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ASSESSING UNIFORMITY BY OFF-TYPES ON THE BASIS OF MORE THAN ONE GROWING CYCLE: RISKS, BENEFITS AND COSTS OF DIFFERENT APPROACHES

Document prepared by experts from the United Kingdom and Germany

The Annex to this document contains a copy of a presentation on "assessing uniformity by off-types on the basis of more than one growing cycle: risks, benefits and costs of different approaches" that will be made at the Technical Working Party on Automation and Computer Programs (TWC), at its thirty-third session.

[Annex follows]

Assessing uniformity by off-types on the basis of more than one growing cycle

Risks, benefits and costs

Adrian Roberts
BioSS
UK

Uwe Meyer
Bundessortenamt
Germany

TWC/33/9

The TWC is invited to consider:

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 in Annex I, as provided by members and observers;

TWC/33/9 Annex I

- Basic scheme is two growing cycles, assessed separately
- Two approaches
  - differ in how they deal with conflicting results between cycles

<u>Approach 1</u>

Third growing cycle in the case of inconsistent results

<u>Approach 2</u>

Combining the results of two growing cycles

Approach 1

Third growing cycle in the case of inconsistent results

Approach 2

Combining the results of two growing cycles in the case of inconsistent results

Suggested revised wording

Approach 1

Third growing cycle in the case of inconsistent results

Approach 2

Combining the results of two growing cycles in the case of inconsistent results

Approach 3

Combining the results of two growing cycles

Additional approach used in UK

Proposed approach 3

- Two growing cycles
- Simply combine the number of off-types over the two cycles
- As for approaches 1 and 2, it is important to verify whether the results for the two cycles are consistent

Proposed approach 3

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 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 is possible.

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	uniform	←consistent
	2	2	uniform	uniform	non-uniform	←inconsistent
	0	3	third growing cycle	uniform	uniform	
	1	3	third growing cycle	non-uniform	non-uniform	
	0	10*	third growing cycle†	non-uniform†	non-uniform†	
	10**	0	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 variety may be rejected after a single growing cycle if the number of off-types found is sufficiently high.

Example

Sample size for each approach and growing cycle

Approach	Growing cycle 1 n1	Growing cycle 2 n2	Growing cycle 3 n3	Combined n1+n2
1	50	50	50	n/a
2	50	50	0	100
3	50	50	0	100

Maximum number of off-types for each approach and growing cycle/stage

Approach	Growing cycle 1 n1	Growing cycle 2 n2	Growing cycle 3 n3	Combined n1+n2
1	2	2	2	n/a
2	2	2	n/a	3
3	3	n/a	n/a	3

Example

Sample size for each approach and growing cycle

Approach	Growing cycle 1 n1	Growing cycle 2 n2	Growing cycle 3 n3	Combined n1+n2
1	50	50	50	n/a
2	50	50	0	100
3	50	50	0	100

Maximum number of off-types for each approach and growing cycle/stage

Approach	Growing cycle 1 n1	Growing cycle 2 n2	Growing cycle 3 n3	Combined n1+n2
1	2	2	2	n/a
2	2	2	n/a	3
3	3	n/a	n/a	3

Type I and type II errors

Type I error: declare variety non-uniform when population is uniform

Type II error: declare variety uniform when population is non-uniform

Type I and type II errors

Tests are set up to achieve a set type I error

- Type I error = 1 – acceptance probability
- 5% in example
- In relation to population standard

Different test can then be compared through the type II errors

- Type II errors are calculated at different levels of off-types in population
- e.g. 2 , 5 and 10 times the population standard

Overall vs stagewise errors

Can set type I error for each stage or growing cycle or for the overall test

- As for current approach 1 and 2 examples

We claim that it is better to use overall error → better reflects true risks for applicant & testing authority

Example

Approaches 1 & 2 have type I error set to 5% per cycle not overall

Approach	Type I error	Type II error			Max off-types	
		2%	5%	10%	Per cycle	Combined
1	0.06%	98.3%	56.1%	3.47%	2	n/a
2	1.27%	89.3%	32.6%	1.39%	2	3
3	1.84%	85.9%	25.8%	0.78%	n/a	3

Approach 3 has the lowest type II errors

Example revisited

Approaches 1a & 2a have type I error set to 5% overall

Approach	Type I error	Type II error			Max off-types	
		2%	5%	10%	Per cycle	Combined
1	0.06%	98.3%	56.1%	3.47%	2	n/a
1a	2.26%	82.7%,	19.1%	0.33%	1	n/a
2	1.27%	89.3%	32.6%	1.39%	2	3
2a	1.84%	85.9%	25.8%	0.79%	1	3
3	1.84%	85.9%	25.8%	0.78%	n/a	3

Approach 1a has the lowest type II errors; approach 2a and 3 are not far behind

Example revisited

Population Standard = 1%

Acceptance Probability ≥ 95%

Sample Size in each of growing cycles 1 and 2 = 50

Maximum number of Off-Types = 1

Sample Size in growing cycles 1 and 2 combined = 100

Maximum number of Off-Types = 3

	Growing cycle		Decision			
	First	Second	Approach 1a	Approach 2a	Approach 3	
Number of Off-Types	1	1	uniform	uniform	uniform	←consistent
	2	2	non-uniform	non-uniform	non-uniform	←consistent
	0	3	third growing cycle	uniform	uniform	
	1	3	third growing cycle	non-uniform	non-uniform	
	0	10†	third growing cycle†	non-uniform†	non-uniform†	
	10*†	0	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 variety may be rejected after a single growing cycle if the number of off-types found is sufficiently high.

Notes on calculating type I and type II errors

For single stage tests (e.g. approach 3), this is straightforward – see TGP/8

For tests made up of multiple stages (approaches 1 & 2), it is a little harder

- Some knowledge of rules of probability required

In the case of approach 1, the overall errors can be calculated directly from the type I and type II errors for the individual stages

- Let p_i^I be the type I error for each cycle and p^I is the overall type I error for approach 1. Then

$$p^I = 1 - (1 - p_i^I)(1 - p_i^I) - (1 - (1 - p_i^I)(1 - p_i^I) - p_i^{I^2})(1 - p_i^I)$$

- Also let p_i^{II} be the type II error for each cycle and p^{II} is the overall type II error for approach 1.

$$p^{II} = p_i^{II^2} + (1 - (1 - p_i^{II})(1 - p_i^{II}) - p_i^{II^2})p_i^{II}$$

In the case of approach 2, we found it necessary to use simulation to calculate the overall errors

Pros and Cons of each approach

Efficiency:
- Approach 3 more effective than approaches 1 and 2 from existing example
- If 1 & 2 modified to 1a & 2a, then all approaches have similar effectiveness (1a slightly better in this example)
- Conclusions may vary according to actual sample sizes employed – discreteness (see TGP/8)

Costs:
- Approach 1 requires more testing, with third cycles being required for some candidates (not many?)

Simplicity:
- Approach 3 is simpler than approach 1 and 2

Conclusions & Proposals

- Propose the addition of approach 3 to TGP/10 draft text
- Looked at risks (type I and type II errors)
  - Best to look at overall risks
  - Example for approaches 1 & 2 can be optimised for overall risks
  - After optimising, all 3 approaches have similar risk levels. This may change if sample size changed.
- Approaches 2 and 3 require less testing than approach 1
- Approach 3 is the simplest
- The approaches are more consistent after optimisation but approach 1 may require third cycle when 2 & 3 give verdicts (uniform or non-uniform)
- All 3 approaches need alerts when results in 2 cycles are seriously different. If the reasons for inconsistency unknown, may require further growing cycle. This element would benefit from further discussion and elaboration

[End of Annex and of document]