

**REPORT OF THE MEETING OF THE EUROPEAN COMMISSION
WORKING GROUP ON AGRICULTURAL CONTAMINANTS
ON SAMPLING AND ANALYSIS FOR AFLATOXINS AND
OCHRATOXIN A**



**LONDON, UK
1-2 DECEMBER 1999**

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(UK Port Health Authority)

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**MEETING ON SAMPLING AND ANALYSIS FOR AFLATOXINS AND
OCHRATOXIN A**

LONDON, 1-2 DECEMBER 1999

*Conference Room 808, MAFF, Nobel House, 17 Smith Square, London
SW1P 3JR, UK*

AGENDA DAY 1

ITEM	TIME	TOPIC
1.	09:30	Welcome and opening address from the UK Ministry of Agriculture, Fisheries and Food (<i>Dr David Atkins</i>)
2.		Domestic arrangements
3.		Introduction to the topics of the meeting.
4.		Implementation of EC Directive 98/53 on sampling and analysis for aflatoxins - UK activities - enforcement sampling (<i>Mr Jon Averns, UK Port Health Authorities</i>)
	11:00	Coffee
	11:20	- public analyst experience (<i>Mr Stephen Guffogg, UK Public Analysts</i>) - sampling for aflatoxins in retail products - sampling for aflatoxins in spices (<i>SANCO 3348</i>) - transit goods e.g. pistachio nuts: what control measures are used or should be used by a Member State upon import of goods via other Member States? (<i>Denmark</i>) - co-operation between Customs and Food Control Authorities (practices in Member States; pros and cons of border inspection of food from non-animal origin) (<i>Denmark</i>)
	12:45	Buffet Lunch
	14:00	- voluntary certification from countries of origin (<i>SANCO 3351, SANCO 3355</i>) (<i>Mr Doug Bloomfield, UK Port Health Authorities</i>)
	15:30	Tea
5.	15:45	Sampling and analysis for ochratoxin A (<i>SANCO 3353</i>) - presentation of studies performed (<i>Dr Bryan Jones, Mr Robin Clifford</i>) - general discussion
6.	17:00	Any other business

AGENDA DAY 2

Plans for visit to Thames Port and Eurofin Public Analyst Laboratory for sampling and analysis demonstration

- 09:30 Bus leaves Dolphin Square Hotel
 - 09:45 Bus leaves Nobel House main entrance, Westminster
 - 11:00 Arrive Thames Port
 - 12:45 Lunch
 - 14:45 Arrive Eurofin Public Analyst Laboratory
 - 17:30 Arrive back at Nobel House, Westminster
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1. INTRODUCTION

In December 1999, the UK welcomed delegates of the European Commission Working Group on Agricultural Contaminants to London to discuss and exchange views on a range of issues on sampling and analysis for aflatoxins and ochratoxin A in food.

In particular, this meeting was timely as Member States were implementing EC Directive 98/53 on sampling and analysis for aflatoxins and it provided an opportunity for early feedback on the new plans. Possible regulatory limits were also proposed for ochratoxin A and suitable sampling plans would be required to support the limits. The meeting provided an opportunity to discuss suitable sampling plans for ochratoxin A. These issues have far-reaching effects on a wide range of interested parties, including government departments, official control authorities, testing laboratories, industry and the consumers whose safety must be protected.

The meeting was held over two days, the first day at the offices of the Ministry of Agriculture, Fisheries and Food (MAFF)* in Westminster, central London and the second day visiting Thames Port and Eurofin Public Analyst laboratory to see practical demonstrations of sampling and analysis for aflatoxins.

To comment on the practicalities of the sampling and analysis issues and to give presentations on their experiences, UK enforcement and analytical experts were invited to the meeting. The experiences of these officials and officials in other Member States using the new sampling and analysis measures at this early stage were discussed. Practicalities of the official plan were considered and ideas for future discussions for the Working Group on ways to improve measures for greater harmonisation between Member States were identified.

This report has been agreed with the Working Group. It summarises the discussions and makes some conclusions which will be useful to the Working Group in developing harmonised legislation on mycotoxins in food.

*Please note that from 1 April 2000 the responsibility in the UK for food safety and standards moved from MAFF to the new Food Standards Agency.

2. AIMS OF THE MEETING

- (i) To discuss Member States' progress and experiences with the new sampling and analysis measures for aflatoxins and to consider any problems or impracticalities which might have arisen.

- (ii) To identify any problems arising due to inconsistent approaches to official control by Member States and to encourage common practices and greater harmonisation where possible.

- (iii) To discuss the possibility of developing origin certification processes to relieve pressure on control authorities and to encourage better industry practices.

- (iv) To consider the requirements for a sampling and analysis plan for ochratoxin A and how these plans might differ from the plans for aflatoxins.

- (v) To conclude on points where controls for mycotoxins should be further discussed within the Working Group.

3. EC DIRECTIVE 98/53 ON SAMPLING AND ANALYSIS FOR AFLATOXINS

3.1 Implementation and enforcement

EC Directive 98/53 on sampling and analysis for aflatoxins came into effect in January 1999 to accompany EC Regulation 1525/98 which sets limits for aflatoxins in certain foods. Member States have until December 2000 to implement the sampling Directive at national levels. The UK implemented the EC Regulation and Directive in June 1999. The Netherlands indicated that they also had implemented the EC legislation. A number of other Member States indicated they had not yet formally implemented the measures, but in the meantime their authorities were already using the official procedures. It was encouraging that Member States were aiming for a consistent approach as soon as possible.

The UK explained that to help clarify and interpret the new measures it was preparing guidance notes for UK control authorities, trade and other interested parties, to ensure that the new legislation on aflatoxins would be fully understood and applied consistently. The guidance given in the document would focus on the following:

- advice on how the legislation relates to other general regulation on food safety, such as the UK Imported Food Regulations and the Food Safety Act;
- prohibited practices, such as chemical treatment and mixing highly contaminated with less contaminated foods to dilute contamination levels to within the limits;
- listing ports of entry which have the facilities to follow the official testing for aflatoxins;
- advice on labelling, stressing the need for clear labelling, such as whether for direct human consumption, sorting/physical treatment or animal feed;
- advice on priorities for testing commodities where contamination is most likely; to clarify options on what to do with rejected consignments, to ensure a consistent approach is applied by control officials.

UK ports had early experience of the new sampling measures and Mr Jon Averbs of the UK Association of Port Health Authorities presented their findings (see slides at Annex 1). Also, Member States commented on their experiences to date.

The official sampling plan was found to be effective, although problems and impracticalities were identified relating to its onerous nature. The unloading of containers, the number of samples required and the large volumes were all resource intensive. Representative sampling and prioritisation were necessary. Where every consignment must be sampled, for example for Iranian pistachios, the resources of the enforcement authorities had been put under pressure.

When a consignment has been rejected by a Member State, the value of sending advance notification by the rapid alert system (RAPEX) to control authorities in other Member States was emphasised. The Commission explained that the RAPEX system was under review and that it was intended to improve the system and also to include materials for animal feed.

3.2 Public Analyst experience

Feedback on the analysis of samples was given on behalf of the UK Association of Public Analysts by Mr Stephen Guffogg who explained his experiences with the analyses for aflatoxins. The analysis of samples using the new plan was found to be effective and thorough in identifying ‘hot spots’ of contamination. However, although the methodology was found to be straight-forward, large quantities of material were required for analysis and the sample preparation time was long. These factors restricted the number of samples that could be tested per day.

A problem was experienced with whole brazil nuts, which are difficult to crack open. Instances were reported where the whole nuts, including shells, were homogenised and high levels of aflatoxin were detected due to contamination of the shells. Contamination on the outside of shells would not necessarily greatly affect the edible part of the nut. Shells included in the samples for testing might lead to unduly high results and this might be unfair to the producer. The Commission had not been aware of such problems with shell contamination, but would consider this point further.

Rejection of contaminated consignments is required if just one out of three sub-samples fails the limit. This led to discussion on whether laboratories allowed

tolerances above the limits and whether tolerances should be permitted. The general view from Member States and the Commission was that the analytical method should ideally allow for analytical variation before finalising and interpreting results, including variation caused by handling samples or environmental conditions.

The sampling Directive specifies that the sample must be homogenised, but does not specify the best method. Member States agreed that slurring was the best way to homogenise, although circumstances could sometimes dictate otherwise. Practical considerations were sometimes necessary, although consistency should be aimed for where possible.

3.3 Retail sampling

The provisions for aflatoxins focus on official control at import. Sample volumes are based upon large lot sizes. However, for retail sampling where smaller volumes are involved e.g. packets, small bags, etc., the provisions are not practicable and concern was raised on how to conduct effective retail sampling. Paragraph 5.5.2 of the sampling Directive refers to sampling lots in retail packing, but no information is given to elaborate on the practicalities of applying the plan at the retail stage.

Official sampling of raw materials can identify contamination at an early stage before processing and packaging complicate sampling considerations and, in general, Member States felt checks should be done as close as possible to the point of origin of the raw material. Nevertheless, sampling at the retail stage was considered to be important because all contaminated foods are not tested at the point of import and in some cases mycotoxin production might continue after packing and upon storage. A problem with identifying a contaminated batch at the retail stage is that it can be difficult or too late to recall the rest of the contaminated batch. Therefore, the emphasis of the official sampling controls should be at points before retail. Where the foods are produced within the EU, for example for some foods with ochratoxin A contamination problems, it will be important to ensure that sampling plans will work well at control sites in addition to ports and border controls. Testing to cover retail products might be best achieved where possible in warehouses. The Commission

indicated it would work on improving ways to further harmonise control measures for contaminants in food, including where retail sampling is necessary.

Different points to control foods exist within the EU and a common consistent approach is required to ensure that the various measures are effective. The importance of surveillance programmes to monitor contamination problems was emphasised. In spite of regulations, surveillance has shown that foods with unacceptable levels of contamination can reach the retail market. Publishing brand names of contaminated retail products, as done in surveys in the UK, was an example of one way to put pressure on industry to ensure levels of contamination in food are kept below the maximum limits. The importance of surveillance monitoring at retail level was emphasised, as a useful tool to encourage industry to develop practices that reduce contamination in food.

3.4 Aflatoxins in spices

Discussions were already underway on a Commission proposal to add certain spices to those foods with maximum limits for aflatoxins. Discussions on the sampling plans proceeded to identify whether they should include considerations other than those in Directive 98/53.

During the discussions, it became clear that consignments of spices are imported in considerably smaller lots than other foods already listed for aflatoxin controls. Lot sizes of greater than 20 tonnes were considered to be inapplicable to spices. Member States agreed to check these details before confirming whether they could agree with modifying the plan for sampling aflatoxins in spices to allow for smaller lot sizes.

3.5 Transit goods/ transshipment and co-operation between Customs and Control Authorities

The delegation from Denmark kindly introduced this item (see abstract at Annex 2). Transshipment of foods between Member States is a problem where the food is given customs clearance without being properly tested at import. Consistent approaches are

needed in each Member State to ensure producers do not seek out loopholes to gain access into the EU.

Member States stressed that more consistent approaches should be used wherever possible to minimise the possibility of untested consignments gaining EU customs approval. Concern was raised where testing is not done at import and the consignment is destined for another Member State. It was felt that where the status of consignments is unclear it should be assumed that no checks have been done.

Member States indicated they would like to see advice given on lots tested at import or where testing should be done at the destination Member State. If the destination authority does not have facilities to test, alternative testing might be arranged. Clearly labelling lots with status details was highlighted as being important, to avoid possible confusion between officials at different locations.

Where customs clearance is given to a consignment, Member States wished to clarify whether it is possible to re-sample in the destination Member States, if contamination problems are suspected or where no testing was done at import before customs clearance was granted. Concerns were raised that free trade rules must not be infringed. The Commission advised that testing after customs clearance would be possible if done as a non-discriminatory, random monitoring activity. Otherwise, consignments should be tested before customs clearance is granted. Despite this point, concerns remained that where representative sampling is done at import, contaminated consignments can reach the retail market. To help overcome this, where enforcement resources are limited, it is important that control authorities prioritise carefully to ensure they test the consignments most likely to be contaminated.

Co-operation between customs and food control authorities may differ in Member States and this inconsistency can cause confusion and possible loopholes for access to the EU. Concerns were raised that customs clearance might be granted on occasions without considering the need for testing. Where lots are more easily sampled at a destination warehouse rather than at a border, tracking systems might be helpful to ensure control authorities and customs officials can co-ordinate testing with customs clearance. However, this procedure might not be possible where products have a

short shelf life and warehouses are not relevant. Control authorities should ideally test consignments at the first opportunity at import, before customs clearance is given.

The Commission highlighted that consistency in testing and monitoring were important, to ensure that less thorough points of entry cannot be mis-used by trade and to ensure that foods with unacceptable levels of contamination do not gain customs clearance and enter free trade in the EU. The Commission explained that cases of 'port shopping' had declined, but nevertheless it was an unacceptable practice which creates greater risks to consumer safety. Systematic sampling controls should be operated by Member States and communication systems to alert against rejected consignments should be improved. Member States supported the need for further discussions on ways to encourage consistent control systems.

3.6 Origin Certification

Origin certification is a way that industry might develop better working practices and provide documents to help alleviate pressures on official control authorities. Mr Doug Bloomfield, UK Association of Port Health Authorities, presented his findings on the possibility of introducing certification measures (see slides at Annex 3). Two proposed systems for certification were given in papers from the US peanut industry and Californian pistachio industry (SANCO 3351 and SANCO 3355 respectively). Mr Bloomfield had recently accompanied officials from the Netherlands on a visit to the US to assess a possible certification system for US peanuts and had been very encouraged.

The use of certification measures is not covered by the EC aflatoxins regulations. The Commission acknowledged that there was no legal basis to recognise such certification for products of non-animal origin, but that was no reason why certification measures could not be introduced in future. Effective certification would help greatly towards controlling contamination. The Commission and Member States gave general support for the possibility of introducing reliable certification measures.

Questions were raised on how to validate possible certification systems. It was recognised that it is easy for companies to produce a certificate, but not so easy to

ensure that it truly represents the standards of the product. An additional concern was that some countries would not have facilities to develop reliable certification measures and they might be put under pressure if certification was to become essential for producers. Perhaps the most effective approach would be for systems to be proposed by industry and assessed and validated within the EU on an individual basis. Equivalence agreements might be an appropriate approach. The system already used for veterinary products was suggested to be a useful model.

It would be important to ensure that certification would not result in an additional layer of checks without any benefit to enforcers or the consumer. Also, it would be important to ensure that effective labelling would be used for lots to accompany certification documents and avoid possible confusion. Certification would be based upon appropriate production standards and checks performed in the country of origin, but it would also require information on storage conditions during transport to provide assurance that levels of mycotoxins would not increase during transportation.

A general conclusion was that if industry could develop reliable certification plans, control authorities would be able use their resources elsewhere to target consignments which might more likely be contaminated. Authorities would be able to prioritise their work more effectively to reduce levels of contamination in food on the market. This would pass on greater protection to the consumer.

4. SAMPLING AND ANALYSIS FOR OCHRATOXIN A

A Commission proposal for regulatory limits for ochratoxin A in certain foods was under discussion within the Working Group. To accompany the proposed regulation, plans would be needed for sampling and analysis.

4.1 Studies on sampling plans

The UK outlined two recently completed studies on sampling plans for ochratoxin A:

- (i) A study which developed a **computer model for calculating sample sizes for cereals** was presented by Mr Robin Clifford, MAFF. A summary of the study and the presentation slides are given in Annex 4. This model was shown to be suitable for calculating sample sizes for cereals where at least 10,000 grains were sampled. The software needs to be verified in practice with different cereals. Copies of the computer programme were made available from MAFF for Member States to test.

- (ii) A study which **compared four different sampling plans for ochratoxin A** in coffee and wheat was presented by Dr Bryan Jones, MAFF. The plans studied were those used for aflatoxins by: the United States Department of Agriculture, the Netherlands (Code of Practice), the UK and the EC (the official sampling plan for aflatoxins). A summary of the study is given in Annex 5. The EC plan was shown to be the most appropriate plan for wheat and the UK plan was found to be the most appropriate for the more heterogeneous contamination in coffee. The EC plan was effective for coffee although more resource intensive.

4.2 Discussion on sampling plans

The Commission document on sampling plans for ochratoxin A (SANCO 3353) was discussed. The plan was taken from the official EC sampling plan for aflatoxins, which the UK study had shown to be effective for both coffee and wheat (see **4.1** above).

Member States considered how commodities prone to contamination with ochratoxin A were different to those for aflatoxins and where different considerations were appropriate. The volumes of lots were likely to be considerably smaller for several of the proposed food commodities, compared with the foods specified for aflatoxins.

Also, the particle sizes of the commodities for ochratoxin A tended to be smaller than those for aflatoxins, for example raisins vs figs, wheat vs maize. Particle size has been shown to be an important factor in determining aggregate sample size requirements, because the number of particles is more important than the total weight when allowing for the distribution of contamination within a lot. Therefore, smaller aggregate sample sizes should be sufficient for smaller particle foods. The Commission suggested reducing the aggregate sample size from 30kg to 10kg for ochratoxin A.

Commodities such as wine, cereals, dried vine fruits and beer are produced both outside and within the EU. Therefore, official controls would not be possible at import for EU-produced foods and would need to occur nearer to the point of retail sale. Also, where official controls are required on final products rather than imported raw materials there would be greater need to sample nearer to the retail stage. Sampling near retail can cause difficulties (as outlined in point 3.3 of this report), for example, sampling plans which require large amounts of sample are impracticable.

The increasing pressure on enforcement resources was made clear, particularly in view of the proposed sampling needs for ochratoxin A and, possibly, other mycotoxins in the future. Greater prioritisation by authorities would be required. The Commission emphasised that no Tolerable Daily Intake can be set for aflatoxins, which pose the greatest health threat and should remain the highest priority for official testing. An alternative suggestion was the possibility of charging importers to help relieve this growing burden on control authorities. The Commission acknowledged this suggestion.

5. CONCLUSIONS

(i) Early experience with the EC sampling and analysis plans for aflatoxins shows them to be effective, although resource intensive. Control authorities need to prioritise effectively where resources are limited. With regulation on ochratoxin A, which potentially affects the whole of the EU cereals market, the need for prioritisation will increase. Therefore, when drawing up future regulatory limits and sampling plans the practical implications should be carefully considered, to ensure that all maximum limits will be enforceable and, therefore, have a true impact on food safety.

(ii) Provisions for official sampling at points other than import need to be further developed. This would help authorities where testing is not appropriate at import, for example, for EU produced foods and where transshipment to other destination Member States is required.

(iii) Confusion can arise with customs controls and food authorities due to insufficient labelling on lots and inconsistent approaches to testing. Labelling provisions need to be agreed to ensure tested or untested lots can be identified and to help clarify the status of lots with customs and enforcement officials in destination Member States.

(iv) General support was given that reliable origin certification measures would help the control authorities use resources more effectively to achieve the required safety standards in food. Certification should be further discussed and a plan of action formalised.

(v) Contamination of brazil nut shells with aflatoxins was identified as a possible problem for rejecting consignments of nuts where the edible part is otherwise acceptable. The influence of contaminated shells on the failure rate of otherwise acceptable edible nuts should be investigated.

(vi) Sampling and analysis plans for aflatoxins in spices need to be agreed, to accommodate smaller lot sizes if appropriate.

(vii) Sampling and analysis plans for ochratoxin A need to be discussed and agreed to accompany the proposed regulation in certain foods. For an effective and enforceable plan it will be important to consider the characteristics of the food commodities and at what sites official sampling would be most appropriate, for example, where products rather than raw materials are regulated and for EU produced goods.

ANNEXES

ANNEX 1

Implementation of EC Directive 98/53 In the UK

Jon Averns

Port Health Services Director
London Port Health Authority



Implementation of EC Directive 98/53 In the UK

Previous Legislation - Aflatoxin Regulations 1992

- Nuts, nut products, dried figs and dried fig products.
- Authorised ports of entry.
- Primary inspection of documentation.
- Further inspection by sampling - e.g. 30 samples groundnuts, total 10kg.
- Statutory limit of $4\mu\text{g kg}^{-1}$ or $< 10\mu\text{g kg}$ for processing.
- Rejection - re-export, use NOT for human consumption, destruction.

Implementation of EC Directive 98/53 In the UK

New Legislation - The Contaminants in Food (Amendment) Regulations 1999

- Amend existing Contaminants in Food Regulations 1997.
- Uses general Food Safety Legislation for enforcement.
- Refers specifically to Commission Regulation and Directive.
- Port Health Authorities empowered with enforcement at specific ports.
- Guidance under preparation by MAFF.

Implementation of EC Directive 98/53 In the UK

Enforcement Approach by UK Port Health Authorities

- Resource implications for increased number of samples per consignment.
- Attempting to maintain sampling levels at Ports.
- Targeting sampling on a risk analysis basis.
- APHA endorsement of origin certification procedures.
- All samples are “official”.

Implementation of EC Directive 98/53 In the UK

UK Port Health Authority Concerns Consignments Failing to Meet Limits

- Should re-export always be permitted?
- At what levels of contamination can treatment be permitted?
- Assessment of treatment processes.
- Can blanching/treatment take place in another member state?
- Principal concern - 100% control over rejected consignments.

Implementation of EC Directive 98/53 In the UK

Other UK Port Health Authority Concerns

- Labelling of consignments intended for sorting/treatment.
- Nuts allegedly for wild bird food use.
- Maintenance of surveillance levels.
- Importations via other member states.
- Consistent approach to enforcement throughout EU.

ANNEX 2

Abstract provided by Denmark (see section 3.5)

Co-operation between Customs and Food Control Authorities

International food trade is increasing in both volume and diversity. Companies are using the “just in time” method to limit expenses for storage. Products come in containers, trucks or packages not intended to be opened before they reach their final destination, where they only will stay a short period before they are sold to the consumers.

Food Control used to be the official authority who guaranteed the food was healthy. Now the companies must ensure that the marketed products are safe and legal and that they fulfil standards. HACCP analyses and auto control systems become more and more important. In general, food control is changing from analyses of products to inspection of a company’s way of living up to its responsibility.

These tendencies make it increasingly difficult to inspect and control food at the border, and call for co-operation between Food Control and Customs Authorities to select which importers or foods to be controlled, before the products enter the Common Market.

The Customs Authorities have information on importers and the imported foods identified by KN codes, country of origin and amount. This information can be used as a basis for Food Control inspection on the premises in either the warehouse or the office of the importing company.

Previous knowledge of fraud or infringements usually lead to intensified control of the company. A co-operation can be arranged between the custom and food authority, so that the food control is informed when the company imports anything. The

imported foodstuffs are not freed for circulation before they are inspected by the food control.

Previous knowledge of frequent contamination usually lead to intensified control of the foodstuff. A co-operation can be arranged between the custom and food authority, so that the food control is informed when certain KN codes or food from certain countries are imported, e.g. figs from Turkey or pistachio nuts from Iran. The approach may also be used in finding foodstuffs planned to be sampled for survey, e.g. raisins or almonds from California.

A company may of course falsify KN codes or countries of origin, but here the Custom and Food Control have a common interest in getting the correct information and to avoid fraud.

ANNEX 3

ORIGIN CERTIFICATE

POSSIBLE BENEFITS FOR
ENFORCEMENT AUTHORITIES

ORIGIN CERTIFICATION

- What are the benefits?
- Is there a legal basis?
- What would the criteria be?
- Who validates acceptability of certificate?
- Time scale for introduction?
- How do origins meet EU standards?

What Are The Benefits?

- Targeted Enforcement
- Best use of limited resource
- Prevention of duplication of effort
- Recognition of good producer practice
- Recognition of Equivalence

ORIGIN CERTIFICATION

- If it is agreed that origin certification could help effective enforcement the questions raised earlier will need to be addressed
- The system in place for veterinary checks may provide a basis for any future origin certification regime.

ANNEX 4

CRITICAL STUDY TO DEVELOP SAMPLING PLANS FOR MYCOTOXINS IN CEREALS AND CEREAL PRODUCTS

1. Effective sampling, sample preparation and analytical methods are required to identify the nature and extent of a mycotoxin problem and to form the basis of quality control. In particular, special methods are necessary to account for the frequent uneven distribution of mycotoxin contamination in foods. Where only a small number of particles are contaminated, they may be highly contaminated. It is important to be able to detect such isolated 'hot spots'.
2. An easy to use computer programme has been developed to check whether cereals and cereal products are contaminated by unacceptable levels of mycotoxins. The computer programme produces sampling plans for the mean level of mycotoxin per unit weight, but does not evaluate data in any way.
3. There are three choices of sampling plan: pragmatic, routine, and regulatory. Routine plans allow the user to select between 4 and 100 incremental samples. Pragmatic plans always have 6 incremental samples and place an upper limit of 10 kg on the sample weight. This is a pragmatic limit suitable for current industrial equipment. The numbers of incremental samples in regulatory plans are set by the load size, and a larger sample weight is required than the equivalent routine plan.
4. The sub-sample weight is user-defined, but restricted to be between 50 g and 200 g. The programme estimates the appropriate sample weight. If the sub-sample weight is 50 g, the sample weight is chosen so that the number of particles in the sub-sample is 100,000 for regulatory plans and 50,000 for other plans. These large numbers ensure approximately Normal sample test results, and a relatively small variance.
5. If the sub-sample weight is greater than 50 g, the sample weight is reduced. This is to make the operational characteristic (OC) curve for this plan the same as the OC curve for the plan where the sub-sample weight is 50 g. As the sample is assumed

to be homogeneous, so the estimated sample weight is not affected by the number of incremental samples. If either of these methods lead to a sample weight below 0.2 kg, then the sample weight is fixed at 0.2 kg. In practice this only applies to ground materials.

6. In order to estimate OC curves, the distribution of the mean estimate is assumed to be Normal, given a sufficiently large sample. This is justified by the central limit theorem, and also by Whitaker et al. (1969), who suggest samples of over 10,000 peanuts have approximately Normally distributed sample test results. Other reports suggest this is true for samples with over 21,000 or 40,000 particles.

7. There appear to be no problems with the operation of the programme. It is simple and straightforward to use. It contains useful information on the weight of 1000 grains of many varieties of cereals and on the regulatory sampling plans.

8. The programme needs to be tested in practice on cereals. Copies of the computer programme are available to Member States from The Food Standards Agency (contact Dr B Jones, Fax 0044 207 238 5331, R210, Ergon House, PO Box 31037, Horseferry Road, London, SW1P 3WG).

ANNEX 5

A CRITICAL STUDY TO DEVELOP A SAMPLING PLAN FOR MYCOTOXINS IN CEREALS AND SIMILAR PARTICULATE COMMODITIES

1. The objectives of the project were to compare the suitability of four aflatoxin sampling plans for ochratoxin A (OA) in wheat and coffee: The United States Department of Agriculture (USDA) plan, the Dutch Code of Practice and the UK plan for groundnuts and the EC plan for aflatoxins. Two lots of coffee (mean OA levels 0.9 and 0.4 µg/kg) and 1 lot of wheat (mean OA level 5.6 µg/kg) were found. These lots were sampled according to the procedure outlined in figure 1. The results indicated that:

- a) The contamination of both coffee lots was a satisfactory fit to a log-normal distribution. The contaminated wheat lot did not satisfactorily fit any of the distributions considered.
- b) The simulations showed that neither the US, UK nor the Dutch plan produced representative samples for ochratoxin A in wheat.
- c) It was better to base a plan for wheat on the EC sampling plan for aflatoxins, taking 20 to 100 incremental samples of 30g, depending on the lot size.
- d) The simulations showed that the UK plan produced representative samples for ochratoxin A in coffee. The increased performance of the other plans was not sufficient to warrant the increase in increments they entailed.
- e) The simulations suggested that the Dutch plan had a relatively high probability of rejecting a lot with mean lower than the action limit. However, it had a much lower probability of accepting a lot with a mean higher than the action limit. For the same action limit, the UK plan was more likely to accept the lot. The US plan was the most likely to generate false positive and false negative results.

2. Only one lot of wheat and two lots of coffee beans were tested, therefore, it cannot be assumed that these OA distributions were accurate representations of OA in other cereal and coffee lots. Further studies need to be undertaken to confirm these findings.

The MYCOTOX program

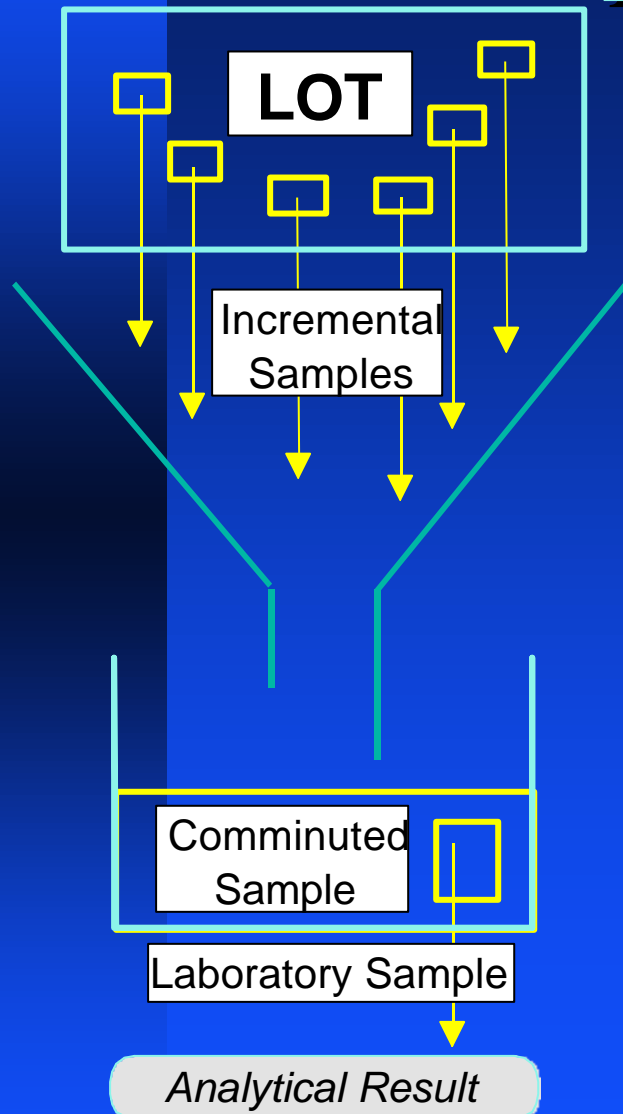
Robin Clifford

Statistics Section, JFSSG, MAFF

What is MYCOTOX ?

- IBM compatible PC program
- Developed by RHM Technology for MAFF
- Based on a model for sampling plans for mycotoxins in cereals
- Makes for easy implementation of sampling scheme at point of cereal intake.

The Sampling Procedure

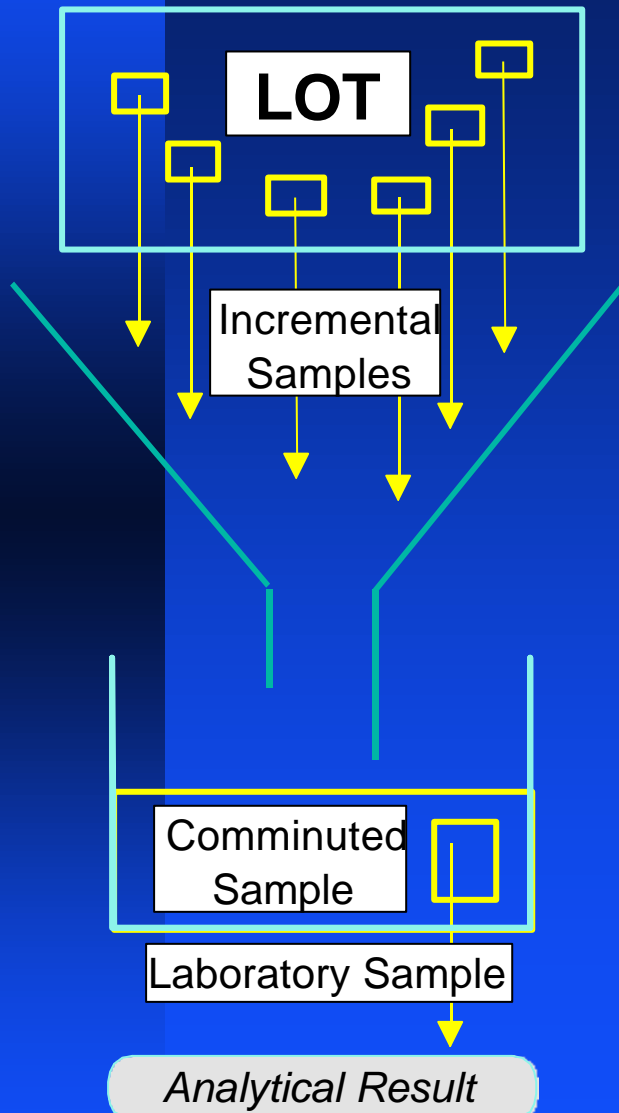


- Take several incremental samples from lot
- Number of incremental samples = number suggested in draft EU plans for lot size
- Pool samples and homogenize
- From comminuted sample, take a laboratory sub-sample
- Analyze sub-sample to get mean level of mycotoxin

Distribution of mean estimate

- If total sample is large enough, estimate of mycotoxin will be approximately Normal
- Need 10,000 + grains
- Mean of estimate = true value of mycotoxin
- Sampling plan chosen so that:
 - Variance of estimate = approx. a fixed proportion of the true value of mycotoxin
 - Number of grains in sample is about 100,000

Variance of mean contamination



- Assumes that sample variance = $k_1(\text{True level} / \text{No. of grains})$
- Assumes sub-sample variance = $k_2(\text{True level} / \text{sub-sample wt})$
- Assumes analytical variance = $(k_3 \cdot \text{True level})^2$
- Assumes k_1 & k_2 are the same for all cereals & mycotoxins
- Estimates k_1 & k_2 from trial of aflatoxin in maize

The sampling plan

- When sub-sample weight = 50 g:
 - Number of grains fixed at 100,000
 - Sample variance + sub-sample variance = approx. 11.9% of True value of contamination
- When $50\text{g} < \text{sub-sample weight} < 200\text{ g}$:
 - Sample variance + sub-sample variance fixed at 11.9% of true value of contamination
 - $38,700 < \text{Number of grains} < 100,000$

The demonstration

The screenshot shows the 'Mycotox' software window with a menu bar (File, Options, Help) and a toolbar. The main area is divided into five sections:

- 1 - Select commodity:** A list box containing: Barley (spring), Barley (winter), Corn, Oats (grits/meal), Oats (spring), Oats (winter), **Rice**, Rye, Sorghum, Wheat (Canada), Wheat (spring), Wheat (winter).
- 2 - Select variety/type:** A list box containing: Long, **Medium**, Short. Below it is a text box with '25' and the label 'Average weight per 1000 grains (grams)'.
- 3 - Weight of sub-sample (test portion):** A text box with '50' and the label 'grams'.
- 4 - Lot acceptance level:** A text box with '5' and the label 'micrograms/kilogram'.
- 5 - Type of sampling scheme:** Three radio buttons: Pragmatic, Routine, and **Regulatory**. To the right is a dropdown menu for 'Lot size range (tonnes)' with options: <1, 1-3, 3-10, 10-20, **20-50**, 50-300, 300-1500, >1500.

At the bottom right, there is a 'Generate' button and an 'EXIT' button.

The results

SUGGESTED SAMPLING PLAN

‘Regulatory’ Sampling Scheme (Lot Size 3-10 tonnes)

Commodity: Rice

Variety/type: Medium

MINIMUM Total Sample Weight: 2.5 kg

[Collect 40 incremental samples of at least 0.07 kg each.]

Weight of sub-sample (test portion): 50 grams

Lot acceptance level: 5 micrograms/kg

Average 1000 Grains Weight: 25.00 g

WARNING: IF ANALYSIS IS NOT CARRIED OUT IMMEDIATELY, SAMPLES MUST BE STORED IN A WAY WHICH DOES NOT CHANGE MYCOTOXIN LEVELS

- Just Minimum Total Sample Weight
- NO variance estimate, NO action level

Other types of sampling plan

- So far, considered 'Regulatory' plans
- Differences in Routine from Regulatory plan
 - To be used by importer, not regulator
 - Based on 50,000 grains, not 100,000
 - Free choice in number of incremental samples
- Pragmatic plans are like Routine plans with:
 - Always 6 incremental samples
 - Minimum Total Sample Weight capped at 10 kg

Other options

- SAVE and OPEN
- PRINT
- HELP

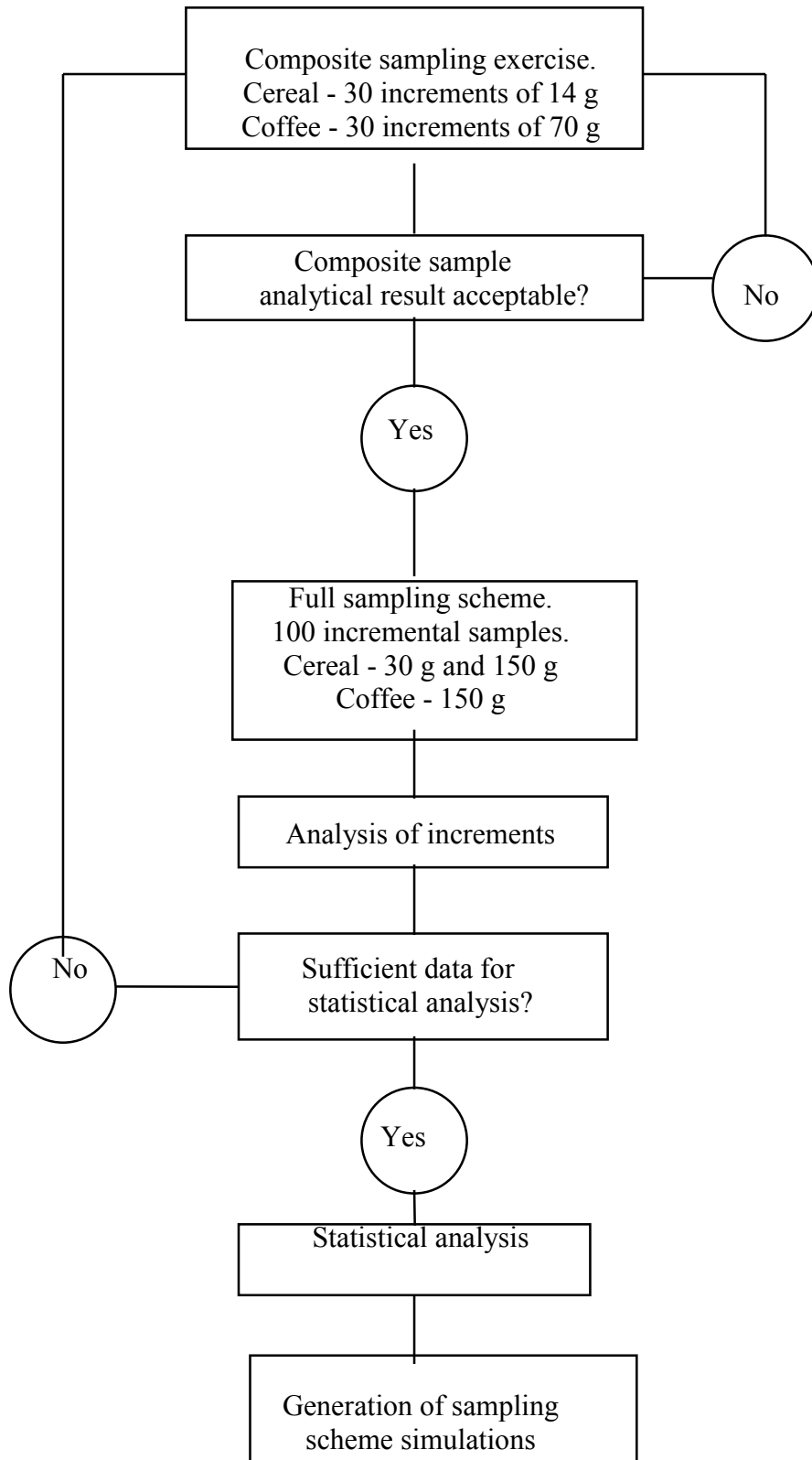


Figure 1. Proposed sampling procedure

ANNEX 6

LIST OF PARTICIPANTS

Name	Country
A. Unkrig	Commission
F. Verstraete	Commission
O. Kraeutler	Austria
M. Deceuninck	Belgium
L. Deman	Belgium
E. Pedersen	Denmark
G. Rasmussen	Denmark
R. Kombal	Germany
R. Weber	Germany
E-M. Apergi	Greece
N. Koulis	Greece
G. Fajardo	Spain
A. Pons	Spain
M. P. Herry	France
J. C. Leblanc	France
W. Anderson	Ireland
J. Quigley	Ireland
K. Andersen	Norway
C. Brera	Italy
L. Graziadei	Italy
S. Blaak	Netherlands
M. Spanjer	Netherlands
M. Barreto Dias	Portugal
E. Carvalho	Portugal
A. Hallikainen	Finland
L. Rajakangas	Finland
A. Jansson	Sweden
T. Moller	Sweden
D. Atkins	UK
J. Averbs	UK
D. Bloomfield	UK
R. Clifford	UK
S. Guffogg	UK
B. Jones	UK
M. Slayne	UK
K. Thomas	UK

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