OCR
Oxford Cambridge and RSA

Thursday 18 January 2024 – Afternoon

Level 3 Cambridge Technical in Applied Science

05874 Unit 22: Global scientific information

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INSTRUCTIONS

- Do **not** send this Insert for marking. Keep it in the centre or recycle it.

INFORMATION

- This Insert contains the pre-release material you have already seen.
- This document has **8** pages.

Pre-release research brief

You should carry out your own research on the themes given in this research brief. Your research will help you to prepare for your exam.

Your research is only for your own use. You must not bring your notes into the exam.

A clean copy of this research brief will be provided in the exam.

In your research you should consider the following themes:

- Categories of information holder
- Impacts on stakeholders
- Location of scientific information
- Quality management of scientific information
- Reasons for transmission of scientific information

The questions in Section A of the exam will require you to draw on the knowledge and understanding which you have gained while researching these themes.

Instructions:

Read the following two pages of information.

Carry out your own research on the themes given above.

Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety

The Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety [1] was published on 25 April 2022.

A Living Modified Organism (LMO) is defined as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

The Cartagena Protocol is an international agreement established during a Convention on Biological Diversity. This convention was originally scheduled to take place in Cartagena, Colombia in 1999 (but was rearranged to Montreal, Quebec in 2000). [2]

The main objective of the Cartagena Protocol is:

“to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements”.

The purpose of the Protocol is to establish rules and procedures for the safe handling, transfer, and use of LMOs.

Detection and identification of LMOs is a vital element in contributing to the implementation of the objectives of the Protocol.

The Biosafety Clearing-House (BCH) [3] is a mechanism set up under the Cartagena Protocol on Biosafety to facilitate the exchange of information on LMOs and assist Parties to the Protocol in better complying with their obligations. The ‘Parties’ are represented by the different countries forming the international agreement.

The BCH provides open and easy access to a variety of scientific, technical, environmental, legal and capacity-building information. The BCH contains the information that must be provided by Parties to the Protocol, such as decisions on release or import of LMOs, risk assessments, competent national authorities, and national laws.

Countries that are not Parties to the Protocol are also encouraged to contribute information to the BCH, and, in fact, a large number of the decisions regarding LMOs have been registered in the BCH by non-Party countries.

The records of country decisions, risk assessments, LMOs, donor and recipient organisms, and genetic elements are cross-referenced in such a way as to facilitate data retrieval. For instance, while looking at an LMO record, all the records for the decisions that reference that specific LMO can be easily accessed and retrieved. In addition, links to available detection methods from external websites, such as from the industry trade association ‘CropLife’ [4] and the European Union Reference Laboratory for Genetically Modified Food and Feed [5], are also accessible through the LMO records.

The BCH also contains other relevant information and resources, including information on national contacts, capacity-building, a roster of government-nominated biosafety experts and links to other websites. Publications are made available as Biosafety Virtual Library Resources.

SSRW Life Sciences

Stan Walters is a laboratory manager at SSRW, a life sciences company which provides a range of analytical testing services to clients across multiple industries. Stan's company can provide many of the methods and techniques that are described in Modules 2, 3 and 4 of the Training Manual.

Stan is keen to ensure that SSRW has a laboratory management system that is compliant with the Quality Assurance/Quality Control Standards (QA/QC) described in **Module 5 of the Training Manual (pages 111–126)** and meets the minimum performance criteria required for accreditation.

Some of these minimum performance criteria include:

- a laboratory documentation system
- sample tracking and personnel.

For example a system for the documentation of laboratory activities includes but is not limited to standard operating procedures for:

- the different methods used to process samples
- equipment used to process samples
- the preparation of reagents used to process samples.

In addition, information relating to the samples to allow for complete traceability include:

- reagent preparation and reagent lot numbers
- temperature controlled equipment e.g. fridges/freezers and incubators
- maintenance and verification/calibration of equipment
- raw data for samples and controls
- the final report for the result of the analysis.

After reading the Training Manual, Stan Walters identifies **three** priorities for the QA/QC standards:

1 **Sample tracking and personnel training:**
- ensure policies and procedures meet minimum performance criteria (refer to **page 114** of the Training Manual).

2 **Equipment maintenance logbook:**
- ensure that the checklist of information kept is thorough (refer to **page 116** of the Training Manual).

3 **Reagent quality control:**
- ensure there is a thoroughly documented procedure (refer to **pages 116-117** of the Training Manual).

[1] A copy of the Training Manual can be obtained here: https://bch.cbd.int/en/database/VLR/BCH-VLR-SCBD-260177

[2] Convention on Biological Diversity: https://bch.cbd.int/protocol/background/

[3] BCH – Biosafety Clearing House: https://bch.cbd.int/en/

[4] CropLife: https://croplife.org/

[5] European Union Reference Laboratory for Genetically Modified Food and Feed: https://gmo-crl.jrc.ec.europa.eu/

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