard in the other growing location, then:

Alternative (a) the trial is repeated at both locations for a second year;

Alternative (b) the trial is repeated at the Leading station (location) (European Union)"

(see document TWA/41/34 "Report", paragraph 49).

9. In the case of "Situation D: Assessing sub-samples within a single test/trial, Approach: Sub-sample as first step of assessment", the TWA agreed that the explanation should be generalized (i.e. no reference to 0 off-types in the subsample) and should provide an explanation of the statistical basis for the approach. The TWA also agreed that the statistical experts from France and Germany should be invited to explain 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 (see document TWA/41/34 "Report", paragraph 50).

10. The TWA, at its forty-first session, noted that the TWC would be invited to provide guidance on the possible consequences of different approaches (see document TWA/41/34 "Report", paragraph 51).

Technical Working Party for Vegetables

11. The TWV, at its forty-sixth session, held near the city of Venlo, Netherlands, from June 11 to 15, 2012, considered document TWV/46/9 "Assessing uniformity by off-types on the basis of more than one sample or sub-sample". The changes in document TWV/46/9 from document TWA/41/9 were made, on the basis of the comments made by the TWA, at its forty-first session, as follows:

- deletion of Approach: "Requirement to meet uniformity standard in both growing cycles" (proposed for the Apple example), in section "Summary of approaches" and in Annex I "Situation A: *Two growing cycles in single location*", as set out in paragraph 10 of this document
- revision of the text for Approach: "Third growing cycle in case of inconsistent results" in Annex II "Situation B: *Two growing locations in the same year*," as set out in paragraph 11 of this document

12. The TWV, at its forty-sixth session, noted the different approaches and the similarity between the approaches used in different UPOV members. It agreed to invite the Technical Working Party on Automation and Computer Programs (TWC) to advise whether to use individual or combined results. The experts from Germany, Italy, France and the Netherlands offered to provide examples and data to the TWC, if needed (see document TWV/46/41 "Report", paragraph 55).

13. The TWV, at its forty-sixth session, agreed that the definition of sample size should be more precise (see document TWV/46/41 "Report", paragraph 56).

Technical Working Party on Automation and Computer Programs

14. The TWC, at its thirtieth session, held in Chisinau, Republic of Moldova, from June 26 to 29, 2012, considered document TWC/30/9 "Assessing uniformity by off-types on the basis of more than one sample or sub-sample", with section "Summary of approaches" and annexes, as set out in this document.

15. The TWC, at its thirtieth session, noted the need for further explanation on the situations described, such as the clarification of whether two growing cycles related to the use of the same sample and were carried out in the same year. The TWC agreed that more detailed information and further analysis were needed in order to give guidance on consequences on the use of the different approaches (see document TWC/30/41, "Report", paragraph 83).

16. The TWC, at its thirtieth session, agreed that France, Germany and the Netherlands would present one or more concrete situations in their countries and the statistical basis of their analysis for its next session (see document TWC/30/41, "Report", paragraph 84).

17. The TWC, at its thirtieth session, agreed that 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 (situation D) would be assessed by experts from France and Germany (see document TWC/30/41, "Report", paragraph 85).

Technical Working Party for Fruit Crops

18. The TWF, at its forty-third session, held in Beijing, China, from July 30 to August 3, 2012, considered document TWF/43/9 Rev. "Assessing uniformity by off-types on the basis of more than one sample or sub-sample", with section "Summary of approaches" and annexes, as set out in this document.

19. The TWF, at its forty-third session, noted the different approaches and the similarity between the approaches used by different UPOV members. It agreed to propose that the Technical Working Party on Automation and Computer Programs (TWC) be invited to advise whether to use individual or combined results (see document TWF/43/38 "Report", paragraph 51).

20. The TWF, at its forty-third session, requested that the expert from New Zealand would provide a presentation on the testing of uniformity of apple varieties arising from mutations, at the TWF meeting in 2013 (see document TWF/43/38 "Report", paragraph 52).

21. The TWF, at its forty-third session, agreed that the definition of growing cycles should be more precise and that, in the future, a detailed description of the way that the examination was to be conducted should be included under "Matters for future consideration" (see document TWF/43/38 "Report", paragraph 53).

Technical Working Party for Ornamental Plants and Forest Trees

22. The TWO, at its forty-fifth session, held in Jeju, Republic of Korea, from August 6 to 10, 2012, considered document TWO/45/9 "Assessing uniformity by off-types on the basis of more than one sample or sub-sample", with section "Summary of approaches" and annexes, as presented in this document. The TWO noted the different approaches used in different UPOV members (see document TWO/45/37 "Report", paragraph 54).

III. DEVELOPMENTS IN 2013

Technical Committee

23. The TC, at its forty-ninth session held in Geneva from March 18 to 20, 2013, considered document TC/49/14 (see document TC/49/41 "Report on the Conclusions", paragraph 114).

24. The TC noted that the TWC would consider further information on the situations presented in Annex I to IV to document TC/49/14, such as the clarification of whether two growing cycles related to the use of the same sample and were carried out in the same year. The TC noted that the TWC had agreed that more detailed information and further analysis were needed in order to give guidance on consequences on the use of the different approaches. The TWC had further agreed that France, Germany and the Netherlands would present one or more concrete situations in their countries and the statistical basis of their analysis for its next session, and that the statistical basis for the acceptable number of off-types in the sub-sample of 20 plants used in the context of a sample size of 100 plants (situation D) would be assessed by experts from France and Germany (see document TC/49/41 "Report on the Conclusions", paragraph 115).

25. The TC agreed that the approach combining the results from two growing cycles, as set out in Annexes I and II, Situation A and B, was not inconsistent with the requirement for "independent" growing cycles. However, it agreed that care would be needed, for example 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 (see document TC/49/41 "Report on the Conclusions", paragraph 116).

26. The TC noted that an expert from New Zealand would make a presentation on testing of uniformity of Apple varieties arising from mutation at the TWF session in 2013 (see document TC/49/41 "Report on the Conclusions", paragraph 117).

27. Subsequent to the TC meeting, the expert from New Zealand agreed to prepare a document to be presented at all the TWP sessions in 2013 (see documents TWO/46/26, TWF/44/26, TWV/47/26, TWC/31/26 and TWA/42/26 "Testing Uniformity of Apple Varieties Arising from Mutation").

Technical Working Party for Ornamental Plants and Forest TreesTechnical Working Party for Fruit Crops

28. The TWO and the TWF considered documents TWO/46/22 Rev. and TWF/44/22, respectively, and noted that (see documents TWO/46/29 "Report", paragraph 63, and TWF/44/31 "Report", paragraph 61):

(a) the TWC had agreed that more detailed information and further analysis were needed in order to give guidance on consequences on the use of the different approaches presented in Annex I to IV of document TWO/46/22 Rev., and that France, Germany and the Netherlands would present one or more concrete situations in their countries and the statistical basis of their analysis for its next session;

(b) the TWC had agreed that 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 (situation D) would be assessed by experts from France and Germany; and

(c) with regard to the approach combining the results from two growing cycles, as set out in Annexes I and II, Situation A and B, the TC had agreed that care would be 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.

Technical Working Party for Vegetables

29. The TWV considered document TWV/47/22 and noted that (see documents TWV/47/34 "Report", paragraphs 62 to 64):

(a) the TWC had agreed that more detailed information and further analysis were needed in order to give guidance on consequences on the use of the different approaches presented in Annex I to IV of document TWV/47/22, and that France, Germany and the Netherlands would present one or more concrete situations in their countries and the statistical basis of their analysis for its next session;

(b) the TWC had agreed that 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 (situation D) would be assessed by experts from France and Germany; and

(c) with regard to the approach combining the results from two growing cycles, as set out in Annexes I and II of document TWV/47/22, Situation A and B, the TC had agreed that care would be 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.

30. The TWV noted that with regard to the situation B, as set out in Annex II of document TWV/47/22, the expert from France indicated that France was now considering each cycle to be independent and was no longer combining the results of two locations, therefore the reference to France and cauliflower was no longer appropriate and that the text should be amended as follows:

SITUATION B: TWO GROWING LOCATIONS IN THE SAME YEAR

Approach: Third growing cycle for inconsistent results

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

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

If the variety is within the uniformity standard in one growing location but is not within the uniformity standard in the other growing location, then

Alternative (a) the trial is repeated at both locations for a second year;

Alternative (b) the trial is repeated at the Leading station (location)
(European Union (Cauliflower))

Approach: Combining the results of two locations

France (Cauliflower)

A variety is considered uniform if it is within the uniformity standard in both locations.

A variety is considered non-uniform if it fails to meet the uniformity standard in both locations.

A variety is considered within the uniformity standard if the number of off-type plants or parts of plants does not exceed the allowed number of off-types for the combined sample (two locations).

31. The TWV agreed that the preferred approach, for the assessment of uniformity for vegetables, was to use the individual results rather than the combined results and requested the TWC to consider the following example when considering the different approaches:

Trial 1: 50 plants / 2 off-types → the variety is considered uniform
(based on a population standard of 1% and an acceptance probability of 95% from a sample of 36 to 82 plants)

Trial 2: 50 plants / 2 off-types → the variety is considered uniform
(based on a population standard of 1% and an acceptance probability of 95% from a sample of 36 to 82 plants)

Trial 1+2: 100 plants/ 4 off-types → the variety is considered non-uniform
(based on a population standard of 1% and an acceptance probability of 95% from a sample of 83 to 130 plants)

If the two trials are considered independent, the variety is considered to be uniform. If the two trials are combined, the variety is considered not uniform.

Technical Working Party on Automation and Computer Programs

32. The TWC considered document TWC/31/22.

33. The TWC noted that it had agreed that more detailed information and further analysis were needed in order to give guidance on consequences on the use of the different approaches presented in Annexes I to IV of document TWC/31/22, and that France, Germany and the Netherlands would present one or more concrete situations in their countries and the statistical basis of their analysis for its next session.

34. The TWC considered 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/31/22, which was introduced by an expert from Germany by electronic means.

35. The TWC requested the experts from Germany to explain 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. The TWC agreed that the statistical basis for this approach would continue to be discussed at its thirty-second session. The TWC agreed that it would not be appropriate to recommend this approach for other crops or sample sizes before it had agreed on the statistical basis.

36. The TWC noted that, with regard to the approach combining the results from two growing cycles, as set out in Annexes I and II to document TWC/31/22, Situation A and B, the TC had agreed that care would be 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.

37. The TWC noted information on testing of uniformity of Apple varieties arising from mutation in New Zealand would be presented in document TWC/31/26 (see document TWC/31/32 "Report", paragraphs 82 to 87).

Technical Working Party for Agricultural Crops

38. The TWA considered document TWA/42/22 and noted that:

(a) the TWC had agreed that more detailed information and further analysis were needed in order to give guidance on consequences on the use of the different approaches presented in Annex I to IV of document TWA/42/22, and that France, Germany and the Netherlands would present one or more concrete situations in their countries and the statistical basis of their analysis for its next session;

(b) the TWC had agreed that 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 (situation D) would be assessed by experts from France and Germany; and

(c) with regard to the approach combining the results from two growing cycles, as set out in Annexes I and II of document TWA/42/22, Situation A and B, the TC had agreed that care would be 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.

39. The TWA requested the Office of the Union to further develop the Annexes to document TWA/42/22 to be presented at its forty-third session with regard to providing the information requested by the TWC for the analysis of consequences of different approaches. The TWA agreed that the experts from France, Germany, the Netherlands and the United Kingdom, should assist the Office in the preparation of the document.

40. The TWA agreed that the different situations should be presented in one example without mention to individual members of the Union. The TWA also agreed that it should be clarified if the two approaches in situation A were inconsistent, or if one of them was more appropriate, and that situation C should refer to the use of samples or subsamples instead of "tests/trials" (see document TWA/42/31 "Report", paragraphs 68 to 70).

IV. DEVELOPMENTS IN 2014

Enlarged Editorial Committee

41. The TC-EDC, at its meeting held in Geneva on January 8 and 9, 2014, considered document TC-EDC/Jan14/23 "Assessing Uniformity by Off-Types on Basis of More than One Sample or Sub-Samples" and the comments made by the TWPs at their sessions in 2013 and made the following comments:

General	to consider whether guidance should be developed for situations A, B, C and D in document TGP/10 and, in the case of situations A and B, whether the guidance should be on the basis of one of the approaches or both approaches.
Annexes I and II	In Approach 2, to add " <u>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,</u> " at the beginning of the third paragraph.
Annex III	to check whether to delete the approach presented in Annex III on the basis that it does not relate to a common situation.

V. SUMMARY OF APPROACHES

42. Annexes I to IV to this document, as amended on the basis of the comments made by the TWPs at their sessions in 2013, summarize different situations when different samples are combined for the overall assessment of uniformity of a variety, as follows:

Annex I: Situation A: Two growing cycles in a single location

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

Annex II: Situation B: Two growing locations in the same year

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

Annex III: Situation C: More than one sample/sub-sample for a characteristic in the same growing cycle

Approach: Additional growing cycle in the case of inconsistent results

Annex IV: Situation D: Assessing sub-samples within a single test/trial

Approach: Sub-sample as a first step of assessment

43. The summary in Annexes I to IV 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.

44. *The TC is invited to:*

(a) note that the TWC proposed to provide more detailed information and further analysis on the consequences of the use of the approaches presented in situations A, B, C and D at its session in 2014, as set out in paragraph 33;

(b) note that the TWC proposed that the statistical basis for the acceptable number of off-types in situation D be considered further at its session in 2014, as set out in paragraphs 34 and 35;

(c) consider whether guidance should be developed in document TGP/10 for situations A, B, C and D, as set out in Annexes I to IV of this document, and in the case of situations A and B, whether the guidance should be on the basis of one of the approaches or both approaches; and

(d) consider whether to delete the approach presented in situation C, as set out in Annex III to this document.

[Annexes follow]

SITUATION A: TWO GROWING CYCLES IN A SINGLE LOCATION

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 after consultation with the applicant. 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.

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.

Example for consideration:

Population Standard = 1%
Acceptance Probability \geq 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
	0	10	third growing cycle	non-uniform

SITUATION B: TWO GROWING LOCATIONS IN THE SAME YEAR

Approach 1: Third growing cycle for inconsistent results

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

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

If the variety is within the uniformity standard in one growing location but is not within the uniformity standard in the other growing location, then

Alternative (a) the trial is repeated at both locations for a second year;

Alternative (b) the trial is repeated at the Leading station (location)

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.

Approach 2: Combining the results of two locations

A variety is considered uniform if it is within the uniformity standard in both locations.

A variety is considered non-uniform if it fails to meet the uniformity standard in both locations.

If the variety is within the uniformity standard in one growing location but is not within the uniformity standard in the other growing location, a variety is considered within the uniformity standard if the number of off-type plants or parts of plants does not exceed the allowed number of off-types for the combined sample (two locations).

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.

Example for consideration:

Population Standard = 1%

Acceptance Probability $\geq 95\%$

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 location		Decision	
	First	Second	Approach 1	Approach 2
Number of Off-Types	2	2	uniform	uniform
	0	3	repeat trial	uniform
	1	3	repeat trial	non-uniform
	0	10	repeat trial	non-uniform

SITUATION C: MORE THAN ONE SAMPLE OR SUBSAMPLE FOR A CHARACTERISTIC IN THE SAME GROWING CYCLE

Approach: Additional growing cycle in the case of inconsistent results

A variety is considered to be uniform for a characteristic if it is within the uniformity standard for the characteristic in all samples or subsamples.

A variety is considered non-uniform if it fails to meet the uniformity standard for the characteristic in all samples or subsamples.

In the case where a variety is within the uniformity standard for the characteristic in one samples or subsamples (e.g. main trial) and not in another samples or subsamples (e.g. ear-row plot), both samples or subsamples are examined in a further growing cycle.

[Annex IV follows]

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 no off-types are observed in a sub-sample.

A variety is considered non-uniform if the number of off-types in the sub-sample exceeds the accepted number of off-types for the whole sample.

If the number of off-types is 1 or more, but below the accepted number of off-types for the whole sample, the whole sample is assessed.

Example for consideration:

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.

[End of Annex IV and of document]