Reporting of analytical results below the reporting limit

Position paper by the Working Group Pesticides

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Introduction

This position paper deals with the reporting of active substance findings below the reporting limit (RL, corresponds to the validated limit of quantification) in an accreditation-compliant test report. The application of the specifications for reporting as described by the SANTE Guideline [1] also for nonofficial laboratories (commercial laboratories) within the scope of accreditation procedures according to ISO/IEC 17025 [2] was specified by the decision of the Sector Committee 'Health Consumer Protection' of the DAkkS [3].

In addition to the legal assessment according to Regulation (EC) No 396/2005 [4], commercial laboratories (also named trade laboratories) often must consider specific customer specifications (secondary standards) as additional conformity assessments in the test reports.

For such specific evaluations it may also be important for the customer to know, whether a substance is detected or not. The indication "< RL" in the report is not unambiguous for this requirement. A detailed indication of the findings is particularly important for samples of organic cultivation, as the consequences of wrong decisions are very serious for such products.

In the following, the risk of possible wrong decisions and the influence of the expanded measurement uncertainty on the conformity statement are discussed.

Risk of statistical errors

Zero hypothesis H_0:
Product does not contain any active substances with contents above the relevant specification.

Consequence: Product marketable / suitable for client

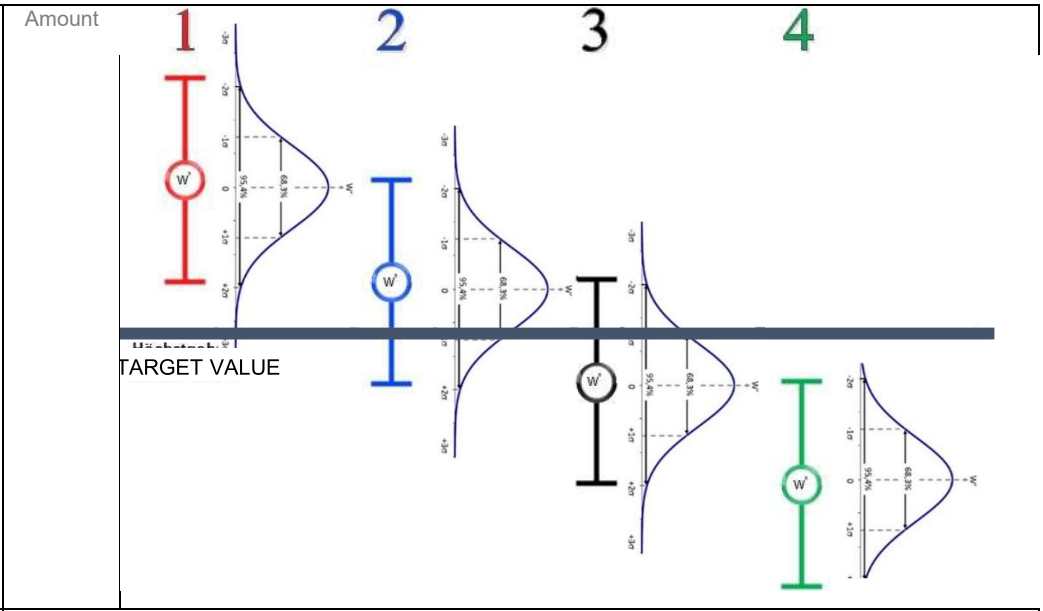
Alternative hypothesis H_A:
Product contains pesticide residues at levels above the relevant specification.

Consequence: Rejection of the product / product (if applicable) not marketable

	α-error	β-error
Definition	H_0 is rejected, although H_0 is true	H_0 is assumed, although H_A is true
Laboratory result	Incorrect, too high / excessive finding	Incorrect, too low / sub finding

Follow	Product is rejected or judged not to be marketable although the specification is met.	Product is accepted and assessed as marketable although the specification is not met.
Damage	Economic damage probable	Economic and health damage possible
Possible consequences for official laboratories	Recourse claims, if applicable	Loss of confidence in surveillance and consumer protection
Possible consequences for trade laboratories	Recourse claims and loss of customers might endanger existence	Loss of confidence in analytical services and possibly economic consequences

Influence of measurement uncertainty on the conformity statement
(new element in ISO/IEC 17025 [2])



Two-sided view	$P_{\square}$				
	$P_{\square}$				
One-sided view	$P_{\square}$	0			
	$P_{\square}$				
Complaint by official lab		X			
Rejection by trade laboratory		X	(X)	(X)	

Official laboratory: ➔ Test for marketability by unilateral application of expanded measurement uncertainty = 50 % (k = 2)

➔ Method "fit for purpose" according to SANTE guideline [1]: RL < MRL (special features: *maximum residue level and default value).

Trade laboratory: ➔ Assessment of marketability analogous to official laboratories

➔ Additional statements on customer specifications may be required

Reporting of results in the test report

The requirement for a test report is a clear and unambiguous reporting of the results. In chapter E2 of the SANTE guideline [1] for quantitative determinations the requirement is described that residues of individual analytes below the reporting limit (RL limit) are to be reported as "< RL mg/kg". To prevent misunderstandings regarding the interpretation of this information, additional explanations may be necessary. In the case of residue levels that have been reliably detected but are below the reporting limit, it is recommended to note that such levels have been reliably detected but are quantitatively below the reporting limit.

If, on the other hand, no residues have been reliably detected according to [1], the statement in the test report "< RL mg/kg" may be misleading for recipients without a corresponding technical background. In such a case, the explanation that a residue cannot be reliably detected should provide clarity.

Examples for information in the test report

Case	Description	Specification in the test report	Example
1	Measured value is above the reporting limit (RL)	Measured value ± expanded MU*	0.21 ± 0.11 mg/kg
2	Analyte is detectable, the measured value is below the reporting limit (RL)	< RL (detectable)	< 0.01 mg/kg (detectable)
3	Analyte is not detectable	< RL (not detectable)	< 0.01 mg/kg (n. d.)

* MU measurement uncertainty

For the information according to case 2, it must be comprehensible that the corresponding analyte has been reliably identified. For this purpose, the requirements of the SANTE guideline Table 3 [1] are mandatory.

Conclusion

The SANTE Guidance [1] summarises the validation and analytical quality control requirements for methods used in the official testing of food and feed for pesticide residues in the EU. A harmonised reporting system is to be sought for these investigations in the sense of uniform administrative action. In view of the different target groups for test reports of official and non-official laboratories, a reporting of results for commercial laboratories supplementing the guideline should be made possible, which allows specific agreements with customers without deviating from the SANTE guideline [1]. For this purpose, the validity of the guideline should be limited to the technical requirements within the scope of the accreditation procedure and the requirements for the test reports should be based on the standard requirements (point 7.8) [3].

A simple reporting according to SANTE [1] ("< RL" without additional information) is still possible.

Literatur

[1] SANTE/11312/2021: Analytical quality control and method validation procedures for pesticide residues analysis in food and feed Implemented by 01/01/2022

[2] ISO/IEC 17025:2017-11: General requirements for the competence of testing and calibration laboratories

[3] revised Decision No. 01-/2018 (18.03.2018) - Decisions in the DAkkS Division - Consumer Health Protection SD 71 4 036 Revision 1.6 of 04.09.2019 (DAkkS is the national accreditation body of Germany)

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Directive 91/414/EEC, as last amended 17 September 2021.