

Inspection and enforcement of contained use and deliberate release of genetically modified organisms

Central Science Laboratory, Sand Hutton, York, YO41 1LZ, UK

Start time daily: 09.30

Finish time daily: approx. 17.00

Trainees: Maltese Environment Protection Directorate.

Summary of course content (timetable is deliberately flexible):

Monday 29/11/04.

1. GMO legislation – deliberate release

Topics covered:

The legislation that underpins the regulatory process in England; the Environmental Protection act and the Deliberate Release (GMOs) Regulations. The enforcement powers of a GM Inspector and what this means in practical terms. The importance of clearly defined enforcement procedures. Standard operating procedures (SOPs). What happens when there are infringements of authorisations to release a GMO? Legal support.

2. Statistics of sampling for GMOs

Topics covered:

Why it is important to ensure that samples taken for analysis for presence of contaminants must be representative samples. Distribution within consignments. The principles that underpin taking a representative sample from a consignment. How the total size of the consignment makes a difference to the sampling regime. Sampling to detect GMOs in very large consignments. Different sampling regimes for different commodities. Confidence limits. Effect of sampling on sensitivity of GMO testing methods. Stats of GM enforcement.

3. Sampling seed and grain

Topics covered:

Practical aspects of seed and grain sampling. Sample sizes. Frequency of sampling. Products usually sampled. Methods of sampling. Sampling large consignments of grain. KeLDA project. Implementation of 1829/2003 and 1830/2003 in UK.

Tuesday 30/11/04.

4. Deliberate release of GMOs: field inspection

Topics covered:

Content of consents to release a GMO (part B and part C) and problems commonly encountered with consents. Examples of consents. The conditions that are applied to consents and why these vary for different crops. Inspection of part C authorisations. Good agricultural practice and why is it important. The role of the GM Inspectorate in ensuring that the consent holder is complying with the conditions. Farm scale evaluation trials. Growing crop inspections. Checklists and SOPs. Field inspector's handbook. Monitoring the release site after the trial. Taking and storage of enforcement samples. The reporting process. Identification of an infringement.

5. Deliberate release of GMOs: field inspection visits and reporting process

Topics covered:

You will be given summaries of two consents to release a GMO and asked to undertake field inspections at two release sites. You will be asked to say whether the sites comply with the conditions laid down in the consent and write a report for the regulatory authority.

Wednesday 01/12/04.

5. Deliberate release: field inspection visits and reporting process (continued)

6. Field inspection programme: management audit

Topics covered:

What is a management audit and why is it done. Checklists and SOPs. Management procedures, chains and protocols. Duty of care and why it is important. How to establish that the consent holder has demonstrated duty of care in releasing the GMO. Timing of management audits. Reporting process.

7. Contained use of GMOs

CU Legislation. Design of CU facilities. Monitoring and Inspection of GMOs in contained use. Risk assessments and emergency plans. Enforcement procedures. Reporting methods.

Thursday 02/12/04.

8. Audit for GM presence - authorised and unauthorised

Topics covered:

Why does the GM Inspectorate audit conventional seed that is marketed in the UK? Principles of auditing. What does adventitious GM presence mean and how might it occur in conventional seed? What crops are included in the CSL audit and why. What information does the Inspectorate look for when auditing for adventitious presence. Guidance, SOPs and seed audit forms. Seed audit handbook. Production assurances. The key elements of PCR testing for GMOs. Thresholds for GM events in seed. What happens if an adventitious GM presence is identified. The reporting process.

You will be given three scenarios of information provided at an audit to work through and provide reports on.

Friday 03/12/04.

8. Audit for GM presence - authorised and unauthorised (continued)

9. Enforcement testing and detection of GMOs (not lab-based)

Detection of GMOs & interpretation of results. Laboratory accreditation. Forensic methods for detection of unknown GMOs. Monitoring for GMOs. Monitoring gene flow.