Flexible Scope Accreditation

International Workshop of GMO-analysis Networking (IWGN)

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Stefanie Trapmann
stefanie.trapmann@ec.europa.eu

Joint Research Centre
IRMM

Serving society
Stimulating innovation
Supporting legislation

Situation in Europe

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GMO events need authorisation

before being placed on the market in Europe
(Regulation (EC) No 1829/2003)

Validated quantification methods and certified reference materials (CRMs)

are available to GMO testing laboratories world-wide
(Regulation (EC) No 1829/2003, (EU) No 619/2011)

Quantitative real-time Polymerase Chain Reaction (qPCR)

is the method of choice applied in Europe

ISO/IEC 17025 accreditation

is mandatory for European GMO testing laboratories
(Regulation (EC) No 1981/2006)

Need for flexible scope accreditation

European Commission

Increasing number of authorised GMO events in Europe

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Legal requirement to perform measurements under ISO/IEC 17025 accreditation

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Need for a harmonised flexible scope accreditation

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Task force

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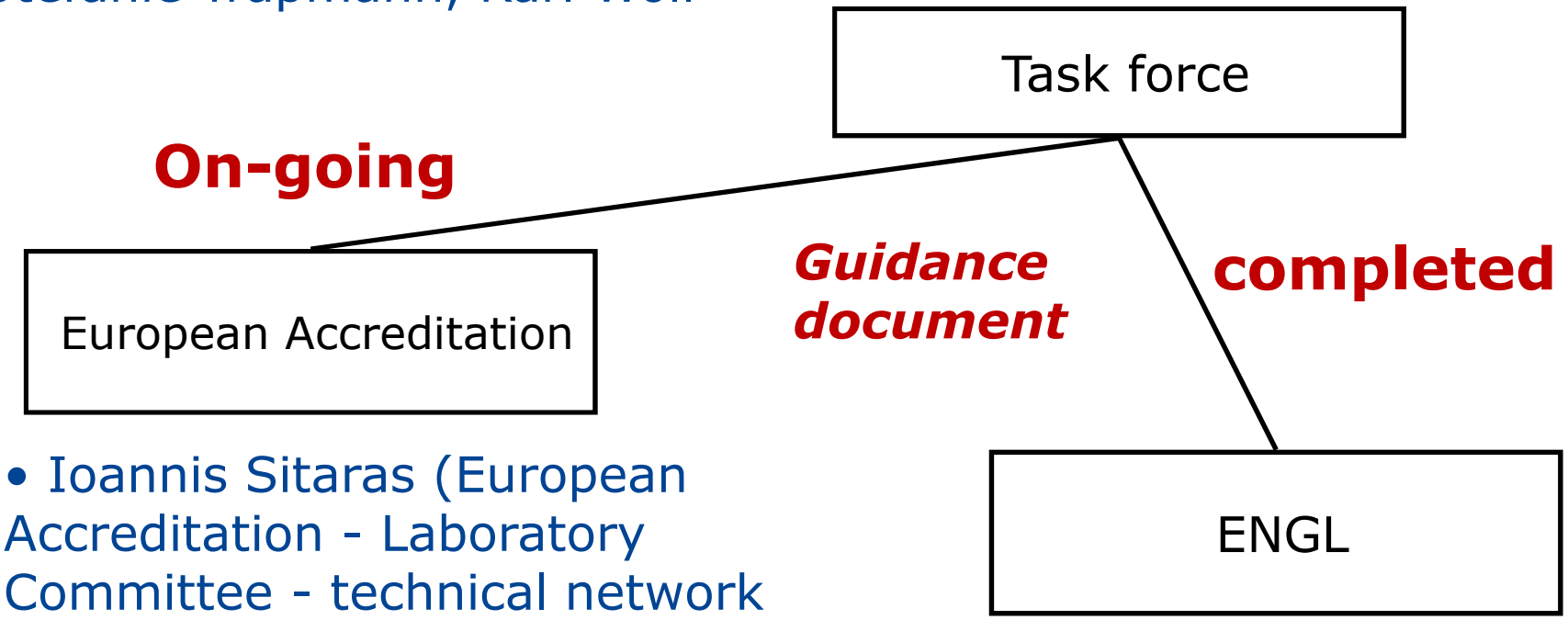
Task Force on the harmonisation of flexible scope accreditation for GMO quantification

- Cristina Aleixo, Philippe Corbisier, Stephane Cordeil, (Chrystele Charles Delobel), Lotte Hougs, Manuela Schulze, Martin Sandberg, Marco Mazzara, Jaroslava Ovésna, Patrick Philipp, Stefanie Trapmann, Karl Woll



- Ioannis Sitaras (European Accreditation - Laboratory Committee - technical network for food and feed testing)

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Guidance document (I)

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'European technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs'

Section 3 Flexible Scope

ISO/IEC 17025 ISO/IEC 17025, Section 1.2
(flexibility divided into 3 categories)

Section 4 Laboratory Sample preparation

ISO/IEC 17025 ISO/IEC 17025, Section 5.4
(homogeneity and representativeness)

Section 5 Method verification and MU

ISO/IEC 17025 ISO/IEC 17025, Section 5.4.5 and 5.4.6
(verification parameters and estimation tools)

Guidance document (II)

European Commission

Section 6 Measurement Unit
ISO/IEC 17025 ISO/IEC 17025, S
(calibration)

Section 7 Selection and Use of RM
ISO/IEC 17025 ISO/IEC 17025, S
(quality control with RMs)

Section 8 Measurement traceabili
ISO/IEC 17025 ISO/IEC 17025, S
5.9.2
(monitoring of key equipment and meth

addressed in Technical Session VI

Section 9 Proficiency Testing
ISO/IEC 17025 ISO/IEC 17025, Section 5.9
(level of participation and PT strategy)

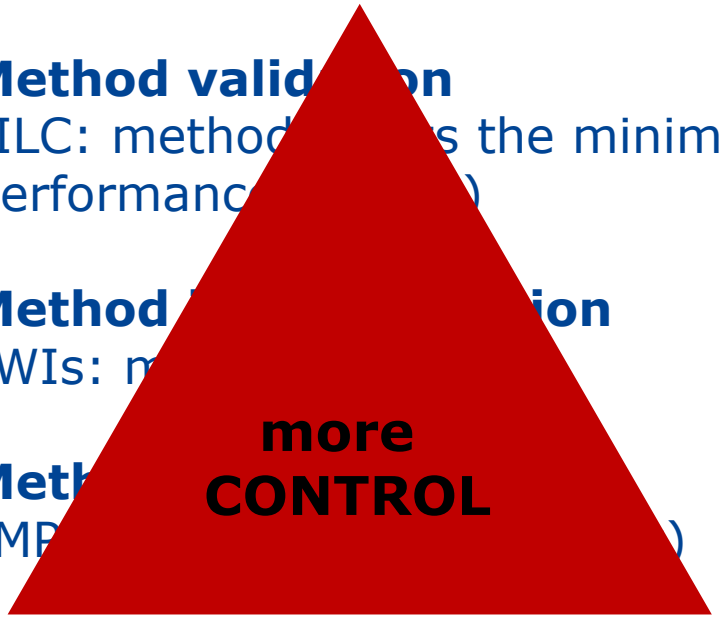
Accreditation

Fixed scope

Method valid on
(ILC: method s the minimum performanc)

Method ion
(WIs: m

Meth
(MP)



Method accreditation
(AB: criteria of ISO/IEC 17025 are met)

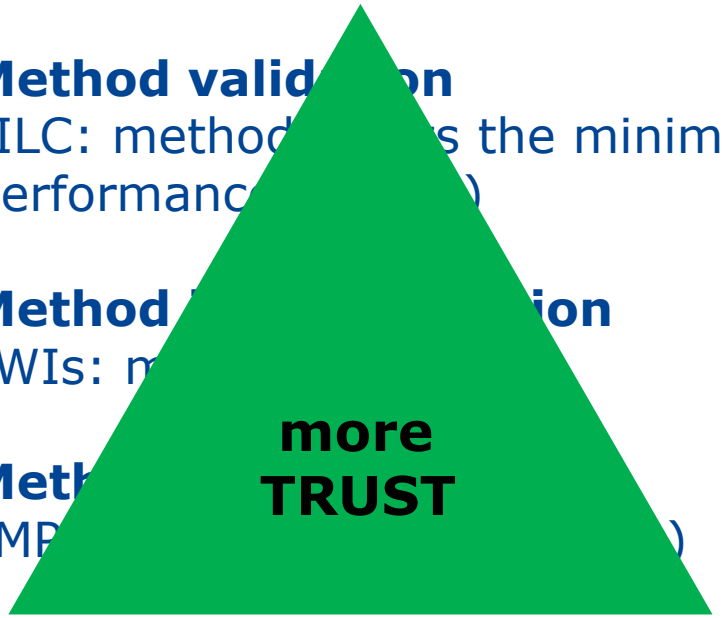
Extension of the scope
(granted by AB after an audit)

Flexible scope

Method valid on
(ILC: method s the minimum performanc)

Method ion
(WIs: m

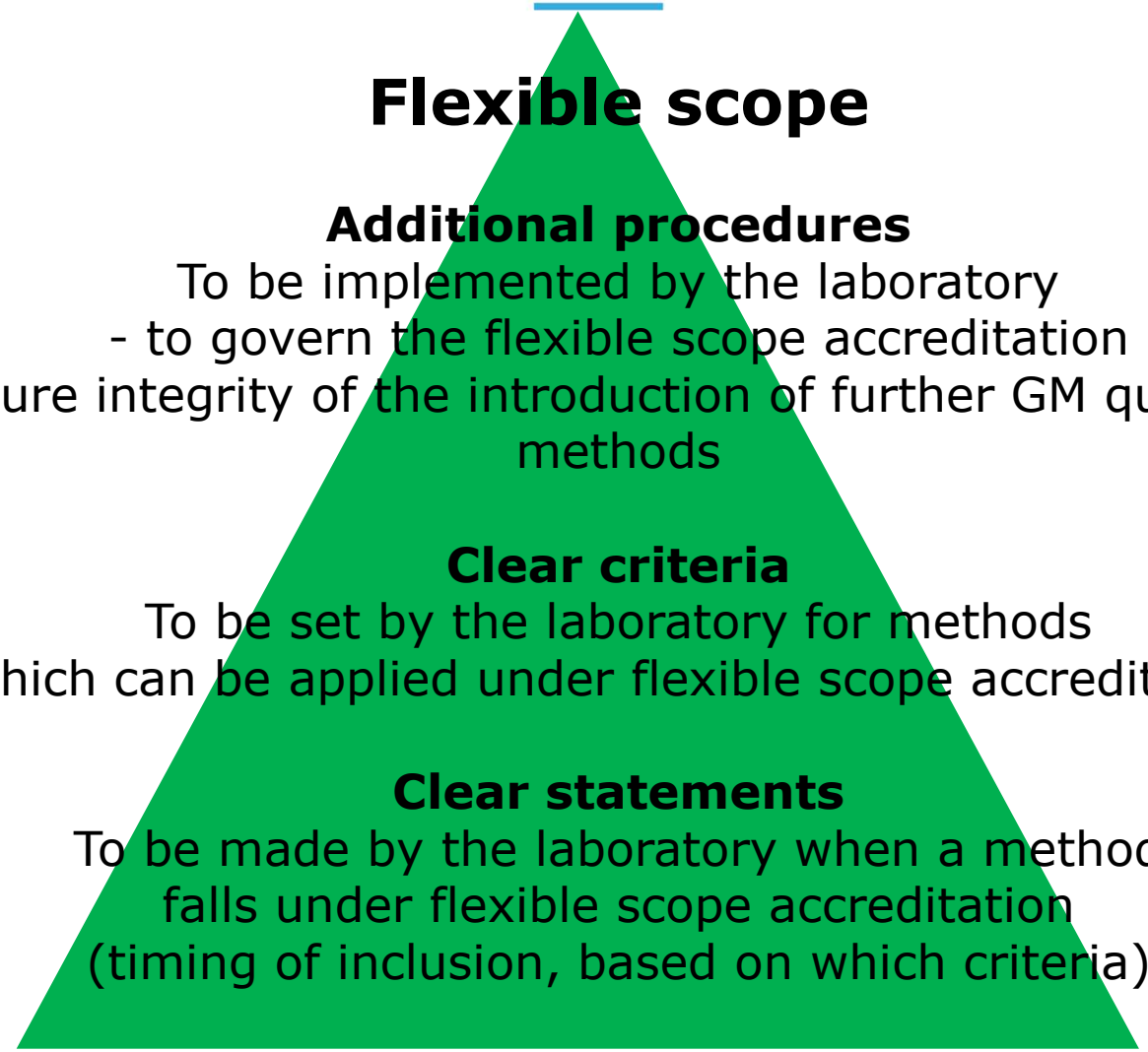
Meth
(MP)



Method accreditation
(Lab: criteria of ISO/IEC 17025 are met, reviewed by AB at the next audit, no scope extension required, provided method falls under an existing flexible scope)

ILC - interlaboratory comparison, WI – working instruction, MPR – minimum performance requirements, AB – accreditation body, ISO – International Standardization Organisation

(additional) Flexible scope requiremenets



Further details: EA-2/15 (2008) *EA requirements for the accreditation of flexible scopes,* http://www.european-accreditation.org/n1/doc/EA-2_15.pdf

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Section 3 Flexible Scope

ISO/IEC 17025 ISO/IEC 17025, Section 1.2

(flexibility divided into 3 categories)

Categories

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(1) Product ☒

- food/feed products (including grains),
- seed (including their ground form),
- vegetative plant parts (e.g. potato tubers, plant leaves)

(2) GM event ☒

- referring to the unique DNA recombination event
- qPCR method targeting the unique junction region
- GM concentration expressed as ratio

(3) Analytical procedure ☒

- DNA extraction method
- Event-specific qPCR method

(4) Range of measurements ☐

- Relevant qPCR measurements are carried out close to a defined (legal) threshold

Flexibility concerning the product

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Allowing changes of the specific product tested

Level of flexibility depending on the products included in the method validation

Example:

Fixed scope – MON 810 maize seeds

Flexible scope –

(a) GM seeds (flexibility concerning the species)

(b) GM plant material (flexibility concerning the plant part analysed)

(c) Differently processed products (flexibility concerning the processing type)

Flexibility concerning the GM event

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Allowing changes of the GM event to be quantified

Level of flexibility depending on the qPCR method

(a) changing taxon-specific target
(b) changing event-specific, taxon-specific target

Example:

Fixed scope – MON 810

Flexible scope –

(a) quantification of GM maize (flexibility concerning the events in maize)

(b) quantification of GM species (flexibility concerning the events independent of the species)

Flexibility concerning the analytical procedure

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Allowing changes of the analytical procedure

Level of flexibility can concern the DNA extraction method and/or the qPCR chemistry

Example:
Fixed scope – CTAB, Taqman chemistry
Flexible scope –
(a) flexibility concerning the DNA extraction method
(b) flexibility concerning the qPCR chemistry

Adjusting the DNA extraction method

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DNA extraction method:

Method performance improvements in terms of
(a) higher DNA yield
(b) better DNA quality
(c) ability to cope with processed samples
typically concerns sample intake, sample preparation or clean-up procedure for a specific matrix

Note: Adjustments of the analytical procedure require validation

Adjusting the qPCR method

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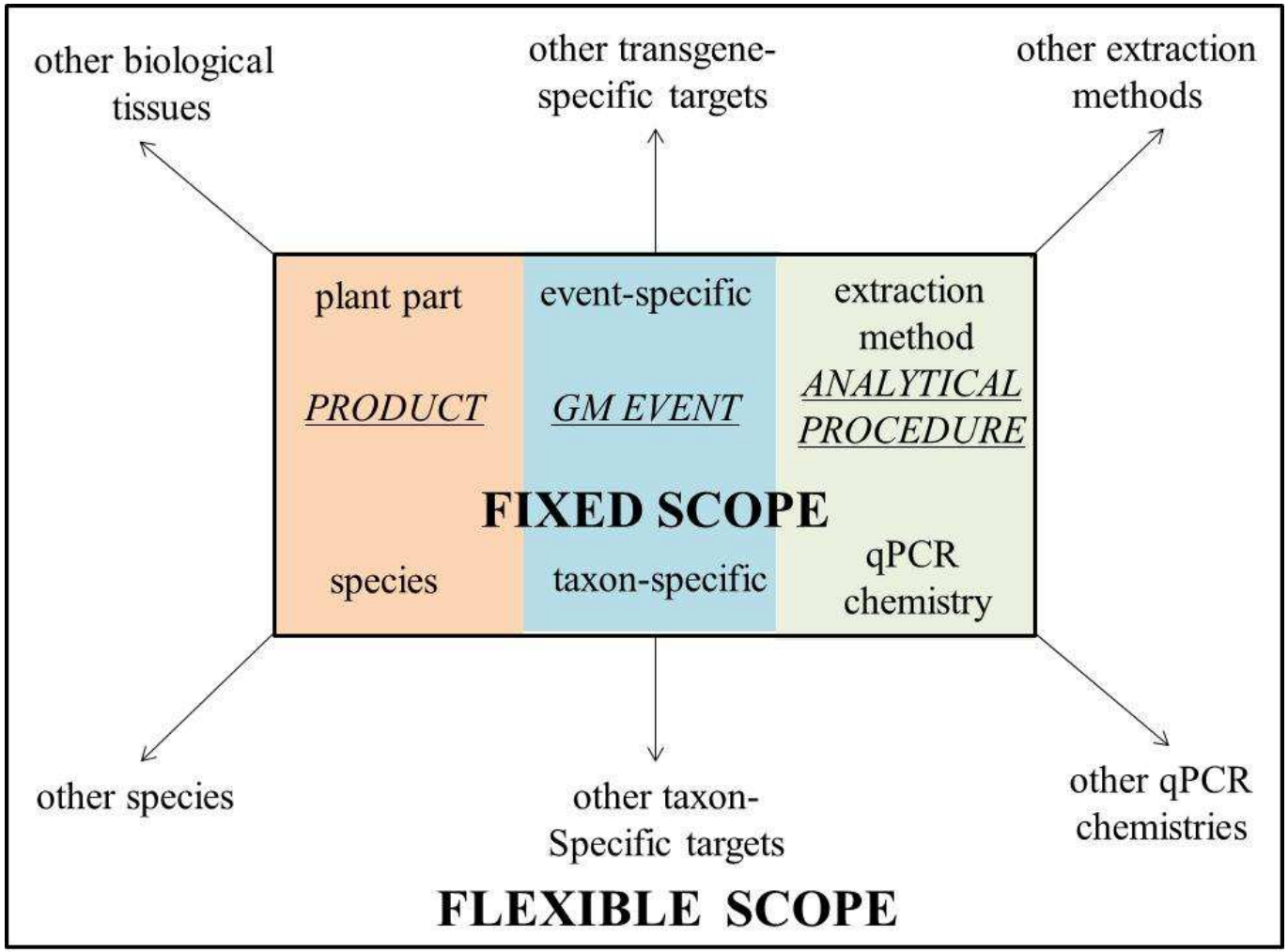
qPCR method:

Method performance improvements in terms of
(a) PCR efficiency
(b) PCR linearity
typically concern changes in the PCR annealing temperatures, in the primer or probe concentrations, changes in the nature of the fluorescent probes and quenchers.

Note: Adjustments of the analytical procedure require validation

Categories allowing flexibility



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Section 4 Laboratory Sample preparation

ISO/IEC 17025 ISO/IEC 17025, Section 5.4

(homogeneity and representativeness)

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Aspects to be taken into account:

- homogeneity of the laboratory sample;
- representativeness of the analytical sample and test portion with regard to the laboratory sample;
- measures to avoid cross-contamination have to be taken by the laboratory (ensuring premises are compliant, including dusting and cleaning).

General recommendations:
ISO 21571:2005 *Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Nucleic acid extraction*
ISO 24276:2006 *Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions*

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Section 5 Method verification and MU

ISO/IEC 17025 ISO/IEC 17025, Section 5.4.5 and 5.4.6

(verification parameters and estimation tools)

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General considerations:

- management system ensuring adequate qualification and training of staff;

- metrology system ensuring periodical calibration of equipment;

- method verification demonstrating that the laboratory is meeting the performance characteristics.

ENGL guidance documents:

ENGL (2008) *Definition of minimum performance requirements (MPR) for analytical methods of GMO testing*, http://gmo-crl.jrc.ec.europa.eu/images/pdfdoc.gif

ENGL (2011) *Verification of analytical methods for GMO testing when implementing interlaboratory validated methods*, http://gmo-crl.jrc.ec.europa.eu/doc/ENGL%20MV%20WG%20Report%20July%202011.pdf

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Method verification parameters:

- sample preparation;
- DNA extraction;
- DNA concentration;
- absence of PCR inhibitors
- specificity;
- Linear range, coefficient of determination and amplification efficiency;
- trueness;
- Relative repeatability standard deviation;
- limit of detection;
- limit of quantification.

ENGL guidance documents:

ENGL (2011) *Verification of analytical methods for GMO testing when implementing interlaboratory validated methods*, http://gmo-crl.jrc.ec.europa.eu/doc/ENGL%20MV%20WG%20Report%20July%202011.pdf

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Section 9 Proficiency Testing

ISO/IEC 17025 ISO/IEC 17025, Section 5.9

(level of participation and PT strategy)

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Aspects to be taken into account:

- PTs are planned activities;
- Strategy forms part of the overall quality assurance;
- Strategy should cover at least one accreditation cycle.

Relevant documents:
EA-4/18 (2010) *Guidance on the level and frequency of proficiency testing participation*, http://www.european-accreditation.org/n1/doc/EA_4-18.pdf
ILAC-P9:11/2010 *ILAC policy for participation in proficiency testing activities*, http://www.ilac.org/documents/ILAC_P9_11_2010.pdf

Further (selected) information

European technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs
(will be published soon as JRC scientific and policy report)

EA guidance documents:
http://www.european-accreditation.org/publications

ILAC guidance series:
https://www.ilac.org/guidanceseries.html

ISO documents:
General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)

and many more……

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Thank you for your attention

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