

Enlarged Editorial Committee

TC-EDC/Mar18/17

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ASSESSING UNIFORMITY BY OFF-TYPES ON THE BASIS OF MORE THAN ONE GROWING CYCLE OR ON THE BASIS OF SUB-SAMPLES

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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-EDC is invited to:

(a) note that the TWC agreed to invite the experts from Germany, the United Kingdom and other members of the Union to submit papers on the analysis of risks associated with each approach for assessing uniformity by off-types on basis of more than one growing cycle, to be considered at its thirty-sixth session; and

(b) consider the comments made by the TWPs, at their sessions in 2017, and formulate a proposal for further consideration by the TWPs, at their sessions in 2018.

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 document TWP/1/17 Rev. "Assessing Uniformity by Off-Types on the Basis of More than One Sample or Sub-Samples".

DEVELOPMENTS IN 2017

Technical Committee

6. The TC, at its fifty-third session, held in Geneva from April 3 to 5, 2017, considered document TC/53/19 (see document TC/53/31 "Report", paragraphs 120 to 125).

7. The TC noted that presentations had been made by France and the United Kingdom to the TWC, TWV and TWA, at their sessions in 2016, and noted 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.

8. The TC noted 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 the other approaches to be presented to the TWA, at its forty-sixth session.

9. The TC agreed 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.

10. The TC considered the draft guidance presented in Annexes I and II of document TC/53/19 as amended by the TWPs, at their sessions in 2016, for inclusion in a future revision of document TGP/10. The TC agreed to invite the TWPs, at their sessions in 2017, to clarify in Annex I whether more general criteria should be considered for a variety to be rejected after a single growing cycle rather than the specific case of having exceeded the allowed number of off types in two growing cycles.

11. The TC agreed that, in conjunction with the revision of document TGP/10, the guidance in document TGP/8/2: Part II: 8: "The method of uniformity assessment on the basis of off-types" should be revised to reflect the practice within members of the Union on the use of methods for more than one single test (year).

Comments by the Technical Working Parties

12. The TWA, TWV, TWO, TWF and TWC, at their sessions in 2017, considered document TWP/1/17 Rev. "Assessing Uniformity by Off-Types on the Basis of More than One Growing Cycle or on the Basis of Sub-Samples" (see documents TWA/46/10 "Report", paragraphs 28 to 35; TWV/51/16, paragraphs 39 to 47; TWO/50/14 "Report", paragraphs 19 to 21; TWF/48/13 "Report", paragraphs 22 to 25; and TWC/35/21 "Report", paragraphs 32 to 35).

13. The TWPs considered the draft guidance in document TWP/1/17 Rev. for inclusion in a future revision of document TGP/10 "Examining Uniformity" and provided the following comments:

Environmental variation

14. The TWV, TWF and TWC agreed with the TWA to propose that the new sentence introduced in the draft guidance, Annex I, should be amended to read as follows:

"It is important to identify whether differences in number of off-types between growing cycles were due to ~~biological~~ environmental reasons or sampling variation."

15. The TWF and TWV agreed to propose a further clarification to the new sentence introduced in the draft guidance, Annex I, for all approaches to read as follows:

"It is important to identify whether differences in number of off-types between growing cycles were not due to ~~biological~~ environmental reasons or sampling variation."

Criteria for rejecting a variety after a single growing cycle

16. The TWPs considered whether more general criteria should be used in Annex I for a variety to be rejected after a single growing cycle rather than the specific case of having exceeded the allowed number of off-types in two growing cycles. The current proposed wording reads 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.”

17. The TWA agreed to propose a more general criterion for a variety to be rejected after a single growing cycle for inclusion in the different approaches of the draft guidance to read as follows:

“If in the first growing cycle a variety exceeds a predefined upper limit of off-types the variety may be rejected after a single growing cycle.”

18. The TWA agreed that the upper limit of off-types could be defined by each authority according to the approaches used for the assessment of uniformity by off-types.

19. The TWF agreed with the TWV to propose to modify the sentence for Approach 1 as follows:

“Furthermore, if a variety clearly 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.

20. The TWC agreed that the predefined upper limit of the allowed number of off-types in two growing cycles was a useful reference for many crops and agreed to propose the draft guidance in approaches 1 and 2 to read as proposed by the TWV and TWF.

Information on the criteria for selecting the most suitable approach

21. The TWA received the following presentations comparing the possible effect on uniformity decisions between Approaches 1 and 3 in document TWP/1/17 Rev., as reproduced in the Annexes to documents TWA/46/4 and TWA/46/4 Add. (in alphabetical order):

- “Effect of different approaches for the assessment of uniformity by off-types – examples for Barley”, prepared by an expert from Germany
- “Assessing Uniformity by Off-types on the basis of more than one Growing Cycle: examples from the Netherlands”, prepared by an expert from the Netherlands
- “Assessing uniformity by off-types on the basis of more than one growing cycle in wheat” prepared by an expert from Poland
- “The United Kingdom’s Experience with Winter Oilseed Rape (WOSR)” prepared by an expert from the United Kingdom

22. The TWA noted the approaches used for the assessment of uniformity by off-types in Germany and Poland for cereals, in the Netherlands for tomato and in the United Kingdom for oilseed rape.

23. The TWV and the TWC received the following presentation, as reproduced in the Annex to documents TWV/51/5 and TWC/35/8:

- “Assessing Uniformity by Off-types on the Basis of More than One Growing Cycle: examples from the Netherlands” by an expert from the Netherlands.

24. The TWV agreed to recall that in the vegetable sector, Approach 1 was the most commonly used.

25. The TWC agreed that the different approaches used in the assessment of off-types on the basis of more than one growing cycle produced different results in some cases. The TWC agreed that smaller sample sizes and number of off-types allowed (e.g. vegetable crops) could highlight borderline cases where different results could be produced when using different approaches.

26. The TWC agreed that the different results obtained using the different approaches for the assessment of off-types on the basis of more than one growing cycle were due in part to the different risks of type I and type II errors associated with each approach.

27. The TWC agreed to invite the experts from Germany, the United Kingdom and other members of the Union to submit papers on the analysis of risks associated with each approach to be considered at its thirty-sixth session.

SUMMARY OF APPROACHES

28. 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-third session and on the basis of the proposals made by the TWPs, at their sessions in 2017, 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 2017.

Underlining (highlighted) indicates proposed insertion of text according to amendments proposed by the TWPs, at their sessions in 2017.

[Text in brackets] (highlighted) indicates alternative proposals made by different TWPs

29. 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.

30. *The TC-EDC is invited to:*

(a) *note that the TWC agreed to invite the experts from Germany, the United Kingdom and other members of the Union to submit papers on the analysis of risks associated with each approach for assessing uniformity by off-types on basis of more than one growing cycle, to be considered at its thirty-sixth session; and*

(b) *consider the comments made by the TWPs, at their sessions in 2017, and formulate a proposal for further consideration by the TWPs, at their sessions in 2018.*

[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, 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 [not] due to biological environmental reasons or sampling variation.

[Furthermore, if in the first growing cycle a variety exceeds a predefined upper limit of off-types the variety may be rejected after a single growing cycle.] / [Furthermore, if a variety clearly 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 [not] due to biological environmental reasons or sampling variation.

[Furthermore, if in the first growing cycle a variety exceeds a predefined upper limit of off-types the variety may be rejected after a single growing cycle.] / [Furthermore, if a variety clearly 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 should be applied when appropriate. It is important to identify whether differences in number of off-types between growing cycles were [not] due to biological environmental reasons or sampling variation.

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	Approach 3
	Number of Off-Types	1	1	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 [not] due to biological environmental reasons or sampling variation.

** [If in the first growing cycle a variety exceeds a predefined upper limit of off-types the variety may be rejected after a single growing cycle.] / [If a variety clearly exceeds 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]

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]