

**Technical Committee**

**TC/53/19**

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

*Document prepared by the Office of the Union*

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**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 TC is invited to:

(a) consider whether to invite experts at the TWP’s, at their sessions in 2017, to provide information on the criteria for selecting the most suitable approach for the assessment of off-types on different types of crops;

(b) note the offers by Germany, the Netherlands and the United Kingdom to provide examples on selecting the most suitable approach for the assessment of off-types to the TWC, at its session in 2017;

(c) note that presentations were made by France and the United Kingdom to the TWC, TWV and TWA, at their sessions in 2016;

(d) note that a proposal for revision of guidance in document TGP/8/2: Part II: 8: “The method of uniformity assessment on the basis of off-types”, will be considered in document TC/53/5 “TGP documents”;

(e) note the offers from France, Germany, the Netherlands, Poland and the United Kingdom to provide examples comparing the possible effect on uniformity decisions between Approach 3 and other approaches to be presented to the TWA, at its forty-sixth session; and

(f) consider the draft guidance presented in Annexes I and II as amended by the TWP’s, at their sessions in 2016, for inclusion in a future revision of document TGP/10.

3. The structure of this document is as follows:

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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/52/20 “Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Samples” and TC/52/20 Add. “Addendum to document TC/52/20”.

## DEVELOPMENTS IN 2016

### Technical Committee

6. The TC, at its fifty-second session, held in Geneva from March 14 to 16, 2016, considered document TC/52/20 and received a presentation by an expert from the United Kingdom on assessing uniformity by off-types on the basis of more than one growing cycle, a copy of which is reproduced in Annex I to this document (see document TC/52/29 Rev. “Revised Report”, paragraphs 118 to 121).

7. The TC agreed that the new proposed “Approach 3: Combining the results of two growing cycles” for the assessment of uniformity by off-types, as presented in Annex I to document TC/52/20, should be considered by the TWPs, at their sessions in 2016.

8. The TC noted that the TWA had agreed to request a video link with the experts from the TWC to discuss the new proposed “Approach 3: Combining the results of two growing cycles” at its forty-fifth session, to be held in 2016, and agreed that the video link should be open to all interested experts.

9. The TC agreed to clarify that the guidance in the Annex I to this document was not intended to be used for the assessment of uniformity by off-types on the same plants in two growing cycles, as the same off-type plants observed in the first growing cycle would still be off-types in the second growing cycle.

### Technical Working Parties

#### *Technical Working Party on Automation and Computer Programs*

10. The TWC considered documents TWC/34/13 and TWC/34/27 (see document TWC/34/32 “Report”, paragraphs 44 and 51).

11. The TWC noted that the TWA had agreed to request a video link with experts from the TWC to discuss the new proposed “Approach 3: Combining the results of two growing cycles” at its forty-fifth session, to be held in 2016.

12. The TWC considered the draft guidance as presented in document TWC/34/13, Annexes I and II, for inclusion in a future revision of document TGP/10, and agreed that cost of trials, consistency of results, time required for decisions and technical aspects of each approach could influence the selection of the most suitable approach for each situation.

13. The TWC agreed that future guidance should provide parameters for decisions on the most suitable approach based on experience of members and agreed to invite examples of different types of crops and the criteria for selecting the approach used for the assessment of off-types. The TWC welcomed the offers from Germany, the Netherlands and the United Kingdom to provide examples to be presented at its thirty-fifth session.

14. The TWC noted the importance of identifying whether differences in number of off-types between cycles was due to biological reasons or sampling variation and agreed that the relevant part of approach 2 and 3 of the draft guidance should be amended to read as follows, respectively:

“Care is needed when considering results that are very different in each of the growing cycles, such as when a type of off-type is observed at a high level in one growing cycle and is absent in another growing cycle. A statistical test for consistency should be applied when appropriate.”

“Care is needed when considering results that are very different in each of the growing cycles, such as when a type of off-type is observed at a high level in one growing cycle and is absent in another growing cycle. A statistical test for consistency ~~is possible~~ should be applied when appropriate.”

15. The TWC considered document TWC/34/27 “Practical experience of assessing uniformity by off-types on oilseed rape and cauliflower” and received a presentation by an expert from France, a copy of which is reproduced in the Annex to document TWC/34/27.

16. The TWC noted the simulation of decisions using approaches 1 and 3 on different crops and agreed on the usefulness of the worked examples. The TWC noted that cases of diverging results between 2 growing cycles are not common as most varieties would either meet or fail to meet requirements in both cycles.

17. The TWC noted the explanation of the requirement of “independent growing cycle” by an expert from France and the preference for a third growing cycle to increase reliability of observations, as presented in the document TWC/34/27, Annex, page 4.

#### *Technical Working Party on Ornamental Plants*

18. The TWO considered document TWO/49/13 (see document TWO/49/25 Rev. “Revised Report”, paragraphs 37 to 40).

19. The TWO noted that the Technical Working Party for Agricultural Crops (TWA) had agreed to request a video link with the experts from the TWC to discuss the new proposed “Approach 3: Combining the results of two growing cycles” at its forty-fifth session, to be held in 2016.

20. The TWO considered the draft guidance as presented in Annex I of document TWO/49/13 and agreed that the term “clear” should be clarified in the sentence: “Furthermore, on the basis of a clear lack of uniformity, a variety may be rejected after a single growing cycle”. The TWO agreed to propose that the sentence in approaches 1 and 2 should read as follows:

“Furthermore, if a variety exceeds in the first growing cycle the allowed number of off-types in two growing cycles, the variety may be rejected after a single growing cycle.”

21. The TWO agreed that it should be clarified in the draft guidance whether there was an assumption of assessing two growing cycles using plant material from a single submission by the breeder (e.g. seeds from the same seed lot).

#### *Technical Working Party for Vegetables*

22. The TWV considered documents TWV/50/13 and TWV/50/13 Add. (see document TWV/50/25 “Report”, paragraphs 42 to 48).

23. The TWV received a presentation on “Practical experience of assessing Uniformity by off-types: Reject after the 1st cycle on the official DUS seed lot” by an expert from France. A copy of the presentation is provided in document TWV/50/13 Add. Rev.

24. The TWV noted that the TWA had agreed to request a video link with the experts from the TWC to discuss the new proposed “Approach 3: Combining the results of two growing cycles” at its forty-fifth session, to be held in 2016.

25. The TWV considered the draft guidance as presented in Annexes I and II to document TWV/50/13 for inclusion in a future revision of document TGP/10.

26. The TWV noted the concern expressed by the representatives of ESA and CropLife about Approach 3, and noted the importance they attached to consistency in results for the assessment of uniformity throughout all members of the Union.

27. The TWV considered the different approaches and noted that in the vegetable sector, Approach 1 was the most commonly used.

28. The TWV agreed that, in conjunction with the revision of document TGP/10: Assessing uniformity by off-types on basis of more than one growing cycle or on the basis of sub-samples, it would be important to review the guidance provided in document TGP/8/2: Part II: 8: "The method of uniformity assessment on the basis of off-types", because it did not reflect the practice within members of the Union. Document TGP/8/2 currently reads as follows:

"8.1.7 Method for more than one single test (year)

"8.1.7.1 Introduction

"8.1.7.1.1 Often a candidate variety is grown in two (or three years). The question then arises of how to combine the uniformity information from the individual years. Two methods will be described:

- (a) "Make the decision after two (or three) years based on the total number of plants examined and the total number of off-types recorded. (A combined test).
- (b) "Use the result of the first year to see if the data suggests a clear decision (reject or accept). If the decision is not clear then proceed with the second year and decide after the second year. (A two-stage test).

"8.1.7.1.2 However, there are some alternatives (e.g. a decision may be made in each year and a final decision may be reached by rejecting the candidate variety if it shows too many off-types in both (or two out of three years)). Also there are complications when more than one single year test is done. It is therefore suggested that a statistician should be consulted when two (or more) year tests have to be used."

#### *Technical Working Party for Agricultural Crops*

29. The TWA considered documents TWA/45/13, TWA/45/13 Add. and TWA/45/13 Add.2 (see document TWA/45/25 "Report", paragraphs 43 to 51).

30. The TWA received a presentation on "Assessing uniformity by off-types on the basis of more than one growing cycle. Drafting guidance" by experts from Germany and the United Kingdom by electronic means. A copy of the presentation is provided in document TWA/45/13 Add.

31. The TWA also received a presentation on "Practical experience of assessing uniformity by off-types on oilseed rape and cauliflower" by an expert from France. A copy of the presentation is provided in document TWA/45/13 Add.2.

32. The TWA, in conjunction with TWC experts via video link, considered the draft guidance as presented in Annexes I and II to document TWA/45/13 for inclusion in a future revision of document TGP/10, including the new proposed "Approach 3: Combining the results of two growing cycles".

33. The TWA agreed with the TWC that guidance should provide parameters for decisions on the most suitable approach based on experience from members. The TWA agreed to provide examples comparing the possible effect on uniformity decisions between Approach 3 and other approaches. The TWA welcomed the offers from France, Germany, the Netherlands, Poland and the United Kingdom to provide examples to be presented at its forty-sixth session.

34. The TWA agreed with the TWC on the importance of identifying whether differences in number of off-types between growing cycles were due to biological reasons or sampling variation and agreed that results from growing cycles using different lots of plant material should not be combined.

35. The TWA noted the concern expressed by some members that the assessment of uniformity on the basis of combining different growing cycles may not be consistent with existing guidance in document TGP/8, Part I, Section 1.2.2 and in particular 1.2.2.7 on independent growing cycles and agreed to further consider this issue on the basis of examples to be provided at its forty-sixth session.

36. The TWA agreed with the TWV that, in conjunction with the revision of document TGP/10 on “Assessing uniformity by off-types on basis of more than one growing cycle or on the basis of sub-samples”, it would be important to review the guidance provided in document TGP/8: Part II: 8: “The method of uniformity assessment on the basis of off-types”, Section 8.1.7 “Method for more than one single test (year)”, because it did not reflect the practice within members of the Union.

37. The TWA noted the concern expressed by the representatives of ESA and CropLife about Approach 3, and noted the importance they attached to consistency in the approaches for the assessment of uniformity throughout all members of the Union.

#### *Technical Working Party for Fruit Crops*

38. The TWF considered document TWF/47/13 (see document TWF/47/25 “Report”, paragraphs 37 to 39).

39. The TWF considered the draft guidance as presented in Annexes I and II for inclusion in a future revision of document TGP/10 and agreed that in the case of fruit, DUS examination is usually done on the same plant material (with the exception of strawberry), and uniformity assessed in a single growing cycle. In some cases a second growing cycle is needed (e.g. mutants for apple), but results from the two cycles are treated independently, and never combined.

40. The TWF agreed with the TWO that the term “clear” should be clarified in the sentence: “Furthermore, on the basis of a clear lack of uniformity, a variety may be rejected after a single growing cycle”. It agreed to propose that the sentence in approaches 1 and 2 should read as follows:

“Furthermore, if a variety exceeds in the first growing cycle the allowed number of off-types in two growing cycles, the variety may be rejected after a single growing cycle.”

#### SUMMARY OF APPROACHES

41. 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-second session and on the basis of the proposals made by the TWPs at their sessions in 2016, as follows:

##### Note for revisions of Annex I

**~~Strikethrough~~ (highlighted)** indicates proposed deletion of text according to amendments proposed by the TWPs, at their sessions in 2016.

**Underlining (highlighted)** indicates proposed insertion of text according to amendments proposed by the TWPs, at their sessions in 2016.

42. 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.

43. *The TC is invited to:*

*(a) consider whether to invite experts at the TWPs, at their sessions in 2017, to provide information on the criteria for selecting the most suitable approach for the assessment of off-types on different types of crops;*

*(b) note the offers by Germany, the Netherlands and the United Kingdom to provide examples on selecting the most suitable approach for the assessment of off-types to the TWC, at its session in 2017;*

*(c) note that presentations were made by France and the United Kingdom to the TWC, TWV and TWA, at their sessions in 2016;*

*(d) note that a proposal for revision of guidance in document TGP/8/2: Part II: 8: "The method of uniformity assessment on the basis of off-types", will be considered in document TC/53/5 "TGP documents";*

*(e) note the offers from France, Germany, the Netherlands, Poland and the United Kingdom to provide examples comparing the possible effect on uniformity decisions between Approach 3 and other approaches to be presented to the TWA, at its forty-sixth session; and*

*(f) consider the draft guidance presented in Annexes I and II as amended by the TWPs, at their sessions in 2016, for inclusion in a future revision of document TGP/10.*

[Annexes follow]

## 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, according to document TGP/8 Part I, Sections 1.2 and 1.3.

The following guidance is not intended to be used for the assessment of uniformity by off-types on the same plants in two growing cycles. Results from growing cycles using different lots of plant material should not be combined.

### **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. It is important to identify whether differences in number of off-types between growing cycles were due to biological reasons or sampling variation. Furthermore, ~~on the basis of a clear lack of uniformity, a if a variety exceeds in the first growing cycle the allowed number of off-types in two growing cycles, the~~ variety may be rejected after a single growing cycle.

### **Approach 2: Combining the results of two growing cycles 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, 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 sample size of growing cycles 1 and 2 combined.

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. A statistical test for consistency should be applied when appropriate. It is important to identify whether differences in number of off-types between growing cycles were due to biological reasons or sampling variation. Furthermore, ~~on the basis of a clear lack of uniformity, a if a variety exceeds in the first growing cycle the allowed number of off-types in two growing cycles, the~~ variety may be rejected after a single growing cycle.

### **Approach 3: Combining the results of two growing cycles**

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.

A variety is considered non-uniform if the total number of off-types at the end of the two growing cycles exceeds the number of allowed off-types for the combined sample.

A variety may be rejected after a single growing cycle, if the number of off-types exceeds the number of allowed off-types for the combined sample (over two cycles).

Care is needed when considering results that are very different in each of the growing cycles, such as

when a type of off-type is observed at a high level in one growing cycle and is absent in another growing cycle. A statistical test for consistency is possible should be applied when appropriate. It is important to identify whether differences in number of off-types between growing cycles were due to biological reasons or sampling variation.

Example:

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	Approach 3
Number of Off-Types	1	1	uniform	uniform	uniform
	2	2	uniform	uniform	non-uniform
	0	3*	third growing cycle*	uniform*	uniform*
	1	3*	third growing cycle*	non-uniform*	non-uniform*
	1	4*	third growing cycle*	non-uniform*	non-uniform*
	4**	1*	third growing cycle*	non-uniform*	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. A statistical test for consistency should be applied when appropriate. It is important to identify whether differences in number of off-types between growing cycles were due to biological reasons or sampling variation.

\*\* If a variety exceeds in the first growing cycle the allowed number of off-types in two growing cycles, the variety may be rejected after a single growing cycle.

[Annex II follows]



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.

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**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]