

<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Laboratory Testing (external) management	<i>Approved by:</i>	
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SCOPE: This procedure applies to employees who are responsible for laboratory testing externally.

PURPOSE: This procedure describes the monitoring production quality by laboratory testing.

RESPONSIBILITY: It is the responsibility of the management to ensure that the following procedures are adhered to and understood by all relevant personnel and the personnel follow State or local health department requirements.

The management is responsible for establishing a quality testing program. The Manager is responsible for ensuring that testing samples are submitted.

INSTRUCTIONS:

INTRODUCTION

1. Food, water and environmental samples (e.g. swabs) may be used as evidence supporting formal enforcement action and/or prosecutions by local authorities or other agencies. It is essential that laboratories have systems in place to ensure that there is an unbroken chain of evidence (continuity of evidence) for that sample and associated documentation from sample transport (if applicable), receipt, through reception, examination and reporting to destruction.
2. Under the terms of the Official Control of Foodstuffs Directive (89/397/EEC) and the Additional Measures Food Control Directive (93/99/EEC) Official Food Control Samples can only be examined by Official Food Control Laboratories. These laboratories are accredited on a method-by-method basis to detect pathogenic microorganisms and indicator organisms routinely determined in food.
3. In certain circumstances, such as where food fails to comply with food safety requirements, or during the investigation of a food poisoning outbreak, authorised sampling officers may wish to submit food samples with the intention that formal enforcement action and/or legal proceedings may ensue if an adverse result is obtained following microbiological examination (hereafter termed formal foods in this document).

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DEFINITIONS

1. Formal sample

A formal sample is defined in the Food Safety Act as any sample (food or swabs) that is taken with the intent that the results will be used to support formal enforcement action and/or prosecution if an adverse result is obtained from the analysis/examination. The sample should be submitted to the Food Examiner at a laboratory accredited for the purpose of examination and which appears on the official list. These samples must be taken in compliance with the Food Safety (Sampling and Qualifications) Regulations 1990 and The Food Safety Act (as amended) Code of Practice 7

Samples which are not taken in compliance with COP 7, i.e. they are taken under the provisions of alternative regulations with specific sampling regimes or when the samples in themselves constitute an offence (e.g. past sell by dates), are not designated as “formal samples.”

Examples of samples that are not covered by the Act include:

- Those samples of food that are the subject of a complaint and are brought to the authority by consumers or other outside agencies
- Samples of food that are submitted to the Food Examiner for monitoring or surveillance purposes alone, i.e. there is no intention at the time of sampling that any enforcement action will ensue from the result
- Samples of food procured under the Act which are not taken for analysis or examination e.g. samples submitted for expert opinion etc
- Samples of food that are taken as evidence in their own right eg use by dates
- Samples that are taken under the provisions of Regulations that have their own detailed sampling provisions and are listed in the Schedule of the Food Safety (Sampling and Qualifications) Regulations 1990

2. Outbreak/food poisoning samples

Samples submitted in the early part of an outbreak/food poisoning investigation are not strictly formal samples but the results may be presented to a court. For this reason it is advisable to treat and process such samples in the same way as formal samples.

PRINCIPLES

1. Samples for examination should, as far as possible, reach the laboratory “in a condition microbiologically unchanged from that existing when the sample was

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taken” .It is essential, therefore to be able to verify the precise conditions of sampling, transport, storage, and examination at all stages. This will require vigorous attention to temperature control, prevention of cross-contamination and thorough accurate documentation.

RESPONSIBILITIES OF THE SAMPLING OFFICER

1. All documentation i.e. request forms, labels etc. should be thoroughly and clearly completed before submission of the sample to the laboratory. Failure to complete the documentation or obtain samples in the specified manner may render an item invalid as a formal sample under the terms of the Act.

2. **Laboratory Notification**
When it is anticipated that a formal sample is to be taken, it is desirable that the sampling officer should notify the Food Examiner in advance to get advice on appropriate samples and sampling technique if required and to ensure prompt receipt and handling.

3. **Sampling**
Unpacked or opened samples should be sampled by an authorised officer using sterile instruments, at the premises concerned, and submitted in sterile, leak-proof, food quality plastic jars or bags. The contained sample should be secured with a tamper-evident seal and labelled, specifying the name of the food, any batch details (e.g. use by dates), the sampling officer and enforcement authority, the place, date and time of sampling and an identification number. The sample may then be placed in a second container e.g. a plastic bag sealed again with a tamper-evident seal. If dummy or sacrificial samples are to be submitted for temperature monitoring purposes they must be clearly marked as such to avoid any confusion.

4. **Sample size**
The quantity of the sample should, where possible, be at least 100g to sampling to ensure that there is adequate sample for the number and type of tests necessary.

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5. Transport

Samples should be securely transported under conditions which minimize as far as possible any changes in microbial numbers i.e.: frozen foods kept frozen, chilled/perishable foods at 0 to 8°C and preferably 0-5°C and other items e.g. ambient shelf stable, canned and dried samples at temperatures not exceeding 40°C

. Hot and cold foods should be transported in separate cool boxes.

Samples should be delivered, directly by the authorised officer where possible, to the laboratory without undue delay

SAMPLE RECEIPT AT THE TESTING LABORATORY

1. Where a formal sample is received in a laboratory other than that at which it is to be examined, it is important that details of receipt and transfer of the sample including signatures of the sampling officer or courier are thoroughly documented together with any other relevant documentation (e.g. cool box identification labels) and that the continuity of the chain of evidence (including temperature control details) is rigorously maintained and monitored.
2. On arrival at the examining laboratory, the sample should be received in person, by a Food Examiner or an appropriately trained and competent member of laboratory staff.
3. Details on the form and sample should be checked and the temperature of the sacrificial, dummy sample or the air immediately adjacent to the sample should be taken and recorded on the request form or use the simulated sample in the cool box to take temperature. To avoid contamination the sample itself must not be probed.
4. The appearance, integrity and condition of the sample and its packaging as received should be recorded. The sample should not be removed from its packaging for this purpose. Any non-conformances should be noted on the request form and relayed to the sampling officer. It is advisable to photograph the sample, as received, whenever possible.

Note: The Foods Standards Agency aim to put photographs of products to be withdrawn on the Food Hazard Warning as an aid to identification.

The forms should be signed by the sampling officer/courier submitting the sample and the person receiving the sample, also recording the date and time. If it is apparent that the sampling criteria detailed in section 4 have not been met,

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the item cannot be accepted as a formal sample, although it may still be tested informally. A Food Examiner may advise resubmission of a similar sample.

Note: It is extremely important that the form is completed correctly.

5. The sample reference number and request form are to be labelled with a unique reference number. All sample details should be recorded in the laboratory day-book and/or entered into the computer system. It is useful to give samples from an investigation a common I (incident) log number to facilitate preparation of Food Certificates at a later stage.
6. If there is any delay before commencement of the required microbiological examination, the sample should be held at an appropriate temperature, which should be recorded, according to a documented procedure.
7. A Food Examiner should be informed of the receipt of a formal sample as soon as possible so that they may verify the sample details and take steps to supervise its further handling and examination.
8. A Food Examiner should establish and document the test parameters required and specify the methods of examination specified for the sample before testing begins.

EXAMINATION OF SAMPLE

1. Examination of formal samples should follow strictly the Standard Operating Procedures for each investigation required. It is important that a person who is trained and has documented evidence that they are competent in the task carries out the agreed tests.
2. The date and time of commencement of the laboratory examination should be recorded on the request form and for all procedures thereafter. The member of staff performing each part of the procedure should sign the record or worksheet on completion of that activity. No elements associated with the test procedure, i.e. plates, tubes, etc. should be discarded until the Food Examiner is satisfied that the examination has been carried out appropriately and has agreed to their release. Repeat testing of any sample should not be performed unless specifically asked to do so by the submitting authority in liaison with the Food Examiner e.g. for quantification. If a quantitative count is required subsequent to a positive enrichment culture, the potential effects of storage must be taken into account when interpreting results.

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3. If a portion of the sample is to be sent to another laboratory for special investigations e.g. toxin detection, it should be submitted in accordance with the recommendations of the reference laboratory. The appropriate steps should be taken to ensure the continuity of evidence. All details of transfer and temperature monitoring should be thoroughly and accurately documented.
4. Bacterial cultures referred to specialist reference laboratories for further testing should be carefully labelled and cross-checked and written records kept of their despatch. It is recommended that the cultures be placed inside a plastic bag, which is then secured with a tamper-evident seal before placing in the transport container.
5. Any sample remaining after portions have been taken for examination should be frozen at -20°C in a monitored freezer in a secure area after examination is complete. Samples should not be discarded until any criminal proceedings relating to the case are complete. In the absence of information from the officer submitting the sample, this would normally be for a period of one year or other period agreed in writing with the local authority concerned. Samples should be clearly labelled with all relevant details. Details of storage and disposal of all portions of the sample should be recorded.

REPORTING

1. Verbal reports. Presumptive positive results should be telephoned to the Environmental Health Officer concerned or appropriate team leader as soon as reasonably practicable. HPA Guidance on the procedure for dealing with presumptive pathogens isolated from ready-to-eat foods will be followed when appropriate. Care should be taken to ensure the identity of the person taking the results. It is essential that all results be recorded clearly and accurately. Computer or paper records may be used. All calculations should be checked and full identification of organisms given only when confirmatory tests have been performed.
2. It is unwise to issue a certificate of examination reporting a presence of a pathogen e.g. Salmonella, in a formal food sample until its identity has been definitely confirmed and the isolate characterised by the appropriate reference laboratory, although interim reports may be issued.
3. When reporting bacterial counts, use the words "less than" or "greater than" in preference to abbreviated forms, as these may cause confusion in a legal context.

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4. Comments may be offered by a Food Examiner in accordance with relevant Health Protection Agency or statutory guidance.

CERTIFICATE OF EXAMINATION

1. A certificate of examination is a legal document and may be used as evidence in legal proceedings by the local authority. It communicates the microbiological results of the formal sample. This applies to both positive and negative examination results unless there is a formal agreement in place with the local authority that a certificate of examination is only required for positive (adverse) results.
2. Only accredited tests may be reported on the certificate of examination. Additional (non-accredited) tests may be reported on the laboratory test report. This information may be used when writing the opinion on the certificate of examination.
3. A certificate of examination is for use only by Local Authorities and may be requested by their officers. Food examiners should establish whether a certificate is required and keep documentary evidence that this has been done. Neither the certificate nor the initial report form should be issued to any third party.

DOCUMENTATION

In the event that legal proceedings are taken the Food Examiner is required to compile a witness statement covering the evidence associated with the formal sample. If the Food Examiner has not carried out the testing personally, there are two options depending on the courts requirements. The first is that the Food Examiner prepares the witness statement and indicates that the work was undertaken under my direction. The second is that other staff that have carried out the work may be required to write individual witness of fact statements. The choice of option will be made following discussions with the Local Authority concerned.

DOCUMENTATION RETENTION:

The records applied to this procedure are to be kept on file for a minimum of 3 years.