



EU Food Safety Platform

MULTI-STAKEHOLDER PLATFORM
FOR FOOD SAFETY IN EUROPE



Beyond speed: performance evaluation and practical applicability of rapid tests for mycotoxin and pesticide monitoring

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Why rapid testing matters



public authorities
enforcing food safety
regulations



Rapid tests in official control

Rapid tests mainly used as **screening tools** - to **classify samples into compliant vs suspect** but **not** to make final legal decisions.

Confirmatory methods are required to validate any suspect result.



Industry/FBO
internal quality assurance and risk
management



Rapid tests in industry and food business operations

Rapid tests are also used to get **quantitative estimates** to take decision on

Quickly accept or reject raw materials

Sort batches into different quality categories

Screen large sample numbers in routine monitoring

Reduce laboratory costs

the same tool can serve different purposes — and must be evaluated accordingly



What makes a test “fit-for-purpose”

➔ Evaluation against analytical performance criteria

Basic performance concepts:

- ✓ Detecting contamination when present (**avoid false negatives**)
- ✓ Not raising unnecessary alarms (**minimize false positive/suspect**)

strict criteria for compliance checks to avoid public-health risks



EU Regulation 519/2014 (mycotoxins)

Screening target concentration (STC)

Cut-off - False negative rate 5%
False suspect rate

Evaluation of
precision profile
embedded

SANTE/11312/2021-v2 (pesticides)

Screening Detection Limit (SDL)

the lowest level at which an analyte has been detected in at least 95 % of the samples (i.e., an acceptable false-negative rate of 5 %).



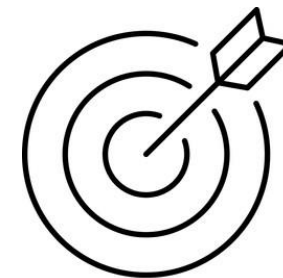
Needs are more variable: quick decisions, cost-efficiency, and batch management are often more important than exhaustive accuracy.

When speed meets reality: fitness-for –purpose according to EU regulation

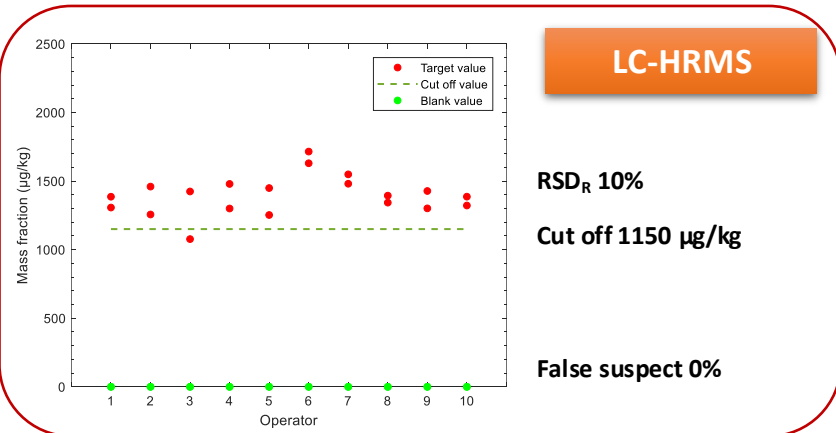
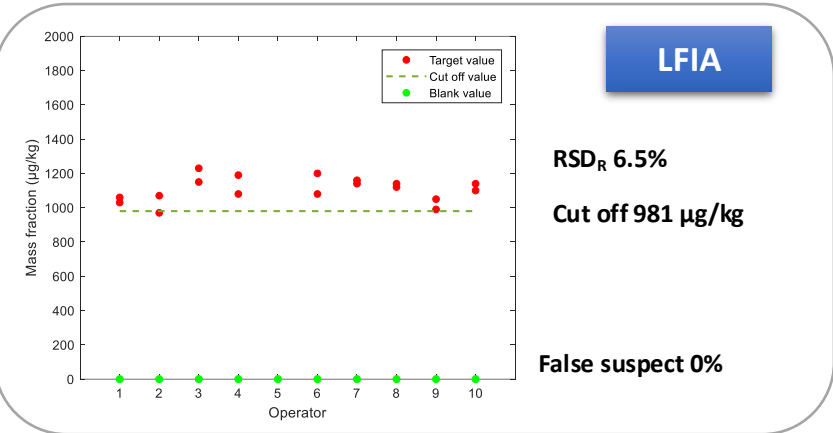
Rapid tests do what they are asked to do:

- **Rapid tests are designed to screen**, not to confirm
- Main regulatory goal: **avoid false negatives**
- EU rules prioritize **consumer safety** over analytical elegance

- Performance must be judged at the **screening target concentration (STC – SDL for pesticides)**

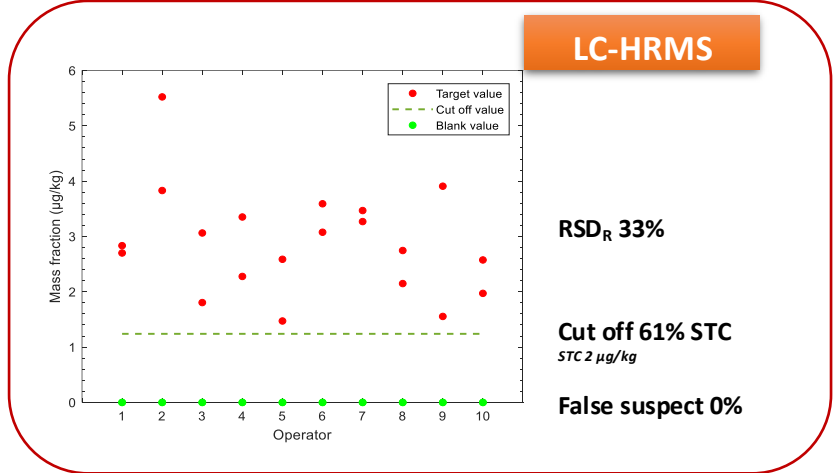
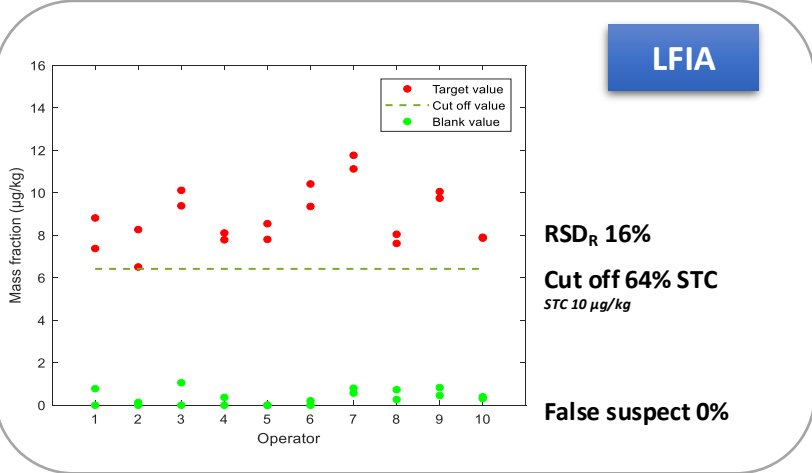


When speed meets reality: fitness-for –purpose according to EU regulation



Deoxynivalenol

Test materials (WHEAT):
Blank: DON ≤ 100 µg/kg
STC: DON 1600 µg/kg



Aflatoxins

Test materials (MAIZE):
Blank: AFB₁, AFB₂, AFG₁, AFG₂ ≤ 0.5 µg/kg
STC: AFB₁ 10.6 µg/kg

Test materials (WHEAT)
Blank: AFB₁, AFB₂, AFG₁, AFG₂ ≤ 0.5 µg/kg
STC: AFB₁ 2 µg/kg



Lattanzio VMT, von Holst C, et al. Evaluation of Mycotoxin Screening Tests in a Verification Study Involving First Time Users.
<https://doi.org/10.3390/toxins11020129>

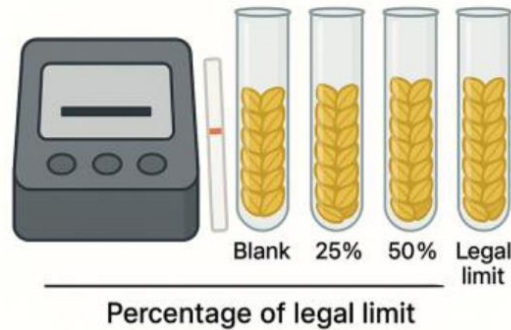
When speed meets reality: fitness-for –purpose according to EU regulation

- ✓ **Both approaches (LFD and LC-HRMS) are able to meet the same objective:** to correctly identify samples at the screening target concentration.
- ✓ **Very different analytical tools can be equally ‘fit-for-purpose’**—if they are evaluated against the correct criterion.
- ✓ **Fitness-for-purpose – according to regulation** - is not about analytical sophistication, but about **meeting the intended objective of the method.**

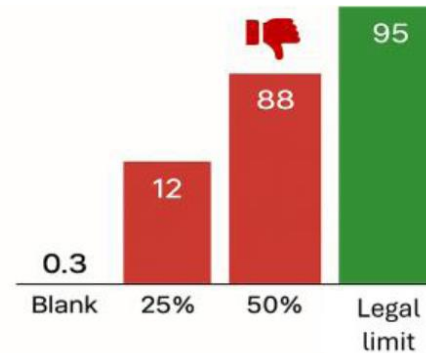


When speed meets reality: fitness-for-purpose by the application of Bayesian statistics

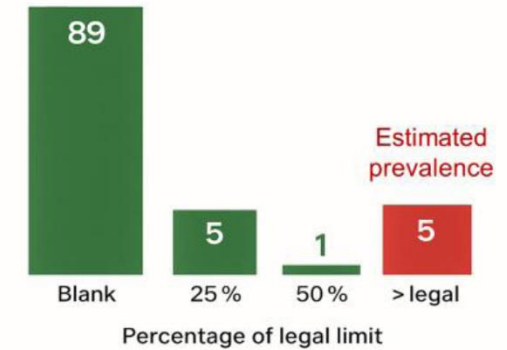
Screening test validation in wheat



Results from validation study Percentage of false and correct suspect results



Estimated DON content in samples Frequency of samples (%)



Source: Previous monitoring programs

Bayes' theorem: combines results from method validation and estimated mycotoxin distribution to calculate the probability of non-compliance



Christoph von Holst

When speed meets reality: fitness-for-purpose by the application of Bayesian statistics

What is the probability that the test gives a suspect result when the sample is non-compliant?



$P_{\text{SUSP/NC}}$

=



Control Test

sensitivity

Validation exercise – false suspect rate

Probability of classification as suspect positive from analysis on **non-compliant samples** (condition)

If I get a suspect result, how likely is it that my sample is really non-compliant?



$P_{\text{NC/SUSP}}$

= Control Test



Posterior probability

The user wants to know:

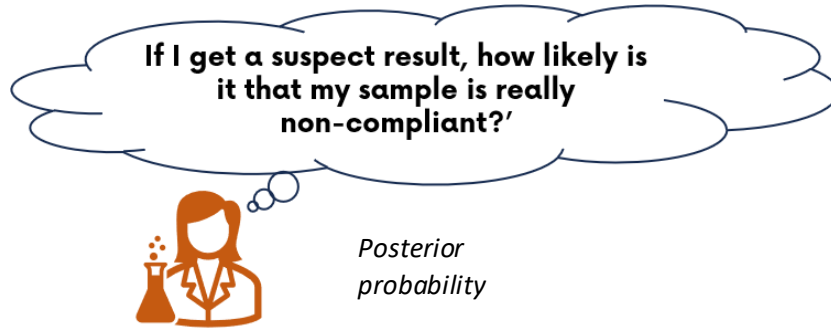
Probability that the sample is non-compliant when **classified as suspect positive sample** (condition)

Bayes theorem

P: probability; SUSP: suspect positive result; NC: non-compliant sample

von Holst C, Lattanzio VMT. Rapid mycotoxin screening: An update on the evaluation of analytical performances and relevant criteria in relation to the method scope. https://doi.org/10.1163/9789004724969_003

When speed meets reality: fitness-for-purpose by the application of Bayesian statistics



$$P_{\text{NC/SUSP}} = \frac{P_{\text{SUSP/NC}} \times P_{\text{Prior probability}}}{P_{\text{Marginal}}}$$

The **linkage** between the **method performance characteristics** in terms of probability of false negative and suspect positive rates and **prior knowledge** concerning the contamination level is established through Bayesian statistics

	Probability
SUSP	Suspect positive result
NC	Non-compliant sample
$P_{\text{NC/SUSP}}$	Posterior probability
$P_{\text{SUSP/NC}}$	Sensitivity

Prior probability is the expected rate of contamination

Marginal probability of suspect positive samples in the whole population – includes:

Rate of *correct* suspect (sensitivity) and *false* suspect results (1- specificity) from the validation study combined with

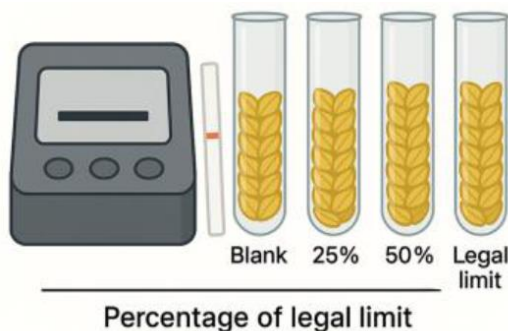
- Prior probability of non-compliant samples
- Prior information on rate of samples below the legal limit at various levels

What Bayesian statistics does is to connect all of these elements and provide something extremely useful: **the probability that a suspect result truly indicates a non-compliant sample.**

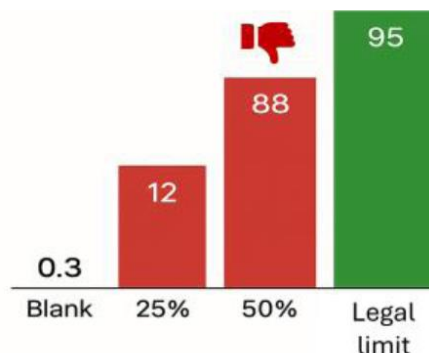
So instead of just measuring analytical characteristics, we obtain a decision-oriented parameter.

When speed meets reality: fitness-for-purpose by the application of Bayesian statistics

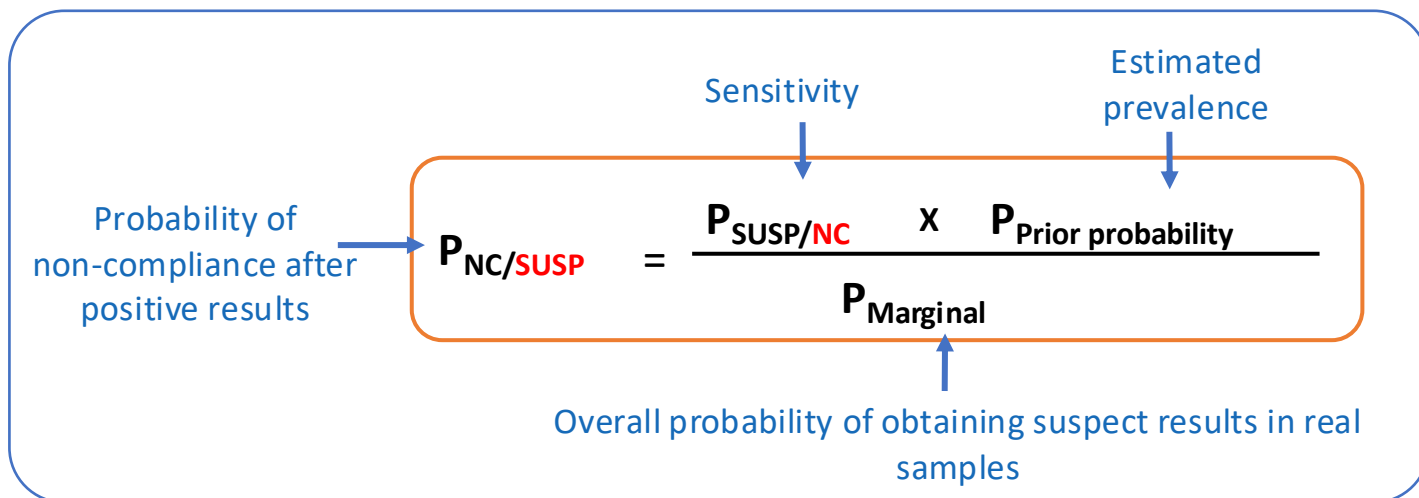
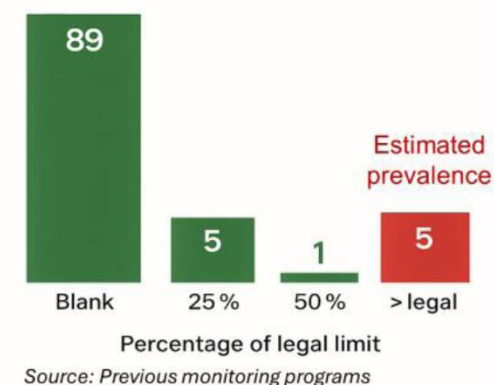
Screening test validation in wheat



Results from validation study
Percentage of false and correct suspect results



Estimated DON content in samples
Frequency of samples (%)



P_{marginal}	7% Low	👍
Probability of non-compliance after positive results	75% High	👍

von Holst C, Lattanzio VMT. Rapid mycotoxin screening: An update on the evaluation of analytical performances and relevant criteria in relation to the method scope. https://doi.org/10.1163/9789004724969_003

When speed meets reality: fitness-for-purpose by the application of Bayesian statistics

- ✓ **fitness-for-purpose** is not defined by the method alone—it emerges from the interaction between the method and the real-world scenario.
- ✓ **Bayesian thinking** provides us with the framework to understand and quantify this interaction



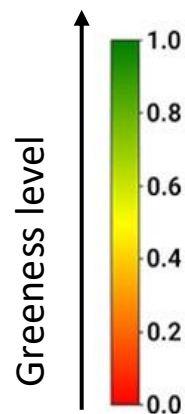
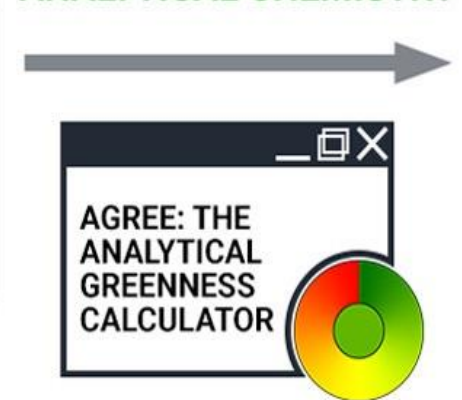
What makes a test “fit-for-purpose”

➔ Evaluation against **environmental** performance criteria

Enforcement of regulatory requirements demand frequent monitoring through analytical approaches that may differ markedly in complexity and environmental footprint

Analytical GREENess (AGREE) metrics

12 PRINCIPLES OF GREEN ANALYTICAL CHEMISTRY



Clock-like graph with:

- 12 sections around the circle for each GAC principle
- Overall score in the middle of the graph (0-1 scale)
- Color scale (red to dark green) indicates the greenness performance

What makes a test “fit-for-purpose”

➔ A Decision-Support Framework integrating analytical performance criteria and AGREE Metrics

- ✓ A **novel decision-support tool** be applicable to pesticide analytical methods (easy to adapt to mycotoxins and other contaminants)
- ✓ It **integrates SANTE validation criteria with AGREE-based environmental metrics**,

The tool allows:

evaluating analytical performance

verifying compliance

and assessing environmental impact

All together



Biancamaria Ciasca

Ciasca B et al. Fitness-for-Purpose Assessment of Methods for Glyphosate Determination in Food: Trade-Off Between Analytical Performance and Environmental Impact.
<https://doi.org/10.3390/foods15030576>

What makes a test “fit-for-purpose”

➔ A Decision-Support Framework integrating analytical performance criteria and AGREE Metrics

Step 1: Define the purpose

- Select **PURPOSE** of your method between **Quantitative Method** or **Screening Method**
- Click the button:

Go to the Analytical Performance Sheet

Step 2: Assessment of Analytical Performance

- Fill in the sheet `3.AP_QM` (quantitative method) or `5.AP_SM` (screening method)
- Click the button:

- Analytical Performance Analysis
- See the result in the corresponding sheet: `4.Score_AP_QM` or `6.Score_AP_SM`.



Step 3: Greenness Calculation

- Fill in the sheet `7.Greenness Calculation`
- See the score table and then click the button:

- AGREE score
- See the corresponding pictogram



Ciasca B et al. Fitness-for-Purpose Assessment of Methods for Glyphosate Determination in Food: Trade-Off Between Analytical Performance and Environmental Impact.

<https://doi.org/10.3390/foods15030576>

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Glyphosate case study

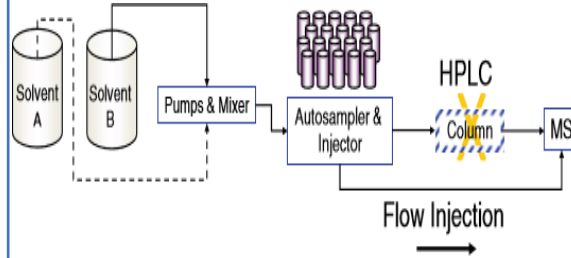
LC-MS/HRMS



Validation data set

LOQ (mg/kg)	Multi-Analyte
RL (mg/kg)	
Trueness	
Precision (RSDr)	
Precision (RSD _{WLR})	
Specificity	
Selectivity	
Linearity	
Robustness	
Uncertainty	
Extraction Efficiency	
Matrix effect, %	
LOD	

FI-MS/MS



Validation data set

LOQ (mg/kg)
RL (mg/kg)
Trueness
Precision (RSDr)
Precision (RSD _{WLR})
Specificity
Selectivity - partial
Linearity
Matrix effect, %

LFIA



Validation data set

Screening Detection Limit
False Positive Rate

Automated LFIA



Validation data set

Screening Detection Limit
False Positive Rate

Parameter	GLY	Ethephon	G lufosinate Am m onium	NAG	M PP	FosetylAl	Phosphonic Acid	
LO Q (m g/kg)	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
RL (m g/kg)	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
Trueness	Recovery, % (SL1-LL)	104	102	119	113	87	109	114
	Recovery, % : (SL2-M L)	104	105	103	87	74	111	112
	Recovery, % (SL3- HL)	103	116	101	120	93	112	105
Precision (RSD r)	RSD r, % (SL1-LL)	8.2	2.2	6	4.8	2.8	4.7	7.3
	RSD r, % (SL2-M L)	2.9	3.3	3.2	2.4	3.6	2.6	1.2
	RSD r, % (SL3-HL)	2.3	2.9	2.7	1.6	2.1	2.5	8.7
Precision (RSD _{W IR})	RSD _{W IR} , % (LO Q)	6.4	8.8	16.3	4.4	10.3	3.9	4.3
Specificity	S _{blank} /S _{RL} , %	0	0	0	0	0	0	0
Selectivity	2 monitored productions	YES	YES	YES	YES	YES	YES	YES
	S/N > 3	YES	YES	YES	YES	YES	YES	YES
	Retention time ± 0.1 min	YES	YES	YES	YES	YES	YES	YES
Linearity	Back calculated deviation (%)	20	20	20	20	20	20	20
	Lowest calibration level ≤ RL	YES	YES	YES	YES	YES	YES	YES
Robustness	Is it a standardized method?	YES	YES	YES	YES	YES	YES	YES
	Meet Control Chart criteria	YES	YES	YES	YES	YES	YES	YES
Uncertainty	Expanded uncertainty (%)	44	44	44	44	44	44	44
Extraction Efficiency		100	100	100	100	100	100	100
Matrix effect, %		0	0	0	0	0	0	0
LO D		NA	NA	NA	NA	NA	NA	NA

LC-MS/HRMS



SAN T E C criteria	GLY	Ethephon	G lufosinate Am m onium	NAG	M PP	FosetylAl	Phosphonic Acid
LO Q ≤ M RL	✓	✓	✓	✓	✓	✓	✓
RL ≥ LO Q	✓	✓	✓	✓	✓	✓	✓
Trueness: (Recovery, %) : 70-120	✓	✓	✓	✓	✓	✓	✓
Precision (RSD r) ≤ 20 %	✓	✓	✓	✓	✓	✓	✓
RSD _{W IR} , % (LO Q) ≤ 20 %	✓	✓	✓	✓	✓	✓	✓
S _{blank} /S _{RL} , % < 30	✓	✓	✓	✓	✓	✓	✓
All Identification C riteria are Met	✓	✓	✓	✓	✓	✓	✓
Back calculated deviation (%) ≤ 30% and lowest calibration level ≤ RL	✓	✓	✓	✓	✓	✓	✓
Meet Control Chart criteria for standardized method	✓	✓	✓	✓	✓	✓	✓
< 50 %	✓	✓	✓	✓	✓	✓	✓
>= 80 %	✓	✓	✓	✓	✓	✓	✓
<= 20 %	✓	✓	✓	✓	✓	✓	✓
LO D ≤ M RL	⚠	⚠	⚠	⚠	⚠	⚠	⚠
Analyte complying with all criteria	✓	✓	✓	✓	✓	✓	✓
Suggested Purpose	Official control						



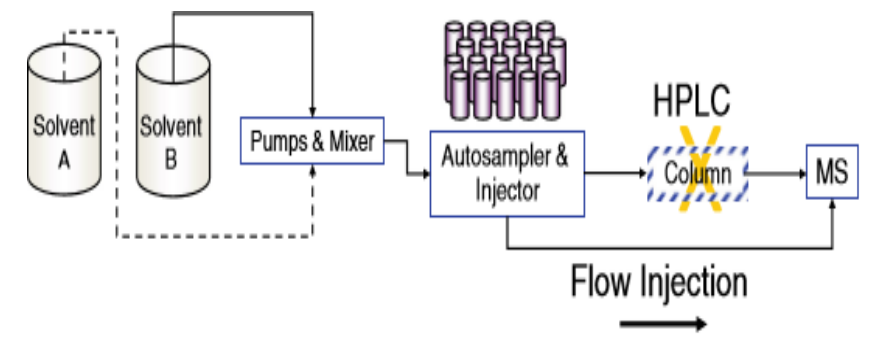
	GLY
MRL (mg/kg)	10
SL1-LL (mg/kg)	2
SL2-LL (mg/kg)	10
SL3-LL (mg/kg)	100

Parameter	GLY	
LOQ (mg/kg)	10	
RL (mg/kg)	10	
Trueness	Recovery, % (SL1-LL)	62
	Recovery, % : (SL2-M L)	97
	Recovery, % (SL3- HL)	111
Precision (RSDr)	RSDr, % (SL1-LL)	10
	RSDr, % (SL2-M L)	7.6
	RSDr, % (SL3-HL)	9.8
Precision (RSDwR)	RSD _{wR} , % (LOQ)	8.8
Specificity	S _{blank} /S _{RL} , %	0
Selectivity	2 monitored productions	YES
Linearity	S/N > 3	YES
	Retention time ± 0.1 min	NA
	Back calculated deviation (%)	20
Robustness	Lowest calibration level ≤ RL	YES
Uncertainty	Is it a standardized method?	NO
	Meet RSD _{wR} , Recovery criteria	NA
Extraction Efficiency	Expanded uncertainty (%)	NA
	Matrix effect, %	NA
	LOD	NA

SANTE C criteria	GLY
LOQ ≤ MRL	✓
RL ≥ LOQ	✓
Trueness: (Recovery, %): 70-120	✓
Precision (RSDr) ≤ 20%	✓
RSD _{wR} , % (LOQ) ≤ 20%	✓
S _{blank} /S _{RL} , % < 30	✓
All Identification Criteria are Met	✓
Back calculated deviation (%) ≤ 30% and lowest calibration level ≤ RL	✓
Meet specified criteria	⚠
< 50%	⚠
≥ 80%	✓
<= 20%	✓
LOD ≤ MRL	⚠

Analyte complying with all criteria	⚠
Suggested Purpose	Self-monitoring

FI-MS/MS



EU Food Safety Platform

LFIA



Parameter	GLY
Level of Interest	1

Parameter	GLY
Screening Detection Limit	1
False Positive	0
Selectivity*	Not Applicable

* for screening method based on MS spectrometry



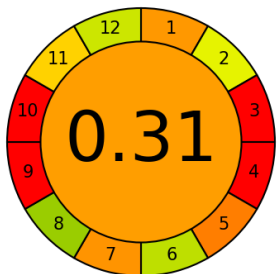
SAN TE C riteria	GLY
\leq Level of Interest	✓
$\leq 20\%$	✓
Identification C riteria are Met	Not required
Analyte complying with all criteria	
Suggested Purpose	Self-monitoring ✓

Looking at pesticides: different approaches to detect glyphosate

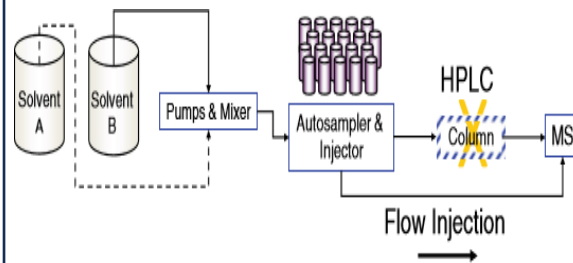
LC-MS/HRMS



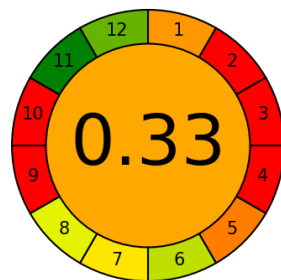
Official control
Risk assessment



FI-MS/MS



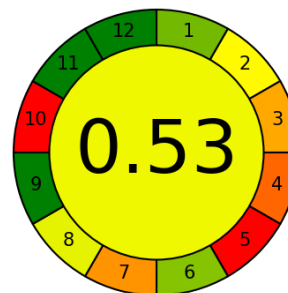
Self monitoring



LFIA



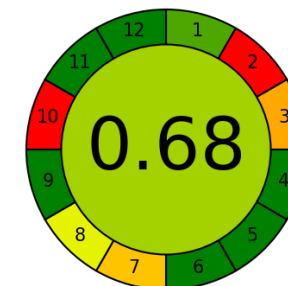
Self monitoring
Screening against STC



Automated LFIA



High-throughput self
monitoring
Screening against STC



1- Direct analysis, 2 – Minimal number of sample and size, 3 – in situ measurements, 4. integration of analytical processes and operations, 5. Automatic and miniaturized methods, 6 – Derivatization, 7 – analytical waste, 8 – multyanalyte methods, 9 – Minimize use of energy, 10 – reagent from renewable source, 11 – Toxic reagents, 12 - safety for operators

What makes a test “fit-for-purpose” – supporting resilience to food safety risks



 **Multiplexing:** *Speed over precision, without losing credibility*

Multi-Hazard & Screening Analytical Standards → increasing attention by standardization bodies

Multi-mycotoxin, multi-allergen, multi-species screening standards, non-targeted screening

They support resilience (Robustness – Adaptation – Transformation)

- Enable broad situational awareness
- Allow rapid reprioritisation of confirmatory testing

Crisis use

- Screening first → confirmatory later
- Expanded matrices beyond normal validation set



- EN 17279 (multi-mycotoxin)
- EN 17644 (LC-MS allergen screening)
- CEN food authenticity screening methods (non-targeted)



- address climate driven and emerging food safety risks,
- support early warning and high throughput monitoring,
- enable rapid and flexible response under crisis conditions,
- and contribute to managing uncertainty and system transformation.



These standards **compress time-to-signal** in emergencies.

Balancing Performance, Purpose, and Sustainability

- ▀ **Fitness-for-purpose depends on the intended application** → official control, self-monitoring, or risk assessment
- ▀ **Quantitative methods (LC-MS/MS)** → highest reliability, required for regulatory enforcement → but demand extensive validation efforts
- ▀ **Simplified methods (e.g. FI-MS/MS)** → promising for routine use, but require further validation (e.g. robustness, uncertainty)
- ▀ **Screening methods (e.g. LFA)** → fast, simple, suitable for large-scale monitoring → require confirmatory analysis for regulatory decisions
- ▀ **False positive rate is critical in practice** → impacts cost, workflow, and environmental footprint
- ▀ **Sustainability matters** → rapid tests are greener, better if automated, while MS-based methods are more resource-intensive

No universally “best” method → only methods that are fit for a specific purpose and context





EU Food Safety Platform

MULTI-STAKEHOLDER PLATFORM
FOR FOOD SAFETY IN EUROPE

THANK TO ALL

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