EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

Training Workshop on
"Practical aspects of regulatory GMO testing"
Ispra, 25-27 March 2015

PROGRAMME

DAY 1 (Wednesday 25 March 2015)

Morning: 9:00 – 12:30 (incl. coffee break 10:30-11:00)

General welcome and training programme introduction (M. Querci)

Participant's presentation

Introduction to the EC JRC, European legislative context in relation to GMOs and/or their products in food, feed or seed, the EU-RL GMFF, the BTSF-MBG Unit Project (M. Querci)

GMO Testing: Objectives, implementation and strategies (M. Querci)

Lunch break: 12:30-14:00

Afternoon: 14:00 – 17:30 (incl. coffee break 15:45 – 16:00)

Presentations on general concepts related to Quality Management and implementation of GMO testing laboratory (overview on ISO technical standards and the accreditation guide) (M. Schulze)

- Lab set-up requirements and lab environment (ISO 24276)
- Handling of samples and Nucleic acid extraction (ISO 21571)
- Qualitative nucleic acid based methods (ISO 21569)
- Quantitative nucleic acid based methods (ISO 21570)

Practical example (G. Moris):

- Review of the "critical quality points" encountered during an analysis

17:30 End of Day 1

DAY 2 (Thursday 26 March 2015)

Morning: 9:00 – 12:30 (incl. coffee break 10:30 – 11:00)

Design & implementation of analytical flow for GMO analysis (G. Moris)

- Experimental design and selection of methods in practice according to the purpose of the analysis
- Implementation of (EU-RL GMFF) validated PCR-methods in an enforcement lab (Method's performance & Method's verification)
- Measurement uncertainty according to the accreditation guide and reporting of results

Unauthorized GMOs, what to do?

- Bioinformatic "excursions" for characterisation of unauthorized GMOs (M. Petrillo)
- Practical example of the detection of EU unauthorized GMOs (G. Moris)

Lunch break: 12:30 -14:00

Afternoon: 14:00 – 17:30 (incl. coffee break 15:45 – 16:00 pm)

Group work (A) + laboratory visit.

The +/- 30 training participants are sub-divided in 4 groups. In this session groups 1 + 2 will proceed with the practical exercise while groups 3 + 4 will visit the EU-RL GMFF laboratory.

Practical Exercise: experimental design, methods selection, analysis of results and reporting

- Matrix approach in GMO analysis (A. Angers)
- *Introduction to the Practical Exercise* (A. Angers)

Phase 1: Each group will receive two unknown samples with some background information, e.g. sampling origin, the labelling of the sample or list of ingredients or information on accompanying documents. The group has to decide the analytical approach (which species should be checked, which GM events should be checked by which methods), select the methods and set up the plan of analysis including considering quality management aspects as reference materials needed.
Phase 2: According to the selection a set of "analytical results" will be provided to the group. The group has to interpret the results and compile the test report.

Visit to the EU-RL GMFF laboratory*: participants will be able to visit the EU-RL GMFF laboratory and discuss with laboratory staff on lab design, work flow including handling of samples as well as handling of reference materials, instruments maintenance and calibration issues. Each group has to write the most important information their got as findings.

17:30 End of Day 2

*** Visit to the EU-RL GMFF laboratory**

Detailed programme

FG Francesco Gatto, SR Sabrina Rosa, PR Patricia Rischitor, MP Mauro Petrillo, SP Steven Price

<table>
<tr><th colspan="2">Group 1 (3)</th><th colspan="2">Group 2 (4)</th></tr>
<tr><td rowspan="5">Lab visit
Grinding room (bdg 20): organisation of the area, equipment …
DNA extraction Room 20A: DNA extraction/quantification/CRM stock /DNA dilutions for Inhibition run
Gel electrophoresis for genomic DNA analysis: Evaluation of the quality of genomic DNA,
Media preparation Room: overview of the area
Mix preparation room: Primer/probe management and mix preparation
PCR set up area (Inhibition run/Screening/identification/qPCR)
PCR instrument (qPCR run view and bias control)
~ 1h 30min</td><td rowspan="5">FG - SR</td><td>NGS: setup of NGS experiments.
~ 20min</td><td>MP</td></tr>
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overview of main applications (zygosity estimation, dynamic array, …) ~ 20min</td><td>PR</td></tr>
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<tr><td colspan="4">~ 30min Q&A, preparation of notes for the debriefing session of DAY 3</td></tr>
</table>

DAY 3 (Friday 27 March 2015)

Morning: 9:00 – 12:30 (incl. coffee break 10:30-11:00)

Group work (B) + laboratory visit.

As defined for afternoon day 2

In this session groups 1 + 2 will visit the EU-RL GMFF laboratory while groups 3 + 4 will proceed with the practical exercise.

Lunch break: 12:30-14:00

Afternoon: 14:00 – 16:00

Each group reports to the others (PowerPoint slides or draft report) on its findings (10 min/group incl. Q&A) + debriefing from "team coaches"

Combination of Requirements for Proper Operation of a Control Laboratory (M. Querci, M. Schulze, G. Moris)

AoB: Discussion on topics of interest to the participants and/or emerged during the training

Conclusions: wrap-up on key learning from the training + feed-back from participants

16:00 End of training programme

Tutors
Maddalena Querci
Manuela Schulze
Gilbert Moris
Alexander Angers
Mauro Petrillo
Peter Henriksson
Francesco Gatto
Sabrina Rosa
Valentina Paracchini
Patricia Rischitor
Steven Price

Supporting documents

- *Guidelines for implementation of a quality system in a GMO testing laboratory and European Technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs)*

- *Verification of analytical methods for GMO testing when implementing interlaboratory validated methods. (JRC S&T Report) EU-RL GMFF / ENGL Guidance document*

- *ISO Standards useful for GMO Analysis*
  - *ISO 24276 General requirements and definitions*
  - *ISO 21569 Qualitative nucleic acid based methods*
  - *ISO 21570 Quantitative nucleic acid based methods*
  - *ISO 21571 Nucleic acid extraction*

- *EU-RL GMFF General procedures + SOPs*