

ISO 16140:2003-05 (E)

Microbiology of food and animal feeding stuffs - Protocol for the validation of alternative methods

Contents		Page
page	Foreword	v
	Introduction	vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General principles for the validation and the certification of alternative methods	3
5	Qualitative methods - Technical protocol for their validation	4
6	Quantitative methods - Technical protocol for their validation	14
	Annex A (normative) Specific rules for the acceptance of external results already obtained in a prior validation scheme	29
	Annex B (informative) Classification of sample types for validation studies	31
	Annex C (normative) Use of naturally contaminated samples and preparation of artificially contaminated samples in validation studies	34
	Annex D (normative) Duplication of samples for the determination of relative accuracy and of relative detection level for qualitative methods	36
	Annex E (normative) Calculation of the confidence intervals associated with the number of samples tested	38
	Annex F (normative) Test applied to the examination of discordant results	39
	Annex G (normative) Points to be considered when selecting strains for testing selectivity	40
	Annex H (normative) Guidelines for the organisation and conducting collaborative studies	42
	Annex I (normative) Determination that negative controls are free of target analyte	45
	Annex J (normative) Replication of samples for interlaboratory studies of qualitative methods	46
	Annex K (normative) Consideration of data	48
	Annex L (informative) Interlaboratory study of qualitative methods: criteria of accordancy, concordance and concordance odds ratio	49
	Annex M (normative) Replication of samples for the determination of relative accuracy of quantitative methods	54
	Annex N (normative) Examples of acceptable and unacceptable situations and range of measurements for the estimation of the regression line for quantitative methods	56

Annex O (normative) Assessment of the linearity of quantitative methods by graphical representation	58
Annex P (normative) Detection and quantification limits for counts	59
Annex Q (normative) Robust estimator of dispersion based on the recursive median S_n from Rousseeuw [6]	61
Annex R (normative) Calculations with the regression method	62
Annex S (normative) Examples of calculations for quantitative methods	67
Annex T (normative) Collaborative study - Ring test results with duplicates	72
Annex U (informative) List of symbols and abbreviations	73
Bibliography	74