Annex 10.4 Evaluation Criteria for Laboratory Performance Assessment

Determination of a single test result

The following requirements must be met to pass a laboratory performance assessment:

- All active substances identified
- Correct quantification of at least n-2 active substances
  (the result per active substance must lie within the range of 70-120% of the added content)
- No incorrect positive active substance finding

The following applies to the awarding of points for a single test:

	Points
Points per participation in a laboratory performance assessment	+2
Points for every incorrectly positively/negatively identified active substance	-5
Points for every incorrectly quantified active substance	-1

For test methods which can be awarded in subcontract, the points are awarded for the participating laboratory; independent from whether the test method was conducted by the laboratory itself or subcontracted. There is no award of points for the subcontracted laboratory.

If a laboratory performance assessment is failed, participation in the next test is obligatory.

Determination of the total number of points

Calculation begins with participation in the first laboratory performance assessment after receipt of QS approval. Previous test results are not included in the evaluation. The following rules apply:

- The points scored in the individual tests are added together.
- A maximum total of 10 points can be scored.
- No negative total number of points is possible (in the event of a negative total number of points, the accumulated number of points is set to zero for the next test).

The following applies to the determination of the total number of points:

	Points
Bonus for laboratories applying for initial approval (starting credit) when participating in a laboratory performance assessment for the first time	+2
Additional graduated points deduction for the repeated occurrence of errors in the first/second/third subsequent test	-1/-2/-3
Obligatory participation in the next test with a total number of points	≤4

Approval is lost:

- if with a total number of zero points the subsequent test is failed
- if after three tests in a row no positive number of total points each was achieved.

Once QS approval has been lost, it can only be regained after a minimum of six months.

- The prerequisites for regaining approval are:
  - Successful participation in a laboratory performance assessment
  - Successful check of documents by QS
  - Successful laboratory audit by QS at the expense of the lab.