

Decision support for the comparative evaluation and selection of analytical methods: detection of genetically modified organisms as an example

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Contents

This document provides a printout of the complete *AnalyticalMeth* DEXi model described but not fully presented in the article due to space limitations. This printout has two sections:

A: Structure of the model, including descriptions and value scales of all attributes

B: All decision tables presented with aggregated decision rules (compact DEXi representation)

Model Version

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Further information on DEXi: <http://kt.ijs.si/MarkoBohanec/dexi.html>

Section A: Model Structure

DEXi

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Attribute tree

Attribute	Description
AnalyticalMeth	Detection and quantification analytical method
FitForPurpose	Is method fit for purpose?
PurposeFitness	Fitness with respect to purpose
Purpose	Primary purpose of analysis: screening or quantification
FitForScreening	Method fitness for screening
Specificity	Is method specific?
LOD	Limit of detection
Robustness	Is method robust?
FitForQuantification	Method fitness for quantification
FitForScreening	Method fitness for screening
QuantitativePerformance	Method performance for quantification
SiteFitness	Fitness with respect to on/off-site applicability
Site	Site of performing analysis: lab or on-site
FitForOnSiteScreening	Method fitness for on-site detection
OnSiteDetection	Is method suitable for on-site detection?
FitForScreening	Method fitness for screening
BestForPurpose	Best-for-purpose method evaluation
Constraints	Constraints for best-for-purpose method
FitForPurpose	Is method fit for purpose?
MethDeveloped	Completeness of method development
Developed	Stage of method development, cost-related
DevelopmentStage	Current state of method development
SOP	Is Standard Operating Procedure available?
SuggestedSamples	Are samples for method development available?
SpecificCharacteristics	Additional characteristics of method development (non cost-related)
SpecificityAssessed	To which extent was method specificity assessed?
Proficiency	Was method tested on proficiency samples?
MethEvaluation	Best for purpose method evaluation
MethPerformance	Performance of the method
MethodType	Method type: DNA extraction, detection or quantification
MethPerformance_Detection	Performance of detection method
Specificity	Is method specific?
LOD	Limit of detection
LOD_Abs	Absolute limit of detection: Targets detected in single reactions
LOD_Rel	Relative limit of detection: Lowest detected percentage of GMO in the sample
Robustness	Is method robust?
InhibitorHandling	Sensitivity to inhibitors
MethPerformance_Quantification	Performance of quantification method
MethPerformance_Detection	Performance of detection method
QuantitativePerformance	Method performance for quantification
Accuracy	How accurate is method?
DynamicRange	Range of target copies suitable for quantification
LOQ	Limit of quantification
LOQ_Low	Low target LOQ
LOQ_Abs	Absolute limit of quantification: Targets quantified in single reactions
LOQ_Rel	Relative limit of quantification: Lowest quantifiable percentage of GMO in sample
LOQ_High	High target LOQ
LOQ_Abs	Absolute limit of quantification: Targets quantified in single reactions
Linearity	How linear is method within range of quantification?
MethApplicability	General applicability of method
MethApplicabilityDetection	General applicability of detection method
SampleProcessing	Method applicability for sample processing
SampleTypes	Ability of method to handle different sample types
MixedSamples	Does method handle mixed samples?
ProcessedSamples	Does method handle processed samples?
RequiredAmount	Required amount of sample (for DNAEx) or DNA (for detection)
MethFunctions	Extent of method functions for detection
Screening	Is method useful for screening?
Identification	Is method useful for identification?
SpeciesDetection	Is method useful for species detection?
Quantification	Is method useful for quantification?
UnauthorisedGM	Can method detect un-authorised GMOs?
OnSiteDetection	Is method suitable for on-site detection?
Costs	Method implementation costs
RunningCosts	Running costs of method operation
Efficiency	Method efficiency
Consumables/Sample	Costs of consumables per sample
Samples/Day	Number of samples that can be analysed in one working day
Targets/Method	Number of targets that can be detected simultaneously
PersonalCosts	Costs of labour per sample
FixedCosts	Fixed costs of method implementation
MaterialCosts	Fixed material costs
EquipmentCosts	Costs of required equipment
InfrastructureCosts	Cost of infrastructure
NonMaterialCosts	Fixed non-material costs
CompetenceCosts	Personal competence required for method
ValidationCosts	Cost of in-house validation (implementation in the lab)

Scales

Attribute	Scale
AnalyticalMeth	unacc ; acc; good; v-good; exc
FitForPurpose	no ; partly; yes
PurposeFitness	no ; partly; yes
Purpose	screening; quantification
FitForScreening	no ; partly; yes
Specificity	no ; yes
LOD	high ; med; low
Robustness	low ; med; high
FitForQuantification	no ; partly; yes
FitForScreening	no ; partly; yes
QuantitativePerformance	unacc ; acc; good
SiteFitness	no ; partly; yes
Site	lab; on-site
FitForOnSiteScreening	no ; partly; yes
OnSiteDetection	no ; yes
FitForScreening	no ; partly; yes
BestForPurpose	unacc ; acc; good; v-good; exc
Constraints	no ; partly; yes
FitForPurpose	no ; partly; yes
MethDeveloped	proof ; partly; almost; fully
Developed	proof ; partly; almost; fully
DevelopmentStage	proof ; opt.assay; tested; prevalidation; validation
SOP	no ; yes
SuggestedSamples	no ; yes
SpecificCharacteristics	no ; partly; yes
SpecificityAssessed	no ; partly; yes ; not-required
Proficiency	no ; yes
MethEvaluation	unacc ; acc; good; v-good; exc
MethPerformance	unacc ; acc; good; exc
MethodType	detection; quantification
MethPerformance_Detection	unacc ; acc; good; exc
Specificity	no ; yes
LOD	high ; med; low
LOD_Abs	insensitive ; med; good
LOD_Rel	insensitive ; med; good
Robustness	low ; med; high
InhibitorHandling	none ; med; good
MethPerformance_Quantification	unacc ; acc; good; exc
MethPerformance_Detection	unacc ; acc; good; exc
QuantitativePerformance	unacc ; acc; good
Accuracy	low ; med; high
DynamicRange	low ; med; high
LOQ	high ; med; low
LOQ_Low	high ; med; low
LOQ_Abs	bad ; med; good
LOQ_Rel	bad ; med; good
LOQ_High	low ; med; high
LOQ_Abs	bad ; med; good
Linearity	low ; med; high
MethApplicability	bad ; acc; good; exc
MethApplicabilityDetection	bad ; acc; good; exc
SampleProcessing	bad ; acc; good; exc
SampleTypes	bad ; acc; good
MixedSamples	no ; yes
ProcessedSamples	no ; yes
RequiredAmount	high ; med; low
MethFunctions	bad ; acc; good; exc
Screening	no ; yes
Identification	no ; yes
SpeciesDetection	no ; yes
Quantification	no ; yes
UnauthorisedGM	no ; yes
OnSiteDetection	no ; yes
Costs	v-high ; high; med; low
RunningCosts	v-high ; high; med; low
Efficiency	low ; med; high ; v-high
Consumables/Sample	high ; med; low
Samples/Day	low ; med; high
Targets/Method	low ; med; high; v-high
PersonalCosts	high ; med; low
FixedCosts	v-high ; high; med; low
MaterialCosts	v-high ; high; med; low
EquipmentCosts	v-high ; high; med; low
InfrastructureCosts	high ; med; low
NonMaterialCosts	high ; med; low
CompetenceCosts	high ; med; low
ValidationCosts	high ; med; low

Section B: Aggregated Decision Rules

The rightmost column in the tables below presents the output decision, based on the information provided in other columns as input.

DEXi

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Tables

	FitForPurpose	BestForPurpose	AnalyticalMeth
1	no	*	unacc
2	*	unacc	unacc
3	partly	acc:good	acc
4	>=partly	acc	acc
5	partly	>=v-good	good
6	yes	good	good
7	yes	v-good	v-good
8	yes	exc	exc

	PurposeFitness	SiteFitness	FitForPurpose
1	no	*	no
2	*	no	no
3	partly	>=partly	partly
4	>=partly	partly	partly
5	yes	yes	yes

	Purpose	FitForScreening	FitForQuantification	PurposeFitness
1	screening	no	*	no
2	*	no	no	no
3	quantification	*	no	no
4	screening	partly	*	partly
5	quantification	*	partly	partly
6	screening	yes	*	yes
7	quantification	*	yes	yes

	Specificity	LOD	Robustness	FitForScreening
1	no	*	*	no
2	*	high	<=med	no
3	*	*	low	no
4	yes	high	high	partly
5	yes	med	med	partly
6	yes	>=med	high	yes
7	yes	low	>=med	yes

	FitForScreening	QuantitativePerformance	FitForQuantification
1	no	*	no
2	*	unacc	no
3	>=partly	acc	partly
4	>=partly	good	yes

	Site	FitForOnSiteScreening	SiteFitness
1	on-site	no	no
2	on-site	partly	partly
3	lab	*	yes
4	*	yes	yes

	OnSiteDetection	FitForScreening	FitForOnSiteScreening
1	no	*	no
2	*	no	no
3	yes	partly	partly
4	yes	yes	yes

	Constraints	MethEvaluation	BestForPurpose
1	no	*	unacc
2	<=partly	<=acc	unacc
3	*	unacc	unacc
4	partly	good:v-good	acc
5	yes	acc	acc
6	partly	exc	good
7	yes	good	good
8	yes	v-good	v-good
9	yes	exc	exc

	FitForPurpose	MethDeveloped	Constraints
1	no	*	no
2	*	<=partly	no
3	partly	>=almost	partly
4	yes	>=almost	yes

	Developed	SpecificCharacteristics	MethDeveloped
1	proof	*	proof
2	partly	*	partly
3	partly:almost	<=partly	partly
4	almost	yes	almost
5	fully	<=partly	almost
6	fully	yes	fully

	DevelopmentStage	SOP	SuggestedSamples	Developed
1	proof	*	*	proof
2	opt.assay	*	*	partly
3	opt.assay:tested	no	*	partly
4	opt.assay:tested	*	no	partly
5	tested:prevalidation	yes	yes	almost
6	prevalidation	*	*	almost
7	>=prevalidation	no	*	almost
8	>=prevalidation	*	no	almost
9	validation	yes	yes	fully

	SpecificityAssessed	Proficiency	SpecificCharacteristics
1	no	no	no
2	<=partly	yes	partly
3	partly	*	partly
4	>=partly	no	partly
5	>= yes	yes	yes

	MethPerformance	MethApplicability	Costs	MethEvaluation
1	unacc	*	*	unacc
2	<=acc	<=acc	v-high	unacc
3	<=good	bad	v-high	unacc
4	acc	bad	>=high	acc
5	acc	<=good	high:med	acc
6	acc	*	high	acc
7	acc:good	bad	high:med	acc
8	acc	good	<=med	acc
9	acc	>=good	<=high	acc
10	acc:good	>=good	v-high	acc
11	good	>=acc	v-high	acc
12	exc	bad	v-high	acc
13	acc	>=acc	low	good
14	acc:good	acc	low	good
15	acc	exc	>=med	good
16	good	<=acc	low	good
17	good	acc	>=high	good
18	good	acc:good	high:med	good
19	good	>=acc	high	good
20	>=good	acc:good	high	good
21	exc	bad	high:med	good
22	exc	<=good	high	good
23	exc	acc:good	<=high	good
24	exc	>=acc	v-high	good
25	good	>=good	low	v-good
26	good	exc	>=med	v-good
27	exc	<=acc	low	v-good
28	exc	acc	>=med	v-good
29	exc	acc:good	med	v-good
30	exc	exc	high	v-good
31	exc	>=good	low	exc
32	exc	exc	>=med	exc

	MethodType	MethPerformance_Detection	MethPerformance_Quantification	MethPerformance
1	detection	unacc	*	unacc
2	*	unacc	unacc	unacc
3	quantification	*	unacc	unacc
4	detection	acc	*	acc
5	quantification	*	acc	acc
6	detection	good	*	good
7	quantification	*	good	good
8	detection	exc	*	exc
9	quantification	*	exc	exc

	Specificity	LOD	Robustness	InhibitorHandling	MethPerformance_Detection
1	no	*	*	*	unacc
2	*	high	low	*	unacc
3	*	*	*	none	unacc
4	yes	high	>=med	med	acc
5	yes	med	low	>=med	acc
6	yes	>=med	low	med	acc
7	yes	high	>=med	good	good
8	yes	*	med	good	good
9	yes	med	>=med	med	good
10	yes	>=med	med	>=med	good
11	yes	low	<=med	good	good
12	yes	>=med	high	good	exc
13	yes	low	high	>=med	exc

	LOD Abs	LOD Rel	LOD
1	insensitive	<=med	high
2	<=med	insensitive	high
3	<=med	good	med
4	med	>=med	med
5	>=med	med	med
6	good	<=med	med
7	good	good	low

	MethPerformance_Detection	QuantitativePerformance	MethPerformance_Quantification
1	unacc	*	unacc
2	*	unacc	unacc
3	>=acc	acc	acc
4	acc	good	good
5	>=good	good	exc

	Accuracy	DynamicRange	QuantitativePerformance
1	low	*	unacc
2	med	<=med	acc
3	>=med	low	acc
4	>=med	high	good
5	high	>=med	good

	LOQ	Linearity	DynamicRange
1	high	*	low
2	*	low	low
3	med	>=med	med
4	>=med	med	med
5	low	high	high

	LOQ_Low	LOQ_High	LOQ
1	high	*	high
2	*	low	high
3	med	>=med	med
4	low	>=med	low

	LOQ_Abs	LOQ_Rel	LOQ_Low
1	bad	<=med	high
2	<=med	bad	high
3	<=med	good	med
4	med	>=med	med
5	good	bad	med
6	good	>=med	low

	LOQ_Abs	LOQ_High
1	bad	low
2	med	med
3	good	high

	MethApplicabilityDetection	MethApplicability
1	bad	bad
2	acc	acc
3	good	good
4	exc	exc

SampleProcessing	MethFunctions	MethApplicabilityDetection
1 bad	<=acc	bad
2 <=acc	bad	bad
3 bad	good	acc
4 acc	acc	acc
5 good	bad	acc
6 <=acc	exc	good
7 acc	>=good	good
8 acc:good	good	good
9 good	acc:good	good
10 >=good	acc	good
11 exc	<=acc	good
12 >=good	exc	exc
13 exc	>=good	exc

SampleTypes	RequiredAmount	SampleProcessing
1 bad	<=med	bad
2 bad	low	acc
3 acc	high	acc
4 acc	med	good
5 good	high	good
6 >=acc	low	exc
7 good	>=med	exc

MixedSamples	ProcessedSamples	SampleTypes
1 no	no	bad
2 no	yes	acc
3 yes	no	acc
4 yes	yes	good

Screening	Identification	SpeciesDetection	Quantification	UnauthorisedGM	OnSiteDetection	MethFunctions
1 no	no	no	*	*	*	bad
2 no	no	yes	no	no	no	acc
3 no	yes	no	no	no	no	acc
4 yes	no	no	no	no	no	acc
5 no	no	yes	yes	no	no	good
6 *	yes	no	yes	no	no	good
7 *	yes	yes	no	no	no	good
8 yes	*	no	yes	no	no	good
9 yes	*	yes	no	no	no	good
10 yes	yes	no	*	no	no	good
11 yes	yes	*	no	no	no	good
12 *	*	yes	*	*	yes	exc
13 *	*	yes	*	yes	*	exc
14 *	yes	*	*	*	yes	exc
15 *	yes	*	*	yes	*	exc
16 *	yes	yes	yes	*	*	exc
17 yes	*	*	*	*	yes	exc
18 yes	*	*	*	yes	*	exc
19 yes	*	yes	yes	*	*	exc

RunningCosts	FixedCosts	Costs
1 v-high	<=high	v-high
2 v-high	>=med	high
3 <=high	med	high
4 high	<=med	high
5 >=high	v-high	high
6 high:med	low	med
7 med	>=high	med
8 >=med	high	med
9 low	>=med	low

Efficiency	PersonalCosts	RunningCosts
1 low	<=med	v-high
2 <=med	high	v-high
3 low	low	high
4 med: high	med	high
5 high	<=med	high
6 med: high	low	med
7 v-high	high	med
8 v-high	>=med	low

Consumables/Sample	Samples/Day	Targets/Method	Efficiency
1 high	low	<=med	low
2 high	*	low	low
3 <=med	low	low	low
4 high	low	>=high	med
5 <=med	<=med	high	med
6 high	>=med	med	med
7 <=med	med	med:high	med
8 *	med	med	med
9 med	<=med	med:high	med
10 >=med	<=med	med	med
11 med	med	<=high	med
12 >=med	med	<=med	med
13 low	<=med	<=med	med
14 high	>=med	v-high	high
15 <=med	med	v-high	high
16 high	high	>=high	high
17 med	<=med	v-high	high
18 >=med	low	v-high	high
19 med	high	<=med	high
20 >=med	high	low	high
21 low	low	>=high	high
22 low	<=med	high	high
23 >=med	high	>=high	v-high
24 low	>=med	v-high	v-high
25 low	high	>=med	v-high

MaterialCosts	NonMaterialCosts	FixedCosts
1 v-high	<=med	v-high
2 v-high	low	high
3 high	<=med	high
4 high:med	high	high
5 high:med	low	med
6 med	>=med	med
7 low	high	med
8 low	>=med	low

EquipmentCosts	InfrastructureCosts	MaterialCosts
1 v-high	high	v-high
2 v-high	med	high
3 high	high	high
4 <=med	low	med
5 high:med	>=med	med
6 med	*	med
7 >=med	high	med
8 low	>=med	low

CompetenceCosts	ValidationCosts	NonMaterialCosts
1 high	<=med	high
2 <=med	low	med
3 med	*	med
4 >=med	high	med
5 low	>=med	low