

# **FOOD STANDARDS AGENCY**

# **GUIDELINES FOR UNDERTAKING**

# **ANALYTICAL SURVEYS**

**Scientific Methods and Laboratory Policy Branch**

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## GLOSSARY

ACMSF .....	Advisory Committee on the Microbiological Safety of Food
ADI.....	Acceptable Daily Intake
AMP .....	Aquatic Monitoring Programme
AOAC.....	Association of Official Analytical Chemists
AQA .....	Analytical Quality Assurance
AR.....	Analysis and Research
COC.....	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
COM .....	Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment
COMARE ....	Committee on Medical Aspects of Radiological Exposure
COMS .....	Communications (Division)
COT .....	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
CPMS .....	Contract & Project Management System
CRM.....	Certified Reference Material
CST.....	Chief Scientists Team
DPA .....	Data Protection Act
EC.....	European Commission
EHO.....	Environmental Health Officer
EIR.....	Environmental Information Regulations
EPPS .....	Electronic Public Procurement System
EU.....	European Union
FAPAS .....	Food Analysis Performance Assessment Scheme
FEPA .....	Food and Environment Protection Act
FEPAS .....	Food Examination Performance Assessment Scheme
FoIA .....	Freedom of Information Act
FoodBASE ..	Food Standards Agency's Open Access Repository
FoodWEB ...	Food Standards Agency's Intranet
FSA.....	Food Standards Agency
FSIS.....	Food Survey Information Sheet
GLP.....	Good Laboratory Practice
HoB.....	Head of Branch
HoD.....	Head of Division
HPA-RP .....	Health Protection Agency Radiological Protection Division
IHRM.....	In-House Reference Material
IQC .....	Internal Quality Control
ISO.....	International Organisation for Standardisation
IUPAC.....	International Union of Pure and Applied Chemistry
JECFA .....	Joint FAO/WHO Expert Committee on Food Additives

LGA.....	Local Government Association
LOD .....	Limit of Detection
LOQ .....	Limit of Quantitation or Determination
MU .....	Measurement Uncertainty
HMD.....	Hygiene and Microbiology Division
PBP.....	Procurement Business Partner
PH.....	Public Health
PO.....	Project Officer
Q&As .....	Questions and Answers
RASFF .....	Rapid Alert System for Food and Feed
RIFE.....	Radioactivity in Food and the Environment Report
SACN.....	Scientific Advisory Committee on Nutrition
SCF.....	EU Scientific Committee for Food (now superseded by the Scientific Committee and Scientific Panels of the European Food Safety Authority)
SMLP .....	Scientific Methods and Laboratory Policy
SOP .....	Standard Operating Procedure
SRQ.....	Survey Requirement
T&Cs.....	Terms and Conditions
TDI.....	Tolerable Daily Intake
TDS.....	Total Diet Study
TRAMP .....	Terrestrial Radiological Monitoring Programme
TSO .....	Trading Standards Officer
UHT .....	Ultra-High Temperature
UK.....	United Kingdom
UKAS.....	United Kingdom Accreditation Service
UKFSS.....	United Kingdom Food Surveillance System
z-score .....	A statistical term relating to a measure of the distance in standard deviations of a sample from the mean

## RELATED GUIDANCE

These are the most up-to-date web links at the time of publication:

<b>Guidance</b>	<b>Location</b>
Freedom of Information Act (2000) and the Environmental Information Regulations (2004)	<a href="http://fsahome/rulesandtools/legislation/Documents/Openness Policy document - FINAL( Legal approved) 210510.docx">http://fsahome/rulesandtools/legislation/Documents/Openness Policy document - FINAL( Legal approved) 210510.docx</a>
Company Contact Points	<a href="http://fsahome/how/science/Pages/surveys_contacts.aspx">http://fsahome/how/science/Pages/surveys_contacts.aspx</a>
Expert Committee Secretariats	<a href="http://www.food.gov.uk/science/ouradvisors/">http://www.food.gov.uk/science/ouradvisors/</a>
Food Standards Agency Approach to Risk	<a href="http://www.food.gov.uk/aboutus/how_we_work/risk">http://www.food.gov.uk/aboutus/how_we_work/risk</a>
Incidents Response Protocol	<a href="http://fsahome/rulesandtools/incidents/Pages/RevisedFSAIncidentResponseProtocol.aspx">http://fsahome/rulesandtools/incidents/Pages/RevisedFSAIncidentResponseProtocol.aspx</a>
Guidelines for Assessing and Acting on Information from Incidents and Surveys	<a href="http://www.food.gov.uk/multimedia/pdfs/assessact.pdf">http://www.food.gov.uk/multimedia/pdfs/assessact.pdf</a>
Food Standards Agency's Openness Code of Practice	<a href="http://www.food.gov.uk/aboutus/how_we_work/copenbranch/">http://www.food.gov.uk/aboutus/how_we_work/copenbranch/</a>
Guidance for the Preparation of a FSIS	<a href="http://fsahome/rulesandtools/communications/Pages/publishing.aspx">http://fsahome/rulesandtools/communications/Pages/publishing.aspx</a>
Food Standards Agency Research Procurement Policy	<a href="http://fsahome/rulesandtools/money/Pages/Procurement.aspx">http://fsahome/rulesandtools/money/Pages/Procurement.aspx</a>
Guidance on Suitable Approaches for the Determination of Measurement Uncertainty	<a href="http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf">http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf</a>
Data Collection, Form Design and Survey Control Procedures	<a href="http://fsahome/rulesandtools/legislation/Pages/SurveyControl.aspx">http://fsahome/rulesandtools/legislation/Pages/SurveyControl.aspx</a>
Food Surveys	<a href="http://www.food.gov.uk/science/surveillance/">http://www.food.gov.uk/science/surveillance/</a>
Accessibility Policy	<a href="http://fsahome/rulesandtools/communications/Pages/accessibility.aspx">http://fsahome/rulesandtools/communications/Pages/accessibility.aspx</a>
HPA National Methods	<a href="http://www.hpa-standardmethods.org.uk/pdf_sops.asp">http://www.hpa-standardmethods.org.uk/pdf_sops.asp</a>
Quality Assurance in Research	<a href="http://food.gov.uk/science/researchpolicy/qacopres/">http://food.gov.uk/science/researchpolicy/qacopres/</a>
ScienceWeb	<a href="http://fsahome/how/science/Pages/default.aspx">http://fsahome/how/science/Pages/default.aspx</a>
Food Surveys Index	<a href="Q:\FSA Shared\UKFSS">Q:\FSA Shared\UKFSS</a>

## INTRODUCTION

1. The Food Standards Agency collects information from non-statutory surveys to form part of the evidence base for the development of food policy. Survey information can help influence the Food Standards Agency's stance in EU discussions; for example in setting new statutory limits on contaminants in food or in reviewing existing limits. The objectives of Food Standards Agency funded surveys are to:

  - protect consumer safety;
  - allow consumers to make informed choices;
  - inform UK negotiations in Brussels and other international meetings;
  - assess the effectiveness of legislation and Codes of Practice;
  - monitor trends both in terms of concentrations and geographical location; and
  - enable consumer exposure assessments to be made.
2. At the time of writing the majority of surveys undertaken by the Food Standards Agency are analytical in nature. That is, they involve physical sampling followed by analysis to yield final results that are then reported to stakeholders. These Guidelines are therefore intended, in the main, to assist staff of the Food Standards Agency in planning, commissioning and conducting analytical food surveys. This notwithstanding, the Food Standards Agency also funds a number of non-analytical surveys (e.g. social surveys based on interviews to explore attitudes and/or behaviours of food businesses or consumers). Guidance on conducting interview-based surveys is beyond the remit of these Guidelines and advice should be sought from statisticians and/or social researchers working in the Analysis and Research (AR) Division. For interview-based surveys directed at local authorities, businesses or farmers, staff are also advised to follow the guidance contained in the following link: <http://fsahome/rulesandtools/legislation/Pages/SurveyControl.aspx>
3. This document provides detailed guidance on the procedures to be followed when carrying out Food Standards Agency funded surveys and is designed to ensure a consistent approach in the reporting of results. Even though this document is a set of 'Guidelines' there are a number of mandatory tasks that need to be undertaken within any survey unless authorisation not to do so has been given by Agency senior management. The mandatory tasks to be undertaken within the survey process are highlighted as **BOXED** text. This notwithstanding, the Agency reserves the right to act more quickly in certain events (e.g. the undertaking of a 'rapid' survey) where the Agency needs to act rapidly to respond to issues of current concern.
4. A flow diagram showing the various stages of a survey can be found at Figure 1 and target timeframes are given in Table 1. Annexes 7 and 8 of these Guidelines

describe theme specific issues where a deviation from the core guidance may be required.

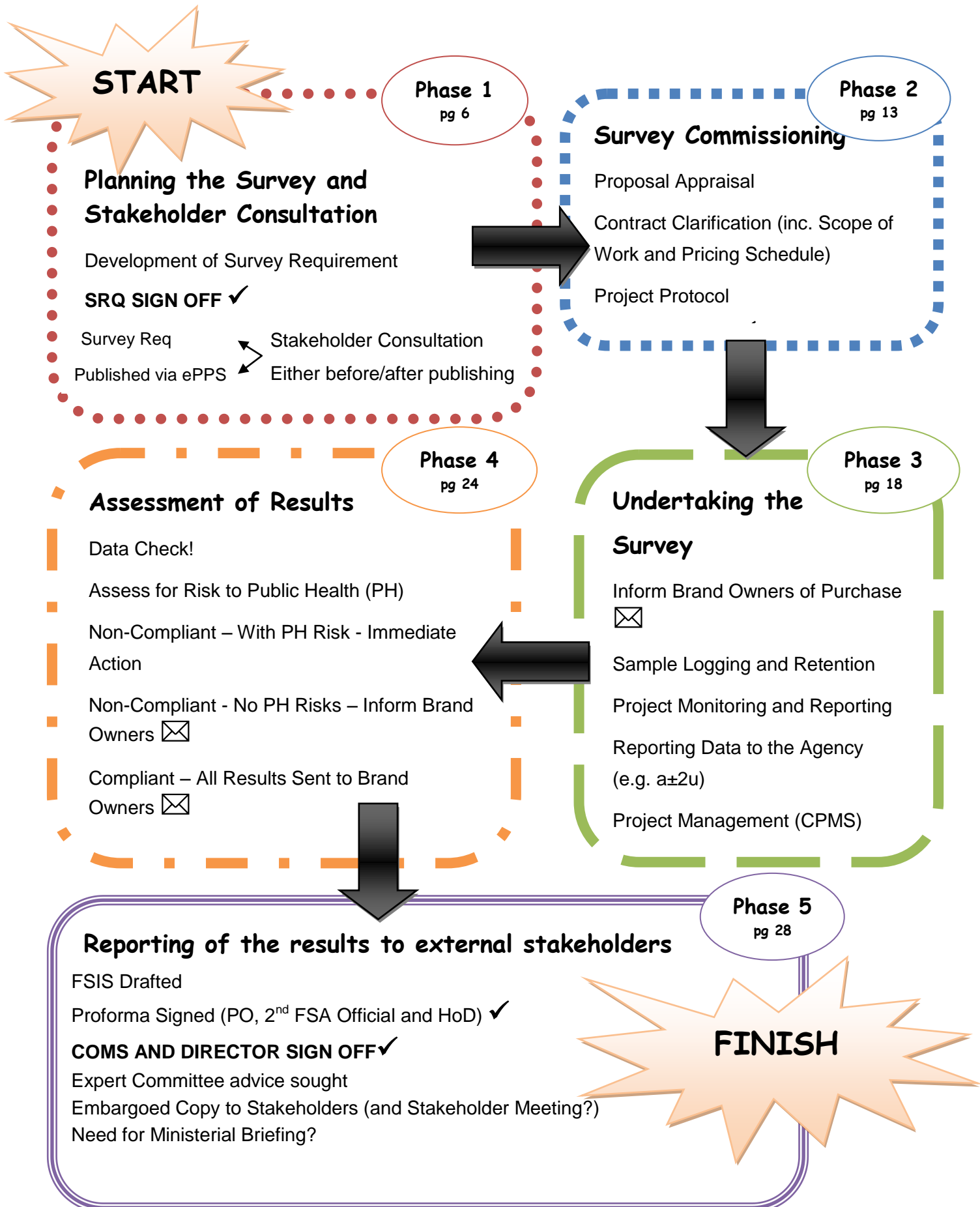
5. These Guidelines apply only to the non-statutory surveys conducted by the Food Standards Agency. The samples collected are 'informal'. The Food Standards Agency will, in some instances, organise a survey jointly with Local Authorities involving the collection of 'formal' samples. The general principles set out in these Guidelines regarding planning, sample logging and handling will still apply although some aspects, particularly timing, may be subject to amendment given legal or other considerations.
6. It is sometimes the case that survey work is procured and undertaken as part of a Food Standards Agency funded research project. For these 'embedded' surveys the principles of these Guidelines should also be applied.
7. These Guidelines provide information of the levels of seniority at which decisions should be taken and some of the specific provisions contained within them (e.g. exceptions from the policy of brand naming). Any decisions to depart from the Guidelines should be endorsed by the Head of Division (HoD).
8. **Project Officers and HoDs should consider throughout the survey process the need and level to which the Agency's Chief Scientist is kept informed of developments within the survey.** For example, if the survey is likely to produce contentious results then it might be prudent to ensure the Chief Scientist is aware of this eventuality before the survey is commissioned.
9. Although the Guidelines are written for the Food Standards Agency's project officers, they are also published on the Food Standards Agency's web site to make transparent the process by which the Food Standards Agency plans, conducts and reports its non-statutory food surveys.
10. Current and potential survey contractors may find parts of this document useful in identifying the responsibilities of the various parties involved in a Food Standards Agency survey.
11. Types of surveys undertaken by the Food Standards Agency vary. A list of the key steps in the survey process is provided in Annex 1. This checklist can be further developed/tailored on a case-by-case basis.
12. The Scientific Methods and Laboratory Policy (SMLP) Branch of the Agency's Analysis and Research (AR) Division are the custodians of the Survey Guidelines and are able to give project officers advice on the general survey process. The relevant Procurement Business Partner (PBP) and the Chief Scientist Team (CST) are able to provide advice on the procurement of surveys. Of particular relevance is the procurement timeline from receiving the survey requirement from a Project Officer

to securing tender responses, evaluating tenders and finalising a contract. European Procurement regulations **may** mean that some time limits apply.

**13. The ten mandatory tasks** to be undertaken within the survey process are highlighted as 'boxed' text. Each colour represents a different phase in the survey process.

Phase 1	A STAKEHOLDER CONSULTATION WITH AN OUTLINE PROJECT PROTOCOL MUST BE UNDERTAKEN BEFORE THE SURVEY BEGINS, ALLOWING 4 WEEKS FOR FEEDBACK.
Phase 2	THE HEAD OF DIVISION SHALL SIGN-OFF THE FINAL PROJECT PROTOCOL BEFORE ANY SURVEY WORK STARTS.
Phase 3	BRAND OWNERS MUST BE INFORMED OF: A) THE SPECIFIC DETAILS OF SAMPLES TAKEN FROM THEIR BRAND; AND B) WHERE APPROPRIATE, THE AVAILABILITY OF A SUB-SAMPLE.
Phase 4	WHERE THE ANALYSIS OF A SAMPLE SHOWS IT TO HAVE POTENTIAL PUBLIC HEALTH IMPLICATIONS, THE RESULTS MUST BE FAST-TRACKED BEFORE THE PLANNED SURVEY COMPLETION DATE SO THAT APPROPRIATE ACTION AND COMMUNICATION CAN TAKE PLACE.
Phase 4	WHERE RESULTS ARE OUTSIDE OF THE EXPECTED RANGE BUT DO NOT POSE ANY THREAT TO PUBLIC HEALTH, BRAND OWNERS ARE INFORMED AND GIVEN (AT LEAST) 3 WEEKS TO RESPOND. RESPONSES SHALL BE INCLUDED IN THE FSIS.
Phase 4	ALL SURVEY DATA AND DATA PROCESSING MUST BE DOUBLE-CHECKED BY SOMEONE WHO HAS NOT BEEN INVOLVED IN THE ASSEMBLING AND INTERPRETING OF DATA.
Phase 4	ALL INDIVIDUALISED RESULTS TO BE SENT TO BRAND OWNERS (WITH AT LEAST 3 WORKING DAYS TO RESPOND) PRIOR TO PUBLICATION OF SURVEY RESULTS.
Phase 5	ALL DECISIONS ON WHETHER BRAND NAMES SHOULD BE WITHHELD FROM THE SURVEY REPORT MUST BE TAKEN AT DIRECTOR LEVEL. THIS MAY ALSO INVOLVE DISCUSSIONS WITH THE AGENCY'S CHIEF SCIENTIST.
Phase 5	THE CONFIRMATION OF COMPLIANCE PROFORMA MUST BE SIGNED BY PROJECT OFFICER, INDEPENDENT FSA OFFICIAL AND HEAD OF DIVISION.
Phase 5	THE FINAL SURVEY REPORT AND COMPLETED PROFORMA MUST BE SUBMITTED TO COMS DIVISION AND THE APPROPRIATE DIRECTOR(S) WHEN SEEKING CLEARANCE FOR PUBLICATION.

**FIGURE 1. The survey process**



**TABLE 1. Timetable targets for Food Standard Agency Surveys**

<b>TIMETABLE TARGETS</b>	<b>STAGES</b>	<b>TIMEFRAME</b>
Laboratory analytical methodology should be validated before survey sample collection commences.	Validation of methodology	-
Sample collection to be undertaken over as short a time period as possible	Sampling	-
Analysis to be completed within 6 weeks of samples being collected – in large surveys, or where a pilot study is required, sampling and analysis should be conducted in batches and co-ordinated so as to meet this target for each batch.	Analysis	6 weeks
Analytical laboratory report to be received within 9 weeks of samples being collected – in large surveys, or where a pilot study is required, analysis and reporting should be conducted in batches and co-ordinated so as to meet this target for each batch.	Reporting of results	9 weeks
An assessment of the results for possible threats to public health should be carried out as soon as they are received. In the case of microbiological surveys, where confirmatory testing may take longer than one week, this assessment should be completed at the earliest opportunity.  Where there is a need to consult expert advisory committees, this should be done at the earliest opportunity.	Assessment	c. 1 week
Manufacturers/brand owners of samples giving 'high' or unusual results to be allowed 3 weeks to provide comments, for publication with the survey results (except where urgent action is needed to protect public health)	Comments on high or unusual results	3 weeks
Manufacturers/brand owners of all samples to be sent individualised results in the same format that they will be released in and given at least 3 days to respond.	Informing all brand owners of results	At least 3 days
Publication of full details of the survey within 20 weeks of sample purchase	Publication of Food Survey Information Sheet	20 weeks

**NOTE:** It should always be the aim to publish the results within 20 weeks of sampling. However, if it is known in advance that the individual targets cannot be achieved a revised timetable should be drawn up and cleared by the relevant HoD during the planning stage. Owing to the size and complexity of microbiological surveys the 20 week target reporting period is often exceeded.

## PHASE 1 – PLANNING THE SURVEY AND STAKEHOLDER CONSULTATION

14. Phase 1 of the survey process begins when the policy need for a survey is identified, for example by the Food Standards Agency Board, an Expert Advisory Committee, a Working Party, etc. The policy need is then refined to produce a Survey Requirement (SRQ) for the procurement exercise and a stakeholder consultation is undertaken before the project formally commences. The survey project may be:
- a completely new piece of work;
  - the outcome of an earlier investigation; or
  - part of a larger work programme.

### Development of the Survey Requirement (SRQ)

15. For the purpose of this document it is assumed that Food Standards Agency funded analytical surveys are procured through open competition although periodically surveys may be contracted through either limited-tender or single-tender processes authorised on a case-by-case basis. **Only FSA Procurement Division may publish tenders and sign contracts on behalf of the agency. The PBP and CST should be contacted at an early stage for advice on the latest survey procurement process.** In support of the procurement process project officers may find the compilation of the following information useful (paragraphs 16 to 32). Additionally, this information can be used to:
- help support external stakeholder consultation (paragraph 33); and
  - help compile information to form the final project protocol (paragraph 66).

### *Justification*

16. This outlines the justification for undertaking the survey and should include a consideration of whether the survey offers a 'value for money' solution to the policy need being addressed. It is therefore necessary to consider estimates of potential costs and benefits.

### *Objectives*

17. The objectives should detail the purpose of the survey and what use will be made of the results. Reference should also be made to how the success of the survey will be judged/measured and key success criteria must be set for this before work formally begins.

### ***Resource Planning***

18. At this stage of the survey process it may be difficult to estimate the contractor staff resource required but it should be possible to estimate the level of internal (i.e. Food Standards Agency) staff resource required to undertake the survey. If there are insufficient Food Standards Agency staff resources available to manage the proposed survey then this needs to be highlighted as soon as possible.
19. The project officer should assess if adequate information and resources are available to enable the survey results to be validated, interpreted and acted upon with appropriate urgency once they are received.
20. At this stage of the survey process it is useful to highlight how cost effectiveness can be maximised. For example, can the same sample be used for several different surveys? This may not always be possible due to the high specificity of methods for preparing and analysing samples for individual analytes but it should always be considered in consultation with other Divisions, as appropriate. It is important to comprehensively describe the use to which the samples will be put. The SRQ should contain details of any samples available to potential contractors to review.

### ***Timetable for Completion***

21. The timetable for completion of the survey should be estimated and clearly documented (e.g. a Gantt or Pert chart) and included in the SRQ. It is important to include key dates (or at least the estimated start and completion date), especially if there are co-dependencies or no flexibility to ensure contractors understand the Agency's expectations. Where it is not practicable to complete the survey within the ideal timeframe (Table 1) reasons for this (which may include examples from previous surveys) should be given, and endorsed by the relevant HoD. It should always be the aim to complete the survey without undue delay.

### ***Quality Expectations***

22. It is useful to highlight at an early stage the expected quality (or type) of survey being undertaken. For example, will the proposed survey be a quick preliminary investigation to produce approximate data or will the proposed survey generate accurate and precise data that will be used for intake and risk analysis? It is important that the intended quality of the survey be highlighted at an early stage to guard against possible over interpretation of the final survey results. Questionnaires to be completed by potential contractors regarding overarching quality assurance standards and accreditation are located in Annex 5. Potential contractors will also

need to sign up to the *Joint Code of Practice on Quality Assurance in Research* (Annex 5).

### **Sampling Specification**

23. As much information as possible should be gathered in the preparation of the sampling specification. The amount of information available for inclusion within the specification will vary from survey to survey. For example, for some surveys it may be possible to define the sampling specification before the work is put out to tender. On other surveys only a general sampling specification may be defined at this time as part of the proposed tender will be to define the sampling protocol, etc. Annex 2 gives details on factors to be considered when developing a sampling specification.
24. The project officer should consult the relevant interested parties within the Food Standards Agency (e.g. devolved countries) at the earliest possible stage when planning a new survey. In particular, a statistician will be able to advise on whether, and how, the aims of the survey can be met effectively (Annex 3). The proposed sampling methodologies must be informed by statistical advice.
25. The total cost of the project and the timely reporting of results are important factors that determine the overall size of the survey, and whether it should be conducted in several rounds of sampling (and analysis). The total number of samples will reflect the need to cover the market realistically. **Ideally, the time between the sample being taken and a result being reported to the Food Standards Agency should not exceed 6 weeks.**
26. Answering the following questions may help develop a preliminary sampling specification:
  - a) Do available resources or scheduling issues limit the size of the survey? What compromises will have to be made and for what reason? All these should be fully documented.
  - b) What relevant prior information (e.g. market share data, previous survey) is available and can it be used to devise a robust sampling plan?
  - c) Are there any regional issues that need to be addressed? Will the sampling plan have to be adjusted to take account of those issues? Coverage in each of the four UK countries needs to be considered.
  - d) There is a presumption that all details associated with samples will be published (note, however, the criteria given in Annex 4 for the limited exceptions to the general policy of releasing brand names). Will all necessary steps be taken to ensure that adequate information on the provenance of samples is captured at the

time of purchase, and that sample logging and other data handling at the laboratory ensure the correct sample details are assigned to each analytical result?

***Analytical Specification (if appropriate)***

27. In addition to the sampling specification, and where appropriate, the project officer should detail the proposed analytical methodology to be used. Again, the amount of analytical information available will often be survey dependent.
28. Answering the following questions may help develop a preliminary analytical specification:
  - a) What is the status of the available analytical methodology?
  - b) Will an exploratory survey be needed first to check the robustness of the methodology for the foods or food products being analysed and/or the analyte stability?
  - c) Are there laboratories available with suitable accreditation, and/or certification, and experience in the required area?
  - d) For quantitative analysis, what is the limit of detection (LOD), limit of quantification (LOQ) and expected measurement uncertainty values?
  - e) For qualitative analysis (e.g. presence/absence), what is the expected likelihood of false positive and false negative results?

***Risk Assessment***

29. The risk assessment should contain details of potential risks, for example to consumers and public health.
30. Answering the following questions will help develop a preliminary risk assessment strategy (this information can be obtained from potential contractors):
  - a) Is there enough information about consumption of the foods to be tested to allow a robust assessment of consumer exposure to be made? If not, how can this information to be collected?
  - b) Are there population groups (infants, the elderly, pregnant women, nursing mothers, ethnic populations, etc.) who may be particularly affected by the analyte of concern? If so, will the survey provide adequate information on foods that may be consumed preferentially by these population groups?
  - c) Will it be necessary to obtain an expert committee opinion, have a previous opinion updated, or have new toxicological aspects considered before the

significance of the survey results for public health can be assessed? If so, what preparatory work can be done before the survey results are available?

- d) Are sufficient toxicological/microbiological data, including established numerical standards where appropriate, available to enable the experts to be able to reach a view?
- e) Can a limit be determined beforehand, above which action will need to be taken to protect public health? If so, steps must be taken to ensure samples exceeding this limit are reported to the Food Standards Agency quickly.

### ***Risk Management and Risk Communication***

**31.** In the event of a risk being realised during the course of the survey it is essential that an appropriate risk management system be in place. The Guidelines for Assessing and Acting on Information from Incidents and Surveys (<http://www.food.gov.uk/multimedia/pdfs/assessact.pdf>) provide guidance for project officers on the procedures for considering action needed to assess, manage and communicate risks identified through the Food Standards Agency's own surveys. Answering the following questions will help to form a preliminary risk management system:

- a) Are any legal issues likely to arise from the survey? If there are any doubts or concerns, seek advice from the PBP, CST and Legal Division.
- b) Will other Member States and the European Commission need to be notified of the outcome via the EU-wide rapid alert system (RASFF) in order to enable them to take action?
- c) Are there any wider issues likely to arise when the survey is published? If so, how will these issues be handled and are there impacts on other Government departments or other stakeholders?

**32.** Risk communication is an integral part of risk management. It is recommended that the project officer consults with the Food Standards Agency's COMS Division, and other relevant Divisions, during the early stages of survey planning in order to develop a preliminary risk communication strategy. The strategy can be further developed/revised, as necessary, when more information becomes available as the survey proceeds.

### **Stakeholder Consultation**

**33. A stakeholder consultation exercise must be undertaken *before* the survey work begins.** This procedure allows relevant trade associations, representatives of

enforcement bodies and the major consumer organisations to comment on the proposed sampling regime and testing methodology before the survey begins. They will thus be sighted on what the Food Standards Agency is proposing to do and can give their views. In some instances this exercise would be part of regular consulting and informing of interested parties which many branches undertake. **It is not expected that more than 4 weeks be allowed for comment.** Where appropriate, consultation can alternatively be undertaken through a relevant Expert Committee and/or Advisory Committee.

34. Stakeholder consultation can be undertaken either before or after the SRQ is published. The timing of the consultation should be developed on a case-by-case basis. **However, the overriding principle is that stakeholders should be informed in advance of plans for Food Standard Agency surveys and given the opportunity to comment.**
35. The consultation document can be considered as an 'outline project protocol' and provides details of the broad scope of the project. As a minimum, this document should include details of:
  - the survey purpose and objectives;
  - the proposed survey design;
  - the preliminary sampling specification;
  - the preliminary analytical specification (if relevant); and
  - any pre-identified statistical analysis which will be undertaken.
36. Where opinion is sought on other aspects of the survey (i.e. risk management strategy) these may also be included in the consultation document. Much of the detail required for the consultation document can be derived from the background information gathered whilst developing the SRQ (i.e. paragraphs 15 to 32).
37. The outline project protocol will eventually be worked up into a detailed final protocol for the project during Phase 2 (Figure 1, see also paragraphs 66 to 69).
38. The consultation may take place during Phase 1 (Figure 1) and the resultant feedback and intelligence used to inform the drafting of the SRQ. This will be of particular use when the survey proposed is not routinely funded by the Food Standards Agency
39. Alternatively, consultation may be undertaken concurrently with the publication of the SRQ (Phase 2) after clearance to proceed with the SRQ has been given. Any stakeholder responses received can then be made available to the appraisal panel and addressed during the formal appraisal of proposals submitted in response to the SRQ. Undertaking the consultation in this way is particularly relevant when the

## Phase 1 – Planning the Survey and Stakeholder Consultation

survey procedures are well established and additional information is being sought to refine/update these procedures. Due care must be taken to ensure the equality of the appraisal process. **The PBP should be consulted where substantive comments arise from the consultation.**

40. Whilst the consultation process may produce suggested amendments to the survey design, it should be noted that if subsequent alterations are considerable and the scope of the survey no longer represents that detailed in the SRQ then the SRQ clearance process may need to be repeated. In this event the decision on how to proceed must be taken by the HoD, in conjunction with the PBP if appropriate.
41. If at any stage of the consultation process the project officer is in doubt as to the appropriate action that should be taken, or if any of the above issues cannot be satisfactorily resolved, they should consult their line manager or senior management for advice.

**A STAKEHOLDER CONSULTATION WITH AN OUTLINE PROJECT PROTOCOL MUST BE UNDERTAKEN BEFORE THE SURVEY BEGINS, ALLOWING 4 WEEKS FOR FEEDBACK.**

## PHASE 2 – SURVEY COMMISSIONING

- 42. New guidance on all stages of commissioning and managing an evidence project will shortly be placed on ScienceWeb (<http://fsahome/how/science/Pages/default.aspx>). The PBP and/or CST should be contacted at an early stage for advice on best practice for survey procurement.** This notwithstanding, the following sections highlight particular issues associated with the commissioning of surveys.

### ***General Issues***

- 43.** Potential contractors should be informed at an early stage that they are expected to follow the relevant sections of these Guidelines and should be provided with a copy on request.
- 44.** All potential contractors are required to give details of proposed analytical quality assurance (AQA) procedures to be employed within the survey by completing Part A of the questionnaire given in Annex 5 which should be submitted with their proposals.
- 45.** The preliminary sampling and analytical specification (if relevant) developed in Phase 1 should be made available to the potential contractors so that they can address the SRQ directly. Other appropriate background information may also be made available.
- 46.** Special attention must be paid to the Food Standards Agency's requirements for AQA (Annex 5) and Measurement Uncertainty (Annex 6) when appraising proposals for analytical surveys. It is often advantageous to invite a member of the SMLP Branch or other appropriate experts in analytical methodology (e.g. a member of a supporting Working Party and/or Methodological Sub-Groups) to the appraisal panel for analytical surveys.
- 47.** The advice of a Food Standards Agency statistician should be sought as to whether potential contractors have, within their teams, statistical expertise that is appropriate for the design, interpretation and reporting requirements of each survey. The statistician should be asked to comment on proposals for surveys with statistical content and invited to the appraisal panel.
- 48.** A member of the Procurement Team should always be in attendance at an appraisal meeting. Depending on complexity, this will be either in person or by teleconference/videoconference.
- 49.** A preferred proposal should be identified through the appraisal process. In doing so, the panel members must consider whether the proposals represent value for money. The expected costs of the survey work (and resources) will already have been

estimated by the project officer, and subsequently cleared by the HoD when preparing the SRQ for the procurement process via EPPS.

### **Contract Clarification**

50. It is vitally important that both the project officer and contractor(s) are clear on the objectives and the specific methods to be employed during the survey. It is often useful to arrange a pre-contract meeting in order to agree final details for the survey, to include:
- timeframes to be adopted;
  - details of the sampling plan;
  - details of sample purchase and logging (further information in Annex 2);
  - methods of analysis;
  - criteria and procedures for confirmation of results; and,
  - finalisation of cost
51. The project officer should make it clear to the contractor(s) that the meeting is to enable progression of the contract award but the contract will only be awarded subject to agreement of the contract contents.
52. Provisions for project management and project monitoring, result assessment and risk assessment should also be made at this stage.
53. Contract clarification of survey projects can be problematic in that it may involve developing contracts with more than one external party. For example, if a single contractor undertakes the sampling and analysis (even if the contractor plans to subcontract one of elements to a named sub-contractor) then this is likely to involve only one set of contract clarifications. However, if the contractor undertaking the sampling is different from that undertaking the end analysis then this can result in multiple contract clarifications which have to ideally be linked in order to create a cohesive protocol.
54. Where possible, much of the substantive information finalised/ascertained in the contract clarifications should be included in the contract or added later as a variation to contract. **The PBP is available for advice on contract clarification (do's and don'ts).**
55. The sampling plan (Annex 2) must be appropriate for the aims of the survey. Wherever possible the sampling plan should reflect market share and range, using commercial market research figures and other relevant data. Where such data are

not available or their accuracy and reliability is in doubt, Trade Associations may be able to provide more reliable information. A Food Standards Agency statistician should be consulted on the derivation of the sampling plan.

56. It is beneficial to agree with the sample purchaser a clearly defined list of samples for purchase from specific outlets and a clear indication of the timing of the purchase and supply to the analytical laboratory. It may also be necessary to state what should not be purchased. It is often useful to develop a contingency plan in the event of a possible shortfall in sample numbers or damage to samples and to avoid any unnecessary duplicate sampling.
57. Details on sample logging (Annex 2) should also be agreed during contract clarification. Purchasers should be given clear, explicit instructions on how to record purchases and the exact details required, in order to ensure the existence of an audit trail and to provide details that may be required in any follow-up action.
58. Ideally, sample preparation details should be agreed with the analytical laboratory before the work commences. Different types of survey require different methods of sample preparation (Annex 2).
59. Where applicable, the project officer should agree with the analytical contractor the AQA procedures to be employed within the survey (Annex 5, Part B). For example, during the survey urgent action may be required (i.e. product recall/withdrawal) owing to the discovery of unacceptable health risks for the consumer. For chemical surveys, wherever possible an 'action level' should be agreed with the analytical contractors prior to the commencement of the survey and the contractor must inform the project officer immediately should any sample(s) be found to exceed this level.
60. For analytical surveys, the sample purchase and analytical work plan of the analytical laboratory should be harmonised so that there is minimal delay between sample purchase and completion of analysis. **The period between sample collection and reporting of data to the Agency project officer should ideally be 6 weeks or less. If, despite good planning, this period is likely to be exceeded then an alternative timeframe must be authorised by the HoD before the contract is issued and survey work commences.**
61. Depending on the type of survey being undertaken and the number of samples involved, the project officer should assess the need for the contract to contain a measure of the acceptable level of transcription error. This should be discussed and agreed with the contractor. This will protect the Food Standards Agency from erroneous reporting and ensure an additional level of quality control. A reasonable

measure will need to be determined on a case-by-case basis when setting up the contract.

62. The format in which survey data is reported to the project officer may vary depending on the type and format of the survey being undertaken. Nevertheless it is often useful to agree with the contractor at an early stage the style, content and format for the data to be reported to the project officer within the contract. For example, the report(s) may include the following:
  - Sampling plan.
  - Analytical method and quality assurance data (see Annex 5 for further details).
  - Full results data.
  - Summary table of the details of the samples collected. This should include description, brand name, batch number, size, where and when obtained and any other relevant information.
63. It is advisable to make financial provisions for independent analyses in the case that results require confirmation. Such provisions can be written in to the contract.
64. The project officer should also consider whether the contractor is a public authority under the Freedom of Information Act (2000) and the Environmental Information Regulations (2004). Being a public authority will affect the way in which the contractor responds to information requests (i.e. FoIA/EIR requests) concerning the survey. Provisions should be made within the formal contract regarding the disclosure of information. Additionally, the FSA is bound by the provisions of the Food Standards Act. The FSA will need to perform such actions, without restriction, to fulfil its responsibilities under this Act.
65. Necessary disclosure of information, including confidential information, due to the FSA's obligations under this legislation will equally apply if the contractor is not a public authority, and this should be highlighted to those contractors as well. No contractual amendment is required here.

### ***Finalising Contract Details and Survey Instigation***

66. Before the formal contract is signed and the survey project officially commences the project officer shall collate all related information gained during Phases 1 and 2. Collectively, this information forms the 'final project protocol', and shall be held on the survey's official file.
67. The final project protocol describes in detail the work to be undertaken by the contractor **AND** the expected work that will be undertaken within the Food Standards Agency itself. The final protocol should therefore include the following information:
  - ❖ The survey objectives which underpin the aim and purpose of the survey.

- ❖ A detailed timetable for survey completion and details (with reasons) of any deviation from the target timeframes given in Table 1.
  - ❖ A clear description of the work to be undertaken and related timelines to be undertaken by the contractor. The project officer should supplement this with additional information pertaining to the work that will be undertaken within the Food Standards Agency itself.
  - ❖ A full methodological protocol, including a comprehensive sampling plan (and analytical methodology if required).
  - ❖ Provisions for survey monitoring, reporting results and risk assessment/management.
  - ❖ Details of how the end results will be used and interpreted within the Food Standards Agency prior to full public dissemination.
  - ❖ Details of how the results will be reported to stakeholders.
68. The final project protocol can be used as a benchmark to assess the success of the survey once completed.
69. The final project protocol must be included in the official file that is sent to the HoD for authorisation to issue the formal contract. In providing this authorisation the HoD must also sign-off the final project protocol as no work can begin on the survey until this authorisation is given. FSA commitment to spend must be through an approved Purchase Order for the full amount of the commissioned work.

**THE HEAD OF DIVISION SHALL SIGN-OFF THE FINAL PROJECT PROTOCOL BEFORE ANY SURVEY WORK STARTS.**

70. **Once authorised the official file containing the relevant paperwork must be sent to the PBP who will issue the formal contract. A contractual agreement must be in place and stored within the Agency CPMS before a supplier undertakes any chargeable work on behalf of the Agency.**
71. The Food Standards Agency publishes on its website summary information on surveys that are currently being undertaken. **When a formal contract has been issued CST must be contacted so that details of the survey can be stored on the Food Standards Agency's website** at <http://www.food.gov.uk/science/surveillance/>. Information to be provided by the project officer, includes:
- the objectives;
  - the duration; and
  - the expected publication date of the survey.

## PHASE 3 – UNDERTAKING THE SURVEY

### General Issues

**72. General guidance on how to manage survey and research projects is available from CST and ScienceWeb.** However, there are a number of issues which are specific to surveys and which must be considered.

### *Informing Brand Owners<sup>1</sup> of Survey Sample Purchases*

**73. Small retail outlets (i.e. those not listed as “large retailers”) must receive the generic leaflet (Annex 9) at the time of sample purchase from the retailer.** The leaflet sets out, in simple terms, the reasons why the Food Standards Agency carries out surveys, how the samples are reported and where more information can be obtained. A pdf version of the leaflet is available from SMLP Branch. Annex 9 also gives alternative and customisable text that may be used to inform retailers when samples are purchased through the internet, mail order, etc.

**74. Large retailers have requested that where samples have been obtained at any of their premises, the leaflet should not be distributed but the contact point notified instead.** A letter should be sent to the contact point along with, if deemed appropriate, a copy of the leaflet. A list of company contact points for large retailers, based on information supplied by the British Retail Consortium and updated regularly, is available to Food Standards Agency staff through the Agency’s internal ‘FoodWEB’, under the heading ‘Surveys – company contact points’.

**75. When the sample purchasing for any one survey (or survey round - see paragraph 25) has been completed, a letter should be sent to all the brand owners, or importers as appropriate, with a list of their samples which have been taken.** The following details should be provided in each letter to brand owners:

- product description and brand<sup>2</sup>;
- batch code;
- country of origin (as for some loose or pre-packed foods this may vary within an identifiable batch);
- ‘best-before date’;
- pack size; and

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<sup>1</sup> For the purpose of informing of samples being taken, a brand owner is considered to be the person or company who ‘owns’ the product. It is a legal requirement that the brand owner is listed on the label however this is not always the case. Where information is lacking and unobtainable the vendor (by default) is considered the brand owner.

<sup>2</sup> Some packaged retail foods (dairy, meat, fish, egg) will include on the pack an EC factory identification code or other numerical/alphanumeric code on the packaging that identifies the factory of origin. In such cases, this information should also be provided to the brand owner.

- what the product will be analysed or examined for / purpose of survey.

The suggested standard text for this letter is given in Annex 10.1.

- 76. The notification letter should be sent to the head office of the relevant brand owner, where it is known, failing that to the address on the label.** Even after every reasonable effort has been made, it may not be possible to identify the brand owner or an appropriate contact address for them. In such cases, the project officer should note what actions have been taken as a matter of record. If necessary clarification may be sought from senior personnel (e.g. line manager, HoB or the HoD).
- 77. Brand owners should be informed of their right to request a sub-sample for their own analysis, in those instances where it is practical to provide sub-samples for analysis on request.** The exception to this is microbiological surveys (see Annex 8 for further guidance) due to likely changes in the quality and microbiological status of the food within a short period of the packaging having been opened.
- 78.** Where sub-samples are to be made available to brand owners, the letter should indicate the period for which the samples will be kept. Although the typical retention period is one year, careful thought will need to be given to the logistics, technical challenges and costs associated with the archiving of samples, as well as the relevant legal and other points.
- 79.** The sample purchase contractor may be best placed to collate this information for each sample and write to brand owners. The project officer should judge whether he/she or the sample purchase contractor should send these letters and, if these are to be sent by the contractor should provide sufficient guidance and notice to ensure this task is completed correctly and in a timely manner. In such cases, a copy of the letters must be sent to the project officer for filing.

### **BRAND OWNERS MUST BE INFORMED OF:**

- A) THE SPECIFIC DETAILS OF SAMPLES TAKEN FROM THEIR BRAND; AND**
- B) WHERE APPROPRIATE, THE AVAILABILITY OF A SUB-SAMPLE.**

### **Sample Logging**

- 80. It is important to ensure samples are analysed and reported to the Food Standards Agency as soon as possible following their procurement, so**

### **appropriate action can be taken where necessary to protect public health.**

Particular attention must be paid to the “use by” or “best before” date of each product. Samples with a shelf life of months or years yet whose “best before” date is imminent will not usually be acceptable for the purposes of the survey. What is acceptable for each individual survey must be clearly set out during contracting (Phase 2).

81. The sample purchaser should send a spreadsheet listing the samples and the contractually agreed details to the Food Standards Agency when each phase of the purchasing has been completed, and also to the analytical laboratory, as directed by the project officer. The spreadsheet format must be agreed in advance and (if appropriate) must be in a suitable format for importing into any subsequent databases. When all the samples have been collected a final, agreed spreadsheet should be submitted. Alternatively, if only a small number of samples are purchased then a copy of the proforma for each sample should be sent, with a summary sheet listing those samples that have been collected. A suitable deadline for this will have been agreed and written into the contract (see Phase 2). Where there is a need to compare results between surveys, project officers should consider whether a standard spreadsheet format should be used for related surveys.
82. Visual images of the labels from the samples, preferably digital photographs of the packs (or photocopies) must be sent to the Food Standards Agency. The images must be of sufficient clarity and resolution to allow all on-pack information to be read, and all recorded sample information to be checked.
83. When the samples are removed from the packages for analysis, the laboratory or analytical contractor must retain the packaging for an agreed time, as detailed in the contract.
84. For some survey work, the packaging may itself be considered as the sample. In food contact materials surveys the packaging may be analysed to destruction. The project officer should advise the sampling and analytical contractors whether duplicate samples are required to allow one set of packaging to be retained.

### ***Sample Retention***

85. Unless analysed to destruction, samples in surveys of chemicals in food must be retained after analysis for further investigation should there be dispute over the results of analysis or any other challenge to the data. Project officers should discuss practical issues regarding sample storage (capacity for storage; stability of samples) with the contractor and must explicitly agree with the contractor a retention period for both the packaging and reserved portions of the analytical sample, which should be stated clearly in the contract. Costs may apply for this service and so should be

included in the contract where known or broken down and added in a contract variation. When setting the retention period, project officers should take account of the following factors, and discuss as appropriate with CST (scientific issues) or the Procurement Business partner (financial or contractual issues):

- a) If the results of the analysis give no cause for concern, it is unnecessary to keep the sample once the results have been published. However, in practice, concerns may arise due to unforeseen circumstances and the project officer should consider the need to retain the samples for longer. Provisions for sample retention may form part of the contract, in such cases and where the results of the analysis give no cause for concern, the samples should be retained for the agreed period.
- b) **Where a result does reveal a problem, the samples must be kept.** Samples that have provided results that give rise to concern must be kept for at least one year.
- c) If, during that time, an analytical result is disputed, the relevant sample must be kept until the matter has been concluded.
- d) If proceedings are not started within a year, but there are indications that such proceedings will be brought, **the relevant sample must be kept until the matter is resolved.**
- e) At the end of the retention period, if no proceedings are indicated, the timing for the destruction of any remaining samples should be discussed with legal advisors.

### Project Monitoring and Reporting

#### *Project Officer - Contractor Communication*

86. **Throughout the course of a survey, there should be open channels of communication between the project officer and the contractor(s).** This will have been itemised in the 'governance' section of the formal contract and this 'contract management' should be undertaken by the Project Officer within CPMS. The project officer should make regular visits to the contractor(s) (and/or *vice versa*) and contact should be maintained outside of these meetings and should include regular updates of progress.
87. Contractors must inform the Food Standards Agency immediately if there are any problems. The Food Standards Agency's standard terms and conditions require that any changes – including those to a sample purchase plan, analytical approach or timetable – must be agreed with the Food Standards Agency in writing before being put into effect by the contractor. The Food Standards Agency expects contractors to

use their best endeavours to accommodate any changes that are required, subject to any changes in costs. The PBP can organise a variation to contract to accommodate any amendments to the existing contract.

### ***Reporting Laboratory Data to the Food Standards Agency***

88. It is useful to have survey data reported at regular intervals as it allows the project officer to identify any problems with data format, documentation, quality, outliers, etc., at an early stage. It is easier to address potential problems as they arise, rather than retrospectively. An ongoing deliverable for providing a progress report or dataset, at agreed regular intervals (e.g. monthly), can be included in the contract. SMLP Branch is able to advise project officers on issues of scientific data quality and AQA (e.g. interpretation of Shewhart control charts). Statistics Branch is able to assist with general data interpretation.
89. The Food Standards Agency needs to be confident that contractors are using best scientific practice when undertaking surveys. In order for the Food Standards Agency to ensure that adequate AQA procedures are in place for a particular survey, potential contractors must provide information, not only at the proposal stage and before work commences, but also periodically over the course of a survey. Further details are given in Annex 5 (Part C).
90. All data from analytical chemistry surveys are to be reported to the Food Standards Agency in the form " $a \pm 2u$ " where " $a$ " is the analytical result, corrected for recovery. The range " $a \pm 2u$ " represents a 95% level of confidence where the true value would be found. The value of " $U$ " or " $2u$ " is the value which is normally used and reported by analysts and is known as the "measurement uncertainty" and may be estimated by the analyst in a number of different ways. Further guidance on calculating and presenting measurement uncertainty is given in Annex 6 and also from the SMLP Branch.
91. Data and compliance with AQA requirements (Annex 5) must be scrutinised when received to ensure that results are valid. Particular care should be paid to double-checking results for accuracy and that appropriate confirmatory analysis has been carried out where appropriate.

### ***Project management***

92. The project officer should assure themselves on a regular basis that contractual milestones/deliverables are being met on time and to a satisfactory level.
93. **Any significant slippage from the agreed contract timetable, and any that cause the phases of the project to exceed the targets in Table 1, or those stated**

**within the authorised final project protocol (paragraph 66), should be notified to the relevant HoD and any remedial action authorised.** The PBP is available to advise on the most appropriate action to take; CST should also be made aware. All necessary steps should be taken to get the project back on track as quickly as possible. If this is not possible, then with agreement, the PBP may authorise a variation to contract for a time extension.

## PHASE 4 – ASSESSMENT OF RESULTS

94. Upon arrival at the Food Standards Agency, survey data should be assessed promptly.
95. In some instances, assessment of the issue may be relatively straightforward and consist of a comparison of the information received with pre-existing limits, guidelines, or standards. Where statutory limits or standards apply, the Food Standards Agency expects food business operators to take such steps as are appropriate in each case to ensure that foods that do not comply are not placed on the market. Where foods already on the market are found not to comply with statutory limits or standards, the Food Standards Agency expects them to be withdrawn and in certain instances, for example where there is a serious or acute risk to public health, recalled from consumers' homes.
96. In the majority of cases, however, assessment of the issue will require informed scientific judgement to assess from the information received the potential consumer exposure to any hazard, and the magnitude and acceptability of any resultant risk. Advice in such cases should be obtained in the first instance from the relevant policy division on the health implications of the chemical, microbiological or radiological agent(s) measured in the survey. If further advice is required, for example where the issue is particularly novel or contentious, appropriate expert opinion should be sought from external independent sources, which will often include reference to one of the Food Standards Agency's scientific advisory committees (Annex 11). Where this is likely, it is essential for the relevant committee secretariat to be consulted at as early a stage as possible about the design and timing of the survey. Contact details for committee secretariats can be found at <http://www.food.gov.uk/science/ouradvisors/>
97. An Agency statistician should appraise the survey data. The statistician will also be able to give advice about what statistical conclusions can be drawn from the data.
98. The assessment of results from the Food Standards Agency's surveys should be viewed within the broader context of how the Food Standards Agency identifies, assesses, and takes action to deal with and then monitors and reviews all food risks. A statement of the Food Standards Agency's approach to risk issues is published on its web site ([http://www.food.gov.uk/aboutus/how we work/risk](http://www.food.gov.uk/aboutus/how_we_work/risk)).
99. **If during a survey findings with potential public health implications are identified these results must be fast-tracked before the planned survey completion date so that appropriate action and communication (e.g. informing local authorities) can take place. Such results may often trigger action under the Incidents Response Protocol**

(<http://fsahome/rulesandtools/incidents/Pages/IncidentResponseProtocol.aspx>). The Guidelines for Assessing and Acting on Information from Incidents and Surveys (<http://www.food.gov.uk/multimedia/pdfs/assessact.pdf>) provide guidance for project officers on the procedures for considering action needed to assess, manage and communicate risks identified through the Food Standards Agency's own surveys.

**WHERE THE ANALYSIS OF A SAMPLE SHOWS IT TO HAVE POTENTIAL PUBLIC HEALTH IMPLICATIONS, THE RESULTS MUST BE FAST-TRACKED BEFORE THE PLANNED SURVEY COMPLETION DATE SO THAT APPROPRIATE ACTION AND COMMUNICATION CAN TAKE PLACE.**

- 100.** Depending on the risk assessment and the nature of the implicated food product(s) and result(s), action may include a request to brand owners to withdraw or recall one or more food products and an associated food alert for action or product recall/withdrawal notice, press release and/or material on the Food Standards Agency's web site, possibly including photographs and further information to allow the implicated product(s) to be readily identified, and reporting through the European Union RASFF system. Other approaches would be informed by the specific issues raised, but may include targeted communication more directly with specific groups of consumers.
- 101.** **Where the analysis of a sample has shown it to be outside expected ranges, but where there were no public health implications that required earlier action, the brand owner should be informed of the results for their samples and allowed (at least) three weeks to provide such comments as they would wish to be published with the survey results (Annex 10.2).** Contractors should be informed in such cases, given the possibility that brand owners may then request one of the retained analytical sub-samples for their own independent analysis (Annex 10.3).

**WHERE RESULTS ARE OUTSIDE OF THE EXPECTED RANGE BUT DO NOT POSE ANY THREAT TO PUBLIC HEALTH, BRAND OWNERS ARE INFORMED AND GIVEN (AT LEAST) 3 WEEKS TO RESPOND. RESPONSES SHALL BE INCLUDED IN THE FSIS.**

- 102.** The project officer should inform both the local and home authorities of non-compliant results sampled from their areas.

**103.** All survey data and data processing must be double-checked by someone who has not been involved in the assembling and interpreting of data. This only applies to data transposed and processed at the Food Standards Agency. All analytical laboratories contracted to the Food Standards Agency are either 3<sup>rd</sup> party accredited or have acceptable quality management systems in place and consequently will have adequate internal data quality checks. The breadth of the work undertaken by the Food Standards Agency means that the double-checking is best done by someone within the same commissioning branch.

**ALL SURVEY DATA AND DATA PROCESSING MUST BE DOUBLE-CHECKED BY SOMEONE WHO HAS NOT BEEN INVOLVED IN THE ASSEMBLING AND INTERPRETING OF DATA.**

**104.** In completing surveys, all brand owners must be given sufficient time (at least three working days) to see their brand results in the form in which they are to be released, prior to publication. This is to give them time to comment on the accuracy of the information and to avoid surprises. A suitable letter template is given in Annex 10.4.

**ALL INDIVIDUALISED RESULTS TO BE SENT TO BRAND OWNERS (WITH AT LEAST 3 WORKING DAYS TO RESPOND) PRIOR TO PUBLICATION OF SURVEY RESULTS.**

### ***Risk management and communication***

**105.** In managing the implications of incidents and surveys, the primary objective of the Food Standards Agency is to protect consumers. For much of the Food Standards Agency's work this means protecting consumers against public health risks that, on the basis of a risk assessment, we judge to be unacceptable. The Food Standards Agency also has a statutory duty to protect other interests of consumers, and we may therefore also take action where we believe there is the potential for consumers to be misled. The Food Standards Agency also has a statutory duty to be proportionate when selecting the most appropriate management option in each case, taking into account not only the nature and magnitude of any risks, but also the likely costs and benefits of any action.

- 106.** Risk management and communication options can include informing stakeholders that no action is needed, providing information and advice to consumers or, where necessary, seeking withdrawal or recall of affected products or batches. Other action may also need to be taken to mitigate the effects of, or minimise the risks of reoccurrence of, the circumstances that gave rise to the incident.
- 107.** In considering risk management options, it is necessary to bear in mind that samples taken for Food Standards Agency surveys do not normally constitute formal enforcement samples. They are intended to provide a representative picture, at one point in time, of the content of particular foods or a range of foods. Risk management consideration should take into account the size and number of samples, and any potential factors involved in sampling at retail level, before decisions are taken.
- 108.** The communication of risks and advice to consumers and other stakeholders is not simply an activity to be added to the end of the survey process once risk management decisions have been taken. A communications strategy must be discussed between COMS Division and interested Food Standards Agency Policy Divisions from the beginning of the process. Communications issues should form part of any ongoing discussion of risk management options. Potential public health implications of Food Standards Agency surveys and their communication will have been discussed by the project officer and COMS Division at the survey planning stage. These discussions will bear in mind that risks will need to be managed and communicated not only on completion of the survey, but also at intermediate stages if emerging results indicate the need for early action to protect public health.

## **PHASE 5 - REPORTING OF THE RESULTS TO EXTERNAL STAKEHOLDERS**

- 109.** There is a presumption in favour of publishing all relevant information from surveys, and advising consumers and other stakeholders on the implications for them and any actions they should take. The communication tools used will vary dependent on circumstances and audiences.
- 110.** If, during the conduct of a Food Standards Agency funded survey, food samples are identified that the contractor or the Agency consider are illegal then the proper course is to inform the home authority of the food business concerned. Depending on the results obtained, the home authority may wish to take formal samples within the official enforcement process. In some circumstances, if a local authority took the survey samples, they could be considering prosecution based on the results. A check should be made with the local authority as to whether they intend to prosecute based on the results of the survey samples, or repeat samples prompted by the survey. In such instances, project officers should seek advice from Legal Division on how to proceed, and it may be necessary to leave some information from the report unpublished, until prosecutions have concluded.
- 111.** If the survey report concludes that some samples were found to be illegal, then even if no prosecutions are to follow, legal clearance should still be sought before publication. The Food Standards Agency should always be in a position to produce evidence to demonstrate that any derogatory comment made in a report about a product, company or brand is true.
- 112. The Food Survey Information Sheet (FSIS) must include the brand names and provenance of samples that were taken, as a matter of factual record unless certain exemptions apply (see Annex 4 and also the Food Standards Agency's Openness Code of Practice<sup>3</sup>).**
- 113.** In addition, project officers should recognise that they might ultimately be asked to release brand names for exemption surveys in accordance with the FoIA.
- 114. All decisions on whether brand names should be withheld from the survey report must be taken at Director level. This may also involve discussions with the Food Standards Agency's Chief Scientist.**

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<sup>3</sup> [http://www.food.gov.uk/aboutus/how\\_we\\_work/copopenbranch/](http://www.food.gov.uk/aboutus/how_we_work/copopenbranch/)

## Phase 5: Reporting of the Results to External Stakeholders

**ALL DECISIONS ON WHETHER BRAND NAMES SHOULD BE WITHHELD FROM THE SURVEY REPORT MUST BE TAKEN AT DIRECTOR LEVEL. THIS MAY ALSO INVOLVE DISCUSSIONS WITH THE AGENCY'S CHIEF SCIENTIST.**

- 115.** The policy of naming brands applies equally to those samples where consumers or other stakeholders are recommended to take specific action and samples where – as in the vast majority of cases – the Food Standards Agency does not recommend any action to be taken.
- 116.** If a survey does not indicate that any action needs to be taken, then no significance should be read into the sampling of any particular brand, the particular retailer or wholesaler from which it was purchased, or into the result of its analysis. The project officer and COMS Division share the responsibility for making this clear to stakeholders and commentators in any survey reports that are issued in such cases.
- 117. The project officer must ensure that the 'Confirmation of Compliance with the Food Standards Agency Survey Guidelines' Proforma (Annex 12) has been completed by:**
- the project officer;
  - an independent FSA official (not directly involved with the survey); and
  - the HoD responsible for the survey and interpretation.

**THE CONFIRMATION OF COMPLIANCE PROFORMA MUST BE SIGNED BY PROJECT OFFICER, INDEPENDENT FSA OFFICIAL AND HEAD OF DIVISION.**

- 118.** The second FSA official is required to check that the final survey report is a) fit for external publication (e.g. editorial checks, scientific checks) and b) the reported objectives and conclusions are aligned with the original authorised protocol for the survey (paragraph 66). If the second official identifies the need for any alterations, it is advisable that the second official re-checks the edited document before signing the proforma. The final version should then be passed to the HoD for sign-off.
- 119. The final survey report and completed proforma must be submitted to COMS Division and the appropriate Director(s) when seeking clearance for publication.**

**THE FINAL SURVEY REPORT AND COMPLETED PROFORMA MUST BE SUBMITTED TO COMS DIVISION AND THE APPROPRIATE DIRECTOR(S) WHEN SEEKING CLEARANCE FOR PUBLICATION.**

- 120. The HoD should ensure that the Food Standards Agency's Chief Scientist is kept fully informed on:**
- the results of the survey;
  - the conclusions drawn; and
  - actions taken.
- 121. When surveys are potentially contentious, the HoD should use their discretion to decide the appropriate degree of involvement of the Food Standards Agency's Chief Scientist, ahead of publication.**
- 122.** In some cases the view of expert advisory committees (such as COT) will be required before the Food Standards Agency publishes survey results. The Food Standards Agency policy is that stakeholders are alerted before public discussion of potentially sensitive results at the advisory committee. The Food Standards Agency's survey results and the committee's opinion should be published as near to the same time as possible. Stakeholders can be alerted a few days before the committee meeting at which the opinion is finalised and the survey results published as soon as possible after this. The advisory committee's initial consideration of the issue and preparation of their draft opinion will be achieved via correspondence with the committee members.
- 123.** Material relating to a survey (i.e. FSIS) must be published on the Food Standards Agency website (<http://www.food.gov.uk/science/surveillance/>). When the FSIS is published on the Agency website CST should be notified so that summary details of the survey and a cross reference to the FSIS can be put on the Agency's open access repository FoodBASE (<http://www.FoodBASE.org.uk>) unless certain exemptions apply (see Annex 4 and the Food Standards Agency's Openness Code of Practice). For further information contact CST. Additional background or underpinning data (in Excel/PDF format) should also be sent to CST for publication at the same time. All PDFs published on the web must meet minimum accessibility legislation (<http://fsahome/rulesandtools/communications/Pages/accessibility.aspx>).
- 124.** Guidance for Food Standards Agency's officers on the preparation of a FSIS can be found on the Food Standards Agency intranet, FoodWEB. Depending on what the survey has looked at and what the results show the survey may be put more prominently on the web site and in certain circumstances a press release will be

issued or a press conference held. It should be remembered that the FSIS will be emailed to people who have registered for this service from the web site.

- 125.** It is important that COMS Division is included in discussions at an early stage about how the results of any survey are going to be communicated. Closer to the proposed publication date, policy officials and the senior press officer (or member of the web team) with responsibility for the policy area will need to draft text for the web site/press release. The draft text will need to be approved by the appropriate senior Agency officials (from both the policy area and COMS Division). The text should embody the main points from the FSIS but should be written in a way that is understandable to the lay-person. At this stage, 'Q&A's should be produced in preparation for media interest and the project officer must also consider any Ministerial briefing required. On publication of a survey, the index of FSA food surveys (to help identify and locate surveys on particular topics) needs to be updated. This list is mainly aimed at industry local authorities or consumers but may also be of use to FSA staff. The list/index can be found on the Food Standards Agency's internal network (Q:\FSA Shared\UKFSS). Once the spreadsheet has been updated let the COMs web team know so that they can upload the amended list onto the Food Standards Agency website.
- 126.** Dates for publication are agreed by COMS Division in conjunction with policy officials and are dependent on the survey being signed off (paragraph 119). Usually surveys are flagged up in the fortnightly diary after approval has been given.
- 127.** Stakeholders may need to prepare their own 'Q&A's briefing in preparation for the publication of the Food Standards Agency's survey results. The project officer should provide such stakeholders, upon request, with an embargoed copy of the FSIS (i.e. excluding brand names and other specific brand-specific information). The release of this information should be timed with respect to any scheduled meeting of the associated expert advisory committee.
- 128.** Brand owners should be informed of the risk management and communication strategy, so they are able to take prompt action in respect of any risks to consumers. The home local authority of the company concerned must be informed of any such contact with brand owners.
- 129.** Depending on the results of a survey and any specific messages to communicate it may be adventitious to hold a stakeholder meeting. This type of meeting usually takes place the day before the complete results of the survey are published. Stakeholders may be invited from relevant consumer, enforcement and food industry organisations. The meetings provide an opportunity for the Food Standards Agency

## Phase 5: Reporting of the Results to External Stakeholders

to present the general findings (at that stage brand-specific information is not released) and to raise awareness of the findings with stakeholders so they are in a position to act on the findings and respond appropriately when the survey is published.

## ANNEX 1. SURVEY CHECKLIST

Survey Control Point	Yes	Date	Name	Comments
<i>Example: Have you undertaken a stakeholder consultation?</i>	<input checked="" type="checkbox"/>	1 April 2005	A N Other	<i>The consultation document was sent to 15 stakeholders (listed on file). Deadline for comments (4 weeks). 5 responses received.</i>
Have you drafted the Survey Requirement?	<input type="checkbox"/>			
Do you have SRQ clearance?	<input type="checkbox"/>			
Have you undertaken a stakeholder consultation?	<input type="checkbox"/>			
Has the required information (to form the final protocol) and contract paperwork been compiled and placed on the official file, and signed-off by the Head of Division?	<input type="checkbox"/>			
Has a formal contract been issued for the survey?	<input type="checkbox"/>			
Have brand owners been informed that samples have been taken and the availability of sub-samples?	<input type="checkbox"/>			
Have results been checked for public health implications?	<input type="checkbox"/>			
Have brand owners been informed of high / unusual results (3 weeks response time)?	<input type="checkbox"/>			
Have brand owners been informed of all individualised results (as to be published) with at least 3 working days to respond?	<input type="checkbox"/>			
Have the relevant parties signed the proforma?	<input type="checkbox"/>			
Have relevant stakeholders been advised of publication date and an embargoed FSIS?	<input type="checkbox"/>			

## **ANNEX 2. PLANNING AN ANALYTICAL SURVEY**

This Annex offers further guidance on planning the survey. It is particularly relevant to 'chemical' surveys, however the principles can be broadly applied across surveys in general. The question lists can be used by the Project Officer to address the sampling plan, sample purchase, sample logging and preparation. The questions and suggestions lists are not exhaustive and care should be taken to ensure that all information relevant to the survey concerned has been provided/requested.

### **Designing a sampling plan**

When planning a survey, the project officer should consult with a Food Standards Agency statistician when attempting to answer the following questions (see also Annex 3).

- a) What size of sample is required, e.g. weight/volume/number of individual units
- b) What range of retailers should be covered? In retail surveys, samples should as far as possible be selected from a range of major and smaller national retail outlets as well as independent retail outlets.
- c) Is there regional variability between products? In certain circumstances it may be acceptable only to sample in some areas.
- d) When is the sample to be taken? Is the product only available at certain times? The level of analytes found may vary with the season.
- e) Will imported food be included? If so, when and where will samples be taken? Consignments may enter the UK at different places and come from different countries at different times of the year, or may cease at certain times of the year.
- f) Is the analyte(s) being surveyed likely to be distributed heterogeneously? Is any information available on its likely distribution within a single sample, between samples of the same batch, or between batches? Does the sample size or number of replicates for each brand need to reflect this potential variability?
- g) Will local practices need to be taken into account? Local Authority officers (EHOs, TSOs) can often provide useful local advice at the planning stage and should be approached through their co-ordinating body, LGA, where local practices may be relevant.

## Sample Purchase

An instructions document must be developed by the project officer and given by the sampling contractor to each sample purchaser, clearly stating the details required; e.g.:

- a) numbers of samples, to include contingency samples where the food is fragile and easily damaged during transport (e.g. eggs);
- b) sample size, volume or weight;
- c) whether the sample can or should be made up from separate packs/sub-samples with the same batch number;
- d) product types;
- e) countries of origin;
- f) type of outlet to purchase from;
- g) the timeframe over which samples are to be obtained;
- h) avoidance of cross or other contamination;
- i) how to store the samples prior to packaging and transportation;
- j) the timing of sample purchase and supply to the analytical laboratory;
- k) if the samples are unpackaged, e.g. milk to be used in the manufacture of a milk product, the intended use should be stated. e.g. cheese manufacture;
- l) sample logging details; and
- m) issuing the Food Standards Agency's explanatory leaflet, reproduced at Annex 9.

## Sample Logging

The sample purchasers must be given clear, explicit instructions on how to record purchases, and the exact details required, in order to ensure the existence of an audit trail and to provide details that may be required in any follow-up action. Details should include:

- a) unique number allocated to sample when purchased, ideally to link with potential details to be maintained by the receiving laboratory in order to maintain traceability
- b) product type and name (sample purchasers should be prompted to record those product attributes that might materially affect the product in a relevant way – for example, whether sampled dairy products are UHT-treated, pasteurised or unpasteurised may be relevant in a microbiological survey)
- c) date and time of purchase (especially important for microbiological surveys)
- d) place of purchase
- e) sample condition at time of purchase
- f) brand (i.e. supermarket own brand or other brand name)
- g) ingredients
- h) nutrition information
- i) description of product
- j) size of packet purchased
- k) packaging type e.g. vacuum packed, modified atmosphere, multipack etc.
- l) suggested serving size for food

- m) the name and/or business name and an address or registered office of either or both of:
- the manufacturer or packer, or
  - a seller established within the European Community;
  - “best before” or “use by” date
  - batch/lot code
  - country of origin, as described on the retail pack
  - any deviations from the sampling instructions document.

### **Sample Handling**

The sample purchasers must be given clear instructions on the packaging of samples prior to their transportation to the laboratory to ensure the establishment of an adequate audit trail and the avoidance of:

- cross or other contamination;
- damage during transportation;
- deterioration of samples of products;
- loss of unstable contaminants or growth and/or changes to the micro-organisms present in the sample due to temperature changes.

The following steps should usually be undertaken:

- a) Confirmation (with the analytical contractor) that suitable arrangements have been made for the receipt and storage of the samples (i.e. at ambient, freeze dried or frozen at  $-x^{\circ}\text{C}$ ).
- b) Assessment of the stability of samples and analytes and, where necessary, of sample temperature during transit before the main collection phase. Necessary arrangements should be made to ensure that storage between sample purchase, transport, and subsequent storage at the analytical laboratory prior to analysis does not prejudice the reliability of the final results.
- c) Specific instructions should be provided to the analytical contractor on how to treat and/or store samples received outside of working hours, so as to maintain the integrity and protect the stability of the samples.
- d) As a general rule, samples that arrive outside working hours should be refrigerated and analysed within 24 hours of receipt at the laboratory. If storage at these temperatures is not possible, provision will have to be made for samples to be received at times when they can be processed immediately upon receipt.
- e) The analytical laboratory should record the overall condition of samples on receipt and the time and date sample was tested.

## Sample Preparation

For chemical surveys, wherever possible, the analytical contractor must homogenise the survey sample<sup>4</sup> and then:

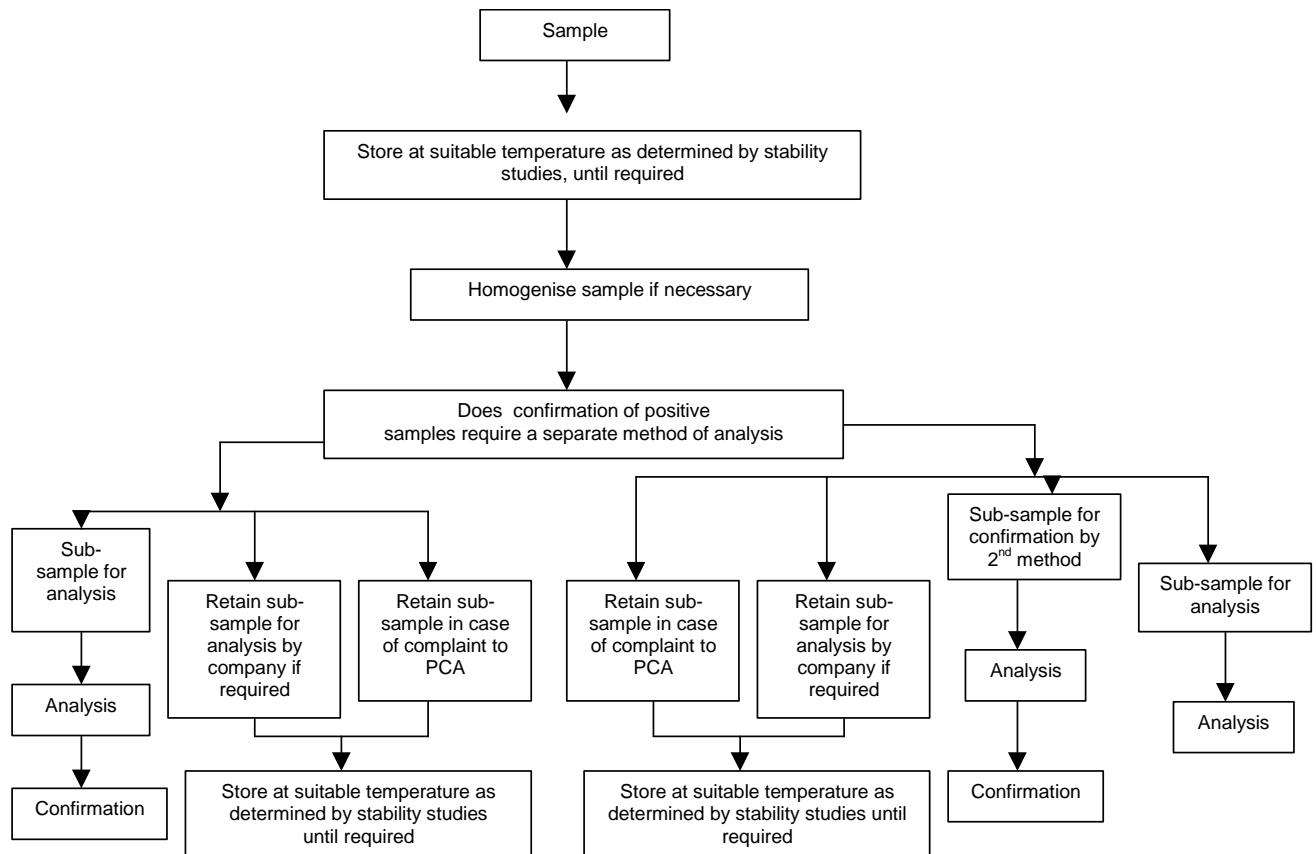
- Divide into four sub-samples.
- One sub-sample should be used for the required analysis/analyses and one for confirmation as necessary.
- The other two sub-samples should be stored under suitable conditions, as determined by stability studies, one for analysis by the company, retailer etc., if required, and one for retention in case the result is disputed.

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<sup>4</sup> Where:

the analytical sample consists of a single, homogeneous sample of a food; or  
the analytical method depends on the detection of heterogeneous particles distributed throughout the matrix (for example, some methods for the detection of irradiation using thermoluminescence),  
the need for homogenisation or other sample treatment prior to division into parts should be discussed and agreed in advance with the analytical contractor and endorsed by the HoD.

## Sampling and sample preparation for chemical and radiological food surveys



## **ANNEX 3. USING A FOOD STANDARDS AGENCY STATISTICIAN**

A Food Standards Agency statistician should be consulted throughout the survey lifecycle, from the planning stage to the reporting stage.

### **Planning the survey**

Among the issues that will need to be considered are:

- Objectives – If the survey contains quantitative measurements talk to a statistician. If the objective is to confirm or detect differences (e.g. across years, countries, between product types) then it should be ensured that sub populations are assigned large enough sample sizes.
- Sample units – what types of units should be sampled, and should they be combined for analysis? For example a UK estimate of milk characteristics can be obtained from taking packs of milk in the supermarket as sampling units and combining analytical units from each into a composite sample for analysis. However, if differences between farms are to be measured, sample units may be taken from the milk bulk tanks in farms and analysed individually.
- Sample size – How many sample units need to be selected? Are usable results relating to parts of the overall sample needed as well as overall results? For example, are results needed for Scotland, Wales or Northern Ireland as well as the UK; are results needed for several different types of food?
- Coverage – What geographic coverage is demanded of the survey to ensure that it is adequately representative for the intended use of the data? A characteristic may be temporally variable, the Food Standards Agency statistician can advise on the sampling period required so that the results are not affected by seasonal or short term phenomena.
- Design of survey – often prior information is available to the Project Officer, for example market share data, pilot study, archived survey data, sampling frames – e.g. list of fruit retailers in local authorities. This information can be usefully and appropriately utilised when defining the sampling plan.

### **Commissioning the survey**

- Contractual clarifications – Data handover requirements including format (see below), documentation, quality and cross-checking. It is important to assess whether the potential contractor has adequate statistical expertise (or access to) to address the

sampling and analytical issues in the tender process. If not the Food Standards Agency statistician may need to take a more hands on approach.

- Data format – the most useful format for the survey data to be delivered to the Food Standards Agency should be agreed with the statistician, bearing in mind there may be a need to preserve consistency in the format for reporting data between surveys, if the results from different surveys will need to be compared. Most contractors are more likely to be helpful if they are told at the beginning of the survey, rather than after they have provided the data in an alternative format. Data formatting should be clear and concise.

### **Undertaking the survey**

- Sample problems – once the survey begins, if the selection of the sample units goes wrong, a statistician should be consulted immediately to decide on the best strategy for retrieving the position. Examples include flawed market share data, non-compliance issues and unforeseen logistical problems. This must not be left until the survey has finished.
- Assessing data – results should be reported to the Food Standards Agency at regular intervals throughout the survey. Double-checking of results is a requirement of these Guidelines and may include checking format, documentation and quality, identifying bad practice, outliers and potential errors. A Food Standards Agency statistician can help with this checking procedure.
- Data analysis – Expert statistical advice is required to [1] allow for the sampling design e.g. re-weighting of data; ensure sensitivity to sampling problems, data errors or assumptions and their potential impact on results and [2] attach accurate confidence bounds to findings.
- Reporting – Ensure the statistician sees copies of the draft reports as they arrive and the final report is sent for comment well before publication. The Food Standards Agency statistician will be able to confirm whether the use of statistical data is correct and appropriate to the nature of the survey.

Food Standards Agency statisticians may also be able to ‘mine’ the survey data in order to generate new hypotheses (not results) and advise on appropriate use of data in exposure assessments. The project officer must not attempt this type of data manipulation without consulting fully with an Agency statistician.

## **ANNEX 4. EXCEPTIONS TO THE POLICY OF NAMING BRANDS**

The Agency's policy on brand naming was endorsed by its Board in April 2003 and again in June 2006<sup>5</sup>.

There is a presumption in favour of releasing full information about survey results, including brand names. This notwithstanding, there may be occasions when releasing information about the source of a sample within a survey report may not be appropriate. The Agency's Code of Practice for Openness<sup>5</sup> gives some examples of well defined circumstances where it may not be appropriate to publish brand names for both legal and practical reasons.

Additionally, the following are examples of other situations where the publication of brand names might not be appropriate:

- Surveys that analyse composite samples of several different brands or foodstuffs. For example, the Total Diet Study.
- Surveys where individual people or individual farms are studied. For example, surveys where individuals' diets or body fluids are analysed, or where a farm with contaminated land is used for experimental purposes and products from that land are withheld from the food supply. It should be noted that farm gate retail samples are not exempt under this clause.
- Surveys of products at an intermediate stage of processing. If anything unusual is found however, this must be fully investigated and any action required to protect public health or prevent consumers from being misled must be publicised.
- Small **ad-hoc** or pilot studies, typically of not more than 30 samples, aimed at (i) developing an analytical or sampling method; (ii) assessing survey design or feasibility; or (iii) verifying data produced by others. In these cases, a limited and non-representative number of samples are likely to have been analysed. If anything unusual is found however, this must be fully investigated and any action required to protect public health or prevent consumers from being misled must be publicised.
- Survey-related activities which do not involve analysis of samples including literature surveys, market surveys and written reviews.

**All cases to withhold brand names from survey reports must be judged on their merits and specifically approved by the relevant Director; there is an expectation that these will be kept to an absolute minimum.**

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<sup>5</sup> <http://www.food.gov.uk/multimedia/pdfs/fsa060607.pdf>

## **ANNEX 5. INFORMATION FOR POTENTIAL CONTRACTORS ON THE ANALYTICAL QUALITY ASSURANCE REQUIREMENTS FOR analytical SURVEYS OF FOOD**

### **Introduction**

The Food Standards Agency needs to be confident that contractors are using best scientific practice when undertaking surveys it funds as these help underpin and develop policy used to protect consumer health and ensure that consumers are not being misled. Adequate analytical quality assurance (AQA) procedures are therefore essential. All contractors who undertake Food Standards Agency funded surveys should:

- use validated methods of analysis, i.e. methods for which performance characteristics have been established;
- use internal quality control procedures conforming to a recognised protocol; and
- participate in proficiency-testing schemes conforming to a recognised protocol (e.g. FAPAS & FEPAS)

The laboratories doing survey work for the Food Standards Agency should also ideally be 3<sup>rd</sup> party accredited for their operating procedures, i.e. be accredited by an Agency such as the United Kingdom Accreditation Service or another internationally recognised accreditation service.

These standards are internationally recognised by the European Commission for official food control laboratories and within the Codex Alimentarius Commission for laboratories concerned with the import/export of foodstuffs.

In order for the Food Standards Agency to ensure that adequate AQA procedures are in place for a particular survey, contractors are required to provide information on the AQA procedures to be used whilst undertaking the survey on the attached questionnaire. This information is required in three parts, the forms for which are sent to the potential applicants during the procurement process. These are:

- A. Quality assurance requirements for survey projects required of potential contractors at the time project proposal forms are completed and when commissioning a survey;**
- B. Information to be agreed with the contractor(s) during contract clarification; and**
- C. Information to be provided by the contractor(s) on an on-going basis once contract is awarded - to be agreed with the Food Standards Agency.**

Potential contractors are asked to provide the information requested in Part A of this document when submitting their survey project proposals in order to aid the assessment of

the relative merits of each project from the analytical/data quality point of view. Parts B and C are not to be completed when submitting survey project proposals. However, Parts B and C should be made available to the potential contractors so that they are aware of what further demands will be made of them, should their proposal be funded, and so can build the costs of providing the information into their bids.

Potential contractors will also need to sign up to the *joint code of Practice on quality assurance in research*. See <http://food.gov.uk/science/researchpolicy/qacopres/>

## QUESTIONNAIRE

### **PART A: QUALITY ASSURANCE REQUIREMENTS FOR SURVEILLANCE PROJECTS REQUIRED OF POTENTIAL CONTRACTORS AT THE TIME PROJECT PROPOSALS ARE COMPLETED**

Potential contractors should provide the information requested below. Please complete either section 1 or section 2 and then sections 3, 4 and 5.

#### **Section 1: Formal Quality System in the Laboratory if Third Party Assessed (i.e. if UKAS Accredited or GLP Compliant)**

Please describe the quality system in your laboratory by addressing the following aspects:

To which scheme is your laboratory accredited or GLP compliant?	
Please describe the scope of accreditation, by addressing: 1. The area that is accredited? 2. For which matrices, and 3. For which analytes or supply a copy of your accreditation schedule.	
Do you foresee any situation whereby you will lose accreditation status due to matters outside of your immediate control, e.g. closure of the Laboratory?	

## Section 2: Quality System if not Accredited

Please describe the quality system in your laboratory by addressing the following aspects:

<b>Laboratory Organisation</b> 1. Management/supervision 2. Structure and organisational chart 3. Job descriptions if appropriate.	
<b>Documentation</b> 1. General lab procedures 2. Methods to be used (adequate/detailed enough to control consistent approach).	
<b>Sample Preparation</b> 1. Location 2. Documented procedures 3. Homogenisation 4. Sub-sampling 5. Sample identification 6. Cross contamination risk 7. Special requirements.	
<b>Equipment Calibration</b> 1. Frequency 2. Who 3. Records 4. Marking.	
<b>Traceability</b> 1. Who did what/when 2. Equipment – balances etc. 3. Sample storage/temperature 4. Calibration solutions: how prepared & stored.	
<b>Results/Reports</b> 1. Calculation checks 2. Typographic checks 3. Security/confidentiality of data 4. Software usage/control	

5. Job title of approved signatory.	
<b>Laboratory Information Management System</b> Please outline the system employed.	
<b>Internal Audits</b> 1. Audit plan 2. Frequency 3. Who carries out the audit? 4. Are internal audit reports available? 5. What are the non-compliance follow up procedures?	
<b>Subcontracting</b> 1. In what circumstances is sub-contracting carried out? 2. How is such sub contracting controlled and audited?	

### Section 3: Proficiency Testing

Please describe the arrangements for external proficiency testing in your laboratory by addressing the following aspects:

Do you participate in proficiency testing schemes? If so, which schemes?	
Which series of the above schemes do you participate in?	
What are your individual proficiency scores and their classification, (e.g. z-scores or equivalent), over the past two years for the analyte/matrices of relevance to this proposal?	
What remedial action do you take if you should get unsatisfactory results?	

## Section 4: Internal Quality Control

Please describe the IQC measures adopted in your laboratory by addressing the following:

What control samples do you use in an analytical run?	
Do you follow the Harmonized Guidelines <sup>6</sup> ?	
What IQC procedures are in place?	
Do you use Certified Reference Materials (CRMs) and if so, how? (e.g. specify the concentration(s) matrix type(s) etc.)	
Do you use In-House Reference Materials (IHRMs) and how are they obtained? (e.g. specify the concentration(s) matrix type(s) etc.) Are they traceable?	
What criteria do you have regarding reagent blanks?	
What action/warning limits are applied for control charts?	
What action do you take if the limits are exceeded?	
Do you check new control materials and calibration standards? If so, how?	
Can we see the audit of previous results - what actions have been taken or trends observed?	
Do you make use of duplicate data as an IQC procedure?	
How frequently are control materials (CRMs, blanks, IHRM etc.)	

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<sup>6</sup> M. Thompson and R. Wood, "Guidelines on Internal Quality Control in Analytical Chemistry Laboratories", *Pure Appl. Chem.*, 1995, **67**, 649-666.

incorporated in the analytical run	
Do you randomise your samples in an analytical run? (including duplicates)	

### Section 5: Method Validation

Please describe the characteristics of the method of analysis you propose to use in the survey by addressing the following:

What methods do you have to cover the matrix and analyte combinations required?	
Do you routinely use the method?	
Is the method accredited?	
Has the method been validated by collaborative trial (i.e. externally)?	
Has the method been validated through any In-House Protocol?	
Is it a Standard (i.e. published in the literature or by a Standards Organisation) Method?	
<p>Please identify the performance characteristics of the methods. i.e.</p> <ol style="list-style-type: none"> <li>1. LOQ</li> <li>2. LOD</li> <li>3. Blanks</li> <li>4. Precision values over the relevant concentration range expressed as relative standard deviations</li> <li>5. Duplicates</li> <li>6. CRMs</li> <li>7. IHRM</li> <li>8. Bias and recovery characteristics including relevant information on traceability</li> </ol>	

9. Reporting limit 10. etc.	
What method was used to determine the LOD?	
Do you estimate measurement uncertainty and, if so, how are such estimates made?	
Do you normally give an estimate of measurement uncertainty when reporting results to your customers?	

## **PART B: INFORMATION TO BE AGREED WITH THE CONTRACTOR(S) DURING CONTRACT CLARIFICATION.**

The project officer should consider and then define the following in consultation with the contractor:

1. What analysis is required for what matrices?
2. The sample storage conditions to be used. Are stability checks for specific analytes undertaken?
3. The methods to be used and a copy of Standard Operating Procedures (SOPs) where accredited, including any sampling and sample preparation protocols, to be supplied to the Food Standards Agency.
4. The IQC procedures to be used. In particular the following should be considered:
  - The use of the International Harmonised Guidelines for IQC<sup>6</sup>.
  - The use of control charts.
  - Randomisation within the run.
  - The composition of the analytical run (e.g. the number of control samples, and in particular the number of blanks, spikes, IHRM's etc.).
  - The reference materials to be used.
  - The determination of recoveries on each batch using procedures as described in the International Harmonized Guidelines with all results to be corrected for recovery except where otherwise specified (e.g. for patulin for historic reasons) and for the recovery data quoted to be reported.
5. The measurement limits (i.e. limit of detection (LOD); limit of determination/quantification (LOQ): and reporting limits etc.)
6. The maximum acceptable measurement reliability (also known as measurement uncertainty) for each analytical result.
7. The treatment of individual results with respect to uncertainty, i.e. as:
  - $a \pm 2u$   $\mu\text{g}/\text{kg}$  where  $u$  is the standard measurement uncertainty (i.e. as if the sample were to be a "historic" surveillance result), or
  - not less than  $a$   $\mu\text{g}/\text{kg}$  where 'a' is the analytical result determined less the measurement uncertainty (i.e. as if the sample were to be an "enforcement style" result) when assessing compliance with a (maximum) limit.
8. Any 'action level' which would trigger the notification of a confirmed analytical result to the Food Standards Agency project officer immediately.

9. The procedures to be used for confirmation of analytical results above the 'action level' before the Food Standards Agency is notified. The Food Standards Agency expects such confirmation to be fast-tracked, as action may be needed to protect public health in respect of any products above 'action levels'.
10. The consistent way of expressing results, e.g. (a) on a wet (as is) basis, on a dry weight basis or on a fat weight basis, and (b) the reporting units for specific analytes to be used throughout survey (i.e. mg/kg etc.)
11. The time interval for the Food Standards Agency visits and for submission of control charts.
12. The procedure for logging in of samples and traceability of sample in the laboratory.
13. The security of samples within the laboratory.

**PART C: INFORMATION TO BE PROVIDED BY THE CONTRACTOR ON AN ON-GOING BASIS ONCE THE CONTRACT IS AWARDED - TO BE AGREED WITH THE FOOD STANDARDS AGENCY**

The contract must specify the information that is to be provided by the contractor to the project officer on an on-going basis throughout the contract to confirm that the contractor remains in 'analytical control'. This information should include:

- copies of the control charts or other agreed measures to monitor IQC;
- records of action taken to remedy out of control situations to be provided at the same time with control charts;
- where action limits have been identified in Part B, the results of samples which exceed the action limits are to be sent to the Food Standards Agency as soon as available; and
- any relevant proficiency testing scheme results obtained during the course of the survey.

## **ANNEX 6. THE TREATMENT OF MEASUREMENT UNCERTAINTY IN SURVEYS UNDERTAKEN BY THE FOOD STANDARDS AGENCY**

### **CHEMICALS IN FOOD**

#### **Introduction**

It is important and required by ISO/IEC 17025 that analysts are aware of the uncertainty associated with each analytical result and estimates that uncertainty. The measurement uncertainty may be derived by a number of procedures. Food analysis laboratories are required, for Codex purposes, to be in control<sup>7</sup>, use collaboratively tested or validated methods when available, and verify their application before taking them into routine use. Such laboratories therefore have available to them a range of analytical data which can be used to estimate their measurement uncertainty.

These guidelines only apply to quantitative analysis.

Most quantitative analytical results take the form of “ $a \pm 2u$  or  $a \pm U$ ” where “ $a$ ” is the best estimate of the true value of the concentration of the measurand (the analytical result) and “ $u$ ” is the standard uncertainty and “ $U$ ” (equal to  $2u$ ) is the expanded uncertainty. The range “ $a \pm 2u$ ” represents a 95% level of confidence where the true value would be found. The value of “ $U$ ” or “ $2u$ ” is the value which is normally used and reported by analysts and is hereafter referred to as “measurement uncertainty” and may be estimated in a number of different ways.

#### **Terminology**

The international definition for Measurement Uncertainty is: "Parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand"<sup>8</sup>

#### **NOTES:**

The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of results of a series of measurements and can be characterised by experimental standard deviations. The other

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<sup>7</sup> As outlined in Codex GL 27-1997 “Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export of Food”

<sup>8</sup> International vocabulary of basic and general terms in metrology, ISO 1993, 2<sup>nd</sup> Edition. CAC/GL 54-2004

components, which can also be characterised by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

It is understood that the result of a measurement is the best estimate of the value of a measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.”

## Recommendations

- a) The measurement uncertainty associated with all analytical results is to be estimated.
- b) The measurement uncertainty of an analytical result may be estimated by a number of procedures, notably those described by ISO<sup>9</sup> and EURACHEM<sup>10</sup>. These documents recommend procedures based on a component-by-component approach, method validation data, internal quality control data and proficiency test data. The need to undertake an estimation of the measurement uncertainty using the ISO component-by-component approach is not necessary if the other forms of data are available and used to estimate the uncertainty. In many cases the overall uncertainty may be determined by an inter-laboratory (collaborative) study by a number of laboratories and a number of matrices by the IUPAC/ISO/AOAC INTERNATIONAL<sup>11</sup> or by the ISO 5725 Protocols<sup>12</sup>.
- c) The measurement uncertainty and its level of confidence must, on request, be made available to the user (i.e. The Food Standards Agency) of the results.

However, even following publication of the ISO Guide, and a EURACHEM Guide which attempted to aid the reader in the better understanding of the ISO Guide, the concept of measurement uncertainty in analytical results still causes considerable debate and potential for misinterpretation in both analytical laboratories and their customers. This extends to both contract laboratories reporting survey data to the Food Standards Agency and the readers of such published data.

The estimation of measurement uncertainty and its incorporation in survey results has highlighted the fact that analytical results are inherently variable, a fact that was well

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<sup>9</sup> “Guide to the Expression of Uncertainty in Measurement”, ISO, Geneva, 1993

<sup>10</sup> EURACHEM/CITAC Guide Quantifying Uncertainty In Analytical Measurement (Second Edition), EURACHEM Secretariat, BAM, Berlin, 2000. This is available as a free download from <http://www.eurachem.ul.pt/>

<sup>11</sup> “Protocol for the Design, Conduct and Interpretation of Method Performance Studies”, ed. W. Horwitz, *Pure Appl. Chem.*, 1995, 67, 331-343.

<sup>12</sup> “Precision of Test Methods”, Geneva, 1994, ISO 5725, Previous editions were issued in 1981 and 1986.

known amongst the Analytical Community but less well appreciated amongst the users of analytical results. It should be noted that analytical variability has always existed; it is only recently that the variability has been estimated in a form that has been readily understood by users of analytical data.

The following web link gives additional guidance regarding suitable approaches for the determination of measurement uncertainty:

[http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling\\_analysis\\_2004\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf)

### **Reporting of Analytical Results on Food Standards Agency Surveys**

All data from analytical surveys are to be reported to the Food Standards Agency in the form " $a \pm 2u$ " where " $a$ " is the analytical result, corrected for recovery. The range " $a \pm 2u$ " represents a 95% level of confidence where the true value would be found. The value of " $U$ " or " $2u$ " is the value which is normally used and reported by analysts and is known as the "measurement uncertainty" and may be estimated by the analyst in a number of different ways.

The estimation of the value of " $a$ " is dependent on:

- the accuracy of the method of analysis used; and
- how well the analyst uses that method, i.e. whether the analytical system is "in control".

The value of the measurement uncertainty " $u$ " is dependent on:

- the inherent precision of the method of analysis used; and
- the number of analytical replicates that are carried out. The more replicates the less the value of the measurement uncertainty.

### **Reporting of Analytical Results by Food Control Analysts**

The procedure adopted by food control analysts (public analysts) in the UK is different from the procedure described used in FSA surveys in that a public analyst will report samples as containing "not less than " $a - 2u$ " in situations where the statutory limit is a maximum permissible concentration. Thus, in any enforcement situation the maximum benefit of the doubt is given to the food producer. This is consistent with the requirement to prove beyond reasonable doubt that a limit has been exceeded, if the case should come to Court. This does mean that the effective enforcement limit is, in the UK, not identical to the numerical value given in legislation.

## **Display of Measurement Uncertainty Results in Food Standards Agency Surveys**

There is no set manner in which the uncertainty attached to survey data is to be displayed. For FSA surveys, the uncertainty can be:

- attached to each analytical result; and/or
- given in a table at concentration intervals covering the range of data reported within that table.

## **Calculation of Measurement Uncertainty**

The calculation of the measurement uncertainty of analytical results is complex and may be undertaken in a number of different ways. For example:

- using a component-by-component approach from a single method in a single laboratory;
- using results from defined internal quality control procedures in a single laboratory;
- using results from collaborative trials used to validate methods of analysis in a number of competent laboratories; or
- using results from proficiency test schemes used to assess the analytical competency of laboratories.

## **Reporting Low-Level Analytical Data**

Ideally surveys should be carried out so that the analytical data being reported are significantly higher than the determination or detection limit of the methods being used (5 times or 10 times higher respectively). However there are surveys carried out where it is necessary to report results which are near to the detection or determination limits. This is acceptable provided note is taken of the increased measurement uncertainty associated with the results. There may be particular difficulties if the measurement uncertainty of a result was such that it appeared to overlap with the specified detection limit, i.e. it was not possible to state with certainty if the concentration of a sample was more or less than the specified detection limit.

## **Radioactivity in Food**

The uncertainty associated with the measurement of the level of radioactivity will be a factor of the time spent counting radioactive decay of the sample, and the sample size. Each of these factors is amenable to straightforward statistical analysis. It is therefore possible to set the parameters for measurement so that a required level of measurement uncertainty is not exceeded. As with chemistry surveys data from radiological surveys are to be reported to the Food Standards Agency in the form " $a \pm 2u$ " where " $a$ " is the best estimate of the true value of the level of radioactivity. The range " $a \pm 2u$ " represents a 95% level of confidence where the true value would be found.

## **ANNEX 7. RADIOACTIVITY MONITORING**

### **Radioactivity in Food and the Environment (RIFE) Programme**

The Food Standards Agency undertakes annual radiological monitoring around nuclear sites and at locations away from nuclear sites. This policy is currently undergoing review with a public consultation on future proposals to be launched in autumn 2011. The following represents the current policy at the time of writing this. The current FSA monitoring programmes look at concentrations of radionuclides in both aquatic and terrestrial foods:

- The *Terrestrial Radiological Monitoring Programme* (TRAMP) entails the sampling of terrestrial foods from farms and allotments within the vicinity of nuclear sites.
- The *Food and Agriculture Radioactivity Monitoring* (FARM) programme requires food samples to be taken from dairies and town markets at locations away from nuclear sites. The FARM programme provides comparative data for TRAMP and part of the data is used to show compliance with the requirements of Articles 35 and 36 of the Euratom Treaty.
- The *Aquatic Monitoring Programme* (AMP) entails the sampling of aquatic foods from several sources including classified shellfish beds, wild shellfish beds and seaweed gathered from coastlines near nuclear power stations, fish landed by private fishermen and those commercially fished. Also, the programme contracts the direct fishing of particular areas and fish is donated by other government departments and international institutions.
- Two further projects, the “total diet study” (TDS) and “canteen meals” projects, are undertaken to produce data that compliments FARM. Part of the data is used to show compliance with the requirements of Articles 35 and 36 of the Euratom Treaty.

The resultant data are used to estimate radiological exposures of consumers living around nuclear sites and the general public, and to show that radiological doses to consumers are acceptable. No branded products are bought for these projects as the exposure assessment targets local foodstuffs. All the monitoring and dose data are published in the Food Standards Agency’s annual RIFE report. As these programmes are mainly nonstatutory (only work related to the Euratom Treaty and for the OSPAR Convention are direction obligations) the general principles of the Survey Guidelines apply and are adhered to whenever possible, except where discussed below.

## **Commissioning**

The design, collection and analysis of the samples in the programmes are not procured as surveillance projects but are either service level agreements or specific contracts.

## **Sample Plan**

Clearance of particular sample types is not required from the HoD. To calculate annual doses to consumers we must take a whole range of available food types.

Samples are often sourced directly from the field with voluntary permission from the farmer. An explanatory letter is given to the farmer at the time of sampling, so no follow-up letters are needed. The various samples are taken over the course of a calendar year as crops mature and get to a harvestable state (e.g. cabbage in the winter, spring greens in spring, lettuce in summer, blackberries in the autumn). The aquatic samples are taken throughout the year when the stocks are available and sample suppliers are notified of results if they request the data.

## **Sample Preparation**

No sub-samples are taken at present due to the limitations of the sample sizes available from private allotments, etc. It is not in the public interest to put restrictions on obtaining only samples that have sufficient for sub-samples, it is more important to obtain samples that give the most appropriate data for the programmes.

## **Analysis**

The Food Standards Agency does not propose the methodology for analysis – the contractors do that. Radionuclide analysis is a very mature field.

## **Risk Assessment / Timetable**

There are no maximum concentration limits for radioactivity in food for routine discharges. It is the annual dose to the consumer that is used to assess the relative risk, as the annual dose limit is defined in statute. The dose that consumers might receive depends on what range of foods a consumer might eat and how much of each food type is eaten over the course of one year. Hence we have to collect and analyse foods over a period of a whole year. In emergencies, or with an accidental release to the environment, Maximum Permitted Levels (MPLs) of radionuclide concentrations in foods are set by the European Council to ensure maximum protection of the public.

## **Informing Brand Owners**

Only when all the analytical results are in at the end of each calendar year do the sample providers receive their results. All the sample owners get results for all supplied samples at the same time to avoid confusion.

## **Reporting**

The data from the TDS and canteen meal projects are reported in RIFE and are not published as separate project reports and no reference to the results is published in the Food Standards News.

RIFE is published in partnership with the Environment Agency, Northern Ireland Environment Agency and the Scottish Environment Protection Agency. The programme for the report's production thus reflects the needs of the four agencies and so can not adhere to the schedules proposed in the Guidelines. There are adequate warning systems in place with the contractors and laboratories to ensure that unusual results are reported to the Food Standards Agency quickly and within the times suggested by the Guidelines.

To keep the report to a manageable size (with four partners' worth of data the report is already over 250 pages) no errors on analytical results are published, although they are available if required.

The terrestrial and aquatic provisional raw data are published on the web site twice a year.

## **Sheep Monitoring for Cs-137 from Chernobyl**

This policy is currently undergoing review, culminating in a FSA Board decision, planned for spring/summer 2011. The following represents the current policy at the time of writing.

Sheep in certain parts of Cumbria, North Wales and South West Scotland are under FEPA restrictions as a result of the Chernobyl accident. Before sheep can be moved from restricted areas, either to other farms or for slaughter and the food chain, each sheep is monitored to ensure they do not exceed prescribed limits. As part of the management programme of the restricted areas, the Food Standards Agency periodically conducts whole flock surveys of farms to assess their suitability for de-restriction. These surveys are called 'Summer Surveys' and may be preceded by a limited screening survey.

Although the principals of the Survey Guidelines are adhered to wherever possible, the nature of these surveys means that this cannot always be the case, as detailed herein:

### **Commissioning**

The surveys are performed on the farms by field officers of the Rural Payments Agency Inspectorate in Cumbria (by the Welsh Assembly Government in Wales and Scottish Executive Environment and Rural Affairs Department in Scotland) under the terms of the Post Chernobyl Control service level agreement. The work is therefore not explicitly subject to Open Competition.

### **Sampling Plan**

The surveys *per se* do not meet a statutory requirement and participation is voluntary, with farmers being paid £1.30 per sheep monitored.

### **Analysis**

The surveys use specific radiological equipment to assess the levels of radiocaesium *in vivo*. This is performed using a rate meter directly on the live sheep. As such it is not a food product that is being assessed but the whole live sheep.

### **Timeframes**

The timeframe for the monitoring is dependent on the farmers, as sheep are monitored within two days of coming down from the fells for clipping. Depending on the number of farms participating in a survey, the duration will typically last two to three months.

Consumer interests are not affected by the delay in publication of results, since all sheep are monitored separately under the terms of the FEPA Order before being allowed to leave the restricted areas.

### **Publication**

Results are published via the Agency website and farms are not identified, nor are farmers invited to comment on the results prior to publication.

## **ANNEX 8. MICROBIOLOGICAL SURVEYS**

### **Introduction**

This is additional guidance for microbiological surveys and should be read along-side the general FSA guidance for surveys. This Annex only addresses areas where further guidance specific to microbiological surveys is required.

Microbiological surveys are commissioned so that the FSA can estimate or measure the level of microbiological contamination in food within the UK. There are a number of reasons for wishing to know this information. It may enable checks to be conducted on food which can alert the Agency to any food safety issues or it may be that the Agency needs to investigate a national problem or requires background information to support a negotiation with the European Commission, for example. In developing research surveys, project officers will need to be aware of the survey work being carried out by other groups. If the survey is looking at the national position following a local outbreak, then the commissioning officer should have access to the local results.

Any survey being carried out for the Agency should take into account any information from previous surveys such as those organised by the LGA/HPA network under direction of the Food, Water & Environmental Microbiological Surveillance Group at the HPA. The work should also take into account the sampling programmes organised by the European Union's sampling programme.

Microbiological surveys carried out by the FSA are to be statistically based, randomised surveys and determine the prevalence level of pathogens in food on a UK-wide basis. Sampling plans should be based on current market share information where appropriate. In some surveys it may be necessary to compare the prevalence of the micro-organisms in the four countries of the United Kingdom and the statistics will need to take this into account with over-sampling in the areas covered by the devolved administrations. The commissioning officer will need to consult with their counterparts in Devolved Administrations at the start of the survey design process.

### **ACMSF SWG – Surveillance Working Group**

The sub-group is in place to advise HMD on all aspects of microbiological surveillance. They will be able to comment on the aims and objectives of the survey, the survey protocol, the sampling plan and the final report. Members of the sub-group could be members of the appraisal panel if this were felt to be appropriate. HMD uses the ACMSF surveillance sub-group to comment on and peer-review/evaluate micro survey final reports and other documents if appropriate. The final report cannot be published unless it is considered by this sub-group.

### **Consultation**

Microbiological surveys can take place at any point of the food production line. However, most of the microbiological surveys are carried out at retail level to reflect the quality of the product available to the consumer. The consultation process will include the major trade organisations representing both small and large retailers. Other consultees can be identified through the relevant policy branch in either the FSA or ODGs.

### **Brand names**

In common with all other surveys, brand names will need to be published. For raw products sold loose, as in the case of meat or fish, the individual retailer will need to be told of the survey and informed the results once the survey is complete. For large retailer chains, the head office will be informed which their premises have been visited and told of the results collectively.

### **Legislative issues**

Unless the survey has been specifically set up to test contraventions of legislation, the samples taken in microbiological surveys can only be seen as unofficial samples. For the permitted levels of micro-organisms in food, refer to the micro-criteria regulations. When the survey is being developed, the commissioning officer needs to be aware of the limits set by the Microcriteria Regulations related to the food sampled and tested. If there is potential for the limits or guidelines set in the microcriteria to be breached, then the FSA's incidents team should be consulted on the potential action to be taken. Should samples be found to contravene the legislative levels, an agreed course of action will have to be in place at the start of the project between contractors and commissioning officer. The relevant policy branches will also need to be involved in this course of action and may also need to take specific action if a sample is found that contravenes the regulations. This may well involve immediately informing an EHO from the area where the sample was purchased, or a home authority in the case of a large retail chain.

## **Method development**

The laboratory methods used in microbiological food surveys need to be standardised. As a first choice, the ISO methods should be used. If these are unavailable then the HPA's national standard methods for testing micro-organisms in food ([http://www.hpa-standardmethods.org.uk/pdf\\_sops.asp](http://www.hpa-standardmethods.org.uk/pdf_sops.asp)) should be used. Any changes to these methods should be validated. If standardised methods are unavailable then they need to be developed and validated under a research contract before any survey is proposed.

## **Length of survey**

Microbiological surveys can vary in length from the snapshot survey if the target organism is present at a relatively constant level in food, to the year-long survey that may enable a view to be taken on the seasonal variation of the target organism. In both cases, the appropriate senior manager will need to be aware of the variation from the normal timetable for surveys.

## **Statistics**

Microbiological surveys normally measure the prevalence of a target organism(s) at retail level within the UK and on occasion may allow comparisons to be made between countries or product types i.e. whole carcasses compared to portions, organic compared to intensively produced. To calculate the number of samples that need to be taken and from which retail outlets, the commissioning officer needs to have information on the retail market and distribution of the samples in the UK. This information can be found from the statistical service in Defra or from an appropriate commercial organisation such as KANTAR or NIELSONS. These are just examples, there may be other organisations that could be approached. If this information needs to be purchased, then appropriate procurement procedures need to be followed. Before embarking on a survey, commissioning officers should reassure themselves that the infrastructure exists for carrying out this size of survey. Potential contractors should also ensure that they could manage a survey of this magnitude, especially if there are multiple target organisms under investigation. Commissioning officers and contractors should also reassure themselves that both parties understand the implications of a random survey and have the required systems in place.

Before a SRQ is submitted for authorisation the commissioning officer needs to outline information on the market share and the level of contamination being investigated. They should liaise with Statistics Branch to develop a sampling plan.

### **Sample purchase and logging**

Samples need to be purchased according to an agreed purchasing plan and timetable. On purchase, samples should be kept at their appropriate temperature according to the legislative requirement; chilled foods should be kept chilled for example. Samples should arrive at the testing laboratory within 24 hours of purchase (48 hours in exceptional cases) and tested within 24 hours of arrival. Where samples have taken 48 hours to arrive at the laboratory, testing should commence as soon as the sample is received. Samples should not be stored or tested after their 'best before or use by' dates. The project officer/leader should consider the need to archive isolates or samples for future reference.

High-resolution digital photographs should be taken of the samples (to record details on packing) on receipt at the analysing laboratory. On purchase, samples should be logged into a computerised database and assigned a unique sample number. This number should be used to identify the sample throughout the survey and should appear on the digital photograph.

### **Sample transport**

Samples will need to be taken throughout the UK and may even involve transportation from remote areas. There may be large numbers of samples to collect. The potential contractor must have a mechanism for transporting samples in such a way as to maintain the integrity of the sample. This may involve hiring appropriate equipment.

### **Project management and exchanges of information**

With surveys involving large numbers of samples and complex analysis they can easily fall short of requirements. Commissioning officers must ensure that there is a robust management plan in place before the survey begins. The plan should take into account foreseeable risks and plans to deal with these risks.

There should be regular communications between contractors and the project officer and this includes the contractor supplying a spreadsheet of results along with the corresponding digital photographs at regular intervals to the project officer. There must be regular management meeting and the FSA might employ an advisor in the case of large projects.

### **Checking of information and accuracy**

Spreadsheets of results produced by the contractor must be accurate and must be checked for accuracy by at least two persons before being sent to the FSA. In the case of large surveys the contractor should carry out a statistically valid analysis of the spreadsheet to ensure accuracy. The Agency's statisticians can advise the contractor on how to carry this out effectively.

### **Informing retailers and brand owners**

With the large numbers of samples being taken in microbiological surveys, informing retailers and brand owners of their results is a major task. Any information from the contractor giving postal details of retailers must be further checked against databases of addresses, Yellow Pages, retailer web sites and the Post Office web site for example. Large numbers of poorly identified retailers means the whole database must be returned to the contractor for checking and will not be acceptable. Following the mail shot informing retailers of the results, any return to sender letters will need to be checked and resent. Alternatively, results for larger retailers can be distributed in an electronic format (e.g. CD-ROM or email attachment) providing that it is protected and that the larger retailers only have sight of their own results. After attempting to contact retailers twice, the project officer can assume that the retailer is no longer trading in the produce under investigation.

## **ANNEX 9. TEXT OF LEAFLET DISTRIBUTED TO SMALL RETAILERS**

### **Introduction and the Data Protection Act (1998)**

The Food Standards Agency has a policy of openness and a commitment to protect and inform consumers. Therefore it normally publishes details of the source of samples tested in all its surveys, including brand names, retailer company names and addresses of retail premises. In certain cases it will be necessary to identify importers of products. In doing this, the Food Standards Agency is fulfilling its function under section 7(1)(a) of the Food Standards Act (1999) to provide advice and information in respect of matters connected with food safety or other interests of consumers in relation to food.

The implications of the Data Protection Act (DPA, 1998) must always be considered when planning a survey. The DPA requires specified data protection principles to be met in respect of personal data; in respect of personal data, in particular it has to be processed fairly and lawfully. To that end, a leaflet, the text of which is reproduced here, must be handed out to any retailer not included in the list of large retailers (see paragraph 74) at the time of purchase. The large retailers should be sent the letter in Annex 10. This will not necessarily apply in cases where local authorities collect samples. In such cases officers may also be taking other samples for their own purposes.

## **Text of the Leaflet to be Distributed During Sample Purchase**

### THE FOOD STANDARDS AGENCY IS CARRYING OUT A FOOD SURVEY

The Food Standards Agency conducts regular tests to ensure that food sold in the UK does not create an unacceptable risk for public health or mislead the consumer. This leaflet has been given to you by someone collecting samples, on behalf of the Food Standards Agency. They have obtained a sample of product (e.g. food, drink, supplements, etc.) from your retail establishment as part of a survey.

This leaflet explains why the Food Standards Agency undertakes surveys and how it will publish the results.

#### *Why is the Food Standards Agency doing food surveys?*

- To check that food is safe for consumers and that they are not being misled.
- To collect information on the composition of food.
- To help develop the Agency's policies on food safety.
- To check if current laws, codes of practice and other measures are working.

### *Why did the Food Standards Agency choose your establishment?*

Your establishment was chosen because it is one of the places where people buy the type of samples the Food Standards Agency are looking at in their current survey.

### *What will happen to the sample?*

The sample will be sent to a laboratory where it will be analysed. The results will then be sent to the Food Standards Agency. Where possible, a portion of the sample will be kept in case the manufacturer of the product asks for further, independent analysis.

### *How will I know which products have been taken?*

A list of all the samples taken for the survey will be held by the Food Standards Agency. This includes the brand names and details of when and where they were bought. Details of the samples purchased from your establishment will be sent to the brand owner as soon as practicable. Those purchased from retail chains will also be sent to the Head Office for that chain.

### *What will happen if the results are unusual?*

The Food Standards Agency will contact the brand owner to explain what happens next. Normally the result of the sample will be sent for comment well before the information is due to be published. However, if there is an urgent need to withdraw or recall the product because its sale is illegal or in order to protect public health, the brand owner will be notified quickly of the action required. The results would then be published without delay. This survey is being carried out to collect information rather than for enforcement purposes but if the results show a hazard to health, or breach relevant legal requirements, your local authority will be informed and they may wish to take enforcement action based on these results or collect further samples as part of an investigation.

### *What will happen with the results?*

At the end of the survey, the results, and all the information about the sample, will be published on the Food Standards Agency's web site (<http://www.food.gov.uk>). Sometimes the results need to be considered by one of the committees of independent scientific experts. This usually happens where the implications of the findings for public health are not completely clear. The expected publication date will be put on our web site. You can call

the Food Standards Agency on +44 (0) 207 276 8000 to be told when this has happened or to be sent a copy.

*How can I find out more?*

If you want more information you can call the Food Standards Agency on: +44 (0) 207 276 8000, and tell them that a sample was taken from your establishment for the following survey.

*[ Print sticky labels with title of survey – to be provided to distributor prior to dispatch ]*

## **Text to be Distributed Following/During Sample Purchase From the Internet, Mail Order Establishments, etc.**

### THE FOOD STANDARDS AGENCY IS CARRYING OUT A FOOD SURVEY

The Food Standards Agency conducts regular tests to ensure that food sold in the UK does not create an unacceptable risk for public health or mislead the consumer. This text has been [given, posted, emailed, etc] to you by someone collecting samples, on behalf of the Food Standards Agency. They have obtained a sample of product (e.g. food, drink, supplements, etc.) from your [include details, e.g. internet site, mail order, etc] as part of a survey.

This text explains why the Food Standards Agency undertakes surveys and how it will publish the results.

*Why is the Food Standards Agency doing food surveys?*

- To check that food is safe for consumers and that they are not being misled.
- To collect information on the composition of food.
- To help develop the Agency's policies on food safety.
- To check if current laws, codes of practice and other measures are working.

*Why did the Food Standards Agency choose your [include details as above]?*

Your [include details as above] was chosen because it is one of the places where people buy the type of sample the Food Standards Agency are looking at in their current survey.

*What will happen to the sample?*

The sample will be sent to a laboratory where it will be analysed. The results will then be sent to the Food Standards Agency. Where possible, a portion of the sample will be kept in case the manufacturer of the product asks for further, independent analysis.

### *How will I know which products have been taken?*

A list of all the samples taken for the survey will be held by the Food Standards Agency. This includes the brand names and details of when and where they were bought. Details of the samples purchased from your [include details as above] will be sent to the brand owner as soon as practicable. Those purchased from retail chains will also be sent to the Head Office for that chain.

### *What will happen if the results are unusual?*

The Food Standards Agency will contact the brand owner to explain what happens next. Normally the result of the sample will be sent for comment well before the information is due to be published. However, if there is an urgent need to withdraw or recall the product because its sale is illegal or in order to protect public health, the brand owner will be notified quickly of the action required. The results would then be published without delay. This survey is being carried out to collect information rather than for enforcement purposes but if the results show a hazard to health, or breach relevant legal requirements, your local authority will be informed and they may wish to take enforcement action based on these results or collect further samples as part of an investigation.

### *What will happen with the results?*

At the end of the survey, the results, and all the information about the sample, will be published on the Food Standards Agency's web site (<http://www.food.gov.uk>). Sometimes the results need to be considered by one of the committees of independent scientific experts. This usually happens where the implications of the findings for public health are not completely clear. The expected publication date will be put on our web site. You can call the Food Standards Agency on +44 (0) 207 276 8000 to be told when this has happened or to be sent a copy.

*How can I find out more?*

If you want more information you can call the Food Standards Agency on: +44 (0) 207 276 8000, and tell them that a sample was taken from your establishment for the following survey.

*[ Print sticky labels with title of survey – to be provided to distributor prior to dispatch ]*

## **ANNEX 10. COPIES OF EXAMPLE STANDARD LETTERS**

- 10.1 Example letter to brand owners informing them of sample purchase.
- 10.2 Example letter to brand owners notifying them that their results were above the reporting level.
- 10.3 Example letter to the contractors informing them that the companies with results above the reporting level have been notified.
- 10.4 Example letter to brand owners notifying them of their results and the date of publication of the FSIS.

## ANNEX 10.1

### EXAMPLE LETTER TO ALL BRAND OWNERS INFORMING THEM OF SAMPLE PURCHASE

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Dear [*name*]

The Food Standards Agency carries out a wide-ranging programme of food surveys to:

- to check for consumer safety
- to obtain data on the composition of food
- to develop its policies on food safety
- to assess the effectiveness of legislation, codes of practice and other measures.

Details of current survey programmes are available on our web site.

The Food Standards Agency is currently undertaking a survey to investigate [*background details of study, including what the product will be analysed or examined for*].

You will wish to be aware that the sample(s) for which the details are attached have been included in the survey and have now been sent for analysis. Once these have been analysed the results will be published by the Food Standards Agency, together with details of the products, including brand name, the name of the manufacturer/brand owner shown on the label, batch code and pack size. Furthermore, you can expect the Food Standards Agency to inform you of your brand's individual results prior to publication. [*Where the analytical sample is to be divided into portions and sub-samples retained, the letter should state "The sample(s) will be homogenised and divided into sub-samples. Those not used for our analysis will be stored for [give period, typically one year], after which they may be destroyed. You may request a sub-sample for your own analysis at any time within this period."*]

Please do not hesitate to contact me if you have any queries. Please return the attached fax-back on receipt of this letter.

Yours faithfully/sincerely

[*name*]

FAX –BACK - ACKNOWLEDGEMENT OF RECEIPT

[Name of retailer]

[Address of retailer]

Please fill in and return to – [name] on Fax No [fax number]

[Reference for letter sent]

I return this fax as confirmation that I have received your letter dated [date].

This letter has been received by:

\_\_\_\_\_ (Name of recipient),

\_\_\_\_\_ (Signature of recipient),

on \_\_\_\_\_ (Date)

Please give name and address for future correspondence if different from that which this letter has been addressed to.

Name: : \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

## ANNEX 10.2

EXAMPLE LETTER TO BRAND OWNERS NOTIFYING THEM THAT THEIR RESULTS WERE ABOVE THE REPORTING LEVEL (BUT WHERE IMMEDIATE ACTION IS NOT REQUIRED) INVITING THEM TO COMMENT

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Dear [*Name*]

As you are aware, a survey is currently being conducted to [*background of study including purpose*]. We are writing to those companies whose products have been found to contain high or unusual levels of [*name(s) of contaminants under investigation*]. I am enclosing the results for your company's products.

Although these findings do not require any immediate action on your part you are invited to send us any comments (maximum 200 words) that you would wish to see published when the full results of the survey are released by the Food Standards Agency shortly. We will need to receive these by 3 weeks from the date of this letter if they are to be included with the survey results.

The analysis was conducted at [*where analysis was conducted*] using a validated method for the determination of [*name(s) of contaminants or microbiological agents under investigation*]. [*Where appropriate: A duplicate sample of the product has been retained by the laboratory and is available should you wish to undertake your own analysis.*]

In line with the Food Standards Agency's policy on openness, a list of all the products sampled including details of brand, type of product and the retail outlet from where it was purchased, will be published with the results.

Please do not hesitate to contact me if you have any queries. You are welcome to discuss your results with me by telephone. Please return the attached fax-back on receipt of this letter.

Yours faithfully/sincerely

[*name*]

## Results of analysis

Date of purchase	Best before date	Brand name	Product	Product description	Batch code	Result

## Measurement uncertainty

*[include details of MU calculation at reporting level ]*

## Method

*[include brief summary of methods ]*

FAX –BACK - ACKNOWLEDGEMENT OF RECEIPT

[Name of retailer]

[Address of retailer ]

Please fill in and return to – [name ] on Fax No. [fax number ]

[Reference for letter sent]

I return this fax as conformation that I have received your letter dated [ date ].

This letter has been received by:

\_\_\_\_\_ (Name of recipient),

\_\_\_\_\_ (Signature of recipient),

on \_\_\_\_\_ (Date)

Please give name and address for future correspondence if different from that which this letter has been addressed to.

Name: : \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

## ANNEX 10.3

### EXAMPLE LETTER TO THE CONTRACTORS INFORMING THEM THAT THE COMPANIES WITH RESULTS ABOVE THE REPORTING LEVEL HAD BEEN NOTIFIED

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Dear [name]

I am writing to inform you that the manufacturing companies for the foods in which [name(s) of contaminants under investigation] above the reporting level, have now been contacted by us. They have been sent a letter with the details of their products which were analysed together with the individual result(s) and have been asked to submit comments for inclusion with the survey results when published.

The companies have been informed that your laboratory performed the analysis and therefore, it is possible that they may contact you. If you are contacted, please provide me with details and forward copies of any letters or other documents received. *Further text can be added to reiterate the provisions for information disclosure laid down in the Terms and Conditions, e.g. requirement to forward information requests within a defined timeframe. The T&Cs will vary depending on whether the contractor is a public authority with FoIA/EIR obligations or a private company – see paragraph 64.*

If you have any queries please do not hesitate to contact me. Please return the attached fax-back on receipt.

Yours faithfully/sincerely

[name]

FAX –BACK - ACKNOWLEDGEMENT OF RECEIPT

[Name of contractor]

[Address of contractor]

Please fill in and return to – [name] on Fax No. [fax number]

[Reference for letter sent ]

I return this fax as confirmation that I have received your letter dated [ date ].

This letter has been received by:

\_\_\_\_\_ (Name of recipient),

\_\_\_\_\_ (Signature of recipient),

on \_\_\_\_\_ (Date)

Please give name and address for future correspondence if different from that which this letter has been addressed to.

Name: : \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

## ANNEX 10.4

### EXAMPLE LETTER TO BRAND OWNERS NOTIFYING THEM OF THEIR RESULTS AND THE DATE OF PUBLICATION OF THE FOOD SURVEY INFORMATION SHEET

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Dear [name]

As you are aware, the Food Standards Agency has conducted a survey of [survey title]. We are writing to you as your product(s) has(ve) been sampled in this survey, and to inform you that the results(s) will be published shortly. I am enclosing the results(s) for your company's product(s) for your information.

In line with the Food Standards Agency's policy on openness, a list of all products sampled including details of brand, type of product and the retail outlet where it was purchased, will be published with the results. *[Maybe add "Furthermore the results will be accompanied by introductory and explanatory text and a draft copy of this is enclosed for your information"].*

If you have any comments to make on the attached results then please do not hesitate to contact me by [date] at the latest.

Please return the attached fax-back on receipt.

Yours faithfully/sincerely

[name]

## Results of analysis

Date of purchase	Best before date	Brand name	Product	Product description	Batch code	Result

## Measurement uncertainty

*[include details of MU calculation at reporting level ]*

## Method

*[include brief summary of methods ]*

FAX –BACK - ACKNOWLEDGEMENT OF RECEIPT

[Name of retailer]

[Address of retailer]

Please fill in and return to – [name] on Fax No. [fax number]

[Reference for letter sent]

I return this fax as confirmation that I have received your letter dated [date].

This letter has been received by:

\_\_\_\_\_ (Name of recipient),

\_\_\_\_\_ (Signature of recipient),

on \_\_\_\_\_ (Date)

Please give name and address for future correspondence if different from that which this letter has been addressed to.

Name: : \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

## **ANNEX 11. CONSULTATION WITH EXPERT COMMITTEES**

### **Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)**

In order to reduce delays to a minimum, the COT secretariat should be consulted during planning of a survey in order to ensure:

- i. that the design of a survey is adequate to allow meaningful interpretation; and
- ii. that there is adequate toxicological information on the substance.

The Secretariat will consider the results of previous COT discussions and any assessments from the SCF or JECFA in deciding whether a detailed review will be required. If it is necessary to prepare a full toxicological evaluation (hazard characterisation) for the COT, the Secretariat will need to commence work on the paper 6 months before the survey is due to be completed.

With adequate planning, it should be possible for the COT to agree a statement at first consideration or by correspondence, if the survey results indicate that exposure is lower than the ADI/TDI. However, if specific advice is needed, or if the evaluation is complex, then a second or third discussion may be necessary. The COT meets 6 or 7 times a year. To facilitate the planning process, the COT Secretariat will organise bi-annual meetings for those conducting surveys, in order to exchange information on the commissioning and progress of surveys and the COT work-programme. Regular liaison between meetings will help to ensure that there are no delays in obtaining the COT advice. The COT Secretariat will also be responsible for input from the Committee on Mutagenicity (COM) or Committee on Carcinogenicity (COC), where required. The full COT statement should be included as an Annex to the FSIS.

### **Health Protection Agency – Radiological Protection (HPA-RP) Division and Committee on the Medical Aspects of Radiological Exposure (COMARE)**

Where necessary, the Food Standards Agency will consult the HPA-RP Division and/or COMARE on the significance of any results for levels of radioactivity in food or other relevant samples. The HPA-RP Division advises on the safety of ionising and non-ionising radiation and is part of the new Health Protection Agency.

COMARE is an independent expert advisory committee with members chosen for their medical or scientific expertise and recruited from universities, research organisations and medical institutes. The committee provides independent advice to all Government

departments and devolved administrations. It is responsible for assessing and advising on the health effects of natural and man-made radiation in the environment.

### **Scientific Advisory Committee on Nutrition (SACN)**

There may be occasions when it is appropriate to consult SACN on the results of surveys. SACN meets twice a year, normally in April and October, and generally conducts its business through meetings. It might take two or more meetings before SACN provides an opinion, therefore, if there is likely to be a need to consult on any results the project officer should contact the SACN secretariat at an early stage. The publication of the results should not be delayed, but the report should indicate that SACN had been consulted and that their full statement will be published at a later date as an Annex to the FSIS.

### **Advisory Committee on the Microbiological Safety of Food (ACMSF)**

For microbiological surveys the ACMSF should be consulted. The ACMSF assesses the risk to humans of micro-organisms which are used, or occur in or on food, and advises the Food Standards Agency on any matters relating to microbiological safety of food. The committee meets every three months. The Surveillance working group of the ACMSF facilitates the provision of ACMSF advice to government in connection with its microbiological food surveillance programme and other surveillance relevant to foodborne disease, particularly in relation to design, methodology, sampling and statistical aspects and reports back regularly to the ACMSF.

Although the ACMSF only meets quarterly, there are established procedures in place for the Committee to deal with urgent business that arises between meetings. In addition, the Surveillance Working Group of the Committee, as a standing group, is on permanent call to deal with any business that requires its attention.

## **ANNEX 12. SIGN-OFF SHEET FOR CONFIRMATION OF COMPLIANCE WITH THE GUIDELINES FOR FOOD STANDARDS AGENCY SURVEYS**

Note: A completed proforma must accompany all surveys sent to COMS Division and the relevant Director(s) when seeking clearance for publication. A copy must also be kept on the relevant policy file.

**Full Name of Survey:**

**Date Submitted for Clearance:**

### **1. FSA Project Officer:**

I confirm that I have followed the Guidelines. If I have needed to deviate from the Guidelines, I have obtained explicit permission to do so from my Head of Division

Name:

Signature:

### **2. Independent check by second FSA Official:**

I confirm I have carried out an independent check of the survey.

Name:

Signature:

### **3. Head of Division:**

I confirm that I have checked and I am satisfied that the necessary processes have been followed in producing this survey.

Name:

Signature:

Date: