ELSEVIER

Food Control 10 (1999) 363–365

FOOD CONTROL

www.elsevier.com/locate/foodcont

Sampling of raw materials and processed foods for the presence of GMOs

John Gilbert *

Central Science Laboratory, Ministry of Agriculture, Fisheries and Food, Sand Hutton, York Y041 1LZ, UK

Received 6 April 1999; accepted 13 April 1999

Abstract

The extent to which sampling of raw materials and foods, for detection of the presence of GMOs, presents a significant problem depends on the type of material to be sampled, the purpose of the analysis and the degree of risk that is acceptable in obtaining a wrong result. Sampling for indications of non-segregation or co-mingling of raw materials is the main area for which sample plans will for the future need to be developed. Fortunately, there is considerable experience in sampling of commodities in analogous areas such as for the presence of mycotoxins in cereals and nuts where well-tested sampling plans could be utilised. © 1999 Elsevier Science Ltd. All rights reserved.

Keywords: Sampling; GMOs; Soya beans; Maize; Processed foods; Sampling plans

1. Introduction

The conventional wisdom in trace analysis is that sampling and sub-sampling errors are significantly greater than analytical errors and that the error increases dramatically with decrease in analyte concentration. The reasoning is based on the assumption which holds true in most cases that analytes (frequently contaminants) are heterogeneously distributed in foods making the taking of a representative sample difficult. Sampling frequently therefore requires the taking of large samples comprising multiple sub-samples, which are subsequently homogenised and mixed, prior to taking of the analytical sample.

Genetically modified (GM) foods are somewhat different in that a uniformly distributed intrinsic component of the food has been changed and the distribution in most cases will be no more heterogeneous than that of the same component in the non-GM food. Thus, in the simplistic situation, where either all the food is GM or all the food is not GM, then a qualitative method could be employed and the manner of sampling would be essentially immaterial. Indeed it could be argued that unequivocal proof of GM material could be obtained by multiple replicate analysis of single maize kernels or single soya beans. The problem in interpretation of the results would occur if only a small proportion of the kernels or beans were found to contain GM material. The question would then arise as to how representative of the whole batch of material were those kernels/beans that were selected for analysis. This then becomes a classical sampling problem with the same considerations as apply in other areas where there is heterogeneous analyte distribution.

Development of sampling plans should be regarded as an integral part of method development, which follows logically after the stage of establishment of adequately sensitive and precise methodology. The availability of methodology with good repeatability is essential in order to study the homogeneity of any batch of material, which is required for development of the sampling plan. However, in the field of analysis of GM material the stage has been reached where quantitative methods with acceptable precision are only now becoming available. Thus, in this paper it is not possible at the present time to provide definitive recommendations on sampling, but rather to draw on work from other areas of sampling and to give some general indications of the issues related to sampling and a few pointers as to what will need to be done in the future.

* Tel.: +44 1904 462424; fax: +44 1904 462426.
E-mail address: j.gilbert@csl.gov.uk (J. Gilbert)

PII: S0956-7135(99)00076-6

2. Type of material

There are three types of materials for which there is an interest in establishing the presence of GM material – firstly, raw materials such as maize kernels or soya beans, secondly ingredients which could be whole or partial components obtained from the raw materials and thirdly finished processed foods. The raw materials are most likely to have been harvested, dried, possibly sorted and transported prior to storage. There will be some mixing during these operations but insufficient to ensure uniform distribution of any heterogeneity. Ingredients derived from raw materials could be in the form of flour, or extracted material such as lecithin where the processing such as milling would result in a degree of mixing/homogenisation. Finally, there are the finished processed foods where the GM material would most likely be only one ingredient of a more complex recipe in which case more uniform distribution could be anticipated.

3. Purpose of sampling

To some extent the purpose of sampling and analysis determines the approach to be adopted. Sampling can either be acceptance sampling or regulatory sampling. In acceptance sampling we are dealing with deciding whether or not a purchaser/importer is prepared to accept a particular batch or lot of material. This will most likely apply to sampling of raw materials and the most important factors in deciding on the sampling regime will be the cost of the sampling, the time involved and the degree of risk the importer is prepared to accept in terms of getting a wrong result. In regulatory sampling the issues are the same but there will be a much greater emphasis on ensuring a high degree of confidence that the sample analysed can be defended as being representative of the bulk material. No sampling regime can guarantee the sample is representative and with sampling one is always dealing with statistical probabilities.

1. *Acceptance sampling*: Involves the application of a pre-determined plan to decide whether a lot of goods meets defined criteria of acceptance. The risks of accepting 'bad' lots or of rejecting 'good' lots are stated in conjunction with one or more quality parameters e.g. quality indices of the plan. Statistical plans can be designed to regulate the probabilities of rejecting good lots or accepting bad lots.
2. *Regulatory sampling*: Unless a decision is taken that all controls for regulatory purposes will be applied at factory level by monitoring the food ingredients, regulatory sampling will have to be applied to processed food products. Thus, analysis will be aimed at testing whether an unlabelled finished product or a finished product with specific claims not to contain GM material actually conforms with the labelling. In both cases the products can be assumed to be reasonably homogeneous, and the issue is likely to be the sensitivity and precision of the quantitative method of analysis and the confidence that the determination for the presence of GM material is above any pre-determined threshold. In the regulatory area if the sampling were to be of the ingredients then it is likely to be particularly demanding in the case where specific positive claims are made as to the foodstuff not containing GM material.

4. Sample plans

In order to develop a sampling plan based on statistical considerations it is necessary to understand something of the nature of the homogeneity of the batch of material being sampled. The distribution of the analyte to be measured can be described in mathematical terms e.g. a negative binomial distribution is frequently used to describe mycotoxin contamination of groundnuts (Knutti & Schlatter, 1982). From this distribution curve, a sampling plan can be proposed the characteristics of which are typically described in the form of an operating curve (Whitaker, 1977). An operating curve indicates the 'Producer Risk' which is the risk (expressed as a probability) of the producer rejecting a batch of material which is within a desired specification, and the 'Consumer Risk' which is the risk of accepting a batch of material which does not conform with the desired specification.

Sampling plans have financial costs associated with them, which are a function of the amount of work involved in taking and analysing the samples before a decision can be taken. Thus the total number of sub-samples required to be taken, the total weight of material that is to be sampled, how the sample needs to be prepared and the number of analyses that are required to be undertaken in order to obtain a decision will all be factors determining the cost. Some sample plans involve the taking of relatively large samples (30–60 kg) made up of a specified number of sub-samples (say 50–100) which then have to be reduced in particle size (say by milling), need to be thoroughly homogenised, and finally need to be sub-sampled prior to analysis (Whitaker, Springer, Defize, de Koe & Coker, 1995). This type of sampling plan has high costs associated with taking and manipulating the samples but may have relatively low costs for the actual analysis as this may only involve two or three determinations. The alternative approach involves taking multiple small samples for analysis where the cost of sampling itself and sample preparation will be quite small. However, as there will be many samples to analyse this type of plan is more appropriate where there are low cost rapid screening tests available.

5. Factors determining the establishment of sampling plans for GMO analysis

A number of factors need to be taken into consideration in the development and adoption of appropriate sampling plans for GMOs in raw materials and processed foods. Clearly a critical factor will be the threshold limit which is set for acceptance of the presence of GM material – the lower this limit the greater the demands will be upon the sampling plan. Clearly also it is essential that a quantitative method of analysis is available which has a better sensitivity than the threshold and an adequate precision. The speed requirement for making a decision will also be an important factor which will need to be taken into consideration in proposing a sampling regime. Clearly in some situations such as delivery of consignments of materials it will not be practicable to wait for long periods of time whilst sampling is undertaken before a decision on acceptability can be made. The point at which the sample can be taken is also important in deciding upon sampling regimes. The ideal situation is when material such as soya beans or maize kernels are being unloaded from barges or trucks when there is the option of continuous sampling of the entire consignment. This is preferable to the situation of large consignments in silos or trucks when it is difficult to access remote parts of the batch even when employing specialised equipment such as sampling probes.

Finally in deciding upon the sampling plan to be adopted there is a need to decide upon the level of acceptable producer risk and conversely the level of acceptable consumer risk. There can be no one hundred percent certainty in the sample being completely representative with any sampling plan and a certain pragmatism is required to decide upon the balance between producer and consumer risk that will be accepted.

6. Conclusions

In the area of GMOs, sampling will mainly be an issue with respect to testing of raw materials and ingredients where most problems of inhomogeneity will exist. Whilst there will be few problems of sampling with processed foods i.e. retail foods, there will be enormous difficulties in developing validated methods of analysis robust enough to cover the full range of food types. For regulatory purposes therefore it will be more practical to carry out sampling at the factory rather than at retail level. To date, there have been no attempts to study the problems of homogeneity of consignments of non-GM material and clearly this work will need to be undertaken to develop sampling plans. For this purpose the experience of sampling in analogous areas will be valuable in developing appropriate plans in this area.

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