



RISK-BASED SAMPLING OF FOOD

A Scientific Approach to Sampling for Analysis

Vol.1: Risk Assessment for Sampling



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Volume 1: Risk Assessment for Sampling

SUMMARY

This paper presents a practical approach to the risk assessment of foods and the assignment of sampling frequencies on the basis of the assessed risk.

Guidance is given on implementation of the scheme, including information regarding associated issues necessary to ensure that sampling and analysis are effective.

This volume is intended as a ‘working document’ that can stand on its own once the system and its supporting database have been established. Before that stage it must be read in conjunction with its companion paper, *Volume 2: Background and Support*, in which is provided background information, including the requirements for the database necessary to support the risk based sampling scheme and ensure the validity of the whole process.

It is recommended that a risk-based approach to sampling and analysis be implemented as a matter of urgency.

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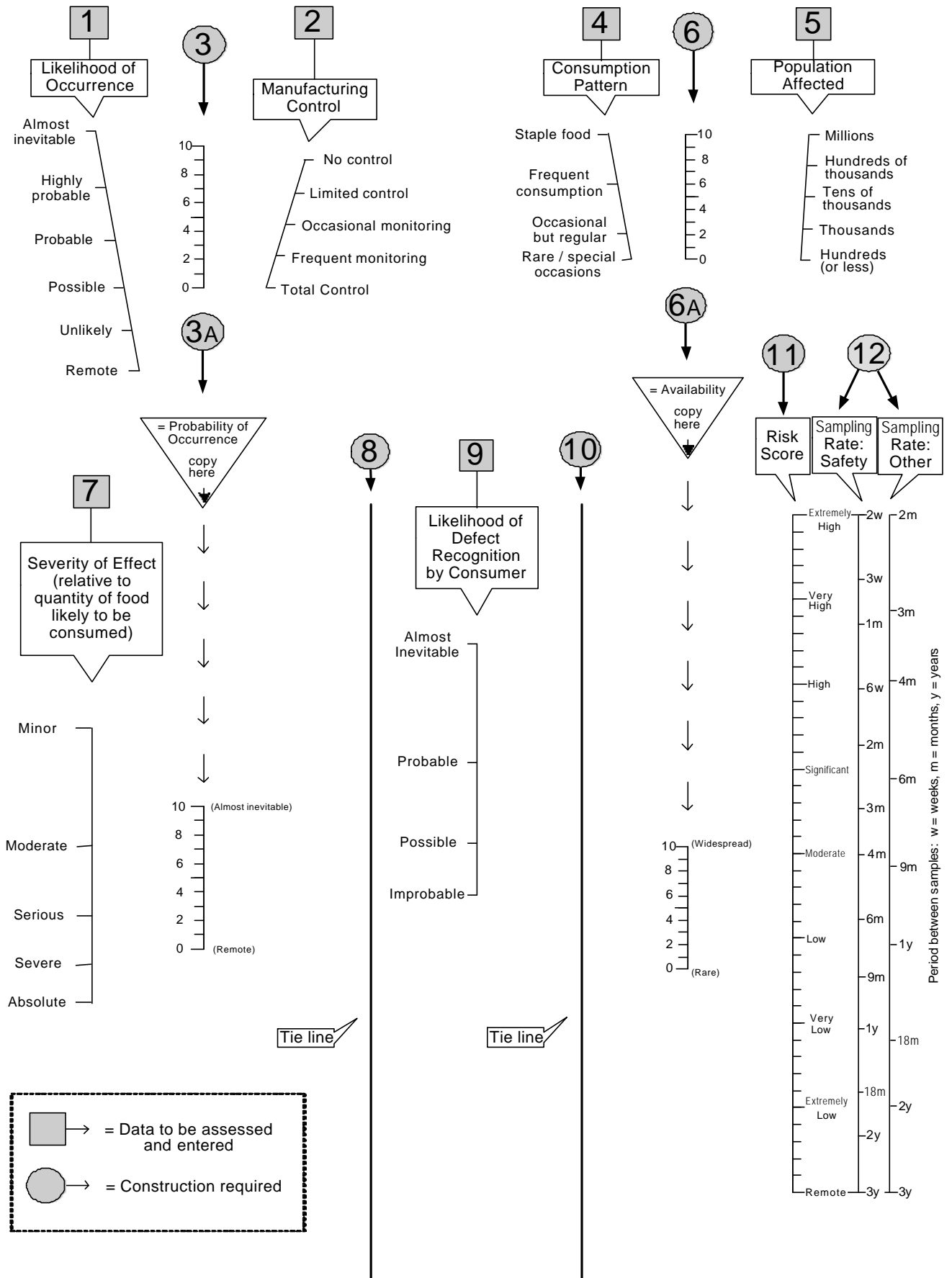
1. Introduction

- 1.1 This paper together with its companion (Volume 2) presents an approach to the sampling of food for analysis that has the potential to maximise the effectiveness of the process by focusing on risk and by avoiding any unnecessary duplication of effort.
- 1.2 The scheme itself is presented in this volume, together with all the notes needed for interpretation and application, including a worked example. Also in this volume are observations and guidance regarding the principles and practice of an effective sampling scheme. In effect this volume is the ‘working document’ with Volume 2 providing background information, including the requirements for the database necessary to support the risk based sampling scheme and ensure the validity of the whole process, and also including additional worked examples.
- 1.3 Throughout both papers except where otherwise explicitly stated the word ‘risk’ is to be construed as being the likelihood of occurrence of any fault with food that may in any way be detrimental to the health, well-being or rights of the consumer, or the likelihood of contravention of food law.
- 1.4 As indicated in Volume 2, these papers are concerned with proposing an effective system for primary sampling and analysis that will afford proper protection to the consumer, and not to consider any resource implications, although it is clearly an essential prerequisite that all enforcement authorities are properly funded and provided with all tools needed to enable them to do the job that is expected of them.
- 1.5 It is suggested that the decision on whether the proposed scale that converts the risk assessment score to a sampling frequency does satisfy the reasonable needs and expectations of the consumer is one that must be made by the Food Standards Agency, amending it if appropriate. Should the decision have any resource implications it would then be for the Government to determine whether or not to endorse the Food Standards Agency’s recommendation and ensure that enforcement authorities have the necessary resources, or otherwise to dictate an alternative level of protection.

2. Risk Assessment Nomogram

- 2.1 The practical application of this scheme for risk-based sampling is based on the use of a nomogram, being a simple and easily used tool to make the mathematical relationships that form the quantitative risk assessment process. The process is not as complex as a first glance at the nomogram may suggest, as will be apparent from a study of the worked example in this paper and the additional worked examples in Volume 2. The nomogram appears on the next page.

Risk Assessment Nomogram – Food Safety



3. Food Defects

Potential safety defects to be considered in the risk assessment process include:

- Naturally occurring toxins (cyanogenetic glycosides, scombrototoxin, paralytic shellfish toxin, etc)
- Contamination from a polluted production environment or contaminated animal feed (heavy metals, dioxins etc)
- Contamination through poor hygiene (bacteria, viruses)
- Contamination by metabolites from micro-organisms (mycotoxins etc)
- Use of unsuitable ingredients (e.g. non-food ingredients such as diethylene glycol etc)
- Poor control over the levels of additives (e.g. excessive levels of preservatives, colours etc)
- Contamination from the harvesting process (insects, foreign plants etc)
- Contamination arising from the production process (residues from pesticides, veterinary treatments, fungicides, foreign objects, contact with machinery etc)
- Deterioration during production or subsequent storage (migration from packaging material, protein breakdown, insect infestation)
- Failure to declare the presence of ingredients to which a consumer individual may be allergic (nuts, fish by-products, milk products etc)

Other potential 'consumer protection' defects to be considered in the risk assessment process include:

- Not being of the nature, substance or quality demanded
- Inaccurate or misleading presentation (pictures, advertisements, description - including the name given to the food)
- Incomplete, inaccurate or fraudulent declarations or claims (whether required or voluntary)
- Failure to comply with compositional standards (legislative, customary or expected)
- Failure to make statutory declarations (presence of genetically modified organisms, irradiated food, meat content etc)

4. Instructions for use of the nomogram

- 4.1 This process must be undertaken for every food.
- 4.2 Some aspects will be common to the same or similar types of food regardless of manufacturer, whilst others will be manufacturer-specific, regardless of product.
- 4.3 Initially the process of assessment is likely to be time-consuming, but as basic data is accumulated the process will become easier, thus once established the process will be nowhere near as complex as it will at first seem. The process would be greatly assisted by inclusion of appropriate data in a national food database.
- 4.4 The instructions that follow should be read in conjunction with Section 1 of this Appendix giving examples of defects, and Section 3 in which the assessment criteria are discussed.
 - i) Assess possible defects applicable to the food. Until such time as a reasonable wealth of comparative data is available this assessment is likely to need the input of appropriate specialists. Officers responsible for making the risk assessment should consult with enforcement scientists as a fundamental part of the process. Defects of similar character may be considered together for further assessment, though remaining individually identified (they may need to be separated as later stages in the assessment may require). Defects that affect the safety of the food will need to be considered separately from other defects because the two categories of defect use different Risk Assessment nomograms
 - ii) Assess the likelihood of occurrence of each of the identified possible defects (meaning before any manufacturing control has been applied). This is another area where the input of appropriate specialists is likely to be necessary, and for which enforcement scientists should be consulted as a matter of course. For each defect or group of similar defects the likelihood should be marked on scale 1 of the nomogram.
 - iii) Assess the degree of control exercised by the manufacturer/producer to prevent the defect in the final foodstuff, and mark on scale 2 of the Nomogram.
 - iv) Draw a straight line linking the points marked on scales 1 and 2, read off where it intersects the scale between (scale 3) (if the line passes below the zero point, take the reading as zero). Mark the corresponding position on the probability of occurrence scale beneath (3A).
 - v) Assess the likely pattern of consumption within the expected distribution area, and mark on scale 4 of the nomogram.
 - vi) Assess the geographical distribution of the product, and mark on scale 5 of the nomogram.

- vii) Draw a straight line linking the points marked on scales 4 and 5, read off where it intersects the middle scale (scale 6) and mark the corresponding position on the availability scale beneath (6A).
- viii) Assess the potential severity of effect of each identified defect (or group of similar defects). Again this is an area where the input of appropriate specialists is likely to be necessary, and for which sampling officers should consult with their Public Analysts as a matter of course. For each possible defect or group of similar defects the severity should be marked on scale 7 of the nomogram.
- ix) Draw a straight line through the marked points on scales 7 and 3A, extending it to reach scale 8.
- x) Assess the likelihood of the consumer recognising the defect in time to reject the food, and mark on scale 9 of the nomogram. (This is another area where the input of appropriate specialists might be necessary.)
- xi) From that point on scale 9, or the nearest end of the scale line if you are above or below it, draw another straight line through the marked point on scale 6A, extending it to reach scale 10.
- xii) Again from that point, or the nearest end of the scale line if you are above or below it, draw another straight line through the marked point on scale 6A extending it to reach scale 11, from which can be read off the overall risk assessment or the particular potential defect, or group of defects, in the particular food (if the line passes above or below the final risk scale simply take the score as the top or bottom respectively).
- xiii) Once the adjoining sample rate scale has been assigned (statistically derived to achieve the desired confidence level), the frequency of sampling can then be read.
- xiv) This frequency is the minimum rate that the food should be sampled for analysis against the particular potential defect, or group of similarly rated defects. The frequency assumes that sampling is random, therefore a rigid timetable should not be imposed, and a certain amount of truly random retail-based sampling should be undertaken.

5. Assessment Notes

The following notes are intended to assist in application of the assessments necessary to assign values for the various scales in the nomogram.

A) Likelihood of occurrence (before any manufacturing/production controls come into play)

Safety

Natural or unavoidable occurrence, farming practices, contamination during manufacture, etc.

Non-Safety

Mistake or deliberate action, whether on the part of the main manufacturer or producer, or on the part of a supplier, or multiple suppliers.

Almost Inevitable = Certainty or no doubt that sooner or later it will occur

Highly Probable = Likely to occur some time in production

Probable = Not surprised if it occurs

Possible = Could occur, but would be unusual for it to happen

Unlikely = Not likely to occur, but not inconceivable

Remote = Virtually inconceivable

B) Manufacturing control (in respect of the defect being considered)

Safety

The degree of control to prevent contamination or deterioration, and the extent of monitoring to detect contamination or deterioration.

From no control to total control. Assessment of this must take into account the stage in the production and distribution chain at which the problem can occur.

Non-Safety

Diligence and track record in avoiding mistakes, meeting standards and correctly labelling ...or otherwise. Ethical vs profit-driven marketing.

The degree of monitoring of raw materials (or supplied product in case of importers), to detect both accidental and deliberate defects.

No Control = Just that, in respect of defect under consideration

Limited Control = Specification for supplied material, covering defect of interest, but without any additional checks or without requirement for supplier to provide evidence of checks.

- Occasional Monitoring = Monitoring for presence of defect from time to time (not on a statistically sound basis or statistically but with inappropriate selection of acceptable quality), or seeking evidence of such monitoring from supplier (with appropriate verification if the source of data is not accredited to EU standards).
- Frequent Monitoring = Defect minimised as far as possible at source, with monitoring on a statistically sound sampling basis (e.g to BS6001 with appropriate selection of acceptable quality), any testing accredited to EU standards.
- Total Control = Defect minimised as far as possible at source, with continuous monitoring of output for the defect being considered (not possible in many cases), with statistical certainty at least 95%. Otherwise 100% certainty that the route of occurrence has been eliminated.

C) Frequency/Quantity of Consumption

Safety and Non-safety alike

From staple foods, through specialist foods eaten in substantial amounts by a small sector of the population in the distribution area, to foods eaten only infrequently.

- Staple Food = Eaten regularly, typically several times per week, in substantial amounts by a large sector of the population in the distribution area.
- Frequent Consumption = Eaten weekly by a high proportion of the population in the distribution area, or more frequently by a smaller proportion.
- Occasional but Regular = Eaten monthly or so by a high proportion of people in the distribution area, to weekly for a smaller proportion of people.
- Rare / Special Occasions = Typically eaten only once or twice a year, or a speciality food generally eaten by only a very small proportion of people

D) Population Affected

Safety and Non-safety alike

This is related to both the proportion of consumers in the distribution area likely to consume the food, and the geographical spread of the distribution area (e.g. from a small area served by a single shop, to nationwide coverage, and from a specialist or luxury commodity to one with mainstream appeal.

- Millions = Wide appeal, and distributed throughout most of the UK.
- Hundreds of thousands = Moderate appeal with nationwide coverage, or wide appeal but only regional coverage.
- Tens of thousands = Wide appeal but only available in a single city or large town, or limited appeal distributed nationally.
- Thousands = Wide appeal but only available in a single small town or single large store, or speciality product but widely distributed.
- Hundreds (or less) = Typically a small single outlet.

E) Severity of effect

Safety

Direct toxicity or other harmful effect. Also the potential for harm to specific categories of person (allergies etc).

Effects may be acute (short-term), chronic (long-term), or cumulative. Consideration has to focus on the worst possible scenario, and must have regard for effect on weaker members of the community.

- | | | |
|----------|--|--|
| Minor | = Distaste through mild vomiting or discomfort, symptoms lasting no more than a day. | = Any food not complying with food law, not otherwise covered below. Label confusing or difficult to understand (but legible and correct). |
| Moderate | = Distressing reaction such as repeated or prolonged vomiting or diarrhoea, or incapacity for several days, but specialist care not required | = Up to 10% deficiency in content of any component (relative), in respect of expected, required or declared level. (Also excess if maximum quoted). Label difficult to read. |

Non-safety

Deficient composition, incorrect description, misleading or fraudulent claims, etc. Loss of enjoyment of a food.

Pecuniary loss (immediate and cumulative) Psychological effects of the consumer learning he or she has been cheated.

Serious	= Incapacity for more than one week, or specialist care required. Not life threatening.	= 10-25% deficiency (relative). Ingredients missing from ingredients list. Food not authentic.
Severe	= Specialist care needed (e.g. hospitalisation), or after-effects lasting many weeks or more. Death possible, but unlikely with appropriate medical care.	= More than 50% relative deficiency. False claims. Fundamental misdescription, e.g lamb described as beef, sugar free when not, etc
Absolute	= Death likely in the absence of (or despite) swift medical attention.	

F) The likelihood of defect recognition by a consumer

	<u>Safety</u>	<u>Non-safety</u>
	Obviously mouldy; overpowering and highly objectionable odour etc.	Patently ridiculous claim etc.
	Need to have regard for minority groups such as the blind, poor sense of smell or taste, etc.	Need to have regard for the less discerning members of society.
	Detection means prior to consumption, and with sufficient concern to reject the food.	Detection means prior to purchase.
Almost Inevitable	= Could not possibly miss, even in poor light, in a hurry, and with below average senses.	
Probable	= Most consumers taking reasonable (normal) care would be likely to spot that something was amiss and would reject the food as a consequence.	
Possible	= Defect detectable to a reasonably aware consumer, without requiring any special skills or experience.	
Improbable	= No outward sign, other than possibly to an expert.	

6. Other Issues Pertinent to Effective Sampling

- 6.1 It is important to note that the frequency of sampling derived by this risk-based scheme is for the UK as a whole, operating a nationwide scheme. For parameters other than those affected by storage and distribution sampling should be primarily focused on sampling at factory/production/import level (which in the case of catering may also be the retail stage). For the system to work it is vitally important that all enforcement authorities are diligent about (and funded for) sampling to the proper extent from manufacturers in their area as the whole country would be reliant upon this as the primary enforcement activity. It is possible that those authorities with relatively few manufacturers could provide the main focus of non-production related sampling.
- 6.2 The rate of sampling determined in accordance with the risk based sampling scheme may dictate a frequency for a food from a given manufacturer that is different from that determined by the risk assessment of premises under the Food Safety Act Codes of Practice. Should the sampling frequency be the greater, it may be necessary to include additional sampling visits between full inspections, and conversely if the sampling frequency is lower it may not be necessary to take samples on every inspection visit, unless dictated by other circumstances or requirements.
- 6.3 Notwithstanding the foregoing paragraphs, in order for the system to work effectively, whether or not statistically based, an element of randomness must exist. This can be achieved in part by including a proportion of sampling at retail level in addition to that programmed at production level.
- 6.4 Retail level sampling is also required to detect problems arising from storage and distribution, and is an essential part of the vigilance necessary to identify products from suppliers not registered and thus not within the control system (where some of the greatest risks from rogue traders and counterfeiters tend to arise).
- 6.5 For the system to be effective every food on the market in the UK - every brand as well as every category - should be sampled at least once over a period of time no matter how low the perceived risk. This effectively defines a lower limit to the sampling rate regardless of any statistical evaluation. It is suggested that the minimum sampling period should be once every three years. In addition, all new labels produced by manufacturers should be approved before they are introduced, though this may require a substantial modification of the Home Authority system in respect of big producers.
- 6.6 In view of the short production life of some foods it is important that an assignment of low risk does not mean that sampling is delayed until after production has ceased - in effect samples should be taken as soon as practicable after the commencement of production of new lines, the risk assessment process defining the follow up period not a delay period before first sampling.

- 6.7 The successful application of this risk-based sampling scheme to determining the appropriate sampling rate for any given food/defect will require the availability of appropriate knowledge in relation to available food types and in relation to pertinent analytical parameters, and similarly will require sufficient knowledge of each of the individual risk factors identified above in order to make the assessment.
- 6.8 It is likely therefore that the provision of relevant information will require primary input jointly from the appropriate specialist enforcement professionals. Where information is unavailable or insufficient, assessments may require input from relevant expert committees (e.g. on such matters as toxicology). Some aspects of the information can only be assessed by the home authority for the manufacturer or importer, therefore it is likely to be most practical for the process to be centred on the home authority, although there is a need for consistency of assessment throughout the UK.
- 6.9 In practical terms the sampling would be most efficient if focused where applicable on the ingredients used by a manufacturer as they may be common to a number of products (such as contamination issues related to the ingredients: pesticide residues, naturally occurring toxins, heavy metals etc). Sampling and analysis of the final products themselves then would be able to ignore factors arising only from the ingredients used, concentrating on factors relating to the manufacturing and marketing process.
- 6.10 For the purposes of sampling and analysis, importers effectively need to be regarded as if they are manufacturers, as indeed would the catering industry, the risk assessment process automatically making any appropriate allowance for different information available about the product or its ingredients and any differences in scale of operation.
- 6.11 The ideal scheme requires sampling to be truly random. It is important therefore that any guidance on timetabling should be shaken up from time to time, thus avoiding sampling to a regular routine, though in so doing due regard must be had for the need to regard the derived sampling frequency as minimum guidance.
- 6.12 All sampling plans and all data derived from sampling and analysis should be fed into the developing national sample database – but with appropriate security to ensure that manufacturing cannot be ‘slewed’ by awareness of sampling plans. At this stage feedback from the database should be used to ensure that any ‘holes’ in respect of commodities or sectors sampled are rectified.

7. Implementation

7.1 In order to apply this risk assessment model in practice, the following additional steps (discussed elsewhere in either this paper or the companion paper, Volume 2) must be undertaken:

- i) Creation of a comprehensive database to support planning and to monitor sampling activity (Section 6).
- ii) Identification to enforcement authorities of the issues to be incorporated into sampling activities, having regard for all the observations made in Section 7.
- iii) Provision of any additional support required by enforcement authorities in carrying out risk assessments, particularly in terms of information regarding the toxic or other adverse effect of contaminants, and, particularly in the case of the less common substances, information regarding their likelihood of occurrence. Central consideration of these issues will help to ensure that the information is both correct and consistent.

8. Recommendations

8.1 In order to maximise the efficiency and effectiveness of the UK's food enforcement system and to provide proper protection of the food consumer it is most strongly recommended that this risk-based approach to sampling be adopted as part of a national sampling strategy as a matter of urgency, taking into account the risk of all potential defects in food and all matters discussed in this paper.

8.2 It is further recommended that while the various parts of the risk-based sampling system are developed, a simplified approach as outlined in Appendix C of Volume 2 be applied as an interim measure with immediate effect.

APPENDIX A – Worked Example using Risk Assessment Nomogram

This Appendix demonstrates the use of the Risk Assessment Nomogram, with a worked example of a full product assessment. Volume 2 presents a number of additional worked examples.

Canned cured pork product

This product has been considered in respect of contamination by pesticides or by heavy metals, excessive preservative, insufficient meat or undeclared added water or collagen. The availability clearly remains the same for each assessment. Sampling is required about every ten months to check the basic composition, but the pesticide and heavy metal contamination only need be checked on at alternate sampling times, while the level of preservative, over which the manufacturer has fairly good control and no profit motive to encourage an excess, need only be checked every third to fourth occasion.

Worked Examples: Full product assessment

