



RISK-BASED SAMPLING OF FOOD

A Scientific Approach to Sampling for Analysis

Vol.2: Background and Support



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SUMMARY

This is a companion paper to *Volume 1: Risk Assessment For Sampling*.

In order to afford proper protection for the consumer, while incidentally assisting the provision of a “level playing field” for food manufacturers, the food law enforcement system must include effective evaluation of the food supply. A fundamental part of this evaluation is the sampling of food and its scientific assessment. This paper and the scheme presented in Volume 1 have been developed primarily in relation to sampling for chemical analysis.

Although the present system of sampling does provide some measure of protection, it is unsystematic and provides very patchy coverage of the food supply. Sampling and analysis would be far more effective if undertaken on the basis of risk using a nationally applied scheme. Risk in this context is taken to be the likelihood of the occurrence of any detrimental defect with a food, whether or not due to natural contamination, system failure or deliberate action. The basing of sampling on risk was one of the recommendations of the Turner Report on the Review of Public Analyst Arrangements in England and Wales.

This paper examines the purpose of sampling for analysis and makes a critical evaluation of the present system. The process and application of quantitative risk assessment are discussed in a pragmatic manner, providing the background information for the comprehensive scheme described in Volume 1.

In addition this paper describes the requirements for the database necessary to support the risk based sampling scheme and ensure the validity of the whole process.

An alternative, simpler, risk assessment scheme is included as part of a description of quantitative risk assessment. Such a scheme could be implemented with less preparation than the full process, and could thus be used for an interim period in the event of any unavoidable delay in implementation of the full scheme, although it is only a partial process and is crude in comparison with the full scheme,

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 Food must:

- be safe
- be compositionally correct
- not contain harmful contaminants
- contain only permitted additives
- be correctly described
- bear all necessary markings
- be labelled truthfully

1.2 In order to check that these requirements are met and thus afford the public effective protection from unsafe, unwholesome, substandard, defective or misdescribed food, it must be subjected to appropriate scientific evaluation. In order to do this, food must first be sampled.

1.3 An additional benefit of the control afforded by effective sampling and testing of food is to provide a 'level playing field' that will assist diligent food businesses to thrive by fair competition. In addition the prevention or early detection of major problems with food can help protect the national economy and so may indirectly benefit even those consumers not directly affected by the food itself.

1.4 The Turner Report on the Review of Public Analyst Arrangements in England and Wales¹, commissioned by the Government in 1998, included a detailed discussion of sampling, culminating in the following recommendation:

A logically derived system for establishing appropriate sampling rates should be developed centrally in consultation with food authorities. This should be based upon planned premises inspection and sampling, complaint and other ad hoc local investigations and border control point inspections. It will require the following subordinate actions:

...(iv) *the development of a systematic approach to the assessment of the risks presented by different types of foodstuffs and associated materials;*

(v) *the development of systems for the arrangement and coordination of national programmes for the chemical analysis of foodstuffs and associated materials. We wholeheartedly concur with the suggested guidance on sampling - indeed this is an area we had long considered to be inadequately addressed.*

- 1.5 This paper together with its companion (Volume 1) 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. It is observed, however, that a certain amount of repetition is likely to be necessary and appropriate both as part of a statistically sound plan and in order to encompass potential problems related to storage and distribution. If an appropriate risk acceptance level is set for the country and adhered to by enforcement authorities, and if sampling and analysis are followed by effective action to rectify any problems identified, the result is likely to be a decrease in the proportion of unsatisfactory foods and increased confidence in the food supply.
- 1.6 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.
- 1.7 It is the purpose of these papers to propose an effective system for primary sampling and analysis that will afford proper protection to the consumer. It is not their purpose 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.

2. Background to Sampling for Analysis

- 2.1 In the 130 years since the commencement of official sampling of the food supply for analysis, the selection of samples has been conducted on an ad-hoc random or semi-random basis modified by information available about likely problems.
- 2.2 Sixty five years ago a minimum sampling rate related to population was recommended by government² (not less than 3 samples per year per 1000 head of population). More recently a rate of 2.5 samples per year per 1000 head of population was quoted as general guidance for sampling for chemical analysis in England and Wales. Towards the end of the twentieth century the average rate of sampling in the UK was only about half that level, although there was considerable variation between authorities, with a few consistently sampling above the recommended rate but many sampling at considerably lower rates.
- 2.3 No minimum extent of analysis has ever been specified or recommended in the UK, with the result that as food complexity and thus analytical costs have increased, the extent of analysis generally has remained static or even decreased.
- 2.4 In some other parts of Europe minimum sampling levels are recommended or required. For example, in Germany there is a statutory minimum of 5 samples per year per 1000 population (including both chemical analysis and microbiological examination), on which a considerably greater degree of analysis is applied than is typical on food enforcement samples in the UK.
- 2.5 Under the existing approaches to sampling and analysis the proportion of food found to be unsatisfactory in the UK is in the region of 20%, a level that has remained constant over several years. In other words about one fifth of all food samples sent to Public Analysts by authorised officers of food enforcement authorities are reported as failing to comply with the law, some in respect of issues affecting safety and others in respect of 'consumer protection' issues, ranging from significant hazards to health and major fraud, to relatively minor failures to comply with technical details of legislation.
- 2.6 Meanwhile various 'scares' have occurred in this or other countries that challenge whether or not the present approach to sampling could reasonably be expected to catch before developing into a major problem. Clear examples are BSE and the 1999 Belgian dioxin crisis. Beyond this, constant vigilance is necessary to ensure that past problems such as heavy metal contamination of milk and fish do not recur.
- 2.7 Two fundamental questions arise from this background in relation to sampling and analysis, in considering which it is appropriate to recognise the radical changes in food production and distribution over the past quarter century or so:
 - i) Is the sampling and analysis of food as currently undertaken sufficient to identify all faults with food from which the consumer should reasonably expect to be protected?
 - ii) Are resources devoted to the sampling and analysis of food appropriately focused to avoid unnecessary duplication and to maximise effectiveness?

- 2.8 The answer to the first question is emphatically negative. With no clear guidance as to the right level of sampling and analysis activity, there is huge local variation in the level and effectiveness of such work. Coupled with the inadequate funding reportedly received by local authorities, and the low priority consequently given by many to food enforcement work, the resultant patchy national coverage of the work should not surprise. The present lack of any national over view of the process is also a factor..
- 2.9 The answer to the second question would also appear to be negative: The absence of an overall strategic view does lead to duplication of effort both unconsciously and consciously, which can waste the limited resources available while other parts of the food supply go untested.
- 2.10 Unconscious duplication occurs when several enforcement authorities focus on the same analysis of the same nationally distributed commodities at the same time, oblivious to the work of others, or where surveillance activities conducted by the Food Standards Agency outside the enforcement system may focus on the same commodities and analysis at the same time as enforcement sampling.
- 2.11 Conscious duplication occurs when one authority learns of a problem with food found by another and replicates the work. This can be done either to demonstrate to the local populace and elected politicians the effectiveness of the local enforcement and consumer protection machine, or to demonstrate that the problem exists elsewhere and does not affect their own consumers. However, a lack of co-ordination with the original authority or others also following up the matter can lead to significant duplication without overall learning anything new or without any greater success at eradicating the problem.
- 2.12 It must be noted, however, that not all apparent duplication is undesirable. A certain amount of repetition may be appropriate as part of statistically sound approach to sampling, while multiple sampling of the same commodity may be necessary where factors related to storage and distribution are significant. It should also be noted also that the mere sampling of the same food twice is not duplication if different analytical parameters are assessed.

3. Basis for Sampling

- 3.1 In order to ensure that protection of the consumer is effective, the frequency of sampling of any particular food and the scope of analysis undertaken on those samples must be soundly based on the risk to the consumer. Too often at present sampling may be based on arbitrary factors such as random projects and surveys planned in isolation arising from particular interest of officers involved in the planning, or a desire to achieve an auditable “benchmark” numerical score, whether or not as a function of the size of population.
- 3.2 The sampling and analysis of food in a well-designed system must aim to have a good chance of detecting faults with food as they arise and before significant effect on the consumer, or indeed to the economy. Examples from the past whose chances of detection today rely on luck more than judgement have included diethylene glycol in wine, tin in canned food, benzene in carbonated drinks and dioxins in contaminated animal feed - indeed apart from the tin example it is most unlikely that the current system stands any chance at all of detecting their occurrence.
- 3.3 The normal surveillance activities of enforcement authorities must include topics such as these as part of a well planned and comprehensive ‘net’ that is likely to require national planning and co-operation. A major challenge is to include within the system an adequate degree of open-minded searching for abnormalities rather than strict adherence to a closed routine. This may require a degree of monitoring of normal patterns of composition in order to detect anomalies when they occur (for example, routine monitoring of the normal ‘fingerprint’ of a commodity using various non-specific broadband techniques).
- 3.4 Risks to the consumer that must be considered in setting the rate of sampling include matters both of safety and other ‘consumer protection’ issues. Safety considerations may arise from contamination by toxic substances, use of unsuitable ingredients, poor control over the levels of certain additives, deterioration during production or storage, and failure to declare the presence of ingredients to which an individual may be allergic. Other ‘consumer protection’ issues include food not being what it purports to be (in terms of basic identity, brand or composition), not containing what it claims or is reasonably expected to contain, or not having a claimed effect. The description of the risk assessment scheme includes a detailed list of potential food defects.
- 3.5 Once a quantitative risk assessment value has been derived for any potential food defect, it then becomes possible to assess a frequency of sampling/analysis according to the risk presented. Different risks and hence sampling frequencies may apply to different aspects of the same food. For example, the risk in relation to potential contamination of a particular product by aflatoxin may be very much greater than that in relation to contamination of the same product by pesticides. The food may need to be sampled relatively frequently for aflatoxin testing, but be checked for pesticide contamination much less frequently.

4. Risk Assessment

- 4.1 Points that must be considered as the basis for determining rates of sampling and analysis based on an assessment of food and its potential faults and resultant risks include the severity of the effect of any given fault with food or its labelling (whether in terms of health, enjoyment or pecuniary loss, each having its own weighting in respect of interdependencies with other factors); the likelihood of a consumer spotting a fault and rejecting the food as a consequence; the likelihood of occurrence of the fault; the consumption pattern applicable to the food; the size of population likely to be affected; the degree of control and monitoring exercised by the manufacturer for all potential faults; and the stage in the production and distribution chain at which the problem can occur.
- 4.2 Factors that must be included in the risk assessment model are detailed on the next page.
- 4.3 Although there are many common features between the risk assessment models for safety and for “consumer protection” categories, it is clear that the issues are subtly different as shown in the table on the following page. For this reason some of the stages in assessment require different interpretations, according to whether or not the issue relates to safety, and it is likely that different risk acceptability levels will apply to safety compared to non-safety issues.
- 4.4 The effect that the different possible defects with food can have on consumers can vary significantly. In respect of those affecting health, effects can range from negligible to fatal. Whether or not serious, they can be short term in their effect, long term, or cumulative. They can affect all consumers, or only susceptible individuals.
- 4.5 Non-health related effects are less measurable. Although financial loss is limited to the value of the food purchased, the psychological effect of being ‘ripped off’ can be greater (and over time the financial loss can mount up), while the effect on enjoyment of the food can be significant. Some defect with food (or arising from its labelling) can offend individuals’ ethical or religious sensibilities. As with safety aspects, the sensitivities and reactions of consumers can vary from person to person.
- 4.6 The making of untrue claims, failure to comply with compositional requirements, and issues of authenticity can be detrimental to other food manufacturers, sometimes quite substantially. In addition, any major defect with food, whether or not health related, can be detrimental to public confidence in both the food supply itself and in governmental commitment to adequate protection of the consumer’s interests, and can even extend to other countries’ confidence in food produced in the UK.
- 4.7 The different risk factors shown have varying degrees of influence over the final risk presented to the consumer, and are not simply additive or subtractive. In order to make a quantitative assessment of risk they must therefore be combined in a manner that balances the relationships between each factor.

Factors that must be included in the risk assessment model:

Factor	Detail - Safety	Detail – ‘Consumer Protection’
The severity of the effect of any defect with the food.	Effect on a consumer’s health arising from any given fault with food, including deficiencies in its labelling (presence of toxic or harmful substances, undeclared allergens etc).	Effect on a consumer’s enjoyment of a food, and/or pecuniary loss or other prejudice, arising from any given fault with food or its labelling. (Deficient composition, incorrect descriptions, misleading or fraudulent claims, etc.)
The likelihood of a consumer spotting a fault.	...and rejecting the food before consumption. (E.g. visibly very mouldy, overpowering and highly objectionable odour etc - but having regard for minority groups such as the blind.)	...and as a consequence either not purchasing the food or making a correct assessment that avoids any loss. (E.g. patently ridiculous claim – but having regard for the less discerning members of society.)
The stage in the production and distribution chain at which the problem can occur.	Related to this factor may be the need to take into account the size of production batch, and whether (particularly in the case of imported food) a consignment is from a single producer or from multiple sources.	This consideration is identical to that in respect of Safety.
The likelihood of occurrence of the fault.	Occurring before any eradication or control measures put in place by the manufacturer.	Whether by accident or deliberate action.
The degree of control and monitoring exercised by the manufacturer.	...to prevent contamination or deterioration etc, or to detect that they have occurred. (The latter will also apply to an importer.) This factor may also need to take into account whether a consignment is from a single large producer or the combined production of a number of smaller producers.	...to catch accidental faults, or by an importer to catch either accidental faults or to catch deliberate faults introduced by suppliers (e.g. prior to importation).
The consumption pattern applicable to the food.	Whether a staple food consumed regularly or in large quantities, or one likely to be consumed only rarely or in small quantities.	Where pecuniary loss is involved this is linked also with the monetary value of the food: high consumption of a low value food may involve the same loss as small consumption of a high value food.
The size of population likely to consume the food.	...and thus potentially be affected by any adverse health effect (this factor includes whether a product is nationally or only locally distributed, and the extent of ‘coverage’ within the distributed area).	...and thus suffer the consequences of any ‘consumer protection’ issue.

- 4.8 In effect a mathematical relationship between all factors must be derived, following which the risk assessment process simply becomes a matter of identifying the value of each parameter and computing the resultant final risk value. Certain of the factors might be determined on a generic basis and applied to similar food/component types, while others are directly related to the manufacturer/supplier. It may be possible to build the risk assessment computation into a sample database, automatically picking up relevant factors from a common registry and thus requiring only a few of the risk factors to be assessed directly for an individual food in order to complete the risk assessment process.
- 4.9 One practical approach to applying these relationships is by use of a multistage nomogram. The use of a nomogram as a tool for quantitative risk assessment was developed by the US Navy in the early 1970s^{3,4}, putting the basic principles (similar to those described in the basic model presented in Appendix C to this paper) into an easily applied form. The New Zealand Ministry of Consumer Affairs further developed the US Navy model in the 1980s specifically for the purposes of product safety assessment^{5,6}.
- 4.10 Although the full risk assessment of food is more complex than for many other consumer products because many more factors can present or modify the risk, the New Zealand model is a proven approach that has been widely used for consumer product risk assessment, its use having extended well beyond its country of origin, including use for such purpose in the UK. It therefore provides a sound basis for development. A copy of this nomogram is appended as Appendix D.
- 4.11 The complex work with a nomogram lies in its design - once produced it is easy to apply, and has the added benefits of low cost and robustness, and is capable of use anywhere, even if 'in the field' it is only possible to make an educated guess as to some of the parameters.
- 4.12 The New Zealand model was not designed for food, nor was it designed specifically to guide sampling. It commences with the actual existence of a specific and identifiable defect, rather than a defect that could occur, and the "probability of occurrence" assigned by the user relates to the probability that the defect will cause the identified potential effect. The final scale then quantifies the risk presented by the identified defect. In the case of the risk assessment of food to guide official food control sampling, the whole purpose of that resultant sampling is to try to 'catch' the defect when it is present, with the effort to do this related to the degree of risk presented to the consumer. The nomogram is thus required to assess and quantify a combination of the risk of a hazard or other defect occurring and the extent of its potential effect on the consumer, not just the probability that an identified potential defect will actually occur, and not the probability that a defect when present will cause a given effect.
- 4.13 Although based on the concepts enshrined in the New Zealand model, the nomogram has been revised to fit the situation it is required to meet, with the addition of other factors appropriate to the assessment. The resultant model at first sight appears far more complex than the New Zealand model, because of the additional factors - but it is not difficult to apply. The proposed model for use for risk based sampling of food is presented in the primary paper *Volume 1: Risk Assessment For Sampling*, together with detailed notes to aid its application.

5. Acceptable Level of Risk

- 5.1 In order to relate the quantitative risk assessment to the required sampling frequency, the level of risk that is acceptable for food must be derived and an appropriate factor applied to the quantitative risk score.
- 5.2 In effect such a factor would trade off the cost of sampling and analysis against the protection of the food supply and protection of the consumer's interests: too rigorous a factor would lead to a high cost of sampling and analysis, whilst too lax a factor would put the consumer at an unacceptable level of risk, cause the consumer to lose confidence in the food supply, disadvantage diligent food businesses and might damage food export trade within Europe and the rest of the world.
- 5.3 In its review of BSE controls⁷ the Food Standards Agency looked at available data in respect of the acceptable expenditure to save a human life, and concluded that a figure of between £1M and £10M per life saved appears to be acceptable in UK society. Translating this to food suggests that society would consider it reasonable to spend up to £10M on food control for every life that the control could save. This could be tied in with the cost of analysis and the risk assessment of potentially lethal food faults to derive the extent of sampling and analysis appropriate to ensure that food is safe. In effect this would set the sampling effort applicable to the high risk end of the safety scale, from which the remainder of the scale could be extrapolated.
- 5.4 In practice, however, this is perhaps not a very valid approach because sampling and analysis by the enforcement authority is not intended to be the primary control of food, but rather is a back-up system with primary responsibility lying with the manufacturers. Even if not used as a guiding principle, however, it does serve to put cost in context.
- 5.5 Instead it is more relevant to consider the factor in terms of the level of confidence that the public can have in the UK food enforcement system identifying any food defects, and taking action to ensure that they are eliminated.
- 5.6 The theoretically correct approach to this would be to assign a statistical confidence limit so that the public can be assured of that level of confidence in enforcement authorities identifying any faults with food. A reasonable value for the statistical confidence limit in respect of safety would be 99%, and 90% in respect of other 'consumer protection' issues which may not justify as high a level of confidence.
- 5.7 Once a confidence limit has been selected, a statistically derived function applied to the overall risk assessment score would indicate the required rate of sampling to satisfy the confidence level deemed to be required. In effect this would place a sampling frequency scale alongside the final risk assessment score scale in the nomogram, enabling the required sampling frequency to be read off directly.
- 5.8 Such a statistically valid approach represents the ideal basis for sampling, however there is a practical limitation that renders it unrealistic for use for the purpose of official food control sampling, in that the required rate of sampling increases as the likely frequency of occurrence of a defect decreases. The consequence of this is that a potential defect with food that presents a high risk to the consumer because of its potential effect and the number of people that could be affected, yet is likely to occur only very rarely would require an extremely high rate of sampling.

- 5.9 To put this in numerical context, one example is sampling for the presence of pesticides. Based on past analytical data showing that the rate of incidence of samples exceeding the maximum limit is about 1%, the Pesticides Safety Directorate⁸ using Codex Alimentarius⁹ guidelines has calculated that 300 samples of each individual commodity would need to be taken to have a 95% chance of detecting foods exceeding the limit. At the lower rates of occurrence that should apply to high risk defects, considerably more sampling would be necessary.
- 5.10 Although this sampling strategy is clearly correct in order to provide maximum assurance that food is safe and free from defects, the level of sampling that would be required is likely to be several orders of magnitude greater than that which might be achievable. However, for as long as the official control of food is not intended as the primary means of control, but rather as a safety net aimed at protecting the public from failures in the primary control that should be operated by food producers (e.g. applying HACCP in respect of food safety, and an equivalent process in relation to other potential defects), the rate of sampling need not follow such a strict regime.
- 5.11 Instead of the rate of sampling being proportional to the risk of occurrence of a defect, it can be related directly to the assessed risk of adverse effects arising from that defect, should it occur. In other words it can be made proportional to the risk presented by any potential defect with food. With this alternative approach, the greater the risk presented by the food, the greater the effort that is justified to be spent on sampling, thus the frequency of sampling becomes a scale attached to the risk assessment scale.
- 5.12 In determining a practical sampling scale to set against the risk score, the two ends of the risk scale have been assigned in a pragmatic manner, having regard for reasonable expectations of consumers with respect to the enforcement system. In effect, in terms of safety it has been assumed that a minimum frequency of sampling all foods should be once every three years, while at the other end of the scale the highest risk product has been assigned an almost continuous monitoring frequency of once per week. For non-safety issues there is less justification for such a tight regime, therefore although three years has still been taken as the minimum sampling frequency, the highest risk end of the scale has been assigned a bimonthly frequency.
- 5.13 This is the basis of the sampling rate scales that have been incorporated as the final stage of the risk assessment nomogram shown in the primary paper *Volume 1: Risk Assessment For Sampling*.

6. Supporting Database

- 6.1 In order for the benefits of risk-based sampling to be realised it is necessary to be able to monitor which foods have and have not been sampled, when the sampling occurred, and the extent of analysis undertaken. The wide distribution of many foods requires this information to be considered on a national scale.
- 6.2 In order to accomplish this a database is required, which must detail all foods available in the UK, and incorporate details of planned sampling and planned analysis, records of actual sampling and analysis, and results of analysis.
- 6.3 Because of the sensitive nature of the information, which would include indications of what is - and is not - to be sampled and with what frequency, and would include detailed information about named foods that had been analysed, the database must be secure and access controlled.
- 6.4 A sample and results database has been set up in Scotland, initially dealing with microbiological data (being a far narrower range of parameters than for chemical analysis). The database has been set up with the direct input and assistance from the Scottish Public Analysts, being designed to be capable of taking data directly from Official Laboratories. As a consequence the Scottish database is capable of becoming the model for a fully-fledged national database of sample and results to support this scheme, requiring only the addition of a database of foods.
- 6.5 Details of how the database(s) required to support, and derive maximum benefit from, the sampling of food should be constructed are presented in Appendix B.

7. Implementation

7.1 The proposed risk assessment model is presented in the primary paper *Volume 1: Risk Assessment For Sampling*. Additional worked examples appear in Appendix A to this paper. In order to apply this risk assessment model in practice, the following additional steps (already discussed in this paper) 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 the section on Other Issues Pertinent to Sampling presented in the primary paper.
- 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. Recommendation

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 and in the primary 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 be applied as an interim measure with immediate effect.

APPENDIX A – Worked Examples using Risk Assessment Nomogram

This Appendix provides further examples in the use of the Risk Assessment Nomogram to supplement the example given in the primary paper. A number of examples in respect of safety and of non-safety defects with food are shown, nomograms with appropriate line constructions appearing after the narrative.

Safety

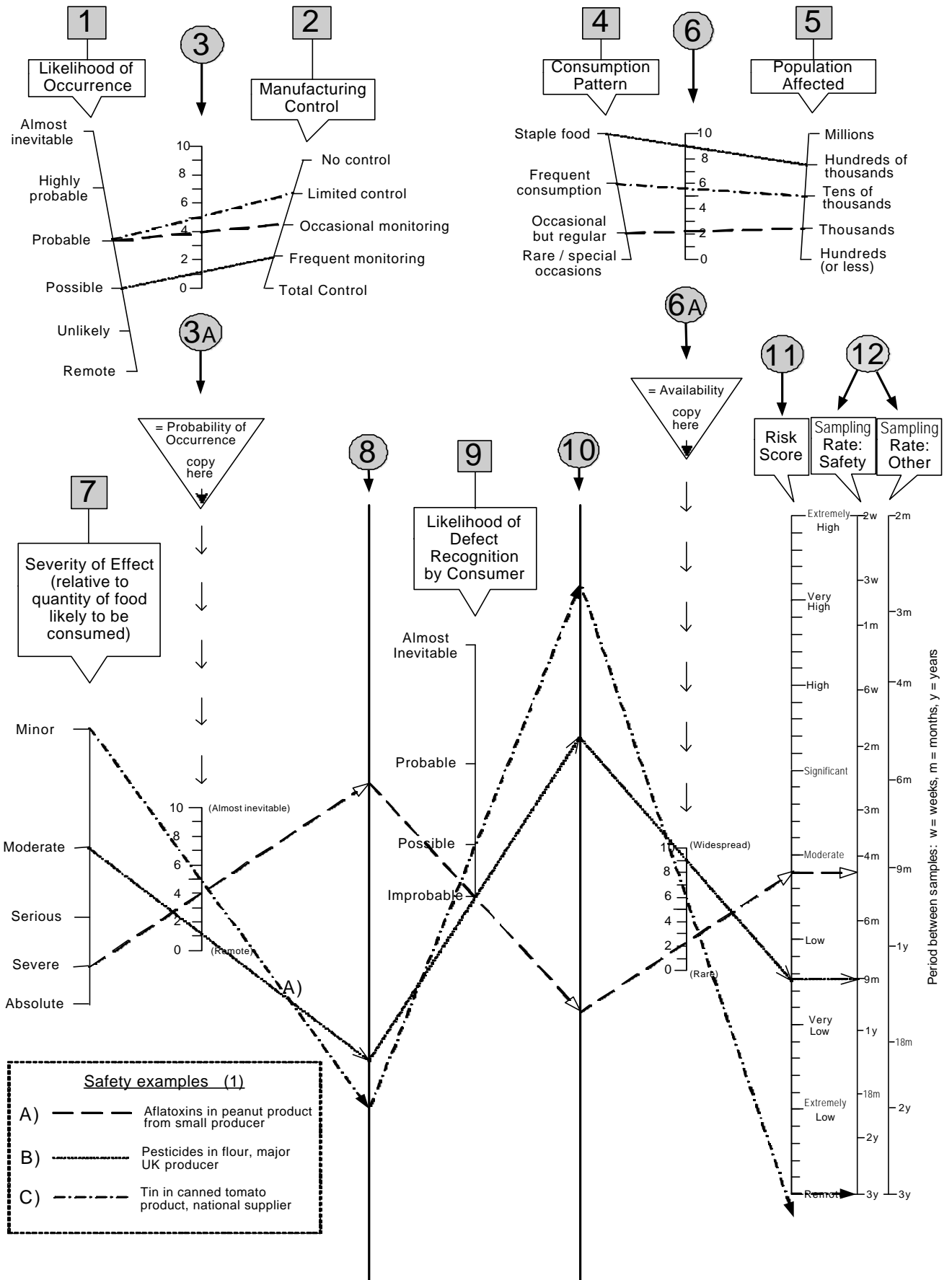
- A) Aflatoxins in a peanut product, from a small manufacturer contracting out analysis periodically. The severity has been assessed as severe because aflatoxin is a potent carcinogen. The assessment indicates sampling every four months.
- B) Pesticides in flour, from a national producer, with a statistically sound programme of monitoring (equally applicable where the source of grain is totally dependable as being properly grown, treated and stored). The severity has been assessed only as moderate, based on the low levels likely to be present if a problem does occur. The assessment indicates sampling every nine months, though this may sensibly be modified in awareness of growing seasons and storage periods (having regard for fumigation of stored product as well as treatment prior to harvesting).
- C) Tin in a canned tomato product, where the problem can develop after the product has left the factory. There is a possibility that a consumer would detect a metallic taste by the time concentrations are sufficiently high to cause adverse health effects. This particular assessment could also be considered under non-safety, as a quality issue, when the same risk score results, the indicated sampling frequency being every three years.
- D) Dioxins in a milk product: an unlikely contaminant normally, but it can arise through contaminated feed or land. The severe potential effect dictates sampling every six months.
- E) Antibiotics in milk, from a small producer. The effects can be severe in persons allergic to, for example, penicillin, while there is a long term risk of increasing bacterial immunity as a result of constant low-level exposure. Sampling is indicated as frequently as every two months.
- F) Diethylene Glycol in wine: a deliberate contamination issue that arose a few years ago. Sampling is indicated annually.

Non-Safety

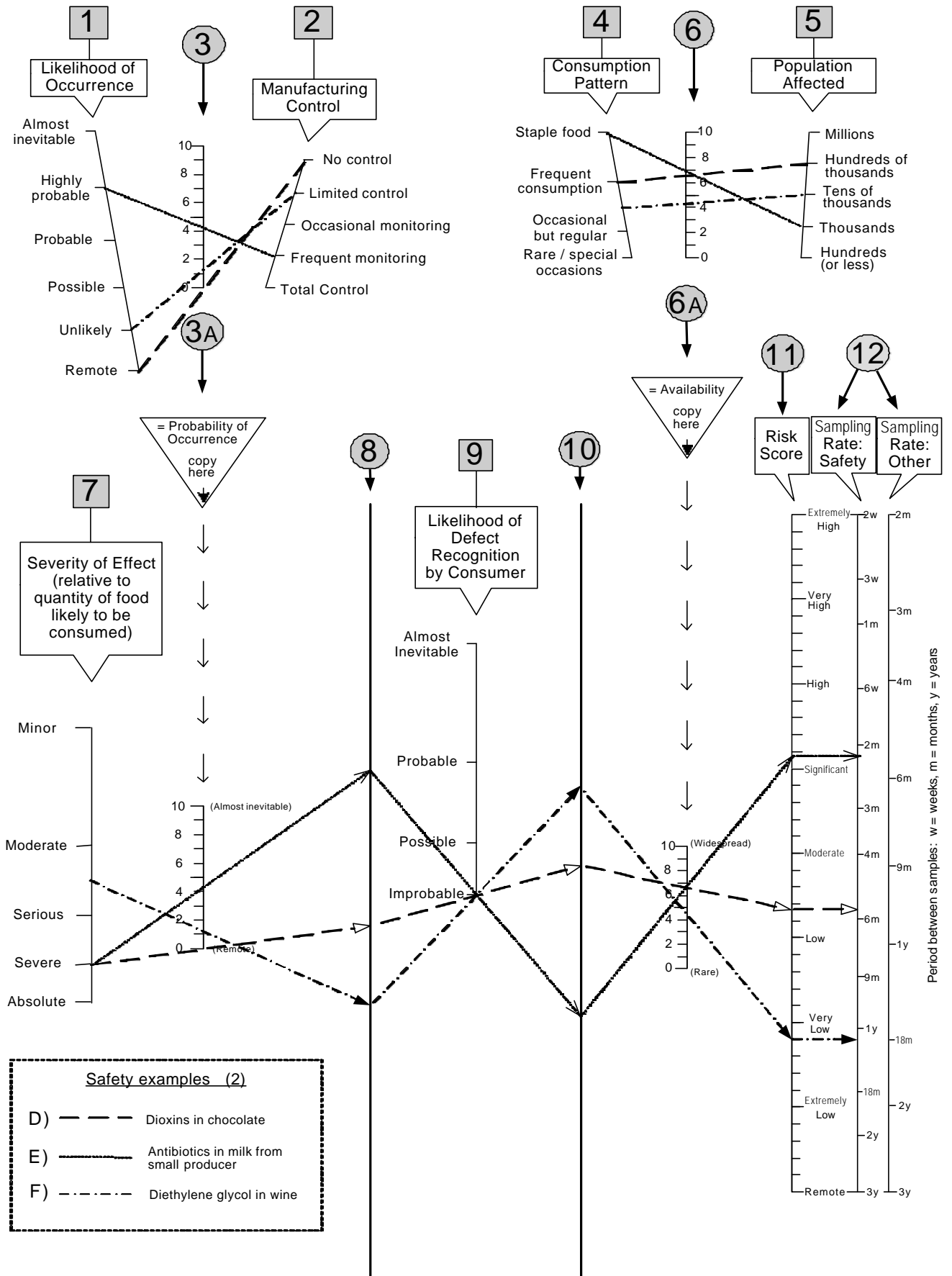
- G) Undeclared genetically modified soya in a bread. The severity has been assessed as severe due to the strong public aversion, with a resultant sampling frequency indicated as six monthly.
- H) Sausages deficient in meat, from a butcher whose recipe places the meat content only slightly above the statutory minimum, but who is reasonably diligent. (A poor track record would raise the probability of occurrence factors, increasing the required rate of sampling.)

- I) Undeclared MRM (mechanically recovered meat) in a widely distributed chicken product having appeal to children. Strong public aversion contributes to the relatively high rating, and six monthly sampling.
- J) Substitution of a different (cheaper) alcoholic beverage in a 'name brand' bottle in a pub. Sampling is indicated a little less than annually. This is another instance where track record is likely to influence the assessment.
- K) A wildly exaggerated health claim on a product distributed nationally – sufficiently wild that sceptical consumers would disbelieve and ignore the claim, though others would not. Sampling indicated a little less than every two years. More particularly, this type of issue should be addressed by scrutinising all new labels when produced – but monitoring will be needed to be sure that new or amended labels do not 'slip through'.
- L) Pork in beef mince. A major issue to those with religious or cultural objections to eating pork, also for anyone allergic. Similar considerations can arise with many other similar contaminations (or partial or whole substitutions, whether or not accidental). Sampling indicated slightly more frequently than annually – but again track record will influence the assessment of probability of occurrence, and thus the sampling requirement.

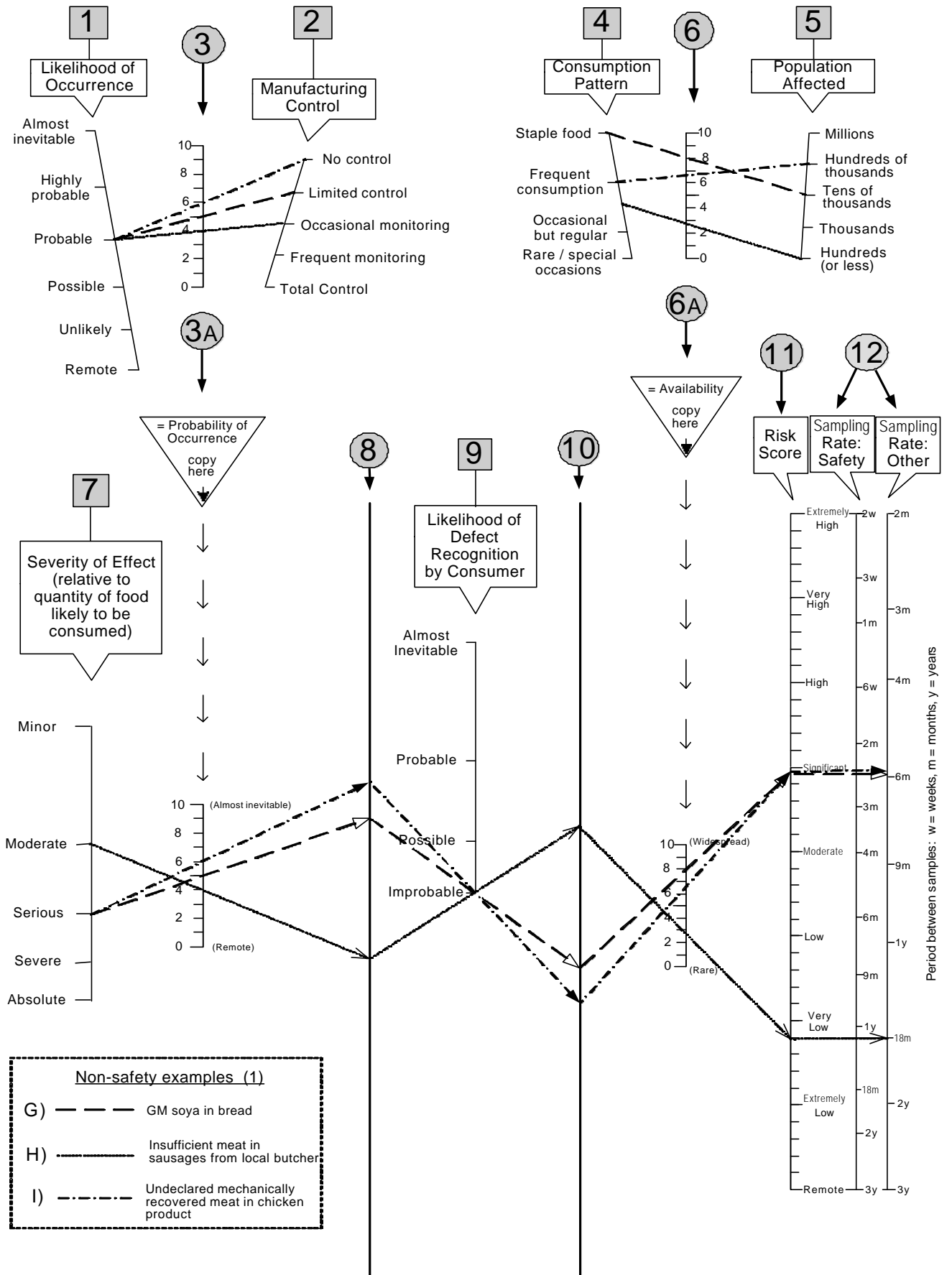
Worked Examples: Safety (1)



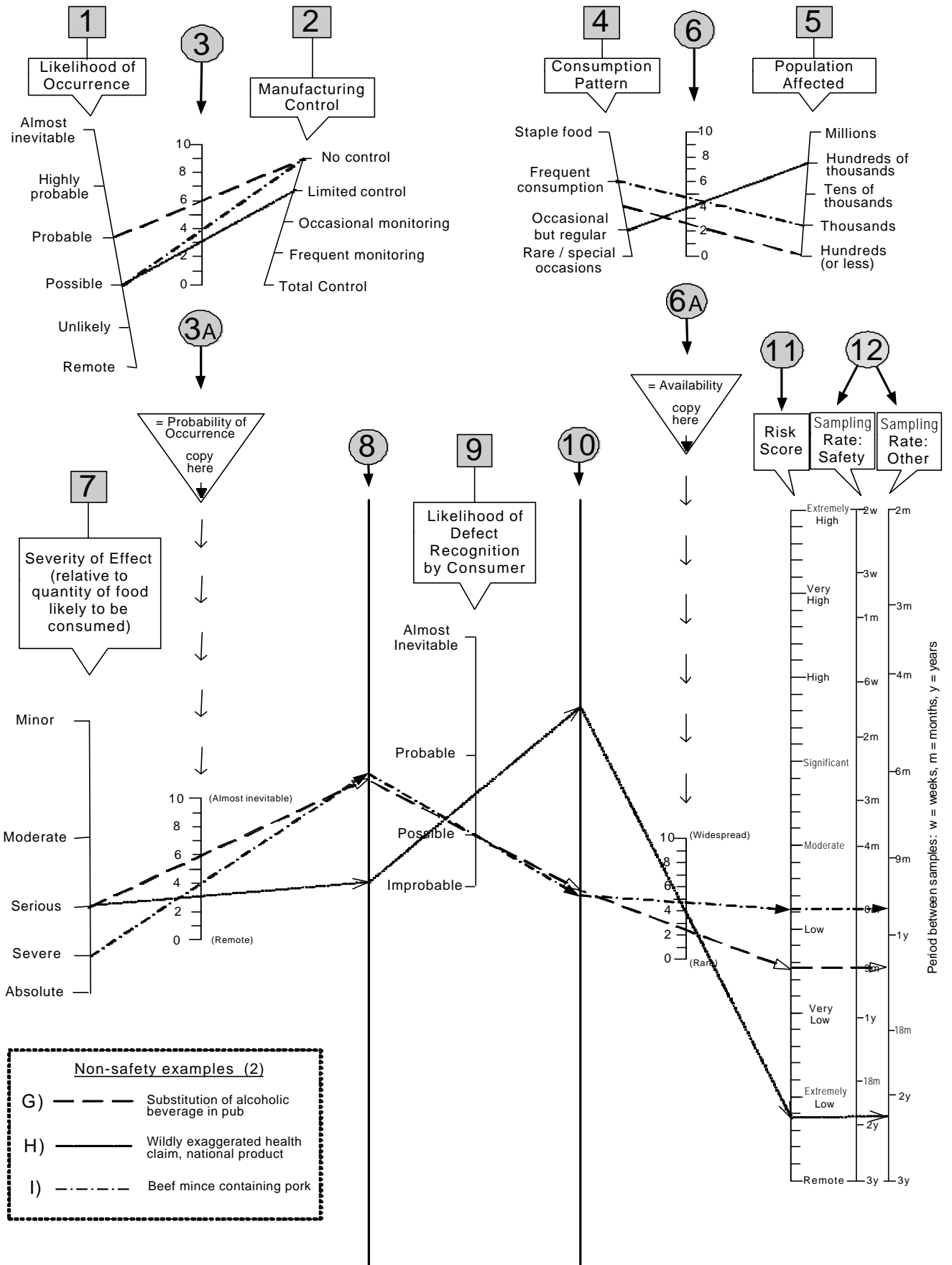
Worked Examples: Safety (2)



Worked Examples: Non-safety (1)



Worked Examples: Non-safety (2)



APPENDIX B – Databases of Food Products and Samples and Results

1 Introduction

- 1.1 In order for risk-based sampling to operate in a satisfactory manner it will require to be supported by a database of food products and a database of food samples and results.
- 1.2 The former is required so as to know which foods are being marketed and hence require sampling. The latter is required so as to store details of the samples collected and the subsequent results of analysis at a single point so that they may be interrogated as required and used to refine the risk-based sampling model.
- 1.3 Although discussion in this Appendix addresses each database as a separate entity, nothing in this proposal precludes their establishment as subsets of a single food database if this can be achieved in a manageable form. Indeed, subject to appropriate control over access and logistics a combined database could be used directly to indicate foods requiring sampling.

2 Products Database

- 2.1 Unless it is known what products are on sale there can be no truly effective mechanism to assess the risk that each presents and to allow confidence that every product is being sampled and analysed at the appropriate frequency.
- 2.2 The establishment of such a database will be a large and on-going task and will require a commitment of time and cost resources to establish and maintain, however it, and is not optional.
- 2.3 Databases already exist for pre-packed foods, albeit in different forms and under diverse ownerships, since such products will inevitably be bar-coded. Each individual producer, manufacturer or importer, and major retailers, already maintain records of which code has been applied to which product.
- 2.4 The establishment of a database of non-pre-packed foods will be considerably more difficult but for risk-based sampling to be successful it is essential that it be done. This is particularly important since many of these foods will be prepared by small producers, frequently with less-rigorous quality control systems in place and hence may present a disproportionately higher risk to the health and well-being of consumers.
- 2.5 The full extent of the information held on the food products database will need to be the subject of discussion between manufacturers and enforcement bodies so as to reach an appropriate balance between comprehensiveness and the pragmatic difficulties of collecting the data.

- 2.6 It is suggested that the following information would be required, as a minimum:
- a) bar code (i.e. the numbers that accompany the code)
 - b) brand name
 - c) fancy name
 - d) statutory name and / or description
 - e) name and address of manufacturer / producer
 - f) name and address of supplier / distributor
 - g) name and address of importer (where appropriate)
 - h) name and address of “home authority”
 - i) country of origin
 - j) minimum durability date
 - k) ingredient list
 - l) net weight or volume
 - m) type of packaging (i.e. non-pre-packed, pre-packed for direct sale or pre-packed)
 - n) nature of packaging material
 - o) nutritional labelling information
 - p) QUID declarations
 - q) alcoholic strength (where appropriate)
 - r) lot number or other batch identifier code
 - s) health mark (where appropriate)
 - t) any other information that must be provided for statutory purposes
- 2.7 The duty to collect, collate and maintain the database of product information must be placed on the enforcement bodies. However, there must also be a duty placed on food manufacturers, producers and importers to co-operate in the provision of the necessary information.
- 2.8 In the case of pre-packed products much of the information will be readily available and in many cases will already be available electronically so that transfer to the enforcement authorities for inclusion in the central database will be straightforward.
- 2.9 In the case of non-pre-packed foods it will be necessary for the enforcement officers to construct the database and subsequently to confirm its accuracy during the routine inspection of food production and preparation premises.
- 2.10 Once the database has been established a requirement must be placed on all food producers, manufacturers and importers to ensure that changes to the information is passed to the enforcement authorities and that before a new or amended product is launched on the United Kingdom market its details are passed to the relevant “home authority” for inclusion in the database.

3 Samples and Results Database

- 3.1 The database of samples and results will be simpler to establish, as it will not require data to be entered in advance. Once established, data will be entered into it on an ongoing basis and, over a period of time, it will grow into a powerful information resource to guide and inform food law enforcement policy and strategies.
- 3.2 Before receiving data the structure of the database will require to be agreed and constructed. Adequate planning is advisable to ensure that the structure fulfils all the known and expected requirements from the beginning since subsequent altering of database structures can be problematical.
- 3.3 As with the products database, the full extent of the information to be held on the samples and results database will need to be agreed, in this case between the Food Standards Agency and the enforcement bodies. It is imperative that the Public Analyst laboratories are fully involved in discussions from the outset as the effectiveness of the database will largely depend on the quality of information that they are able to provide.
- 3.4 It is suggested that the database should include at least following information:
 - a) a unique sample identifier number
 - b) laboratory name or code number
 - c) laboratory reference number
 - d) sampling authority name or code number
 - e) sampling authority reference number
 - f) name of sampling officer
 - g) date and time sample procured
 - h) name and address of premises where sample procured
 - i) reason sample obtained (enforcement, survey etc)
 - j) date and time sample received at the laboratory
 - k) name of person receiving sample at laboratory
 - l) status of sample (formal, informal, complaint, survey etc)
 - m) sample name
 - n) product database identifier (this is essential to relate the sample to a food product and to prevent having to store all product data within the samples database also)
 - o) sample type
 - p) seal number
 - q) minimum durability date
 - r) batch / lot number
 - s) results of analysis
 - t) opinions and observations of Public Analyst
 - u) name of Public Analyst producing the report
 - v) date of report
 - w) satisfactory / unsatisfactory status
 - x) reason for being unsatisfactory

- 3.5 It is essential that responsibility for collation of the data be placed with the Public Analyst laboratories. The first reason for this is simply pragmatic, there are considerably fewer laboratories than there are food authorities therefore it will be simpler to ensure consistency and accuracy of the data and also to ensure that it is transferred to the central database on regular basis. The second reason for this is that the most important information, the results of analysis and opinions and observations on the sample, will be provided by the Public Analysts and their staff.
- 3.6 The database information should be stored on a secure server operated by a suitable agent on behalf of the Food Standards Agency and local authorities. Access should be provided for examination and query over a secure internet link requiring user identity and password.
- 3.7 Local authorities should be permitted full access to the data stored only for those samples for which they were the originating authority. Similarly, laboratories should be permitted full access only to those samples which they have analysed.
- 3.8 All local authorities, laboratories and the Food Standards Agency should be permitted access to anonymised summary (i.e. statistical) data for all samples recorded on the database.
- 3.9 These levels of access will permit the Agency and local authorities to examine the data stored so as to form opinions on the risk posed by various types of food and to show where greater effort may be required.
- 3.10 Care must be taken to prevent the data being used out of context for inappropriate purposes such as producing “league tables” of sampling effort per food authority.

4 Recommendations

- 4.1 It is recommended that the database of food products be established as quickly as possible since it will require a considerable amount of time and effort to collect the data before the system will be operable.
- 4.2 Whilst this database is being prepared discussions on the form of the samples and results database should be ongoing. It would be possible for data to be collected into this database even before the products database was complete. This would have the advantage of allowing the system to advise on risk based sampling in the shortest possible time.
- 4.3 The databases can only fulfil their intended purpose if the integrity of the data collected is assured.
- 4.4 Food producers, manufacturers and importers must have imposed on them a duty to co-operate with local authorities in maintaining accurate data within the products database.

- 4.5 Only samples submitted to official food law enforcement laboratories and central government laboratories will be accepted into the samples and results database.
- 4.6 Samples analysed in “screening” and other laboratories with quality, methodology and proficiency that have not been verified as meeting EU requirements for the official control of food, or with interpretations made by persons not appropriately qualified, must not be included. To include such data of questionable or uncertain validity could cause severe distortion of the dataset and result in incorrect conclusions being drawn.
- 4.7 A database of samples and results of microbiological examination has recently been established in Scotland and will be extended soon to include samples and results from chemical analysis. This database fulfils all of the requirements detailed in this paper.
- 4.8 It is strongly recommended that the Scottish system be used as a model when the samples and results database is extended to cover the whole of the United Kingdom.
- 4.9 The databases will be successful in achieving their intended purposes and allowing risk based sampling to operate in its intended manner only if they are accurate and complete. Contribution of data must be made an obligation for all food authorities and food law enforcement laboratories. A voluntary system would result in a skewed dataset and could lead to incorrect judgements being made.
- 4.10 Consideration should be given to the inclusion of the sample and products databases as subsets of a single food database, subject to appropriate control over access and logistics.

APPENDIX C – Relating Sampling to Risk: a Basic Approach

This Appendix discusses a more basic approach to quantitative risk assessment, starting from the basic principles used in the full nomographical approach. From the basic approach a simple model has been developed to relate the sampling of food to risk, easy to use and capable of immediate implementation. Its use is commended as an interim measure while the risk assessment process described in the main body of this paper is being introduced and its necessary supporting database established.

1 Basic Quantitative Risk Assessment Model

1.1 The most basic model for risk assessment involves pitting the severity of effect against the likelihood of occurrence, as in the following simple example for a potentially harmful contaminant:

Table 1: Example of a simple risk assessment model

	Slightly harmful	Moderately harmful	Extremely harmful
Unlikely to occur	Trivial risk	Low risk	Moderate risk
Likely to occur	Low risk	Moderate risk	Substantial risk
Very likely to occur	Moderate risk	Substantial risk	Intolerable risk

1.2 In this simple example the likelihood of occurrence incorporates all influential factors including the control exercised by the manufacturer. An extra level of control may occur at this stage as no foods having an “intolerable” assessment of risk should be allowed to exist, therefore if any are identified immediate action must be taken to reduce the risk if the food is to continue to be marketed.

1.3 This particular example is only applicable to defects that impinge on the safety of food: in order to address non-safety issues of consumer protection a parallel model is needed where “harmful” is replaced by “damaging to the consumer’s interest”. For the sake of clarity of presentation in this Appendix this parallel requirement has been omitted though the process of developing the risk assessment model.

1.4 In order to produce a simple quantitative risk assessment, the basic risk assessment criteria as shown above could be assigned numbers, for example on simple scales of 1 to 3, where 1 is the least harmful and 3 the most, and where 1 is the least likely to occur and 3 the most likely. From this the overall risk assessment can be expressed as the product of the two factors, yielding an overall numerical score (1 to 9), as in Table 2:

Table 2: Quantitative overall risk assessment (simplified)

	Value	Slightly harmful 1	Moderately harmful 2	Extremely harmful 3
Unlikely to occur	1	1	2	3
Likely to occur	2	2	4	6
Very likely to occur	3	3	6	9
Result = simple mathematical product of the assessed values				

- 1.5 In Table 2 the final risk ‘score’ for an extremely harmful contaminant that is unlikely to occur appears identical to that for a slightly harmful contaminant that is very likely to occur. This may not necessarily be a true equality of risk, but is simply the scoring by this very simple risk assessment model. For a truly effective system more stages for each scale may be applicable, while each scale may not necessarily be linear.
- 1.6 If the above model were to be applied to faults with food the resultant risk scale from trivial to intolerable (in numerical terms for the present example, the values 1-9) could be used as the basis for assignment of rates of sampling particular foods for particular analysis, from few/infrequent to many/frequent. In reality the numerous factors affecting risk in relation to food should make the model multi-dimensional such that a combination of the data derived from the individual risk criteria weighted according to their effect on overall risk is necessary to enable a full quantitative assessment of risk to be made. This consideration has led to the full nomographical approach described in the main body of this paper and presented in an earlier Appendix.

2 Frequency of Sampling/Analysis

- 2.1 At its simplest the translation from risk assessment value to sampling frequency could be a direct relationship, so that in a given period the food should be subjected to the defined analysis the number of times indicated by the numerical risk assessment figure. Using Table 2 as an example, if the period is assigned as one year the food assessed in Table 1 as trivial risk would be sampled once a year, low risk twice in the year, moderate risk 3 to 4 times, substantial risk every two months and intolerable risk every 6 weeks.
- 2.2 This linear relationship in practice may give insufficient weight to the higher risk situations, or may give too much weight to the lower risk situations. It should, however, be feasible to develop a model that uses an appropriate mathematical function to weight the figures to give a statistically sound chance of detecting the faults that is proportionate to risk.
- 2.3 The example of a weighting factor shown in the next table (Table 3) has been designed to give an exponential relationship giving greater weighting for higher risk foods than lower risk foods when compared with the linear example. The numerical value is given as the mathematical exponential constant e raised to the power of the value found by the simple multiplication of the two scales in Table 2.

**Table 3: Quantitative risk assessment (simplified)
incorporating example exponential weighting function (notional)**

	Value	Slightly harmful 1	Moderately harmful 2	Extremely harmful 3
Unlikely to occur	1	2.7	7.4	20
Likely to occur	2	7.4	55	403
Very likely to occur	3	20	403	8103
Result = e^x , where x = product of assigned values (1-9) and e is the mathematical exponential function (2.72)				

- 2.4 To translate these figures into sampling rates, if it were desired to cover the lowest risk food at least once in, say, a 3 year period, dividing all the above by 2.7 (the value for the trivial risk food) gives the number of times every three years that the foods would need to be sampled, giving the following frequencies in practice:

Table 4: Example of possible derivation of sampling frequency (notional)

	Slightly harmful	Moderately harmful	Extremely harmful
Unlikely to occur	Trivial risk: Sample every 3 years	Low risk Sample once a year	Moderate risk 1: Sample every 5 months
Likely to occur	Low risk Sample once a year	Moderate risk 2: Sample every 2 months	Substantial risk : Sample weekly
Very likely to occur	Moderate risk 1: Sample every 5 months	Substantial risk: Sample weekly	(Intolerable risk: Sample twice per day)
Frequency of sampling = the numerical risk assessment value from table 3 divided by the value for the trivial risk food in that table (=2.7), giving the number of times to be sampled every 3 years.			

- 2.5 In practice the mathematical factor in table 3 and the period in table 4 need to be derived statistically on the basis of acceptable risk in order for the sampling frequency to provide appropriate protection for the consumer.
- 2.6 With this simple model this is the stage at which it is appropriate to return to the separate but parallel issues of safety and other “consumer protection” matters. The following table (Table 5) presents an alternative derivation of frequency that may be appropriate to those aspects of consumer protection that have no bearing on safety.

Table 5: Sampling frequency for “consumer protection” issues

	Slight risk of compositional defect	Moderate risk of compositional defect	High risk of compositional defect
Not very likely, but possible if things go wrong	Trivial risk: Sample every 6 years	Low risk Sample every 2 years	Moderate risk 1: Sample every 10 months
Moderate likelihood that it will occur occasionally	Low risk Sample every 2 years	Moderate risk 2: Sample twice a year	Substantial risk : Sample monthly
Almost certain to occur occasionally	Moderate risk 1: Sample every 10 months	Substantial risk: Sample monthly	Intolerable risk: Take action to reduce risk
Frequency of sampling = the numerical risk assessment value from table 3 divided by the value for the trivial risk food in that table (=2.7), giving the number of times to be sampled every 6 years.			

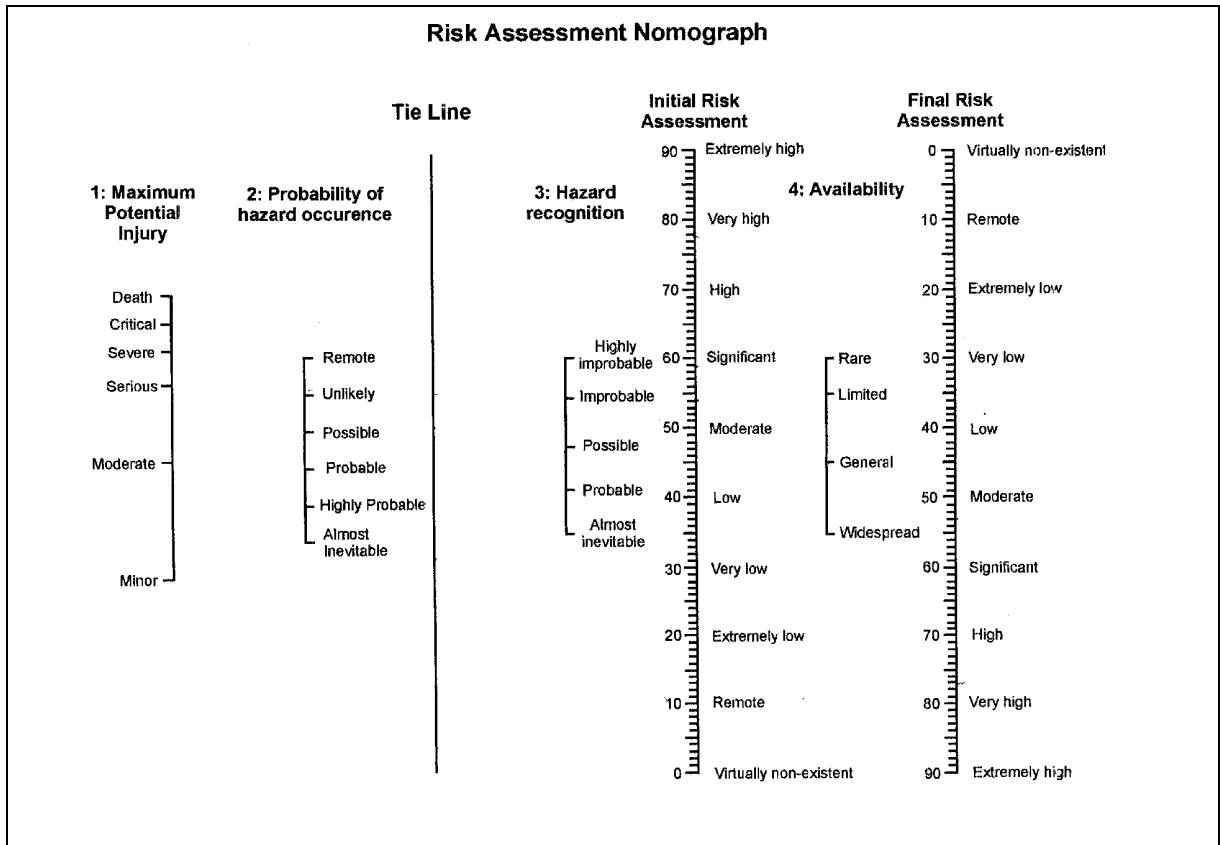
Note: For the purpose of this scheme labelling faults are effectively included under compositional faults, but all new labels produced should be inspected.

3 **Practical Application – An Interim Risk Based Sampling Scheme**

- 1.1 If adopted by every enforcement authority in relation to all locally produced or manufactured foods (i.e. full ‘factory enforcement’ sampling), using a basic risk assessment table this would be a real move to a risk-based approach to sampling, albeit in a rather crude manner. In view of the all-embracing nature of the two risk criteria in this simplified model it is critical that all necessary professional input is available to assess the rating criteria. (Information is needed regarding manufacturing control, likelihood of contamination in factory and earlier, toxicity of contaminants, ease and temptation to adulterate, understanding of the effect of individual components on interpretation of overall data, etc)
- 1.2 If sampling data were also to be fed into a simple national sample database (preferably capable of expanding or transferring its data into the full database needed for sample planning and control) this would provide a means of identifying areas of duplication or of underactivity. As soon as possible all sampling plans and all data derived from sampling and analysis should be fed into the developing national sample database to better aid sample planning and control.
- 1.3 **IMPORTANT:** The other observations made in Volume 1: Risk Assessment For Sampling under the heading “other issues pertinent to effective sampling” continue to apply to this simplified approach to risk-based sampling as much as they do to the comprehensive scheme.

APPENDIX D – The New Zealand Risk Assessment Nomogram

For reference the New Zealand product safety risk assessment nomogram is presented below (sections 4.9 – 4.13 of the main body of the paper refer).



APPENDIX E – References

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- ¹ Report on the Review of Public Analyst Arrangements in England and Wales, MAFF, 1998
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- ⁹ Codex Alimentarius Commission, Principles of Risk Analysis, FAO/UN 1999