

Technical Committee

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UNIFORMITY ASSESSMENT ON THE BASIS OF OFF-TYPES: METHOD FOR MORE THAN ONE SINGLE TEST (YEAR)

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EXECUTIVE SUMMARY

1. The purpose of this document is to report on developments concerning the revision of guidance in document TGP/8/2: Part II: Section 8: “The method of uniformity assessment on the basis of off-types” to reflect the practice within members of the Union on the use of methods for more than one single test (year), in conjunction with the revision of document TGP/10 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 consider the proposal for the revision of guidance in document TGP/8/2: Part II: Section 8: Subsection 8.1.7: “Method for more than one single test (year)”, on the basis of the draft set out in Annex II to this document in conjunction with the comments by the TWPs, at their sessions in 2018.

3. The structure of this document is as follows:

EXECUTIVE SUMMARY 1

BACKGROUND 2

 CURRENT GUIDANCE IN DOCUMENT TGP/8 2

CONSIDERATION BY THE ENLARGED EDITORIAL COMMITTEE 2

CONSIDERATION BY THE TECHNICAL WORKING PARTIES 2

ANNEX I Extract from document TGP/8: Part II: Section 8: “The method of uniformity assessment on the basis of off-types”

ANNEX II Draft proposal for the revision of document TGP/8: Part II: Section 8: “The method of uniformity assessment on the basis of off-types”

4. The following abbreviations are used in this document:

- CAJ: Administrative and Legal Committee
- 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 TC, at its fifty-third session, held in Geneva from April 3 to 5, 2017, considered document TC/53/19 “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” and 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) (see document TC/53/31 “Report”, paragraph 125).

Current guidance in document TGP/8

6. The current guidance in document TGP/8: Part II: Section 8: “The method of uniformity assessment on the basis of off-types”, Subsection 8.1.7: “Method for more than one single test (year)” is reproduced as Annex I to this document.

CONSIDERATION BY THE ENLARGED EDITORIAL COMMITTEE

7. The Council, at its thirty-fourth extraordinary session, held in Geneva on April 6, 2017, decided to organize a single set of sessions from 2018, in the period of October/November (see document C(Extr.)/34/6 “Report on the decisions”, paragraphs 12 to 14). From 2018, the meetings of the TC will take place on October/November instead of March/April. The TC-EDC will meet twice a year; once in the period of March/April and once in conjunction with the TC sessions later in the year.

8. Based on the recommendation of the Consultative Committee, the Council decided to adopt the proposals of the TC, at its fifty-third session, to use contingency measures in the transitional period until the fifty-fourth session of the TC, to be held in October 2018; for TGP documents, the TC-EDC would consolidate comments made by the TWPs at their sessions in 2017 and, in the absence of consensus between the TWPs, to formulate proposals for further consideration by the TWPs at their sessions in 2018 (see document C(Extr.)/34/6 “Report on the decisions”, paragraphs 12 to 14).

9. The TC-EDC, at its meeting held in Geneva, on March 26 and 27, 2018, considered document TC-EDC/Mar18/16 “Uniformity assessment on the basis of off types: methods for more than one single test (year)”.

10. The TC-EDC agreed to invite the expert from the United Kingdom to draft a proposal for the revision of guidance in document TGP/8/2: Part II: Section 8: Subsection 8.1.7: “Method for more than one single test (year)” for consideration by the TWPs, at their sessions in 2018.

CONSIDERATION BY THE TECHNICAL WORKING PARTIES

11. The TWA, TWC and TWV considered document [TWP/2/10](#) and the draft proposal for the revision of guidance in document TGP/8/2: Part II: Section 8: Subsection 8.1.7: “Method for more than one single test (year)”, prepared by the expert from the United Kingdom, as set out in Annex II to document TWP/2/10 (see documents TWA/47/7 “Report”, paragraphs 30 to 32; TWC/36/15 “Report”, paragraphs 50 to 56; and TWV/52/20 “Report”, paragraphs 31 to 34).

12. The TWC agreed with the draft proposal for the revision of guidance in document TGP/8/2: Part II: Section 8: Subsection 8.1.7: “Method for more than one single test (year)” by the expert of the United Kingdom.

13. The TWA agreed that a clarification should be added to paragraph 8.1.7.1, approaches (b) and (c), that results from growing cycles using different samples of plant material should not be combined, as provided in the proposed guidance for document TGP/10 on assessing uniformity by off-types on the basis of more than one growing cycle or on the basis of sub-samples.

14. The TWC and TWV agreed with the TWA that the results from different growing cycles should only be combined if the tests are done with the same submission of plant material.

15. The TWA agreed that the two-stage test described in paragraph 8.1.8 would only be possible when uniformity for a variety was considered separately in each cycle and assessed on a third growing cycle in case of divergent results (paragraph 8.1.7, approach “a”).

16. The TWV agreed with the TWC that the two-stage test described in paragraph 8.1.8 should be clarified to state that it is for testing in a single growing cycle.

17. The TWC considered document [TWC/36/7](#) "Risks associated with assessment of uniformity by off-types on the basis of more than one growing cycle" and received a presentation by experts from Germany and the United Kingdom, a copy of which would be provided as document TWC/36/7 Add.

18. The TWC agreed to invite the experts from Germany and the United Kingdom to develop examples demonstrating the risks and consequences for decisions on uniformity to be presented at its next session.

19. The TWC noted the importance of considering the risks associated with assessment of uniformity by off-types on the basis of more than one growing cycle and agreed that it would not be practical to develop tables with the allowed number of off-types for such cases. The TWC noted that, in future, software might be needed to calculate such risks.

20. The TWV agreed with the TWC on the importance of considering the risks associated with assessment of uniformity by off-types on the basis of more than one growing cycle and agreed that the calculation of a predefined upper limit of uniformity should be clarified. In that regard the TWV noted the approach developed by France for the theoretical calculation of a predefined upper limit as the maximum off-types accepted plus one on the total sum of the plants for 2 testing cycles (for example each growing cycle requires 20 plants, the predefined upper limit for the assessment of uniformity on the first cycle would be based on the number of off-types accepted plus one on the total number of plants on the basis of the sum of plants to be observed on 2 cycles, in that case 40 plants).

21. The TC is invited to consider the proposal for the revision of guidance in document TGP/8/2: Part II: Section 8: Subsection 8.1.7: "Method for more than one single test (year)", on the basis of the draft set out in Annex II to this document in conjunction with the comments by the TWPs, at their sessions in 2018.

[Annexes follow]

EXTRACT FROM DOCUMENT TGP/8: PART II: SECTION 8:
"THE METHOD OF UNIFORMITY ASSESSMENT ON THE BASIS OF OFF-TYPES"

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.

8.1.7.2 *Combined test*

The sample size in test i is n_i . So after the last test we have the total sample size $n = \sum n_i$. A decision scheme is set in exactly the same way as if this total sample size had been obtained in a single test. Thus, the total number of off-types recorded through the tests is compared with the maximum number of off-types allowed by the chosen decision scheme.

8.1.7.3 *Two-stage test*

8.1.7.3.1 The method for a two-year test may be described as follows: In the first year take a sample of size n . Reject the candidate variety if more than r_1 off-types are recorded and accept the candidate variety if less than a_1 off-types are recorded. Otherwise, proceed to the second year and take a sample of size n (as in the first year) and reject the candidate variety if the total number of off-types recorded in the two years' test is greater than r . Otherwise, accept the candidate variety. The final risks and the expected sample size in such a procedure may be calculated as follows:

$$\begin{aligned}\alpha &= P(K_1 > r_1) + P(K_1 + K_2 > r \mid K_1) \\ &= P(K_1 > r_1) + P(K_2 > r - K_1 \mid K_1) \\ &= \sum_{i=r_1+1}^n \binom{n}{i} P^i (1-P)^{n-i} + \sum_{i=\alpha_1}^{r_1} \binom{n}{i} P^i (1-P)^{n-i} \sum_{j=r-i+1}^n \binom{n}{j} P^j (1-P)^{n-j}\end{aligned}\quad (3)$$

$$\begin{aligned}\beta_q &= P(K_1 < \alpha_1) + P(K_1 + K_2 \leq r \mid K_1) \\ &= P(K_1 < \alpha_1) + P(K_2 \leq r - K_1 \mid K_1) \\ &= \sum_{i=0}^{\alpha_1-1} \binom{n}{i} P_q^i (1-P_q)^{n-i} + \sum_{i=\alpha_1}^{r_1} \binom{n}{i} P_q^i (1-P_q)^{n-i} \sum_{j=0}^{r-i} \binom{n}{j} P_q^j (1-P_q)^{n-j}\end{aligned}\quad (4)$$

$$n_e = n \left(1 + \sum_{i=\alpha_1}^{r_1} \binom{n}{i} P^i (1-P)^{n-i} \right) \quad (5)$$

where

- P = population standard
- α = probability of actual Type I error for P
- β_q = probability of actual Type II error for q P
- n_e = expected sample size
- r_1, α_1 and r are decision-parameters
- P_q = q times population standard = q P
- K_1 and K_2 are the numbers of off-types found in years 1 and 2 respectively.

The decision parameters, α_1, r_1 and r , may be chosen according to the following criteria:

- (a) α must be less than α_0 , where α_0 is the maximum Type I error, i.e. α_0 is 100 minus the required acceptance probability
- (b) β_q (for $q=5$) should be as small as possible but not smaller than α_0
- (c) if β_q (for $q=5$) < $\alpha_0 n_e$ should be as small as possible.

8.1.7.3.2 However, other strategies are available. No tables/figures are produced here as there may be several different decision schemes that satisfy a certain set of risks. It is suggested that a statistician should be consulted if a 2-stage test (or any other sequential tests) is required.

8.1.7.4 Sequential tests

The two-stage test mentioned above is a type of sequential test where the result of the first stage determines whether the test needs to be continued for a second stage. Other types of sequential tests may also be applicable. It may be relevant to consider such tests when the practical work allows analyses of off-types to be carried out at certain stages of the examination. The decision schemes for such methods can be set up in many different ways and it is suggested that a statistician should be consulted when sequential methods are to be used.

[Annex II follows]

DRAFT PROPOSAL FOR THE REVISION OF DOCUMENT TGP/8: PART II: SECTION 8:
“THE METHOD OF UNIFORMITY ASSESSMENT ON THE BASIS OF OFF-TYPES”

8.1.7 *Method for more than one single growing cycle*

8.1.7.1. Often a candidate variety is assessed in two growing cycles. The question then arises of how to combine the information from the individual cycles in order to make a decision on uniformity. Three approaches are described:

(a) The uniformity for a variety is considered separately in each cycle. If the verdicts are the same, then the overall decision is based on this common result. However, if 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. In this case, the overall decision is based on the uniformity assessment for the third cycle.

(b) The uniformity for a variety is considered separately in each cycle. If the verdicts are the same, then the overall decision is based on this common result. However, if the variety is within the uniformity standard in one growing cycle but is not within the uniformity standard in the other growing cycle, then the information from the two cycles is combined. In this case, 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 size then the variety is considered uniform.

(c) The information on uniformity for a variety is combined over the two cycles. 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 size then the variety is considered uniform.

For all three approaches, 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.

8.1.7.2 These three approaches are described in greater detail in document TGP/10 “Examining Uniformity”. The risks associated with different approaches can be calculated according to the principles described in this Section. Calculations of risks can be complex and it is advisable to consult a statistician.

8.1.8 *Assessing uniformity on the basis of subsamples within a single test or trial*

8.1.8.1 Sometimes it may be possible to reduce the costs of off-type assessment by carrying it out in two stages. First a sub-sample of plants is examined. Based on the number of off-types in the sub-sample, either a verdict on uniformity is reached or (secondly) the whole sample of plants is examined.

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

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

8.1.8.4 If the number of off-types is between the predefined lower and upper limits, the whole sample is assessed.

8.1.8.5 The predefined lower upper limits should be set considering comparable Type I and Type II errors in the sub sample and the whole sample. Setting up such two-stage tests is complex, and it is advisable to consult a statistician.

[End of Annex II and of document]