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Quality assurance in food microbiology — a novel approach

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Abstract

The introduction of quality systems as a requirement of laboratory accreditation is causing microbiologists to review current practices. The need for Quality Assurance (QA) in food microbiology is of growing importance and this paper presents a novel approach to implementing QA based on a system which is analogous to the Hazard Analysis Critical Control Point approach adopted by the food industry. The basis of the QA system is the recognition of Quality Assessment Points (QAPs). Several Quality Control and monitoring practices are suggested for each of the QAPs with the overall aim of developing a Total Quality Assurance system for food microbiology laboratories. © 1998 Elsevier Science B.V. All rights reserved.

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1. Introduction

Food producers and the manufacturing industry are embracing Total Quality Management (TQM) as the way to ensure quality of service or product. For food microbiologists TQM should be translated into Total Quality Microbiology. There are a number of legislative pressures on modern food testing laboratories which are demanding implementation of TQM. The Official Control of Foodstuffs Directive (Anon., 1989a) is a framework directive for the establishment of the single market and in order to ensure safety of food products this has been supplemented with the Additional Food Control Measures Directive (Anon., 1993). This latter document introduces the concept of official laboratories which must be accredited, use validated methods and must participate in approved proficiency testing schemes.

Many countries have accreditation bodies and some are linked via a scheme known as the European co-operation for Accreditation of Laboratories (EAL). There is a multilateral mutual recognition agreement (MLA) amongst accreditation bodies who have to meet the requirements of the EN 45003 standard (Anon., 1995a). Examples of some of these bodies or agencies are given in Table 1. To become accredited by these bodies, testing or calibration laboratories must meet the standards laid down in EN45001 (Anon., 1989b) and ISO/IEC Guide 25 (Anon., 1990). In the UK these are embodied in the National Accreditation of Measurement and Sampling (NAMAS) accreditation standard M10 and

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Table 1
Accreditation bodies which are part of the European Accreditation of Laboratories (EAL) — Multilateral Mutual recognition Agreement (MLA)

Country	Accreditation body
Denmark	DANAK
France	COFRAC
Germany	DAP
Ireland	INAB
Italy	SINAL
Netherlands	RvA
Sweden	SWEDAC
UK	UKAS (previous name NAMAS)

regulations M11. Guidance on how to meet these requirements in food testing laboratories has been explained comprehensively by Wilson and Weir (1995). Furthermore, to attain Total Quality Microbiology a systematic approach is required and a detailed account of the quality control needs for food microbiology has been described by Bolton (1998).

First the terms Quality Assurance and Quality Control must be clearly defined and understood.

Quality Assurance is: all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Quality Control is: the operational techniques and activities that are used to fulfil requirements for quality.

2. The approach

Hazard Analysis Critical Control Point (HACCP) is now well established internationally as the approach which must be implemented to ensure production of safe food (ICMSF, 1988; Codex, 1993). The basic principles of this system are compared with the appropriate Quality Assurance requirements in food microbiology in Table 2. The key steps are:

(i) To produce a flow diagram of the process as shown in Fig. 1.
(ii) To identify Quality Assessment Points (QAPs). These are the points in the process which need critical assessment and control.
(iii) To define the quality control or monitoring activities. These may be visual, physical, chemical or microbiological procedures.
(iv) To identify verification procedures.

2.1. Quality assessment point 1 — sample

The quality of the final result and the ability to interpret the microbiological findings is dependent on the quality of the sample tested. To ensure that the sample is of the quality required it should be taken in accordance with the recommendations of the ICMSF (1986). Samples should be accompanied by the correct documentation, all relevant details recorded and the condition of the sample determined. It is

Table 2
Comparison of the steps in the HACCP system and the approach to developing a Quality Assurance programme in food microbiology

Steps for HACCP	Steps for Quality Assurance
Assemble a HACCP Team	Assemble a quality team
Description of the product	Not relevant
Identification of intended use	Not relevant
Flow diagram of total food process	Flow diagram of Food Microbiology process
On site confirmation of flow diagram and facility	Confirmation of flow diagram and designated laboratory space
Listing of hazards	Identification of quality needs
Establish Critical Control points (CCPs)	Establish Quality Assessment Points (QAPs)
Establish monitoring system for each CCP	Establish quality control and monitoring activities for each QAP
Establish corrective actions	Establish response to failures
Verification procedures	Verification procedures
Documentation and record keeping	Documentation and record keeping

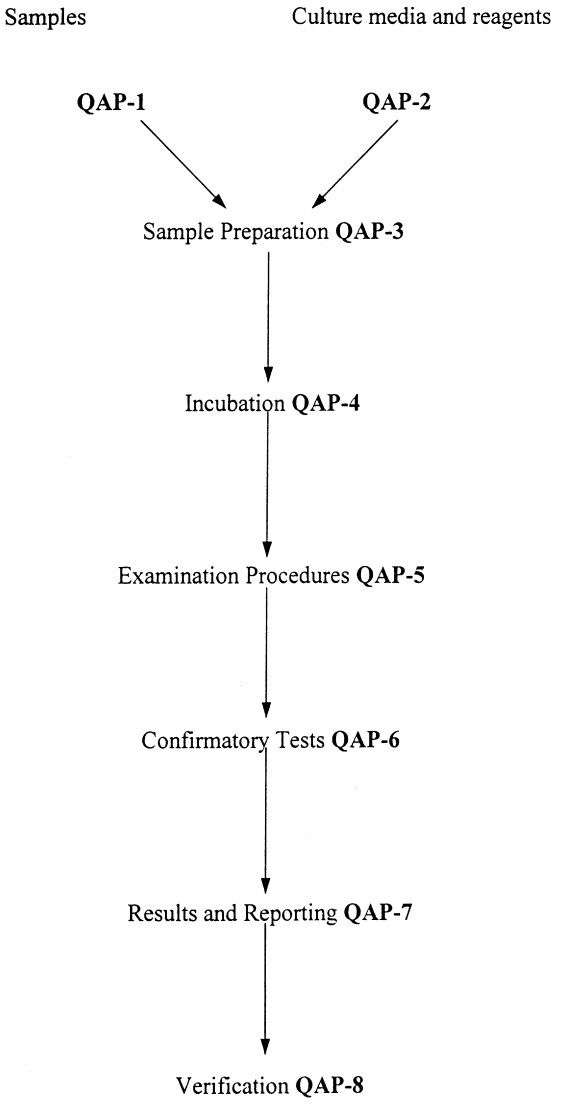

Fig. 1. Typical food microbiology process and the associated Quality Assessment Points (QAPs).

imperative that samples are stored correctly prior to testing to prevent any changes in the microbiological status.

2.2. Quality assessment point 2— culture and reagents

At this point all culture media should undergo Quality Control (QC) checks before release. Media may be assessed for productivity, selectivity, colonial morphology, sterility, pH and appearance. There are numerous approaches to media QC but those detailed by the Working Party on Culture Media of the International Committee on Food Microbiology and Hygiene (ICFMH) are appropriate (Corry et al., 1995). It is important at this stage to use reference cultures from national or international collections to ensure traceability. For laboratories who wish to use ready poured media then these should be obtained from ISO9000 approved suppliers who should also provide Quality Control certificates.

2.3. Quality assessment points 3 and 4 — sample preparation and incubation

Both of these QAPs require physical QC checks to ensure performance of equipment. At QAP-3 calibration of equipment, and performance checks (mass, time, volume) are important to ensure correct sample preparation. Errors at this stage, if unnoticed, can be multiplied at later stages in the process and lead to inaccurate results. At QAP-4 the key QC activities are related to physical monitoring of equipment. New equipment should be commissioned before use and thermometers used for monitoring temperatures should be calibrated and traceable to national standards. Daily monitoring checks and regular cleaning and maintenance schedules are essential to ensure satisfactory performance of in use equipment.

2.4. Quality assessment point 5 — examination procedures

Microbiologists consider this one of the most important QAPs in the food microbiology process. If methods are documented in the form of standard operating procedures and are based on reference or standard methods then the important aspect is Internal Quality Control. The problem is what to do, when to do it and how frequently to do it. Internal QC may be undertaken by using combinations of the following: duplicate samples, reference materials and artificially inoculated natural samples.

Duplicate samples, should be tested by more than one analyst and give an indication of the overall performance and consistency of the results. This approach is satisfactory for total viable count, coliform and *Escherichia coli* methods when there is a reasonable chance that these organisms are present

in the naturally contaminated samples. The main disadvantage is that examination of duplicate samples is not suitable for regular internal QC of pathogen detection methods due to the low frequency of naturally occurring positive samples. The alternatives for pathogen detection are to use the reference materials provided by the RIVM (Bilthoven, The Netherlands) (Janning et al., 1995; In't Veld et al., 1996) or to use artificially inoculated natural samples. The latter has the advantage that critical levels of the target organism can be added to a food product (preferably the same type of food as that under examination) which contains natural background flora.

The frequency of QC testing is dependent on the number of samples processed, the number of staff involved and the frequency of use of a particular method. As a guide, duplicate sampling could be performed daily, internal QC with reference materials and artificially inoculated samples weekly or monthly. There are no fixed rules but the laboratory should implement a system which provides confidence in the methods used. It is probably useful to perform more frequent internal quality control checks when implementing the system and to review the needs later.

2.5. Quality assessment point 6 —confirmatory tests

Many laboratories perform confirmatory tests for indicator organisms and pathogens. It is important to use positive and negative controls for each test and to use reference organisms for this purpose. Many commercial identification kits are available for confirmation ranging from biochemical profile kits to immunoassay tests. These also require appropriate internal QC procedures but the frequency will depend upon the use, storage and shelf life of the product.

2.6. Quality assessment point 7 — results and reporting

Having performed the tests and recorded the results it is important to check calculations and potential transcription errors. The final report should also be checked to ensure that it meets the quality standards specified by the laboratory and the accreditation body.

2.7. Quality assessment point 8 — verification

As with the HACCP system the verification stage is important to ensure QA. The following examples are important verification procedures.

(i) An Internal Failure Reporting system (IFR) should be introduced so that system failures, media or reagent failures etc. can be recorded. Appropriate action can then be taken and documented to confirm that the quality system is under control.

(ii) It is essential to participate in proficiency testing schemes so that the laboratory performance can be assessed independently.

(iii) Finally, a system for auditing the quality system and of reviewing the findings will convince external agencies that the system is operating successfully.

2.8. Microbiology staff

The above approach can only function successfully if staff are involved and understand the principles of the quality system approach. It is important that staff are appropriately qualified, have been trained to the laboratory procedures, are competent to perform the microbiological tests and are able to continue their professional development.

This approach if implemented, maintained and fully documented will produce Total Quality Microbiology and should satisfy the major requirements of accreditation bodies.

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