THE APPLICATION OF HACCP TECHNIQUES TO THE MANAGEMENT OF *FUSARIUM* TOXINS IN CEREALS

FSA Project Number C03009

Final Report

Report No. CCPDG/54784/Final

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Date: 31st March 2004

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ACKNOWLEDGEMENTS

This report describes work performed within the context of Work Package 1 of the European Union Framework V Programme (Quality of Life and Management of Living Resources (QoL), Key Action 1 on Food, Nutrition and Health) project entitled Hazard Analysis Control of Food Contamination: Prevention of Fusarium Toxins Entering The Human and Animal Food Chain (CONTROLMYCOTOX FOOD).

Funding for this work comes in equal proportion from the UK Food Standards Agency (grant number C03009). and the European Union Framework V Programme (Quality of Life and Management of Living Resources (QoL), Key Action 1 on Food Nutrition and Health, contract number QLK1-1999-00996).

The UK Food Standards Agency also made available information from a yet to be published report (Project Number C03004) for use in this exercise. All data from project number C03004 remains the property of the Food Standards Agency and cannot be reproduced without their permission.

The author thanks Mr. Campbell Anderson, CCFRA for the construction and updating of the literature data-bases and for useful discussions during the project.

EXECUTIVE SUMMARY

i. The European Union (EU) is one of the world's major cereal producing blocks, producing significant quantities of barley, maize and wheat. Most of the crops are destined for either direct human consumption or for inclusion in livestock feed rations.

ii. In common with other parts of the world, these crops can become infected with members of the genus *Fusarium*. Diseases mediated by these organisms can affect one or more parts of the plants including the ear. The diseases lead to diminished yields and reductions in technological quality. They are therefore of considerable economic consequence. Members of this genus also produce mycotoxins which can contaminate harvested grain. While some of these mycotoxins can, to one degree or another, on occasions be found in all three crops (e.g. zearalenone and the trichothecenes such as deoxynivalenol), others tend to be restricted to one particular crop (e.g. the fumonisins in maize). These mycotoxins are considered to be important both in terms of livestock and public health. There is currently no evidence to suggest that epidemics of toxicoses have occurred in humans within the EU. However in at least one Member State, levels of contamination have occasionally risen, leading to product recalls from the general public.

iii. Mycotoxin production by members of the genus *Fusarium* is generally a field event, dependent on a range of factors. At its most fundamental, it is incumbent on the vendor (farmer, grain merchant etc.) to provide wholesome grain and for the purchaser to assure himself of compliance. This is best achieved using quality assurance principles, in other words prevention is better than cure.

iv. This report describes the results of a survey of literature relating to mycotoxin contamination of grain, together with the trading and processing of grain within the EU. These data have been subjected to critical path analysis using HACCP (Hazard Analysis Critical Control Point) principles. The results of these analyses have been used to identify points within the supply chain where control can be effected to reduce the risk of mycotoxin contamination occurring.

v. In-house and external literature data bases, including the internet were searched and a library of approximately 3,000 entries compiled. These were subsequently interrogated and analysed.

vi. Analyses for the flow of grain from field to primary processor were performed within the context of a 'Universal set flow diagram, (Figure 3; page 20),' which describes the generalised flow of grain within the EU.

vii. These data were subjected to critical path analysis and both critical and quality control points (CCP's and QCP's) identified (summarised in Table 1; page 37). CCP's and QCP's were as follows:

Field preparation – The natural mycoflora present is dictated by its location, in particular in terms of climate and geology. How the farmer responds to these constraints is important in ensuring that any inoculum is kept to a minimum. Poor field hygiene practices (e.g. mismanagement of the previous crop's stubble and inadequate weed control) both contribute to the progressive accumulation of mycotoxigenic species. Similarly, mono-cropping or the adoption of wheat-maize rotations also promotes accumulation of the inoculum. Accumulation is best prevented by a programme of weed management and stubble burial together with crop rotation practices which break the infective cycle (e.g. based on the inclusion of *Brassicas* and/or legumes).

Sow Seed – Control can to one degree or another be effected through the choice of cereal variety and also the application of fungicidal pre-treatments. Both cereal species and variety can influence not only susceptibility to *Fusarium* spp. infection but also mycotoxin production. Thus while contamination with the trichothecenes and zearalenone has been reported for all of the cereal crops considered, fumonisin contamination appears to be restricted to maize. There are numerous programmes throughout the world aiming to develop new varieties resistant to *Fusarium* spp. infection; however, success to date has been limited. A second factor to be considered is the treatment of the seed with antifusarial agents prior to sowing. Certain fungicides and bacterial preparations have been shown to inhibit the crop weakening diseases (e.g. foot-rot) mediated by *Fusarium* spp. and thereby make the plant more resistant to subsequent ear infection.

Crop Development – The two principal factors influencing the development and maturity of the crop are the climate and the interventions made by the farmer. Climate influences mycotoxin production at a number of levels:

- The composition of the mycoflora and its ability to produce mycotoxins;
- The actual infective process, infection is to a large degree mediated by a splash dispersal process whereby spores and other infective material are carried to the flowers by rain water hitting the ground. This may only occur for a limited period during anthesis;
- Induction of plant stress, e.g. by drought, so promoting *Fusarium* spp. infection and development;
- Damage of the late developing crop due to lodging.

In terms of interventions by the farmer the key factors concern:

- Irrigation and the reduction of plant stress due to drought plus the avoidance of spray irrigation during anthesis, which might have a similar effect to rainfall;
- The correct application of fungicides and other treatments in terms of composition, concentration and timing.

Crop Maturity – This was not considered to be a CCP. The key decision that has to be made at this point is when to harvest. This is sometimes governed by the conflicting needs of optimising crop potential and harvesting before environmental conditions change for the worse and prejudice the crop.

Harvest – A key factor of concern with regard to mycotoxins is grain moisture at harvest. Generally speaking the optimum water activity for *Fusarium* spp. mycotoxin production is in the region of 0.98 (equivalent to a moisture content of approximately 25% at 25°C). Generally speaking moisture contents of small grain crops at harvest are often below this. This is not always the case with maize, where grain moistures of approximately 30% have routinely been reported. A second factor to be considered is the degree of *Fusarium* damage in the crop. This can, under certain conditions, be an indicator of the risk of mycotoxin contamination. What is critical in both cases is that the farmer should have strategies in place to respond to both the moisture of the crop and the degree of damage it exhibits.

On Site Farm or Third Party Transport - Key factors in controlling the grain at this stage rest with:

- Ensuring the hygienic maintenance of equipment (primarily to reduce the chance of infection by *P. verrucosum*);
- Keeping levels of damaged grain to a minimum;
- In the event of wet harvests ensuring that grain is dried expeditiously and not held wet for long periods of time.

On Farm/3rd Party Storage - Grain storage forms part of the pre-requisite programme. It is incumbent on farmers, co-operatives, merchants etc. to store grain under conditions where it is kept cool, dry and free from infestation by storage pests. Stock control systems must be in place to ensure that non-conforming grain is not mixed with wholesome material. In cases where grain is stored wet in the presence of a preservative such as propionic acid, care must be taken to ensure that levels and uniformity of application are sufficient to suppress both fungal growth and mycotoxin production.

Grain Drying - Grain drying is usually of importance to storage mycotoxins (e.g. ochratoxin A) rather than those produced by *Fusarium* spp. However, incorrect use of dryers or use of damp air (as might occur when using ambient air drying systems) may promote further mycotoxin production.

Transfer to primary processor – Transport of grain to the primary processor is usually governed by pre-requisite programmes concerning the hygiene and security of the load.

viii. Similar studies were performed for the manufacture of bread, beer, cornflakes and maize starch (Summarised respectively in Table 2, page 62; Table 3, page 78; Table 4, page 94 and Table 5, Page 104). In the case of bread, with the exception of the question of grain storage neither the milling nor baking processes introduce steps where mycotoxin concentrations can increase by virtue of additional *Fusarium* spp. activity. However, there are steps, particularly in the milling process which can assist in reducing the risk of mycotoxin consumption by the consumer. Key points where control can be exerted concern the provenance of the grain and application of appropriate supplier assurance schemes (which incorporate mycotoxin surveillance programmes) and, depending on local conditions, introduction of equipment which can remove *Fusarium*-damaged grains (e.g. gravity tables) in the screen room.

ix. A similar result to that obtained with flour milling and bread baking was found in the beer model. The key element of control rests with ensuring that raw materials are appropriately regulated. This is achieved at primarily by ensuring that: the grain is not infested with the fungi, mycotoxin contamination is low and that moisture is controlled. This means that not only have appropriate supplier assurance schemes to be in place but also that suitable strategies for the storage and drying of wet grain must be implemented. The only step in the process which might contribute to increased mycotoxin production by fungi is during the steeping process prior to germination. Since this is an essential part of the malting process the only controls that can be instituted are to ensure that any fusarial inoculum in the dried grain is as low as possible. With the exception of storage and stock control, no other steps in the process were considered to influence the amount of mycotoxin contamination in the finished product.

x. Commercial products produced from the dry milling (cornflakes) and wet milling (starch) have been evaluated. As in previous studies, the integrity of the original raw material is the key factor in minimising the risk of mycotoxin contamination. Although no steps after the release of maize were considered to have the potential of contributing to the risk of increased fungal mycotoxin producing activity, a number of process steps e.g. separation of fines, thermal treatments and steeping could contribute to significant reductions in some of the mycotoxins associated with maize.

xi. The results of this exercise demonstrate that development of appropriate risk reduction practices primarily on farm or in store will significantly assist in containing the hazard of adverse mycotoxin exposure to the general public. A number of easily measurable quality parameters have been identified which enable such systems to be monitored and their efficacy can be verified by appropriate mycotoxin analyses. The overall efficacy of such systems can be enforced by appropriate supplier quality assurance (SQA) programmes.

1.0 INTRODUCTION

(Additional information is provided in Section A of the technical annex)

1.1 Context

The European Union (EU) currently occupies most of the central and western parts of the European land-mass together with the principal offshore islands. As such it can be divided into a number of broad climatic zones. These include the temperate maritime climate experienced in the British Isles, those of the Mediterranean regions in the south and the continental climates experienced in the centre and east of the Union (144). Broadly speaking, there is a north-south shift in the types of cereals grown (16). The principal cereal crops grown in the north tend to be barley, rye and oats together with wheat. The profile of the crop changes, the further south one migrates, with the emphasis moving more towards wheat and eventually wheat and maize. Figure 1 summarises significant cereals' production by EU Member States.

Cereals' production within the EU has increased from 158 million tonnes in 1990 to a peak of 192 million tonnes in 1998 and 182 million tonnes in 1999 (16). During that time there has been, where the climate permits, a net shift from barley to maize production. Based on 1999 figures, the EU currently contributes approximately 16.5%, 38.0% and 6.0% of the world's wheat, barley and maize production respectively. Most cereals are grown for either human or livestock consumption. In the case of wheat the proportions are 38% for direct human consumption and 39% for animal feed, the figures for coarse grains (principally maize and barley) are 5% and 60% respectively (16).

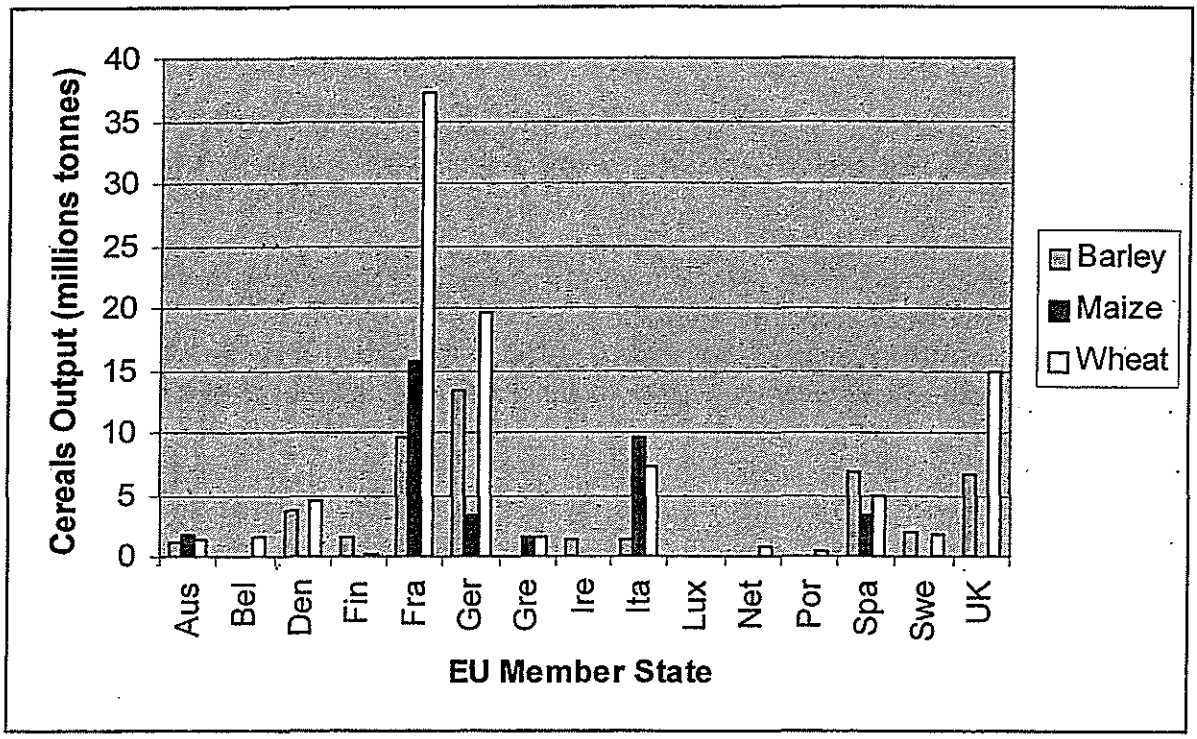
1.2 The Significance of the Genus *Fusarium*

Members of the genus *Fusarium* are important plant pathogens, particularly of cereals. They are known to mediate both root and ear diseases (manifested by, for example, pink and/or deformed grains -'tombstones,' see reference 23). Over 20 members of the genus have been found to be associated with grain producing crops (48). To this list must be added *Microdochium nivale,* which is also a significant ear-blight inducing fungus, although not a member of the genus *Fusarium.* However, this mould does not appear to be generally mycotoxigenic. While *F. graminearum* predominates on a global basis, *F. culmorum* is the more significant in the cooler maritime regions of northern Europe (147). The diseases elicited by these fungi are of considerable commercial importance both with regard to yield and technological quality (47).

Plant diseases associated with *Fusarium* spp. (but not *M. nivale*) also have implications regarding public health, since some strains of different members of this genus produce mycotoxins known to be harmful to both man and livestock (8). It has been estimated World-Wide, that 25% of food crops are contaminated with mycotoxins, with those from *Fusarium* spp. making a significant contribution (47). The toxicological status of these compounds has recently been reviewed by the EU Scientific Committee on Food (166-171). In addition, some aspects of the biology of

Fusarium spp. mycotoxins together with their relevance in the application of quality control measures have also recently been published (164).

Figure 1 1999 EU Member State Cereals (Barley, Maize and Wheat) Production (based on data in 16)



Key

Aus	Austria	Ger	Germany	Net	the Netherlands
Bel	Belgium	Gre	Greece	Por	Portugal
Den	Denmark	Ire	Republic of Ireland	Spa	Spain
Fin	Finland	Ita	Italy	Swe	Sweden
Fra	France	Lux	Luxembourg	UK	United Kingdom

With regard to mycotoxins, of direct relevance to wheat, barley and maize are the trichothecenes (e.g. T-2 toxin, HT-2 toxin, deoxynivalenol, nivalenol) and zearalenone. An additional group of *Fusarium* spp. mycotoxins of significance to man, the fumonisins, are associated with maize. These compounds elicit a diverse range of toxic effects experimentally and a number of them have been shown to be involved in human and livestock mycotoxicoses (8, 48, 97, 167, 184). While no major outbreaks of human toxicoses attributable to *Fusarium* spp. mycotoxins have been reported in the EU, levels of contamination of deoxynivalenol in commodities within

certain Member States (e.g. the Netherlands) have prompted cause for concern (88). In some cases this has led to product recalls from the general public (15). In common with other mycotoxins, codes of good agricultural practice are currently being proposed to assist in trying to reduce the incidence of these contaminants (13, 19). It has also been suggested that the next evolution in the process would be the application of HACCP principles to their control (6, 9) and preliminary results of such approaches have been already been reported (6, 163).

1.3 Rationale

In common with other mycotoxins found in bulk commodities, developing management systems for the control of those produced by *Fusarium* spp. is complicated. Factors for consideration include:

- Only some strains of any known toxigenic species of *Fusarium* have the capacity to produce a particular mycotoxin (121);
- Mycotoxin production by *Fusarium* spp. is a field event (132). Consequently it is affected by both controllable factors (e.g. agronomic practices) and uncontrollable ones (e.g. climate);
- Mycotoxin production itself, is usually a consequence of secondary metabolism, this is influenced by a plethora of factors not limited to the classical ones of temperature, water activity, pH and nutrient availability (e.g. 124, 126), but also, in some cases, to others such as physical, (e.g. 155) or chemical (e.g. 62) stress;
- Mycotoxin contamination of bulk commodities is generally heterogeneous (59);
- There is evidence that the quantity of mycotoxin produced may not be proportional to either the amount of fungal biomass or the level of *Fusarium* spp linked damage (20);
- Definitive measurements for fungal biomass or mycotoxin contamination take a disproportionate time (days) in relation to the requirements of, 'Just In Time' (JIT) practices (requires decisions in minutes) operated by modern food processors;
- The sale and supply of grain is usually subject to a contract between vendor (i.e. the farmer and, where applicable, intermediaries e.g. grain merchants) and purchaser (e.g. miller, maltster, feed-compounder etc.). Contracts often include or make reference to a specification setting out quality (including safety) criteria. These define what is wholesome. Thus, on one hand, vendors have a contractual responsibility to supply wholesome grain. On the other hand, purchasers must have systems in place which can demonstrate, at an appropriate level, that raw materials comply with those specifications.

Reducing the risk of the hazard of mycotoxin contamination is therefore best achieved by managing the crop in an appropriate manner. This is essentially a quality assurance (QA) approach (preventing one's mistakes happening in the first place - in other words: *prevention is better than cure*') rather than one of quality control (QC - preventing one's mistakes reaching the customer). Good QA management is based on a thorough understanding of the production system, in particular of its strengths and weaknesses. The latter are best identified through a process of critical path analysis. The results of these analyses can then be integrated into

appropriate operating and management systems. This has been successfully used by the food industry in the form of Hazard Analysis Critical Control Point (HACCP), which has been defined as:

"A system of food-safety assurance based on the prevention of food-safety problems (117)"

This report provides an analysis of what is currently known about *Fusarium* mycotoxins together with the commercial flow of the three major cereals grown in the EU, wheat, maize and barley. Using food quality management techniques such as HACCP, this information has been analysed and key factors influencing the production of these mycotoxins identified.

2.0 METHODOLOGY

The underlying philosophy behind this analysis is based on the HACCP approach. There are 7 underlying principles underpinning HACCP (117). These are:

1. Conduct a hazard analysis;
2. Determine the critical control points (CCP);
3. Establish critical limits;
4. Establish a system to monitor control of the CCP;
5. Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control;
6. Establish procedures for verification to confirm that HACCP is working effectively;
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

In applying the philosophy of HACCP to this kind of analysis, it is necessary to have a clear understanding and agreement of the terms used. In the context of this work, the following definitions apply.

CRITICAL CONTROL POINT (CCP):	*'A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (117).'*
CRITICAL LIMIT	*'A criterion which separates acceptability from unacceptability (117)'*
QUALITY CONTROL POINT (QCP):	*A step at which control can be applied to manage some aspect of the quality of the product. It may also have the potential of ameliorating a food safety hazard.*
HAZARD:	*Something prejudicial to public health.*
PREREQUISITE PROGRAMME:	*A defined set of activities considered as being essential to the achievement of good agricultural/manufacturing practice.*
RISK:	*The probability of the hazard occurring.*
RISK FACTOR:	*An aspect of any step within a system (e.g. flow through supply chain, manufacturing process etc.), which can increase the risk of a hazard occurring.*

Given the biology of the problem and that there has been no final decision at an EU level on what are permitted residue limits for mycotoxins produced by the genus *Fusarium*, the hazard has been quantified in a conceptual rather than a numerical term as:

The occurrence of Fusarium spp. mycotoxins which exceed limits that can be expected from good practice

It should also be noted that one recent development in the application of HACCP has been the concept of the pre-requisite programme. The rationale behind such programmes is that there are a number of activities, which are fundamental to producing safe products of the appropriate quality required by good agricultural or manufacturing practices. Examples would include: measurements of commercially significant parameters (e.g. moisture), preventive maintenance and pest control in stores. These have also been taken into account.

This has been a 'desk' exercise, which has involved reviewing and analysing the following knowledge bases:

- Current practices for producing and handling grain within the EU;
- Literature regarding the occurrence of mycotoxins cereals and related topics;

Literature was accessed through a number of sources, principally computerised abstract facilities and the internet. Information from these exercises has been collated on to a data base using "Reference Manager 9.5™" software (www.refman.com). By integrating knowledge of the biology of mycotoxin production with that of the grain supply chain, as well as cereal-product manufacturing systems, it was possible to describe the flow of grain from field to end-consumer and identify those aspects that may contribute to the risk of the hazard of mycotoxin contamination occurring *(Principle 1)*. Using these outputs, Critical Control Points (CCP's) were identified *(Principle 2)* along the supply chain using a decision tree (Figure 2) approach (117). In addition it was also possible to identify Quality Control Points (QCP's). These are points, albeit not critical, where additional actions can help to ameliorate the problem.

CCP's and QCP's have been identified by interpreting mycotoxin contamination of cereals as essentially a three-stage process - infection, growth and mycotoxin production. Although this is a simplistic view, in that it does not immediately take into account the large number of intrinsic and extrinsic factors affecting mycotoxin production, it does provide the intellectual basis on which to apply the 'prevention is better than cure' philosophy regarding mycotoxin contamination proposed by Battaglia *et al* (27). Applying this philosophy therefore, one can deduce that measures to prevent mycotoxin contamination of the cereal can take place at one or a combination of three levels:

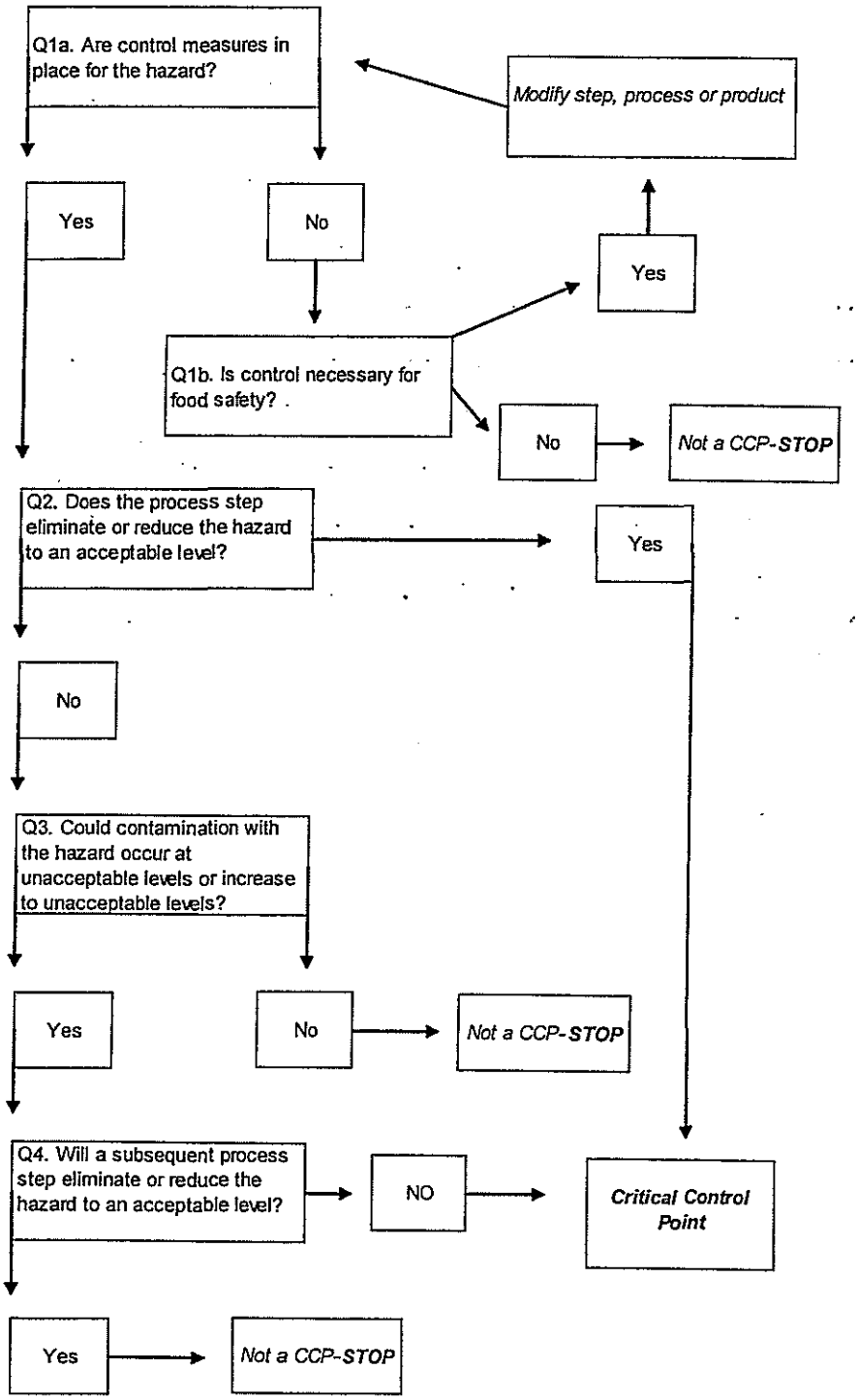
- Reduction of successful infection;
- Suppression of fungal growth;
- Inhibition of mycotoxin production.

Having identified CCP's and QCP's, parameters which could be measured were identified and (where possible) critical limits suggested (principle 3). The study also permitted identification of possible monitoring and verification systems (principles 4 and 6), together with corrective actions (principle 5) in the event that critical limits were exceeded.

A prerequisite of any HACCP study is a detailed understanding of the process from start to finish. At its simplest, the commercial flow of grain can be described as beginning with the farmer preparing the ground to sow his seed through crop development and maturity to harvest. The harvested crop may either be sold on or used to feed animals on farm. If sold, customers range from feed compounders to millers and maltsters. For the purposes of this study, these customers are regarded as the primary processors who either sell their product for direct consumption (e.g. in animal feed) or to a secondary processor (e.g. baker or brewer). It is the latter group, who transform the intermediate product (e.g. flour, malt, maize grits etc.) into a product suitable for retail to the consumer. It must be emphasised that this is a very simple view of the flow of grain through the food chain. The results of more detailed analyses for cereals, from field to primary processor are presented in sections 3.2 and 3.3 below. Results for a selection of finished products are presented in sections 3.4 (wheat, bread), 3.5 (barley, beer), and 3.6 (maize, cornflakes and starch).

Similarly, it is possible to consider the chronology of mycotoxin production in a simplified manner, i.e. beginning with fungal infection and progressing through growth and development to mycotoxin production. In the case of the cereals considered in this study, infection is the process by which the vegetative fungal material invades the flower and germinates. This is followed by mycelial development (growth), which, under appropriate conditions is accompanied by mycotoxin production. This is an extremely simplified model; however, it forms the intellectual basis for addressing the large number of extrinsic and intrinsic factors which not only affect fungal development but also mycotoxin production.

Figure 2 Decision Tree Used for The Identification of Critical Control Points (taken from Leaper, reference 117



3.0 RESULTS

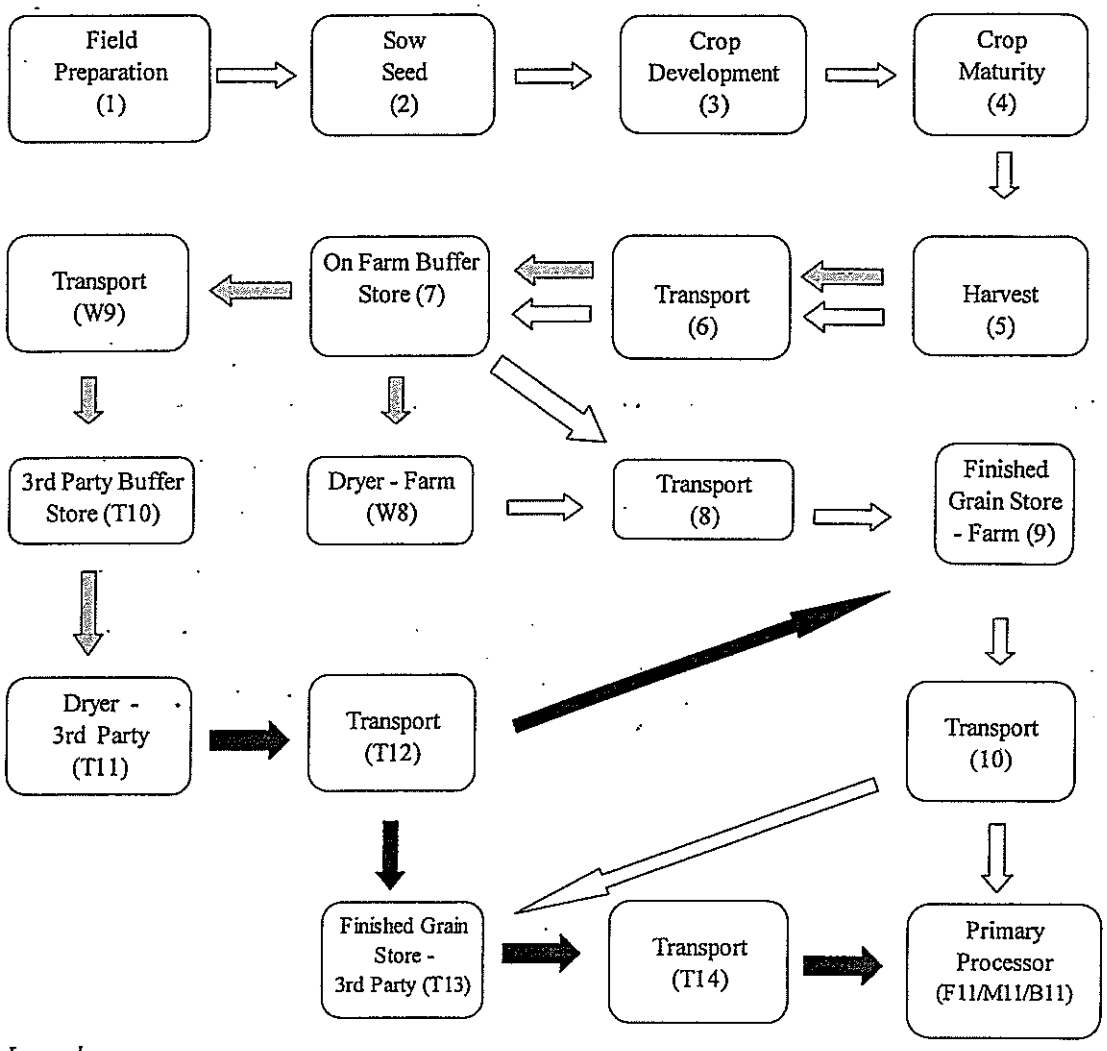
3.1 Literature Database

As a result of surveying in-house and external databases a library of approximately 3,000 entries relating to the topics of *Fusarium* infection of cereals, mycotoxin production and cereals production was constructed. This was interrogated and the outputs analysed. Information directly relevant to the studies undertaken is cited here. Supplementary information is summarised in the technical annex.

3.2 Characterisation of the Commercial Flow of Grain From Farm to Primary Processor

Following analysis of the literature and discussions with others involved in the general EU grain trade, a 'Universal Set' model for grain flow has been developed (Figure 3). Any regional or trade differences can be described as subsets of the universal model. For instance, grain harvested at potentially high moisture contents ('Wet') and supplied directly from the farm to a third-party (e.g. barley supplied to maltsters in Northern Europe, maize directly to elevators) can be described by a simplified version (Figure 4). Similarly, grain harvested at low moisture contents ('Dry'), for example bread-making wheat in Italy, can be described by another simplified derivative (Figure 5). The involvement of third parties relatively early in the supply chain should be noted. These can be either farm co-operatives or grain traders/merchants. In the latter case these individuals may not have actual physical control over the grain and only act as an agent for the farm or co-operative in selling the grain.

Figure 3 'Universal Set' Diagram Describing Generalised Flow of Grain from Field to Primary Processor Within The EU



Legend

Source Location

Farm — Primary Processor (F = Flour-Mill; M = Maltster, B = Maize Processor)

Farm, wet grain (W6 - W8)

3rd Party (T8 - T14);

Figure 4 Generalised Flow Diagram for Grain Harvested Potentially 'Wet' and Supplied Directly From Farm to a Third Party (e.g. Maltster or Co-operative Elevator)

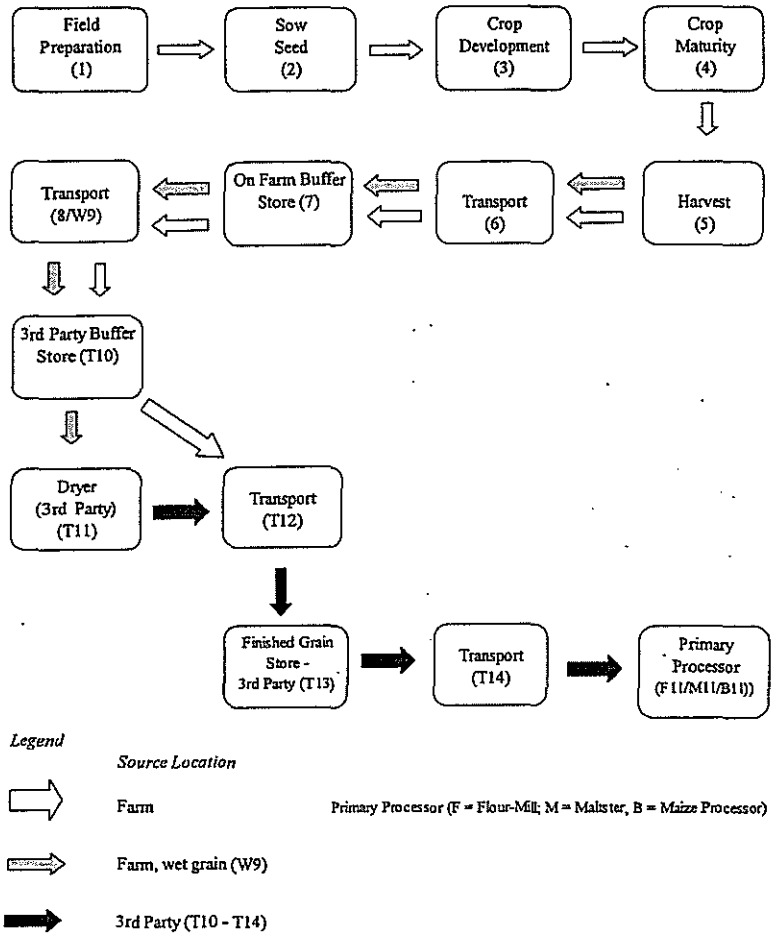
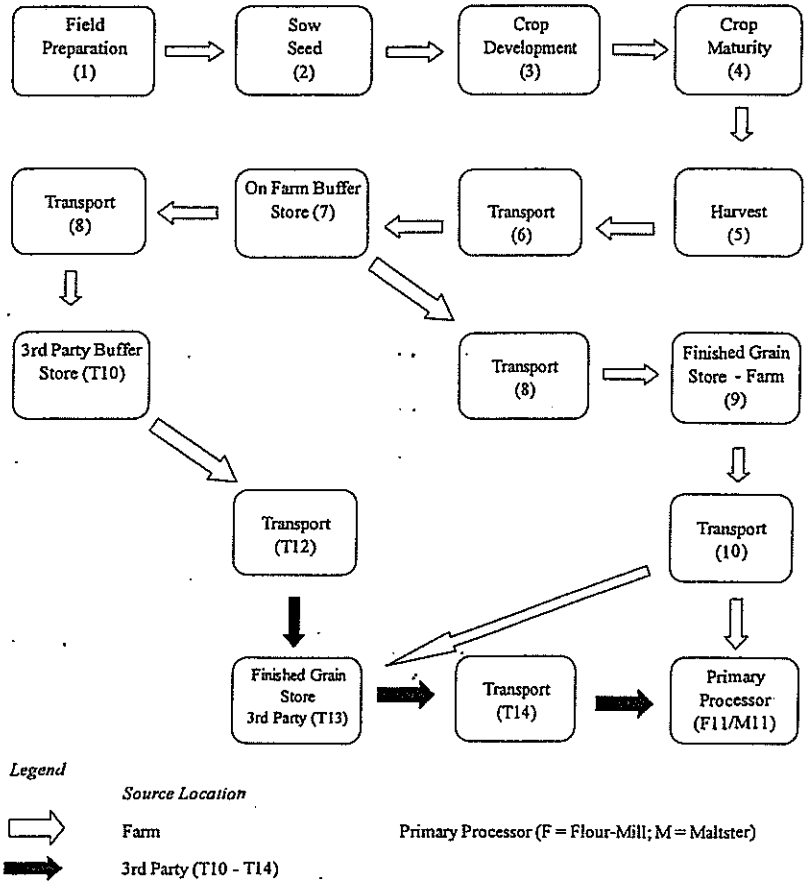


Figure 5 Generalised Flow Diagram for Grain Harvested 'Dry' and Supplied Either Directly or Through a Third Party (e.g. Co-operative Elevator)



3.3 Review and Analysis of Literature Database Within the Context of EU Cereal (Wheat, Barley and Maize) Production: Farm to Primary Processor.

(Additional information is provided in Section B of the technical annex)

Having characterised the flow of grain through the supply chain (Figure 3), the literature data base was interrogated, risk factors identified and their implications with regard to management of the supply chain discussed. A summary of these results is presented in Table 1. Applying the strategy discussed in section 2, these data are discussed for each step (or group of steps) within the contexts of one or two broad strategies - prevention of fungal infection and/or, suppression of fungal growth together with suppression of mycotoxin production

3.3.1 Stage 1 - Field Preparation

Overview

The key approaches that can be taken at this stage to reduce the incidence of mycotoxin contaminated grain are concerned with reducing and/or maintaining at a low level, the amount of infective fungal material present in the environment.

Geographical Location

In common with other organisms, *Fusarium* spp. have evolved to fit into preferred ecological niches. One risk factor that cannot realistically be controlled is geographic location. Numerous studies have shown that the mycoflora varies with location. Within the context of mycotoxins, Bottalico (37) observed that the most frequently encountered mycotoxins in small grain crops (wheat and barley) were deoxynivalenol and zearalenone (the fumonisin group of mycotoxins only being found in maize). He also reported an increased occurrence of fumonisin B_1 the further south the maize was grown. With regards to small grain crops, in particular wheat and barley, differences in which were the predominant fungi found were observed (e.g. *F. graminearum* in southern Europe and *F. culmorum* in the cooler maritime regions). Three of the determinants governed by location are: climate, the cultivation of maize (both discussed later) and geology. Certain mineral deficiencies (e.g. zinc) have been shown to predispose crops to increased risk of *Fusarium* spp. infection (86).

Soil Management

Soil management also assists in ensuring plant vigour. This applies both in terms of optimising soil elemental balances in particular nitrogen and possibly zinc as well as operating adequate irrigation (discussed below). Ground nitrogen treatments in particular, can contribute to the risk of both *Fusarium* spp. linked diseases and the incidence of mycotoxin contamination. Inappropriate application of nitrogen fertiliser may therefore be an additional risk factor. For example work in Germany (32) has shown no difference in the degree of mycotoxin contamination between organic and non-organic farming methods. However, experience in the Italian Po valley has suggested a link between the use of manure instead of urea on farms which

have moved over to organic wheat production and increased incidence of fusariosis and mycotoxin contamination (35). The benefits of using urea were also observed by Teich *et al* (187).

Field Hygiene & Crop Rotation

While climate and geology are either impossible or difficult to control, regulation of the substrate on which the fungi grow is possible. Both crop residues left after previous harvests, as well as weeds, have the potential for being sources of infection (91, 98). Maize stubble in particular is particularly refractory to degradation in the field and has been identified as a good substrate for the propagation of *Fusarium* spp (28). Thus keeping the amount of infective material to a minimum has two components: maintaining good field hygiene and operating appropriate crop rotation practices. In the case of field hygiene this means keeping surface plant litter to a minimum and adopting appropriate stubble management policies. Stubble management is particularly important with stubble burial and crop-rotation leading to the lowest survival rates of fungi (58). Care must be taken in the methods of management since some methods (e.g. stubble burning) can actually exacerbate the system (118, 180). These results suggest that ploughing rather than the adoption of no tillage agricultural methods are preferable. This can be combined with other soil disinfestation practices, e.g. solarisation; where possible, exposing ploughed soil to the late summer and autumn sun, as practised in some parts of Italy. Solarisation has been shown to lead to a substantial reduction in the numbers of *Fusarium* spp. present in the soil (5).

If stubble management is a contributory factor to modifying the amount of infective potential present in the environment, crop rotation is a means of changing the substrate and helping to prevent the accumulation of one particular pathogen. Mono-cropping or rotations based solely on wheat and maize have been shown to enhance the risk both of both *Fusarium* spp. - linked diseases and mycotoxin contamination (186), while rotating the cereal crop, in particular with either legumes (110) and/or *Brassicas* (111) can lead to reduced risk.

Hazard & Risk Analysis (Also Refer to Table 1; Risk Factor 1.1)

On the basis of current knowledge, stubble management, crop rotation and choice of nitrogen fertiliser can be considered to be CCP's on the basis that correct application of these practices, singly or in combination, significantly reduce the potential of infection. Given local variations and the significance of substrate, optimised use of climate at the time of ground preparation (e.g. solarisation) were considered to be QCP's.

3.3.2 Stage 2 - Sow Seed

Overview

Role of Species & Variety

In terms of sowing the seed, the key challenges rest with regards to the choice of crop variety and steps to assure the healthiness of the seedling (164).

It has been known for some time that the variety or hybrid-type are contributory factors in the susceptibility of maize (40), wheat (191) and barley (41) to *Fusarium* spp infection. Plant species can also be a determinant in what mycotoxins are produced. This is particularly marked in the case of the fumonisins. Generally speaking this group of mycotoxins is only found in maize, although there have been reports of very low levels occasionally being found in wheat and barley (44). This may in part be explained by laboratory studies. Visconti and Doko (194) have shown that *F. moniliforme* isolates from maize produced larger amounts of fumonisin mycotoxins compared with isolates obtained from wheat and barley. Subsequently Marin *et al.* (125), studied fumonisin producing strains of *F. moniliforme* isolated from maize. They observed that while the strains readily grew in culture, using media based on wheat, barley or maize, fumonisin production could only be seen when the strains were grown on maize based medium.

There is continuing interest in the breeding of cereals resistant to *Fusarium* spp. mediated disease (130). It has been known for some time that at an agronomic level, cultivar plays an important role in determining susceptibility not only to infection but also to mycotoxin production. For example, studies both in Canada (54) and Europe (60) have shown some varieties of durum wheat (*Triticum durum*) to be more susceptible to deoxynivalenol contamination than varieties of standard wheat (*T. aestivi*). Similar studies have shown that variety is a key determinant for barley (4) and maize, where late maturing varieties have been shown to be particularly susceptible (123). Although breeding programmes for developing *Fusarium* spp. resistant varieties of wheat and barley exist (49, 76), success has been limited. This has been mainly due to a lack of understanding of the mechanisms of resistance, particularly in the case of wheat (196). A further factor is that the extent to which varieties exhibit resistance is to some degree determined by the geographic location of where the crop is grown (158).

More success has been seen with maize. Methods for screening resistant hybrids and mapping of QTL's associated with both disease resistance and reduced ability to accumulated deoxynivalenol have both been achieved (148). In the case of maize, in particular, resistance can be conferred not only in terms of resistance to the mould or mycotoxin but also in terms of resistance to insect vectors, which also contribute to the incidence of the condition (83). For example, some genetically modified (GM) varieties of maize producing the *Bacillus thuringiensis* Cry IA(b) gene product have been shown not only to be more resistant to *Fusarium* spp. infection (67, 140, 141) but also, on occasions, resistant to accumulation of fumonisin B_1 (67, 140).

A cautionary note needs to be sounded regarding the development of *Fusarium* spp. resistant varieties. In terms of breeding for *Fusarium* spp. resistance, the mechanism of resistance should not be one that involves the reversible inactivation of mycotoxins. Savard (161) has suggested the possibility that yeast in either the baking or brewing processes could convert plant-derived deoxynivalenol conjugates back to the original toxin. Similarly, development of resistant-strains simply on the basis of increased tolerance to a particular mycotoxin would not be desirable, if it led to apparently healthy plants being contaminated with increased amounts of that compound.

Seed Pretreatments

Choice of variety is one determinant at this stage in the food-chain that can contribute to altered risk of *Fusarium* spp mediated infection and mycotoxin production. A second determinant concerns steps which can be taken prior to sowing and which will promote seedling health and assist in the eventual development of a healthy plant. These can relate either to the soil in which the seed is sown and seed treatments which help to prevent early seedling diseases.

Plant vigour can be affected by early root diseases, a number of which are the result of *Fusarium* spp. infections (130) and/or sowing density. Ellen and Langerak (72) have observed that fungal infection of the growing plant is greater at lower compared with high densities of sowing. These are relative terms and sowing at a too high density can also increase disease risk (87). Pretreatment of seeds prior to sowing has also been evaluated for the potential to prevent *Fusarium* spp. linked diseases. These have included both bacterial vectors (e.g. the use of *Erwinia herbicola* against *F. culmorum* infection of wheat (107) and the use of certain pesticides e.g. triazoles, (45)). It must be remembered that these fungicide treatments have their effect through reducing the incidence of weakening conditions (e.g. foot-rot) as opposed to inhibiting infection of the kernel *per se*. The possibility that the mould and mycotoxins could make their way from infective sights in the plant roots to the developing kernel has been considered. However, studies such as those by Parry and co-workers (55, 99) suggest that in the case of wheat and barley, grain contamination with *Fusarium* spp. mycotoxins occurs as a consequence of a splash dispersal mechanism (discussed in section 3.3.3).

Hazard & Risk Analysis (also refer to Table 1; Risk Factors 2.1-2.3)

Given the current state of knowledge and the confounding factor of geographical variation, both the choice of variety and application of seed treatments are considered to be QCP's. Given that crop density is a factor and can be controlled, the density of sowing can be considered to be a CCP. The target limit would be a sowing density that would achieve optimum yield.

3.3.3 Stage3 - Crop Development

Overview

There are two key factors influencing the generation of mycotoxins during crop development. These are climate and interventions in the form of crop treatments. The two topics will be discussed separately.

Climate

In broad terms the effects of climate on mycotoxin contamination of cereals can be seen in the work of Lew *et al.* (120). They observed that in central Europe, where grain (with the exception of maize) is usually harvested at moisture contents less than 16%, field mycotoxins, in particular those produced by *Fusarium* spp. are of greater relevance than storage mycotoxins (e.g. ochratoxin A) which are of considerable concern in maritime areas. As mentioned in section 3.3.1, climate influences the composition of the mycoflora, the capacity of the mould to successfully infect the crop and the ability of the infecting mould to eventually produce mycotoxins. Although climate can be modified by Man, he cannot be effectively in control of it. Climate therefore cannot be considered to be a CCP *per se*. However, an understanding of the effects of climate on the three components of eventual mycotoxin production enables the development and eventual implementation of risk-reduction strategies.

Reference has already been made to the work of Bottalico (37), who observed a north-south change in the predominant mycotoxin producing *Fusarium* species present in small grain crops. There are also temporal changes in the composition of the fungal mycoflora (26, 138) which are probably related to seasonal climatic changes (26, 114). These changes can be further aggravated following atypical weather, for example Perkowski *et al.* (151) observed that the *Fusarium* spp. mycoflora of experimental triticale crops changed from one year to the next, following an unusually long snowy winter.

Climate is a key determinant in the infection process. High relative humidity and ambient temperatures in the range of 11-23^{o}C favour the release of the infective principle (ascophores). Successful infection is promoted by rainfall during anthesis and kernel development (3). Subsequent studies (79) have shown that *Fusarium* ear blight epidemics in small grain crops are associated with multiple inoculation events with coincident wet periods at anthesis. Where *Fusarium* spp infection involves toxigenic strains, there appears to be a positive correlation between rainfall at the time of anthesis and subsequent deoxynivalenol contamination (112, 113). Similar conclusions have been made concerning deoxynivalenol contamination of maize (155).

Fusarium spp. infection is not the only stage in the route to mycotoxin production affected by climate. It also influences mould growth and toxin production. At its most basic, one component of climate (temperature) can favour the predominance of one species over another. For example Boshof *et al* (36) demonstrated *F. graminearum* to be pathogenic in wheat at higher temperatures (22-24.6^{o}C) than *F. crookwellense,* which exhibited greater pathogenicity at lower temperatures

(13.8°C). In terms of rainfall, early studies on zearalenone contamination of maize in Canada (182) demonstrated that the occurrence of this mycotoxin was favoured by heavy rainfall in August, which promoted epidemic development of the already present mycotoxigenic fungi.

Climate can also have other effects. This is particularly true with regard to any stress-effects that might be put on the plant (e.g. drought). There is evidence that when wheat seedlings are put under drought-induced stress, they are more prone to both *Fusarium* spp. induced root- (29) and ear - (43) diseases. Heat or drought induced stress are believed to be key factors in promoting fumonisin contamination by *F. moniliforme* or *F. proliferatum* in maize (177), and in a more general sense deoxynivalenol in cereal-based consumer products (2). Irrigation would therefore appear to be a means ameliorating these adverse effects. However, care must be applied in its use. The type of irrigation used may in itself be a contributory factor in the incidence of *Fusarium* spp. linked problems. For example, in one epidemic of *Fusarium* ear blight associated with a drought in Idaho, USA, most of the disease was found on farms where sprinkler as opposed to rill irrigation was being used (131). This may in part be due to irrigation at time of anthesis. This practice is not recommended (31) since it would have a similar effect to rain in promoting infection and subsequent toxin production. The role of drought-induced stress is well recognised in the production of maize in Southern European regions. Crops are well irrigated and harvested at relatively higher moisture contents (>20%) which require post-harvest drying at the elevator (193). Such a practice has implications on mycotoxin production in the crop post-harvest (discussed in sections 3.3.6 and 3.3.7).

Climate is a significant predictor of the risk of mycotoxin production and computer models have been developed to use climatic variables as predictors of *Fusarium* spp. diseases for specific areas (136). However, an emphasis on the word, 'risk' must be made. Adverse weather conditions are only one contributory factor, and the utility of a decision approach based only on weather conditions during crop development and harvest has been questioned (96).

Crop Treatments

A key intervention during the production of any crop is its treatment with a variety of agents either to regulate growth or to protect against pests and disease. Given that the plant's general state of health is a key determinant in successful mould infection and eventual mycotoxin production, correct application of the appropriate compounds plays an important role in any control strategy. From first principles, a key treatment that would ultimately influence mycotoxin production is the application of appropriate fungicides. Currently, with commercially available fungicides and optimal conditions, it is estimated that control of *Fusarium* ear blight is between 60 and 70% effective (100).

At its simplest, fungicide application can favour or reduce mycotoxin production by either the selective elimination of competing organisms within the kernel mycoflora (21, 71) or by directly inducing biochemical synthesis of the toxin (61, 62). Evidence that a particular fungicide can either suppress or promote mycotoxin production can be contradictory. Such is the case for tebuconazole. Literature exists which either indicates that the fungicide can promote mycotoxin

production (50, 80), or that it can be an effective agent in managing not only *Fusarium* ear blight, but also mycotoxin contamination (71, 94, 102). While some fungicides also appear to be effective in managing both *Fusarium* ear blight and mycotoxin contamination e.g. triadimefon and propiconazole (38), other compounds effective against *Fusarium* ear blight (e.g. azoxystrobulin) appeared to be associated with increased levels of mycotoxin contamination (179). In the latter case, the increased level of contamination could be attributed to the selective action of the fungicide towards *Microdocchium nivale* (101).

Care needs to be used in the timing and rate of application of these fungicides. Mis-timed application and/or application at rates below those recommended by the manufacturer can either be ineffective or actually promote mycotoxin production (18, 133). Guidelines for the correct application of foliar fungicides for the treatment of ear blight have been published (18) and include:

- Immediate preparation of fungicide spray if the weather is wet at anthesis;
- Use of mixtures of fungicides to ensure a broad spectrum effect to include mycotoxigenic species;
- Application in accordance with manufacturers' specifications (do not use reduced doses);
- Spray as soon as possible after infection (or not at all).

Fungicide application may also have consequences subsequent to harvest. Recent work financed by the UK Food Standards Agency (Project Number C03004, manuscript submitted) suggests that on occasion, fungicide application may promote post-harvest production of ochratoxin A in wet grain.

Fungicides are just one of a number of chemical agents available to the farmer in order to regulate the crop. Only a few studies have been performed evaluating the effects of herbicides. However, one study (159) looking at a range of herbicides showed no attributable effect on the soil mycoflora. Other chemicals (e.g. fertilizers and growth modulators) which directly interact with the plant may also have an effect. Work by Ellen and Langerak (72) found that delayed application of initial and/or supplemental nitrogen dressings promoted the infective process in winter wheat. Others (115) have shown crop lodging to be a risk factor in the incidence of deoxynivalenol contamination. More recently, studies financed by the UK Food Standards Agency (Project Number C03004, manuscript submitted) has confirmed these results and shown that under certain conditions, concentrations of deoxynivalenol and nivalenol can increase by almost an order of magnitude over an eight week period in naturally contaminated lodged crops. Lodging reduction measures (e.g. application of growth modulators) might therefore be expected to contribute to a reduced risk of mycotoxin contamination.

A third group of chemicals that might be applied by the farmer are insecticides. As briefly discussed in section 3.3.2, insect damage has been identified as a contributory factor to increasing the severity of *Fusarium* spp. damage in maize (69, 82) as well as wheat and barley (65). Application of the insecticide malathion has been shown to control insect infestation and also, indirectly, to reduce contamination with mycotoxigenic fungi (68, 69). Similar results were also

found for fonophos, carbaryl and maneb in the case of zearalenone contamination of maize effected by *F. graminearum* (70).

Organic (Eco) Farming

Organic (or eco) farming practices generally involve the application of a far more restricted number of crop treatments. Although organic farming practices result in changes to the soil mycoflora (73) evidence (22, 127, 162) that one method of farming is better than the other in terms of mycotoxin contamination is insufficient and contradictory to reach any definitive conclusions.

Hazard & Risk Analysis (also refer to Table 1; Risk Factors 3.1-3.4)

As already discussed, climate (risk factor 3.1) cannot itself be controlled and it cannot not be considered to be a CCP *per se.* However its consequences with regard to mycotoxin contamination can be anticipated and appropriate strategies developed. This is particularly the case with regard to minimising drought induced stress and avoiding spray irrigation during mid anthesis. Use of weather forecasts should also enable the farmer to decide on the necessity or otherwise of the use of foliar fungicides and making sure that that not only are these prepared in advance, but also that appropriate means of delivery are available. Correct response to adverse weather would therefore be considered to be CCP.

In terms of other interventions, application of the HACCP decision tree approach would suggest that incorrect selection and application of fungicides (risk factor 3.2) is a significant risk factor, the control of which would warrant classification as a CCP. Given the limited experimental evidence available, correct use of fertilizers (risk factor 3.3) would be graded as a QCP. Control of insect infestation (risk factor 3.4) particularly in the case of maize would be considered as a CCP on the grounds that it can contribute to a significant reduction in the risk of the hazard. However, this issue is complicated, particularly given the restrictions imposed by organic farming methods.

Post-harvest management strategies are also important and governed by events at this stage. This applies both to the field mycotoxins (e.g. deoxynivalenol and nivalenol) following crop lodging but also to the storage mycotoxin ochratoxin A, where there appears to be a relationship between fungicide application and subsequent toxin production if the grain is wet.

3.3.4 Stage 4 - Crop Maturity

Overview

Once the crop has reached maturity, a decision has to be made to harvest. The key point at this stage is actually effecting harvest and avoiding over-wintering. This problem generally applies only to northern Member States and then only under adverse winter conditions. Over-wintering is known not only to contribute to increased risk of mycotoxin production (114), but is also a contributory factor in the incidence of at least one *Fusarium*-linked human mycotoxicosis; alimentary toxic aleukia (167).

Hazard & Risk Analysis (Also Refer to Table 1; Risk Factor 4.1)

While steps can be taken to avoid over-wintering, this factor is still governed to a large degree by climate (inherently uncontrollable). Thus any control steps can only be considered as being QCP's. Notwithstanding these observations, over-wintering should act as a trigger for further control once the grain has been harvested to ensure that contaminated material is not released.

3.3.5 Stage 5 - Harvest

Overview

As the crop reaches maturity it progressively loses moisture, resulting in a change in water activity and a consequential change in the kernel mycoflora. *Fusarium* spp. generally grow and produce mycotoxins at an optimum water activity (a_w) in the order of 0.98 (39, 57, 124, 126) this is equivalent to a moisture content in excess of 25% at 25°C (89). *Fusarium* spp. mycotoxin production appears to take place only at certain times during kernel development. Early studies showed that deoxynivalenol contamination occurs relatively early in kernel development in both wheat (174) and maize (200). In contrast, production of zearalenone and fumonisins in maize appear to occur later in the development of the kernel (53, 200).

A second factor to be taken into consideration is the quality of the grain. The appropriateness of using parameters related to fusarial ear diseases in wheat and barley as a predictor of the risk of mycotoxin contamination is controversial. While some workers (e.g. 149, 150) have found good correlations between damage and contamination, others (e.g. 71) have not. The whole question may revolve around what is the predominant infective organism, *M. nivale* or *Fusarium* spp. Thus in cases where the preponderant organisms belong to the genus *Fusarium* a correlation may exist. Where the key organism is *M. nivale,* no such correlation exists. If fungicides which only select for *M. nivale* are used there is a risk that, while disease damage might be controlled, competing mycotoxigenic *Fusarium* spp. will not. The consequence being that apparently disease free wheat will be significantly contaminated with *Fusarium* spp. mycotoxins.

Hazard & Risk Analysis (also refer to Table 1; Risk Factor 5.1)

Essentially there are two risk factors which have to be addressed at the point of harvest:

- The moisture content of the crop is sufficient to promote fungal growth and mycotoxin production;
- Potentially contaminated material is not segregated.

In terms of crop moisture, the harvest step is not a critical control point. While it is desirable to harvest at low moisture contents, this is sometimes not possible for either agronomic reasons (e.g. maize, discussed above) or climatic factors (wet harvest season). Subsequent steps, in particular timely transfer to the grain dryer (Figure 3; steps 6, 7, W9 & T10) and effective drying (steps W8 and T11) will substantially reduce the risk of the hazard occurring. Since *P. verrucosum*, which can produce ochratoxin A, grows at lower water activities (0.81), and has also has a lower optimum water activity for mycotoxin production (0.85, 137), than *Fusarium* spp., any action limit for prioritising drying would have to be based on this hazard. Using data correlating water activity and grain moisture values such as that from Henderson (89) a theoretical moisture limit of 17% based on the lower a_w value for *P. verrucosum* might be considered. However recent work (25) has highlighted the problems associated with grain parcels and their potential to suffer from ochratoxin A contamination. In the light of this and other work, UK recommendations are that grain should be dried to 14.5% moisture or below (11). It is important to remember that, within the context of the HACCP philosophy, determination of a measurement (e.g. moisture) is not considered to be a process step (117). Moisture determinations are therefore a method of measuring compliance with requirements and are a means of monitoring or verification. They are an integral part of good agricultural practices and are therefore considered to be part of the pre-requisite programme.

In terms of moisture measurement both in the field and in storage there are two important points to note:

- Moisture measurements on the farm, particularly in the field are made using indirect measurements (e.g. moisture meters), rather than by an approved laboratory reference methods. Consequently it is essential that such measuring equipment is regularly calibrated against standards traceable to recognised methods of analysis.
- Effort can be concentrated on measuring composite samples and/or determining average moisture contents rather than of individual batches.

The failure to recognise these two points and act on them can have adverse commercial consequences (as discussed by Christiensen *et al.*, 52). A similar philosophy needs to be applied to the question of damaged kernels. Poor quality grain as a consequence of *Fusarium* ear blight should be considered suspect and segregated pending further investigation. A similar philosophy should be applied to crops (in particular wheat) which have been treated with only a strobulin type fungicide which selects against *M. nivale*. At harvest therefore, the key risk factors are

strategic - insufficient assessment of the crop together with a failure to implement appropriate strategies to manage crops with a high potential of contamination following harvest

Thus while harvesting of wet grain, or grain showing signs of ear blight cannot be considered to be a CCP, the need to implement an appropriate management strategy to minimise the hazard of mycotoxin contamination should be considered as one.

3.3.6 Stages, 6, 8, W9 & T12 - On Site Farm or Third Party Transport

Overview

Vehicles and trailers used in the transportation of cereals need to be of an appropriate hygienic standard. Cleaning regimes and accepted practices have been set out in documents issued by third-party accreditation schemes either at a trade level as in the UK (12a) or at legislative one, as in the case of the Netherlands (154). While strictly not part of the remit of this project, it is worth noting that recent work (25) has shown that grain contamination with *P. verrucosum* appears to be mainly attributable to contamination in the combine, trailers and store. In this case, the sources of the inoculum are residues which had not been removed during cleaning operations.

Hazard & Risk Analysis (also refer to Table 1; Risk Factors 6.1 & 6.2)

Two potential hazards operate at this point:

- Mixing of damaged and wholesome batches of grain in the trailer prior to transfer;
- Delaying transfer of wet grain and so permitting further mycotoxin production.

Under certain circumstances, damaged grain can be an indicator of *Fusarium* spp. mycotoxin contamination. It has also been shown to be a potential inoculum for *P. verrucosum* (UK Food Standards Agency: Project Number C03004, manuscript submitted). Damaged grain is also a significant component of the admixture fraction of supplied grain which is closely governed by trade specification. Its regulation therefore forms part of the pre-requisite programme.

More critical to the process, is for wet grain to be transferred expeditiously to the dryer to avoid any further toxin production. Experience in tropical areas has shown that even short delays in transferring wet maize to the dryer have been reported to lead to 10-fold increases in fumonisin contamination levels (146). Other work performed in the UK and on behalf of the UK Food Standards Agency (Project Number C03004, manuscript submitted) has shown that grain held in bins at moisture contents between 19 and 23% experienced substantial temperature increases (in some cases to in excess 60°C) over for long periods. As the authors pointed out, a key cause for concern in Member States experiencing a maritime climate is in years when the grain is exceptionally wet and drying capacity cannot meet demand. In this case the holding time before the grain is dried is critical with regard to the production of ochratoxin A, and given the temperature/moisture profiles possibly other mycotoxins apart from fumonisins produced by *Fusarium* spp. Prompt transfer of damp grain to the drier is therefore considered to be a CCP.

3.3.7 Stages, 7, 9, T10, & T13 - On Farm/3rd Party Storage (Buffer & Finished Grain)

Overview

Grain storage is of considerable commercial importance and ranks as a pre-requisite programme within the context of this project. There is evidence that even when stored at low moisture contents (11-14%), *Fusarium* spp. can survive for long periods (months) in stored maize, albeit with no attendant mycotoxin (fumonisin) production (146). While storage conditions are considered to be more important within the context of mycotoxins produced by storage fungi e.g. ochratoxin A by *P. verrucosum;* cases have been reported of *Fusarium* spp. producing mycotoxins in stored grain (7, 32, 95, 173). Some of the data are controversial, since mycotoxin activity was reported at moisture contents equivalent to water activities at which mycotoxin activity would not be expected to occur (e.g. 32). This may, in part, be due to heterogeneity in moisture distribution which would not be reflected if average moisture contents were used (see above). As Christiensen *et al.* (52) has pointed out, 'it is the highest moisture content that prevails in any portion of the bulk at any given time.' Storage at high moisture levels is considered to be a significant problem for maize. Reference has already been made to the effects of delaying drying on the potential for fumonisin contamination (146). In areas where maize is stored on the cob for long periods (e.g. when used for animal feed) either in cribs or on the plant, it has been suggested that incidences of disease related to zearalenone intoxication are more likely to be due to improper storage than pre-harvest development (198).

Hazard & Risk Analysis (also refer to Table 1; Risk factors 7.1 -7.6)

The principal hazards in store relate to moisture and contaminated grain and the need to segregate and address nonconforming lots of grain.

In terms of any temporary or buffer store (Figure 3, stages 7 & T10), appropriate measures of moisture determination and strategies to manage high moisture lots are critical factors. Strategies must be in place to ensure that wet grain should be dried and with what priority. This is therefore considered to be CCP (see also section 3.3.8).

In the case of maize there is also a need to consider the prompt shelling of kernels from the cob followed by speedy drying (198). While this usually happens for crops intended for commercial consumption, it might not be case for maize consumed either at a subsistence level or intended for on-farm feeding to livestock. In the latter case consideration might be given to ensiling the crop. *Fusarium* spp. are aerobic organisms and do not produce zearalenone under anaerobic conditions (74). However, it should be noted that in the same study, it was observed that if an air interface with part of the crop was allowed to exist, it was possible for mycotoxin production to occur there. Correct management of the ensiling process could therefore be considered to be a CCP. Given the cost of inert gasses, ensuring that the head space above the remaining ensiled crop remains anaerobic, particularly as it is being drawn off to feed livestock would be considered to be a QCP.

Other methods have also be used to control fungal activity in stored wet grain intended for animal feed. Most notably these include treatment with organic acids, in particular, propionic acid. These treatments have been shown to be efficient in inhibiting *Fusarium* activity both in small grain cereals (178) and maize (139). The acid is usually applied using an augur and spray unit, the rate of application being dependent on the moisture of the grain (160).

In a report recently prepared for the UK Food Standards Agency (Project Number C03004, manuscript submitted), concern was expressed over the potential for misapplication, particularly in terms of the strength of the preservative, together with the rate and uniformity of application. Laboratory studies, by the same group, demonstrated that in artificially inoculated lots of barley sub optimal application of propionic acid led to *P. verrucosum* growth and ochratoxin A production.

In terms of HACCP therefore, the key risk factor is a failure to apply sufficient material to suppress fungal activity. This is controllable by ensuring that the correct strength of preservative is used and that the equipment used is well maintained and calibrated to references traceable to national standards. Consequently this step is considered to be a CCP.

With regard to the finished grain store (Figure 3, stages 9 & T13), the blending of wetter with drier grains or wholesome and unwholesome grain should be avoided. Failure to do so can lead to additional fungal growth in store (51). Given that such problems may be more difficult to detect further down the stream, this is also considered to be a CCP.

Irrespective of whether in buffer or finished grain stores, grain must be stored under conditions that maintain its overall integrity including prevention of fungal spoilage and mycotoxin production. These steps therefore form part of the pre-requisite programme (see also section 2.0). Guidelines for best practice in storage already exist (e.g. 11) and are readily available.

3.3.8 Stages W8 & T11 - On farm or third party grain drying

Overview

As discussed previously, *Fusarium* spp. infection is a field phenomenon as too, for the most part is the production of *Fusarium* spp. mycotoxins. Grain drying is of particular concern with regard to the storage mycotoxins, in particular ochratoxin A. As already discussed in section 3.3.6, the overall time taken between harvest and completion of drying is critical if mycotoxin production is to be avoided. Thus in addition to the time taken from harvest, the speed at which wet grain is dried is also important. The latter is determined by the nature of air drying system and the way that any moisture front moves through the system. This is particularly the case for systems using ambient air. Work performed for the UK Food Standards Agency (Project Number C03004, manuscript submitted) has concluded that grain drying using ambient air is appropriate, subject to the caveat that grain is dried quickly. This depends on the humidity and temperature of the air available, the air flow rate and the efficiency of the ventilation installed.

While the above generally applies to storage mycotoxins such as ochratoxin A, it can also apply to *Fusarium* spp. if the grain moisture is sufficiently high at harvest. The need for drying in terms of *Fusarium* spp. mycotoxins appears to be most significant in the case of crops grown in the wetter and cooler northern parts of Europe, where late varieties are often cultivated and harvest moistures can be high as well as maize grown in southern Europe where the potential for fumonisin contamination exists (discussed above).

Hazard & Risk Analysis (also refer to Table 1; Risk factors 8.1 & 8.2)

Poor drying practices caused through the choice of inappropriate drying systems and/or poor management of drying regimes have been shown to contribute to an increased risk of mycotoxin contamination. This is true for both storage mycotoxins such as ochratoxin A (103) and those produced by *Fusarium* spp. (116). Grain drying is therefore considered to be a critical control point with a critical limit of <14.5% being set on the basis of the risk of ochratoxin A contamination by *P. verrucosum*, which is active at lower water activities, compared to those required by *Fusarium* spp.

3.3.9 Stages 10, T14, F11, M11 & C11 - Finished grain store to primary processor

Overview

The transfer of grain from finished grain store to any intermediary and ultimately the primary processor will be considered together. A more detailed analysis of grain acceptance practices is discussed in the analyses relating to the manufacture of bread, beer, and maize products (see below).

Transport of grain is often governed by industry codes of practice (10, 189) and compliance with such codes is a commercial pre-requisite, the same applies to grain quality for use by a particular industry (e.g. flour in the UK, 10).

Hazard & Risk Analysis (also refer to Table 1; Risk factors 9.1 - 9.3)

The key risk factors at this stage concern either the promotion of fungal activity due to water ingress into the truck or cross contamination of the load either through residues of heavily contaminated grain from a previous delivery or through mixing wholesome with contaminated grain. These aspects are all controlled through GMP. This would include dedicated use of trailers for food-use; appropriate hygiene procedures; secure covering etc. GMP for hauliers can be documented within codes of practice which are enforced contractually, as in the case of the UK (189).

Table 1 Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)

1.0 *Stage 1, Field Preparation*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
1.1	Agricultural practices which lead to the development of a soil ecology favourable to the growth or survival of toxigenic *Fusarium* spp by:				
1.1.1	*Permitting accumulation of substrate for growth of toxigenic Fusarium spp.;*	Operate a stubble management policy by reducing surface plant debris residues to a minimum; e.g. by dispersal through soil.	Y -- Y* **CCP** * Step can significantly *reduce* risk of hazard.	Stubble adequately buried.	Consider archaeological, environmental, & economic impact of 'deep-ploughing' vs. 'no till' systems. Avoid stubble burning.
		Operate proactive crop rotation e.g.: • avoid serial cropping or alternating wheat with maize; • use cereal/legume /*Brassica* rotations.	Y -- Y* **CCP** * Step can significantly *reduce* risk of hazard.	A *minimum* of cereal to no cereal rotation to be used.	Changes in producer prices at EU/world levels can lead to shift to monocroping (e.g. move to maize).

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

1.0 ***Stage 1, Field Preparation – Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
1.1.2	*Failing to make best use of climate;*	Use climate to best advantage; e.g. in Mediterranean climates, leave land ploughed and fallow under autumn sun prior to sowing winter varieties (solarisation).	N N* QCP * Climate is a variable out of the control of the grower.		
1.1.3	*Operating soil management practices that lead to a chemical imbalance which promote growth of Fusarium spp.*	Apply nitrogen fertiliser judiciously.	Y -- Y * CCP	Minimum needed for optimum yield.	Where manure is used, combine with appropriate tillage systems. Use urea in preference to ammonium nitrate.
		Optimise soil elemental balance,	Y -- N N Y* QCP * Arriving at ideal balance may not be cost effective.	Experimental studies have suggested ≥ 2mg Zn kg^{-1} soil.	e.g. Zn deficiency associated with increased risk of *Fusarium* spp. infection.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

2.0 ***Stage 2, Sow Seed***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
2.1	Poor choice of cereal variety as evidenced by:				
2.1.1	*Variety is prone to Fusarium spp. infection;*	Choose *Fusarium* spp. resistant varieties.	Y -- N N Y* **QCP** * See QA/QC aspects entry		1. Levels of resistance in varieties still less than optimum. 2. Knowledge of underlying molecular biology poor. 3. Seed to be purchased from approved suppliers. 4. Maintain genetic integrity of on-farm retained seed. 5. Choose early in preference to late varieties.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

2.0 ***Stage 2, Sow Seed - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
2.1.2	*Mechanisms of Fusarium spp. resistance favour mycotoxin production or involve inactivation of mycotoxin by subsequently reversible means (e.g.yeast fermentation).*	Develop varieties resistant to initial fungal infection, rather than growth. Where resistance to mycotoxin is also involved, the mechanism must be based either on altered target site or irreversible degradation.	Y* -- Y* **CCP** * Theoretically yes (but see QA/QC points 1 & 2 for risk factor 2.1.1).	When using *Fusarium* spp. resistant varieties, use only those which have been shown neither to stimulate mycotoxin production nor reversibly inactivate mycotoxins.	Plant breeders to characterise mechanisms of resistance and mycotoxin inactivation.
2.2	Seed sowing rates result in either low plant densities or very high densities which favour ease of infection at anthesis.	Optimise planting density.	Y -- Y* **CCP**	Sow to achieve optimal yield	Crop and farm dependent.
2.3	Seed treatments inadequate to protect against fungal root infections leading to subsequent reductions in plant vigour and resistance to head blight infection.	Use appropriate biological or chemical seed treatments.	Y -- Y* **QCP** * Uncertainty as to how reproducible any reduction would be		Treatments to be of proven efficacy.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

3.0 ***Stage 3, Crop Development***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
3.1	Climatic events favour mycotoxin contamination:				Fusarium spp. ear infection favoured by drought and by cool, moist weather at anthesis.
3.1.1	*'Splash' dispersal of spores following rainfall;*		N N QCP		Be prepared to adopt additional measures against fusariosis following adverse weather during anthesis.
3.1.2	*Drought-induced stress promotes mycotoxin production;*	Adopt irrigation practices, which reduce incidence of stress.	Y -- Y* CCP * Step can significantly *reduce* risk of hazard.	Soil moisture as determined by local 'Good Agricultural Practices.'	Monitor soil moisture and verify by crop inspection. Control at this point assumes that appropriate sources of irrigation water available.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

3.0 ***Stage 3, Crop Development – Continued.***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
3.1.3	*Irrigation practices facilitate splash dispersal;*	Consider timing of irrigation.	Y -- Y* CCP * Step can significantly *reduce* risk of hazard.		Avoid spray irrigation during anthesis.
3.1.4	*Failure to recognise that prolonged lodging can promote mycotoxin contamination.*	Ensure mycotoxin management system is in place.	Y -- Y* CCP * Step can significantly *reduce* risk of hazard.		Monitor crop at harvest for mycotoxin contamination and segregate if necessary.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

3.0 ***Stage 3, Crop Development - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
3.2	Poor control of fungal infestation through incorrect selection and/or application of fungicides.	Prompt use of appropriate fungicides at correct rate of application. Ensure prompt drying of crop, if wet at harvest (fungicide application may promote ochratoxin A production post-harvest).	Y -- Y* CCP * Step can significantly *reduce* risk of hazard.	Application rates should be: • In accordance with published instructions; • Made within 3 days of infection (or not at all).	1. Fungicides should not act selectively, leaving toxigenic fungi. 2. Applications should be made using correctly calibrated equipment (monitoring). Appropriate records detailing formulation, time of application and other relevant information to be kept and periodically inspected to ensure compliance (verification).

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

3.0 ***Stage 3, Crop Development - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
3.3	Crop fertilizer and growth regulator regimes applied in a manner that makes the crop more susceptible to infection.	Apply fertilizer and growth regulators in a timely manner.	Y -- Y* QCP * Experimental evidence is still inconclusive, particularly with regard to organic farming systems.	Rates and times of application should be in accordance with published instructions.	See Risk Factor 3.2, QA/QC points 2 & 3.
3.4	Poor insect control systems promote infection by *Fusarium* spp. (applies mainly to maize).	1. Use appropriate insecticides at correct rate of application. 2. Use insect resistant varieties.	Y -- Y[1] CCP[2] Y -- Y[1] CCP[2] [1] Step can significantly *reduce* risk of hazard. [2] If GM variety, cannot be applied to organic farming systems.	Application rates should be in accordance with published instructions.	See Risk Factor 3.2, QA/QC points 2 & 3. Cultivation of GM crops complicated by legal restrictions and public perceptions.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

3.0 ***Stage 3, Crop Development - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
					Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of crop assurance schemes.
4.0	***Stage 4, Crop Maturity***				
4.1	Over-wintering of grain leading to increased risk of mycotoxin production.	Practice is only undertaken as a consequence of necessity due to climatic conditions, which are inherently uncontrollable.	Y -- N Y Y **QCP**		

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

5.0 ***Stage 5, Harvest***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
5.1	Grain moisture sufficient to permit continuing growth of *Fusarium* spp and mycotoxin production.	Where moisture exceeds limits, transfer grain to dryer with minimum of delay and dry in an efficient manner.	Y -- N Y Y QCP	Target: <15% (based on risk of ochratoxin contamination).	1. Moisture measurements made using appropriate methodology together with equipment that is correctly maintained & calibrated. 2. Strategy in place to ensure that 'wet' grain is transferred to dryer on a prioritised basis (see 5.3).
5.2	Parcels of grain show signs of ear blight	Segregate diseased grain if possible.	Pre-requisite programme.	Customer specifications detail admixture levels.	Ensure that QC systems identify batches of grain on basis of disease state.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

5.0 ***Stage 5, Harvest***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
5.3	No strategy in place to respond to adverse post harvest conditions favouring mycotoxin production.	Ensure strategy in place and effected.	Y -- Y CCP		Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of crop assurance schemes.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

6.0 ***Stages 6, W9, 8 & T12, On Site (Farm or Third Party) Transport***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
6.1	Batches of wholesome and diseased grain mixed together.	Identify diseased material and keep separate.	Pre-requisite programme	Customer specifications detail admixture levels.	Ensure that QC systems identify batches of grain on basis of disease state.
6.2	<u>Stages 6 & W9 (transport ex harvest & wet grain) only</u> 'Wet' grain delayed in transit, leading to continuing *Fusarium* spp. growth and mycotoxin production.	Adequate transport facilities in place.	Y Y CCP		Maximum holding times for 'wet' grain set and enforced. Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of crop assurance schemes.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

7.0 ***Stages 7, T10, 9 & T13, On Farm/3rd Party Storage (Buffer and Finished Grain)***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
7.1	Stages 7 & T10 'Wet' grain held too long in buffer store, prior to drying.	Grain holding times kept to a minimum. 'Driest' grain kept in preference to 'wettest' grain.	Y -- Y CCP		Employ appropriate stock control systems. Develop appropriate algorithms to assess risk of toxin production as a function of moisture content. Operate appropriate moisture and temperature controls.
7.2	Grain moisture, at receipt, sufficiently high to permit subsequent *Fusarium* spp mycotoxin production.	Measure moisture content before storage and reject or redirect high moisture grain.	Y -- Y CCP	< 14.5% (based on risk of ochratoxin A contamination).	See also 5.1 & 5.3.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

7.0 ***Stages 7, T10, 9 & T13, On Farm/3rd Party Storage (Buffer and Finished Grain) - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
7.3	Batches of wholesome and mycotoxin-contaminated grain mixed together.	Non-conforming material correctly identified and controlled.	Y -- Y CCP		Operate 'control of non-conforming material' procedures. Stages T10 & T13 only Set and enforce specifications regarding acceptance criteria for evidence of *Fusarium* spp. damaged grain (monitoring). Perform periodic and systematic mycotoxin analyses to verify compliance by both suppliers and also with in-house operating procedures (verification).

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

7.0 ***Stages 7, T10, 9 & T13, On Farm/3rd Party Storage (Buffer and Finished Grain) - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
7.3 contd.		Stages T10 & T13 only Only purchase from farms that adopt and can demonstrate best practice.			Employ appropriate stock control systems. Operate supplier approval system e.g.: • grain only purchased from approved suppliers; • farms must be certified under recognised crop assurance scheme; • audit all elements of supply chain on a periodic and systematic basis according to risk and previous history (verification).

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

7.0 ***Stages 7, T10, 9 & T13, On Farm/3rd Party Storage (Buffer and Finished Grain) - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
7.4	Ensiling operations not optimised to inhibit fungal activity during storage.	Applies to livestock feed only Operate to best practice.	Y -- Y CCP		
7.5	Oxygen content of silage headspace increases to permit *Fusarium* spp activity.	Applies to livestock feed only Consider use of inert gasses to maintain minimal oxygen partial pressure & operate to best practice.	Cost implications QCP		
7.6	Preservative e.g. propionic acid applied at incorrect rate or in manner that does not ensure good mixing.	Applies to livestock feed only Apply at the correct rate using equipment demonstrated to achieve efficient mixing.	Y -- Y CCP		Ensure dilutions are prepared correctly and monitored by analysis before use. Ensure dosing equipment is correctly maintained and calibrated.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

7.0 ***Stages 7, T10, 9 & T13, On Farm/3rd Party Storage (Buffer and Finished Grain) - Continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
7.7	Stages 7, 9, T10 & T13 Grain moisture/temperature rises to permit production of *Fusarium* mycotoxin.	Ensure storage units adequately proofed. Minimise moisture migration in stored grain. Maintain grain at low temperatures to minimise grain respiration together with fungal growth and toxin production.	Pre-requisite programme		Proofing audits. stored-insect pest control, preventive maintenance. Cool where necessary. Suitable and regular monitoring of temperature and moisture. Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of crop assurance schemes.

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

8.0 *Stages W8 & T1,1 On Farm/Third-Party Drying*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
8.1	Grain drying favours localised mycotoxin production, due to dynamics of process or moisture front phenomena.	Use of appropriate dryer technology.	Y -- Y CCP		Determine moisture flow through grain mass to ensure that moisture migration does not promote fungal activity.
8.2	Grain improperly dried and released into finished grain store.	Use of appropriate dryer technology. Non-conforming product segregated and redried.	Y -- Y CCP	< 14.5% (based on risk of ochratoxin A contamination).	Operate appropriate process monitoring systems including grain moisture analyses (monitoring). Consider periodic mycotoxin analyses on basis of risk (verification).

Table 1 **Hazard/Risk Analysis for EU Cereal (Wheat, Maize & Barley) Production From Farm to Primary Processor (See also Figure 3)**

9.0 *Stages 10, T14, F11, M11 & C11, Finished Grain Store to Primary Processor*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
9.1	Grain moisture rises due to water ingress, permitting subsequent production of *Fusarium* spp. mycotoxins.	Trucks adequately proofed against water damage of grain.	Pre-requisite programme		Trucks operated in accordance with trade association &/or governmental requirements.
9.2	Contamination with residues from previous mycotoxin contaminated grain.	Trucks subject to adequate hygiene procedures.	Pre-requisite programme		
9.3	Batches of wholesome and mycotoxin-contaminated grain mixed together.	Non-conforming material correctly identified and controlled.	Pre-requisite programme		Operate 'control of non-conforming material' procedures. Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of crop assurance schemes.

3.4 Review and Analysis of Literature Database Within the Context of EU Wheat Processing from Primary Processor to Consumer using Bread as a Worked Example.

(Additional information is provided in Section C of the technical annex)

3.4.1 Introduction

For the purposes of this study, the manufacture of bread has been divided into two parts, flour milling and bread baking. *Fusarium* spp. infection has economic consequences over and above any associated with the problem of mycotoxin contamination. Infected wheat exhibits fundamental quality defects. These range from discolouration and reduced grain density to impaired baking quality (63, 64, 129). A similar format to that used in section 3.3 has been adopted and a summary of the risk analyses performed is presented in Table 2.

3.4.2 Stages F11 to F25 - Grain Reception to Storage of Finished Flour at Bakery

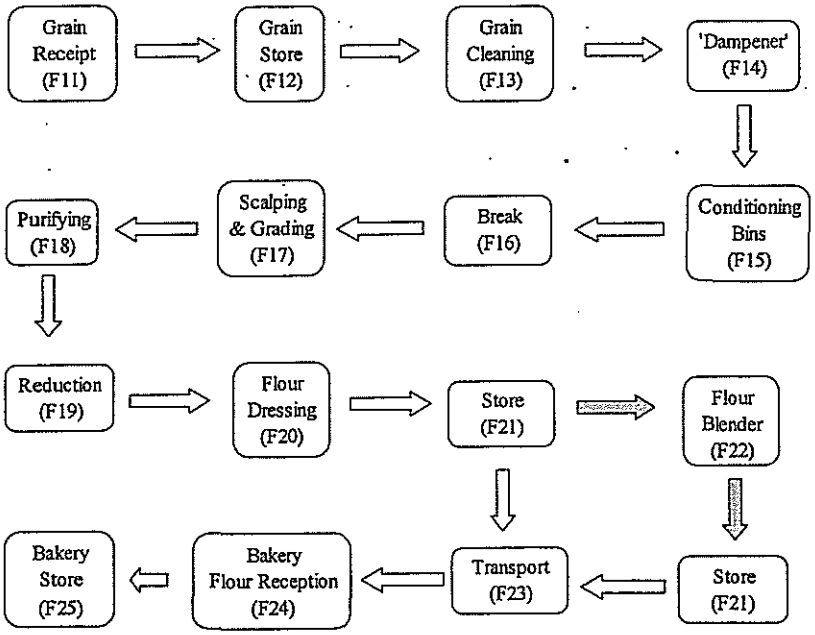
Overview

A flow diagram summarising flour production is shown in Figure 6. Most modern industrial flour production involves a progressive grain-reduction process using a system of roller mills (discussed in 108). Grain is accepted by the mill in accordance with previously agreed specifications. The bases of these are usually set at a national level, reflecting the quality parameters necessary for good flour production and the constraints of that year's harvest. They not only deal with the technological qualities of the grain, but also with the history of its production and prior storage. Responsibility for setting and monitoring these requirements can be effected either by the industry itself (as in the case of the UK, e.g. reference 10) and/or through the direct authority of the Member State, e.g. the Netherlands, reference 14). After being accepted into store (Figure 6; stage F12), wheat is held until required. The same constraints discussed in section 3.3.7 (On Farm/3rd Party Storage - Buffer & Finished Grain) regarding maintaining grain integrity in store apply here as well.

When needed, grain is transferred to the screen room (stage F13), where it is cleaned by passing it through a number of machines. These effect the removal of foreign material together with under- or over- sized grains. Failure to remove damaged grains at this point can result in mycotoxin contamination of flour (1). In some countries, where *Fusarium* ear blight is a significant problem, equipment (e.g. the gravity table) which separates the less dense damaged kernels from wholesome ones has been developed and installed in the screen room (188). Once cleaned, the moisture of the wheat is then increased to approximately 15.5% (conditioning), to improve milling quality. Water is added to the grain in a dampener (Stage F14) followed by holding in conditioning bins to arrive at the desired moisture content. Holding times are usually in the order of hours to achieve the necessary equilibrium (92, 93).

Conditioned grains then pass through a system whereby they are first fragmented (Figure 6; stage F15) and the starchy endosperm subsequently removed from the bran, (stages F16 & F17). This is in itself a progressive process, involving a number of break mills (*Break Release*). Grain particles are separated on the basis of size by a sieve process and either re-enter the break operation or pass on to the second stage of the process (*Reduction*). 'Break-release' leads to the production of two fractions, bran (seed coats) and the starchy endosperm. The coarse endosperm is ground to a flour of desired particle size (stages F18-F20) through a further system of roller-mills (between 8 and 16 grinding stages). The process not only brings about the generation of a flour with the desired particle size, but also effects a separation of the starchy endosperm from the embryo and any remaining bran.

Figure 6 Generalised Flow Diagram for Milling of Grain to Flour and Its Delivery to the Bakery.



Depending on the type of mill, dressed flour is either supplied directly to the customer or blended with other flours to achieve a desired technological specification (shaded arrows).

According to how the mill operates and/or customer requirements, flour may be transferred directly to store for onward shipping to the customer (stage F21). Transfer to customer is effected either in bulk-tanker or in pre-packed units (stage F23). In some cases however, one lot of flour may be blended with other lots (stage F22) to achieve desired technological qualities prior to storage and eventual dispatch.

Flour is accepted by the bakery against a pre-agreed specification. Depending on the relationship between the bakery and the mill, and the JIT practices operated by the bakery, acceptance at the weighbridge is usually on the basis of a certificate of analysis relating to technological properties and moisture content.

Hazard & Risk Analysis (Also Refer to Table 2; Risk factors 10.1 - 17.1)

Grain Reception & Storage

The key risk factor concerning mycotoxin contamination and flour milling is the actual purchase and eventual acceptance of the grain into the mill. As will be discussed below, with the possible exception of grain storage, no operation in the flour milling or bread baking process actually leads to an increase in mycotoxin contamination due to *de novo* synthesis by fungi. Application of critical path analysis and best practice, places the onus on the supplier to provide wholesome (i.e. which meets specification regarding mycotoxin contamination) grain. In terms of responsibilities therefore, it is for the purchaser to set and enforce specifications which meet commercial and legal requirements and for suppliers to adhere to them. Once the grain enters the production stream no single step in the milling process can be 100% guaranteed to effect removal or reduction of mycotoxin contamination.

Modern mills operate to a large degree on JIT principles. The miller therefore faces the challenge that, particularly with locally supplied grain, only weighbridge checks (20-30 minutes) can be performed to determine acceptability. These would include tests for moisture, admixture and *Fusarium* spp. damaged kernels. Rapid reliable methods for mycotoxin analysis which are accepted by both processors and suppliers and which would support the commercially significant decision to reject a non-conforming load are currently not available. The situation becomes more complex in areas where local conditions mean that the risk of significant contamination is high. In such cases mills must operate more rigorous monitoring and verification systems.

Given the above, knowledge of the provenance of the wheat is crucial. A risk assessment has to be made as to whether grain can be allowed to pass directly into the production stream or whether it should be quarantined pending analysis and positive release. No general rule can be applied, however, grain supplied with an appropriate certificate of analysis and/or received through a verifiable supply chain might be considered as acceptable for immediate use. Monitoring with respect to contamination would take the form of ensuring that this grain was always received from approved suppliers who meet specification. This would not however obviate the need for mycotoxin analyses, which would still have to be performed as part of a surveillance programme to verify compliance with systems in place. The frequency, at which such samples would be taken, would have to be determined on a case by case basis and vary from year to year, depending on external factors such as the severity of *Fusarium* ear blight epidemics. Grain of poorer provenance, or from areas known to be at high risk to *Fusarium* spp. mycotoxin contamination would probably have to be held pending analytical results. This applies particularly to loads transported by ship over long distances. There are apocryphal reports of grain shipments

becoming contaminated with mycotoxins as a result of the cargo becoming wet due to adverse weather in transit.

In terms of grain and flour storage together with transport (Figure 6; stages F12, F21, F22, F23 & F25) the same factors as discussed in 3.3.7 apply.

The Milling Process

With the possible exception of screen room activities, all further operations within the mill are considered to be either QCP's or to constitute elements of the normal pre-requisite programme operating in the mill. Introduction and operation of equipment such as gravity tables in the screen room (Stage F13) to remove *Fusarium*-damaged kernels are considered to be either a QCP or a CCP depending on local conditions. As discussed in section 3.3.5, although in certain cases damage appears to be a reasonable index assessing risk of mycotoxin contamination, other examples exist where it is not. In cases where strong correlations between damage and mycotoxin have been noted, separation on the basis of differential density can result in significant reductions in deoxynivalenol and zearalenone contamination (46, 143, 188). However, appropriate monitoring (i.e. real-time) systems need to be in place to ensure that such equipment is performing efficiently. Recent work (157) has described image analysis systems connected to neural networks capable of continuously measuring the efficiency of such equipment.

Operation of the dampener and conditioning bins is considered to fall within the mill's pre-requisite programme. A catastrophic failure of the system which permitted fungal outgrowth would also render the grain technologically unsuitable. Although the reductive process itself (Stages F15 to F20), whereby grain is converted to flour can result in a reduction in the amount of mycotoxin present in the flour (119), this not always the case (143). Taken in conjunction with commercial evidence that technologically acceptable flour or semolina can be used to manufacture product, which was subsequently recalled on the basis of its deoxynivalenol content (15), it is considered that any risk reduction associated with these operations is peripheral. In addition, it was considered that no risk factors contributing to the occurrence of mycotoxins were associated with the steps themselves.

Bakery Flour Reception (Stage F24)

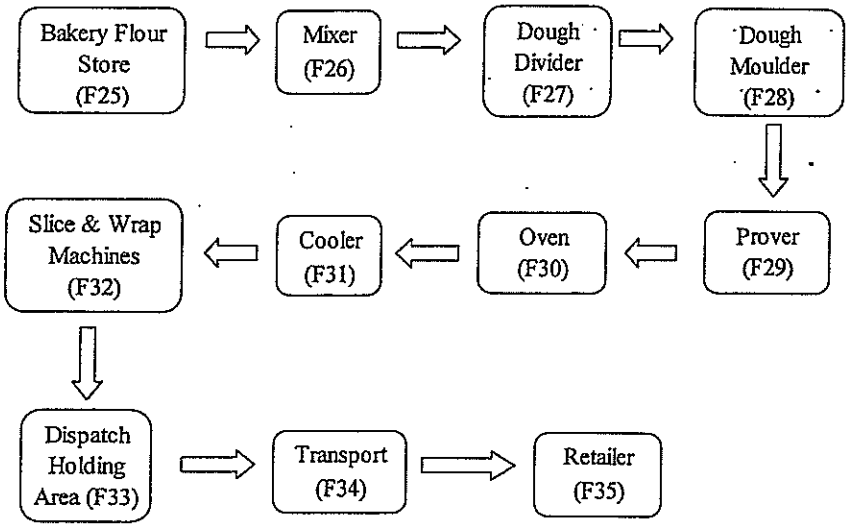
If JIT principles apply at the flour mill, they are practiced to a far larger degree in the modern bakery. The significant risk at this stage is receipt of contaminated flour. Given that stock turn-around times can be in the order of only a few days and that little or no laboratory provision is made at plant level, the key method of control rests on an assured supplier system backed up by a surveillance programme, based on periodic mycotoxin analyses.

3.4.3 Stages F25 to F35 - Flour Storage to Receipt by Retailer

Overview

Most industrial bakeries now operate on 'no-time' dough making methods, for example the Chorleywood Bread Making Process (CBP). These processes are characterised by the use of comparatively high-energy inputs during the mixing process compared with more traditional baking methods. From a HACCP (though not necessarily technological) point of view, baking methods such as the CBP are reasonably easy to analyse. A simplified flow diagram of the latest developments in the industrial application of the process for pan bread is shown in Figure 7.

Figure 7 Generalised Flow Diagram For The Baking Of Bread And Its Subsequent Delivery To The Retailer



Essentially flour, yeast, water and other ingredients are brought together and mixed under defined conditions (Figure 7; stage F26). The resultant dough is tipped out of the mixer and dispensed in pieces of desired mass using a 'divider' (stage F27). These are then transferred to a machine (moulder, stage F28) where they are mechanically processed and usually deposited into baking tins. Moulded dough is then transferred to the prover to allow for yeast fermentation (stage F29) and then directly to the oven (stage F30) where it is baked. Once baked, bread is depanned (step not shown in flow diagram), cooled, sliced and wrapped (stages F31 to F33). The finished product is then transferred to a dispatch area (F34) for onward delivery to the retailer (F35). While dough mixing is a batch process, dough handling and bread baking are effectively continuous.

Hazard & Risk Analysis (Also Refer to Table 2; Risk factor 18.1)

Excluding the possibility of purchasing flour from non-approved sources (discussed above), there are no significant risk factors associated with the bread baking process. The thermal stability of the toxins concerned (172, 185) means that the baking process itself cannot be considered to be a decontamination step. One factor (common to both baking and brewing) to bear mind is the potential for plant detoxification products (e.g. conjugates) to be reconverted back to the original toxic form. Savard (161) has suggested that plant produced glucoside and fatty-acid conjugates of *Fusarium* spp. mycotoxins such as deoxynivalenol may be broken down to the original active toxin during yeast fermentation. This is, however, a question that would be more appropriately addressed at a plant breeding rather than processing level.

In terms of the finished product, bread is considered to be an ambient-stable product with a relatively short mould-free shelf life. Mould growth *per se* is a continual challenge to the bread industry and is actively controlled. However, the route of infection is primarily through the bakery environment rather than any particular raw material. This phenomenon is not considered to be of relevance in the present study.

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

10.0 *Stage F11, Flour Mill Grain Reception*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
10.1	Grain is purchased from areas with high or unknown risk of mycotoxin contamination.	Where possible purchase grain of known provenance.	Y -- Y CCP	Statutory or based on risk assessment.	Operate supplier approval system e.g.: • Grain purchased from approved suppliers; • Suppliers can demonstrate traceability back to farm; • Suppliers operate demonstrable quality assurance schemes; • Audit all elements of supply chain, frequency determined by risk and previous history (verification); • Operate mycotoxin surveillance programme to verify compliance and effectiveness (verification)

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

10.0 ***Stage F11, Flour Mill Grain Reception - continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
10.1 Contd.		Where provenance of grain is poorly known (e.g. imports), operate positive release system based on mycotoxin analysis.			Operate segregation and quarantine systems. Only recognise certificates of analysis issued by suitably accredited laboratories. Back up with periodic analyses by a third party (verification). Where no certificate of analysis available or doubts exist, only release parcel on basis of analysis performed in approved laboratory. Ensure that sampling regimes are appropriate and conform to local requirements.

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

10.0 ***Stage F11, Flour Mill Grain Reception - continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
10.2	Grain supplied of a quality indicative of a risk of existing or potential mycotoxin contamination.	Grain showing unacceptable levels of *Fusarium* spp. damage and/or high moisture content rejected as unacceptable at weighbridge.	Y -- Y CCP	As set in commercial specification.	Enforce specifications regarding acceptance criteria for evidence of *Fusarium* spp. damaged grain and moisture content (monitoring).
					Failure to meet specifications is considered to be commercial grounds for rejection.

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

11.0 *Stage F12, Grain Store*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
11.1	Batches of wholesome and mycotoxin-contaminated grain mixed together.	Operate appropriate stock control systems to ensure that grain subject to positive release is quarantined.	Y -- Y CCP		See 10.1. Ensure stock control measures can support functioning traceability system.
11.2	Grain moisture/temperature rises to permit production of *Fusarium* mycotoxin.	Ensure storage units adequately proofed. Minimise moisture migration in stored grain. Maintain grain at low temperatures to minimise grain respiration.	Pre-requisite programme		Proofing audits. Stored-insect pest control, preventive maintenance. Suitable and regular temperature and moisture monitoring.

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

12.0 *Stage F13, Screen Room*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
12.1	Screen-room practices do not ensure removal of *Fusarium* spp. damaged grain.	Use appropriate separation technology to remove defective material, e.g. gravity tables.	Y Y* Q/CCP * This depends on local conditions. In some cases a good correlation between damage and contamination exists. In others, mycotoxin contamination can also occur in apparently undamaged grain. Thus even if all damaged grain was removed, the potential for contaminated grain passing through the system still exists.	Company specification	Specifications ensure good separation of defective material. Appropriate monitoring systems installed for screened wheat, e.g. optical measuring devices. Appropriate systems in place for the safe disposal of defective material.

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
13.1	Mill breakdown in conditioning area leads to time/moisture conditions which permit *Fusarium* spp. outgrowth and/or mycotoxin production.	Preventive maintenance programme. Segregate potentially non-conforming material pending further analyses. Time & moisture monitoring equipment.	Pre-requisite programme		Time and moisture parameters set to pre-empt mycotoxin production. Operate 'control of non-conforming material' procedures. Risk of this occurring low since conditions favouring mycotoxin production incompatible with optimised flour production systems.
14.0	***Stages F15 to F20, Flour Production***				
14.1	No risk factors identified.				

Table 2 Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)

16.0 *StageF23, Flour Transport,*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
16.1	Flour moisture rises due to water ingress, permitting subsequent production of *Fusarium* spp. mycotoxins.	Trucks adequately proofed against water damage of grain.	Prerequisite programme		Trucks operated in accordance with trade association and/or governmental requirements. Wet flour would not flow well on arrival and would be detected and rejected.
16.2	Contamination with residues from previous mycotoxin contaminated flour.	Trucks subject to adequate hygiene procedures.	Pre-requisite programme		Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

17.0 ***Stage F24, Bakery Flour Reception***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
17.1	Flour fails to meet specification.	Deliveries are made on basis of certificates of compliance or analysis.	Y -- Y CCP		Set and enforce specifications regarding acceptance criteria. Failure to comply with specification as determined by weighbridge checks constitutes commercial grounds for rejection. Operate supplier approval system (for principles see 10.1).

Table 2 **Hazard/Risk Analysis of EU Wheat Processing From Flour Mill Through to Consumer – Example, Bread (See also Figures 6 & 7)**

18.0 ***Stages F25 to F35, Bread Production & Delivery***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
18.1	No risk factors identified.				

3.5 Review and Analysis of Literature Database in the Context of EU Barley Processing from Primary Processor to Consumer using Beer as a Worked Example.

(Additional information is provided in Section D of the technical annex)

3.5.1 Introduction

As in the previous study, the description of the beer-brewing process has been divided into two, barley malting and beer-brewing itself. Simplified flow diagrams describing each process are shown in Figures 8 & 9 respectively. The same format used for bread has also been used here and a summary of the risk analyses performed presented in Table 3.

In the case of beer, the economic consequences of *Fusarium* spp. infection could be considered to be greater in malting than in flour milling. Not only are the public health consequences of mycotoxin contamination of concern, but also the adverse effects on key technological parameters. These begin with reduction of malting quality, e.g. impaired germination (85) and progress through poor brewing quality as a consequence of impaired yeast fermentation (33, 34) to reduced stability of the finished product ('gushing,' reference 142).

3.5.2 Stages M11 to M24 - Grain Reception to Storage of Malt at Brewery

Overview

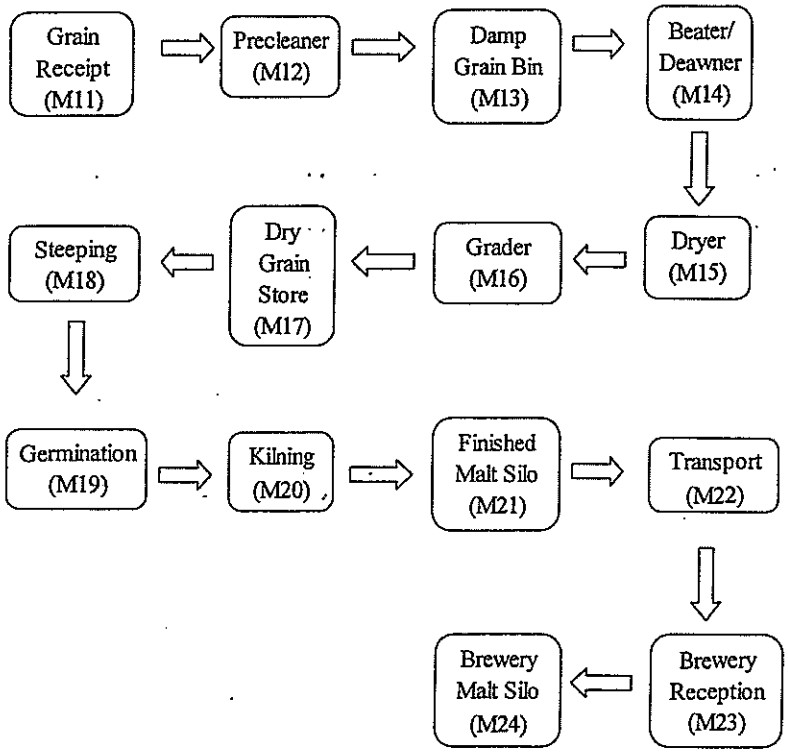
Both the malting and brewing processes has been described in detail by Bamforth and Barclay (24) and what follows is a brief summary.

Given the costs of transportation and the premium nature of the final product, maltsters are usually located in close proximity to the barley growing areas. Malting barley is purchased in accordance with strict specifications direct from the farm. In addition to the normal requirements concerning freedom from foreign matter, infestation, odour and taint, specifications also demand shipments to meet requirements concerning variety, moisture, size, protein content and modification potential (the latter term refers to the ability of the grain to germinate in terms of viability and dormancy).

The malting industry generally prefers to exert as much post-harvest control on the grain as possible. Consequently grain that meets specification is accepted shortly after harvest and transported directly to the maltster. On receipt it is subjected to a pre-cleaning step (Figure 8; stage M12), before being temporarily stored in a holding area (damp grain bin, stage M13). The length of time the grain is held is dependent on its moisture content, with parcels of higher moisture content being kept for the shortest period of time. In countries such as the UK where harvest moisture contents can be in excess of 16%, the grain has to be dried. Drying (stages M14/M15) improves the storage properties of the barley but must be undertaken in a controlled manner to maintain maximum viability during the actual malting process. Given the criticality of the process, grain drying is often undertaken by the maltster rather than the farmer. Once dried

and cleaned, grain is transferred to the dry-grain store (stage M17) where it is held until required for malting.

Figure 8 Generalised Flow Diagram for Malting of Barley and the Delivery of Malt to the Brewery.



The malting process essentially consists of three stages, steeping, germination and kilning (Figure 8; stages M18-20). The objective of the steeping process is to raise the moisture content of the barley from between 11 and 12% to between 43 and 46% moisture, within a 48-72 hour period. After the moisture content of the barley has been appropriately increased, the grain is allowed to germinate. The objective of the exercise is not only to permit germination but also to modify the endosperm to provide the maximum amount of extractable material through the development, distribution and action of enzymes. Once germination and endosperm development have occurred, the process is halted by drying (kilning) the germinated grain (green malt) down from a moisture content of approximately 43% to between 2 and 3% to form malt. The finished product is stored for a minimum of approximately four weeks prior to dispatch to the brewer.

Hazard & Risk Analysis (Also Refer to Table 3; Risk factors 19.1-26.1)

Grain Reception & Storage (Grain and Malt)

Unlike the case of flour (discussed above), given the generally intimate relationship between maltster and farmer, provenance of the grain is not going to be an issue. The key risk factors relate to the probability of incoming barley being contaminated with high levels of mycotoxins and/or having a moisture content conducive to their production in store prior to drying. The question of mycotoxin contamination in incoming grain has already been discussed in sections 3.3.7 and 3.4.2. Although there is a minimum holding time of two weeks before malt is supplied to breweries, use of current mycotoxin analytical techniques where the results still take days to obtain would be incompatible with the bulk handling practices used by the industry. Consequently similar systems to those discussed for flour mills (section 3.4.2) would have to be in place. Of equal concern, is the receipt of wet grain, something which happens frequently in the northern parts of the EU. It is therefore necessary to ensure that the moisture content of incoming grain is correctly measured and that grain drying is prioritised accordingly. Given the impact that both of these actions can have on the risk of contamination, activities concerned with grain receipt, the time of holding in the damp grain bin and grain drying, are all considered to be CCP's with respect to mycotoxin production. For the same reasons as discussed in section 3.3.7, storage of dried grain and finished malt are considered to fall within the pre-requisite programme.

Steeping, Germination & Kilning

As discussed previously, steeping involves increasing the grain moisture content from 11-12% to between 43 and 46% moisture, over a 48-72 hour period. Evidence is available to show that under such conditions there can be *Fusarium* spp. outgrowth (78), however, in another study (165), mycotoxin (deoxynivalenol) content decreased at this stage. Unfortunately, mycotoxin production resumed during the germination process and rose to between 18-114% of the original level of contamination (165). In reality there is nothing that can be done during the actual malting process to mitigate these effects. Reducing any mycotoxin contamination that might occur at this stage can only be achieved by having an appropriately rigorous pre-requisite programme which keeps the amount of *Fusarium* spp. contaminated grain entering the system to a minimum.

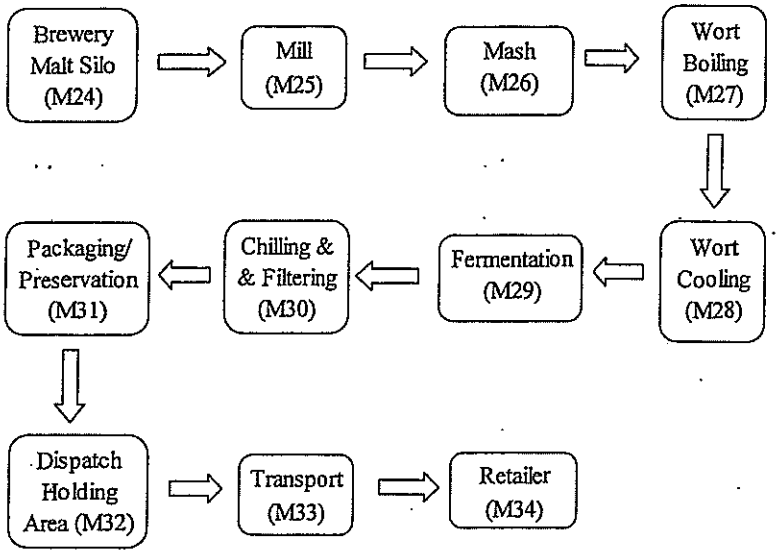
3.5.3 Stages M24 to M34 -Beer Brewing

Overview

Malt is received from the maltster and held prior to use (Figure 9; stages M23 & M24). The brewing process proper begins with the milling of malt (stage M25). This is done to facilitate access by water to the grain particles during mashing stage (stage M26). This is the process whereby the components of the endosperm are solubilised and leached out for use during the fermentation process. It involves mixing the milled malt with two to four volumes of hot water. The process is principally geared to the hydrolysis of starch by endogenous α-amylases. The final

product ('sweet wort') contains principally sugars, amino acids and peptides, which is filtered off once the process has been deemed to be completed.

Figure 9 Generalised Flow Diagram For The Brewing Of Beer And Its Subsequent Delivery To The Retailer



The sweet wort is then transferred to the next stage of the process, where hops and sometimes sugar are added and the resultant mixture boiled (Figure 9; stage M27). This process not only extracts those aspects of the hops, which give beer its characteristic flavour, but also sterilises the wort. The 'hopped wort' is then cooled (stage M28) and subsequently fermented following the addition of yeast (stage M29). The product of the fermentation is often referred to as, 'green' beer. Once fermentation has been completed, the beer is stabilised (stage M30) by chilling, filtering and holding before being packaged (stage M31) into barrels, kegs, cans, bottles etc. Depending on its nature, product can be pasteurised as a means of further preservation (not shown). Finished product is then held (usually at ambient) pending dispatch (stages M32-M34).

Hazard & Risk Analysis (Also Refer to Table 3; Risk factor 27.1)

A key problem with the brewing process is that certain mycotoxins are extracted from the malt during the preparation of the wort (90). The 'extractability' is a function of the chemical structure of the mycotoxin, thus while deoxynivalenol was found to be readily extracted, zearalenone was not (90). The only mechanism by which this can be controlled is through ensuring that contaminated malt does not enter the system (discussed in the previous section), for example through a supplier assurance programme. Within the context of the brewing process itself, a

similar result to the analysis (Table 3) obtained for bread was obtained and none of the steps were considered to contribute to the risk of mycotoxin contamination.

Table 3 Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example Beer (See also Figures 8 & 9)

19.0 Stage M11, *Grain Receipt*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
19.1	Grain is contaminated with *Fusarium* spp. mycotoxins at levels above those expected by good practice.	Only purchase from approved suppliers who can demonstrate appropriate *Fusarium* control practices Grain showing unacceptable levels of *Fusarium* spp. damage rejected as unacceptable at weigh-bridge.	Y -- Y CCP	Statutory or based on risk assessment.	Operate approved suppler scheme (see risk factor 10.1, Table 2). Set and enforce specifications regarding acceptance criteria for evidence of *Fusarium* spp. damaged grain (monitoring). Failure to comply with specification as determined by weighbridge checks constitutes commercial grounds for rejection.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

19.0 **Stage M11, *Grain Receipt - continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
19.2	Grain with moisture content, at receipt, sufficiently high to permit subsequent *Fusarium* spp. mycotoxin production not detected.	Measure moisture content before storage and segregate nonconforming grain. Prioritise drying of grain parcels with the highest moisture contents first.	Y -- Y CCP		Operate appropriate stock control systems with regard to holding of grain in damp grain bin.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

20.0 *Stage M13, Damp Grain Bin*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
20.1	Batches of wholesome and mycotoxin-contaminated grain mixed together.	Grain only purchased from approved suppliers. Operate appropriate stock control systems to ensure that suspect grain subject is quarantined.	Y -- Y CCP		Operate 'approved supplier' scheme. Ensure stock control measures can support functioning traceability system.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

20.0 ***Stage M13, Damp Grain Bin - continued***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
20.2	Grain moisture/temperature rises to permit production of *Fusarium* mycotoxin.	Ensure storage units adequately proofed. Minimise moisture migration in stored grain. Maintain grain at low temperatures to minimise grain respiration.	Pre-requisite programme		Proofing audits. stored-insect pest control, preventive maintenance. Suitable and regular temperature and moisture monitoring.
20.3	Damp grain is held too long in store leading to mycotoxin production.	Ensure stock control systems are adequate and operating.	Y -- Y CCP		See risk factor 20.1
					Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

21.0 *Stages M14 & M15, Deawner and Drying*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
21.1	Grain drying favours localised mycotoxin production, due to dynamics of process or moisture front phenomena.	Use of appropriate dryer technology.	Y -- Y CCP		Determine moisture flow through grain mass to ensure that moisture migration does not promote fungal activity.
21.2	Grain improperly dried and released into finished grain store.	Use of appropriate dryer technology. Non-conforming product segregated and redried.	Y -- Y CCP	< 14.5% (based on risk of ochratoxin A contamination).	Operate appropriate process monitoring systems including grain moisture analyses (monitoring). Consider periodic mycotoxin analyses on basis of risk (verification). Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

22.0 *Stages M16 & M17, Grader and Dry Grain Store*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
22.1	Grain moisture/temperature rises to permit production of *Fusarium* mycotoxin.	Ensure storage units adequately proofed. Minimise moisture migration in stored grain. Maintain grain at low temperatures to minimise grain respiration, *Fusarium* spp. growth and toxin production.	Pre-requisite programme		Proofing audits. stored-insect pest control, preventive maintenance. Suitable and regular temperature and moisture monitoring. Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

23.0 ***Stages M18, M19 & M20, Steeping, Germination and Kilning***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
23.1	Levels of *Fusarium* spp. contamination sufficiently to result in further outgrowth and mycotoxin production after grain moisture content raised.	Ensure only wholesome grain purchased. Operate previous functions to minimise any further *Fusarium* spp. activity.	Pre-requisite programme		All prior operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of GMP quality assurance schemes.

Table 3 **Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)**

24.0 *Stages M21 & M24, Maltster and Brewery Malt Silos*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
24.1	Malt moisture rises to permit production of *Fusarium* spp. mycotoxins. (Malt having a moisture content capable of sustaining *Fusarium* spp. growth would not be commercially acceptable).	Ensure storage units adequately proofed. Minimise moisture migration in stored malt.	Pre-requisite programme		Proofing audits. stored-insect pest control, preventive maintenance. Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 3 Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)

25.0 ***Stage M22, Malt Transport***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
25.1	Malt moisture rises due to water ingress, permitting subsequent production of *Fusarium* spp. mycotoxins.	Trucks adequately proofed against water damage of grain.	Pre-requisite programme		Trucks operated in accordance with trade association and/or governmental requirements.
25.2	Contamination with residues from previous mycotoxin contaminated malt.	Trucks subject to adequate hygiene procedures.			Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 3 Hazard/Risk Analysis of EU Barley Processing: From Maltster Through to Consumer – Example, Beer (See also Figure 8 & 9)

26.0 ***Stage M23, Brewery Malt Reception***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
26.1	Malt fails to meet specification.	Deliveries are made on basis of certificates of compliance or analysis.	Y -- Y CCP		See risk factor 17.1, Table 2.
27.0	***Stages M25-M34, Wort Preparation, Beer Brewing and Subsequent Dispatch to The Retailer***				
27.1	No risk factors identified.				

3.6 Review and Analysis of Literature Database Within the Context of EU Maize Processing from Primary Processor to Consumer using Breakfast Cereals and Starch as Worked Examples.

(Additional information is provided in Section E of the technical annex)

3.6.1 Introduction

In some respects, of all the cereals considered, maize is consumed in the most diverse ways; ranging from the whole kernel (e.g. 'corn-on-the cob'), through to its use as a raw material either in a kibbled form ('grits') or as a finely ground flour. Maize is also a significant raw material for the production of starch intended for either food or industrial (e.g. paper manufacture) uses. The processes by which maize can be mechanically reduced and converted into food ingredients have been described by others (108, 128) and are summarised in Figures 10 to 12. While maize directly intended for use in food as grits or flour is 'dry' milled (Figure 10); that for starch is 'wet' milled (Figure 11). In this section, an analysis of the manufacture of a particular maize based breakfast cereal, 'cornflakes' (Figure 12) will be considered, followed by an examination of wet milling.

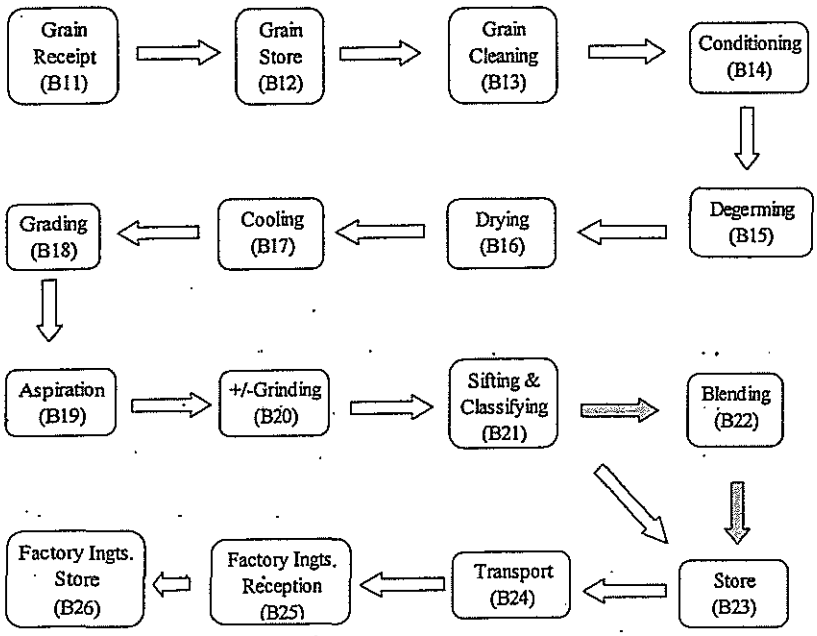
As in previous studies, risk analyses have been summarised in tabular form (Tables 4 & 5)

3.6.2 Stages B11 to B26 - Grain Reception to Storage of Maize Grits at Factory

Overview

Maize kernels are received by the mill (Figure 10, stage B11). Prior to use it is cleaned (stage B13), this involves dry methods similar to those used for wheat and barley and also a washing step. Cleaned maize is then conditioned to a moisture content of approximately 25%. Subsequently, the germ is removed from the maize (degermination, stage B30), usually by attrition milling. Essentially two particle streams are generated by this process. One is of large particles ('tail' or 'hominy' stock) and the other comprises fine particles ('through' stock). These two streams are usually kept separate until close to the end of the process (stage B22). The tail stock is dried (14% moisture, if end product), cooled, sifted and aspirated (stages B16-B19). If not required as flaking grits, it is subjected to further particle size reduction (stage B20). Through stock is dried to approximately 18% moisture and subjected to the same process. Flaking grits used in the manufacture of cornflakes (discussed in 3.6.3, below) are then stored ready for dispatch to, and eventual receipt by, the breakfast cereal manufacturer (stage B26).

Figure 10 Generalised Flow Diagram for the Production of Maize Grits & Maize Flour



Hazard & Risk Analysis (Also Refer to Table 4; Risk factors 28.1-36.1)

Grain Receipt and Storage

As in the studies concerning bread (section 3.4), provenance of grain is likely to be an issue. Survey data in the UK (135), which imports its maize mainly from mainland Europe or Argentina, has indicated that grain from Argentina was more likely to be contaminated with high concentrations of fumonisins (>1000 µg/kg) and zearalenone (> 100 µg/kg). A subsequent publication (175), expanding on this study, demonstrated that with European grown maize, the further south the port of origin, the greater the mean fumonisin content. Operation of effective supplier approval systems and positive release systems supported by appropriate traceability systems would therefore be considered to be critical control points.

Grain and finished product storage together with transport have been discussed in other contexts (section 3.3.7) and the same considerations apply in this case. In terms of the technology of dry milling, the area where control can be exercised is initially at the cleaning stage (B13). Some mycotoxin contamination (e.g. fumonisins) appears to be associated with the fines (105). Work both in the UK (135) and South Africa (183) has shown that fines-removal can bring about moderate reductions in fumonisin concentrations. A cautionary note needs to sounded, since this effect appears to be to a degree mycotoxin dependent. No such reduction was seen with

zearalenone (135). Given the variability in the effect and that levels can still be high in grain after the process, the step is considered to be a QCP.

The Dry Milling Process

As in the case of flour milling, ensuring operation of the conditioning or degerming processes (Figure 10; stages B14 & B15) would be considered to be covered under the pre-requisite preventive maintenance programme. However, the drying stage is considered to be a CCP on the same grounds as discussed previously for risk factors 8.1 and 8.2 (section 3.3.8), with a critical limit of 14.5% set on the basis of the risk of ochratoxin A contamination. Subsequent to this step no further risk factors within the process were identified.

3.6.3 Stages B26 to B34 - Cornflake Manufacture

Overview

Numerous studies (134, 192, 195) have shown heavily processed foods such as cornflakes to have relatively low levels of fumonisin contamination. Cornflakes are a useful example to study, since one method of manufacture involves the use of the HTST (high temperature short time) technology. One form of this technology (extrusion), is increasingly used in the production of compound animal feeds.

The manufacture of cornflakes has been described by Matz (128). It begins either with the cooking of grits in a pressurised vessel containing a suitable flavouring syrup at 15-23 psi for 1 to 2 hours (Figure 11; stage B27); or by the extrusion (stage B28) of maize flour and other ingredients to generate a pellet which can be subsequently flaked. Cooked grits and pellets are dried (stage B29) to approximately 28-31% moisture, before being crushed in flaking rollers (stage B30). At this point the moisture content of the flakes is approximately 10-15% and the flakes have a plastic consistency. In order to achieve the crisp texture and low moisture content (3%), typical of these products, the flakes are toasted in an oven (typically 300°C for 50 seconds). Toasted flakes may then be sprayed with a vitamin and/or coating mix and dried (stage B33) before being sent for packing (stage 34) and onward dispatch (stages B35 to B37).

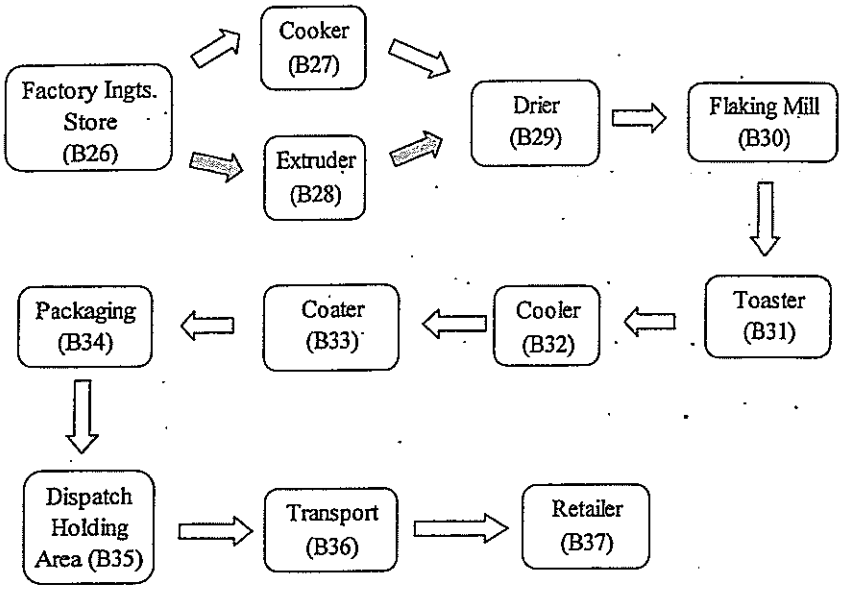
Hazard & Risk Analysis (Also Refer to Table 4; Risk factors 36.1-40.1)

Some thermal processes, for example extrusion, have been shown under certain conditions to degrade particular mycotoxins, such as the fumonisin group (106), but not others (e.g. deoxynivalenol, reference 199). Where reductions have been seen, these have been in the order of 50%, insufficient to explain the low levels of fumonisins typically associated with the cornflakes. In the light of work by Girolamo *et al.* (84), it can be hypothesised that thermal conditions associated with the toasting step effects the most degradation. It therefore seems likely that with regard to thermal degradation of fumonisins, the cooking or extrusion steps (stages B27 and B28) can be considered to be a QCP on the grounds that a subsequent step (toasting, stage B31) would effect fumonisin destruction. Given that toasting is the last thermally destructive

process, failure to operate at the correct temperature would be considered to be a CCP. It is not possible to specify a numerical value for the critical limit, given variations in toaster design and limited data in the literature.

Subsequent steps in the process (Figure 11; stages B32 - B37) are not considered to contribute significantly to the question of mycotoxin contamination.

Figure 11 Generalised Flow Diagram for the Production of Flaked Maize Breakfast Cereals



3.6.4 Stages B11, B38 to B47 - Wet Milling of Maize

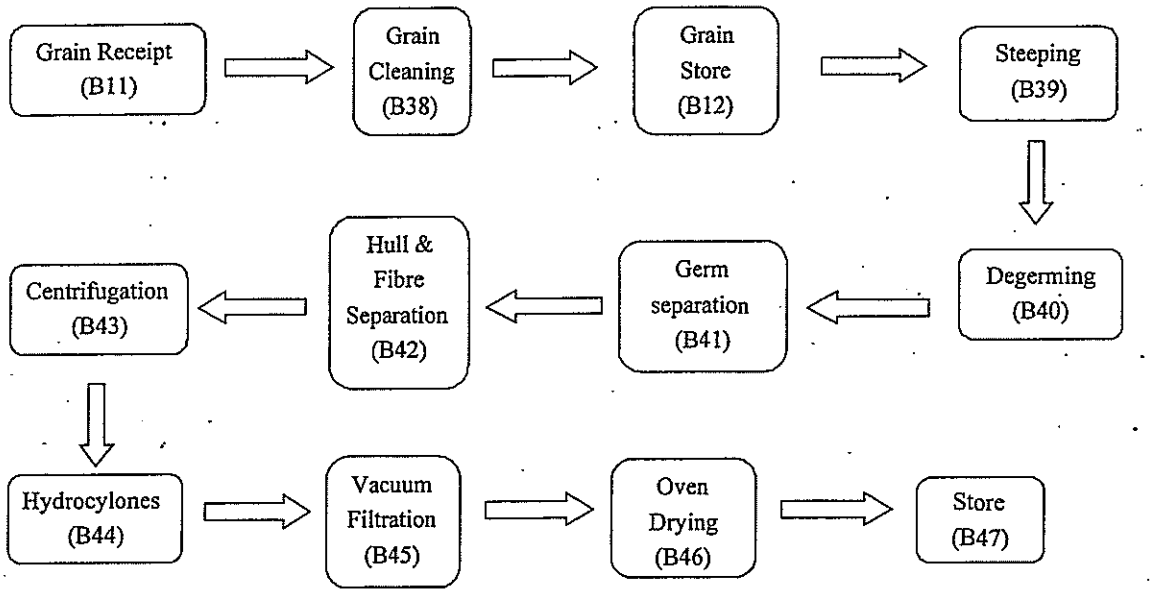
Overview

Wet milling of maize is a second reductive process for the processing of maize. It has been described by others (108, 128) and what follows is only a brief summary. Wet milling is primarily aimed at the production of starch for industrial or food use. The process also generates valuable by-products, including maize germ (feed-stock for the manufacture of maize oil) and maize gluten.

A simplified flow diagram of the process is shown in Figure 12. Grain is received (stage B11) and once cleaned (stage B38), to remove foreign matter and fines, held in store (stage B12). When required for milling, grain is withdrawn from store and steeped in water at between 49 and 55°C for 36 to 48 hours. Sulphur dioxide (0.1-0.2%) is added to the water to inhibit germination and undesirable microbiological activity. Once the kernels are suitably softened, the germ is separated (stage B40) by attrition milling and the resultant slurry diluted. The germ is separated

from the slurry in hydrocyclones (stage B41). The remaining mass is then ground and the starch separated from the fibre component by sieving (stage B42). Eventually the protein (gluten) fraction is removed by centrifugation (stage B43). The resultant starch stream is then purified and eventually dried (stages B44 to B46) before being sent to store (stage B47) prior to further processing.

Figure 12 Generalised Flow Diagram for the Wet Milling of Maize



Hazard & Risk Analysis (Also Refer to Table 5; Risk factors 41.1 - 43.1)

Studies (30) have shown that it is possible to isolate mycotoxin (fumonisins and zearalenone) - free starch (but not maize gluten) from contaminated starting material. As discussed in the case of dry milling; provenance of the grain and appropriate stock control systems are considered to be critical control points, while grain cleaning would be considered to be a QCP. In terms of the rest of the process only one further potential CCP was identified. This was risk factor 42.1 (Table 5) and concerned the level of sulphur dioxide present in the water during steeping (stage 39). Hypothetically, failure to control levels of sulphur dioxide at this point could lead to further fungal activity. Although steeping has been shown to have an extractive effect of fumonisins (42) and T-2 toxin (156), the efficiency of extraction in such systems is not well understood. Given that under certain circumstances any reduction achieved might not be sufficient to bring levels of mycotoxin down to acceptable levels, steeping is considered to be a QCP.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

28.0 *Stage B11, Maize Mill Grain Reception*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
28.1	Grain is purchased from areas with high or unknown risk of mycotoxin contamination.	Where possible purchase grain of known provenance. Where provenance of grain is poorly known (e.g. imports) operate positive release system based on mycotoxin analysis.	Y -- Y CCP	Statutory or based on risk assessment.	Operate approved supplier scheme (see also risk factor 10.1, Table 2).
28.2	Grain supplied of a quality indicative of a risk of existing or potential mycotoxin contamination.	Grain showing unacceptable levels of *Fusarium* spp. damage and/or high moisture content rejected as unacceptable at weigh-bridge.	Y -- Y CCP	As set in commercial specification.	Set and enforce specifications regarding acceptance criteria for evidence of *Fusarium* spp. damaged grain – monitoring (see also risk factor 10.2, Table 2).

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

29.0 *Stage B12, Grain Store*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
29.1	Batches of wholesome and mycotoxin-contaminated grain mixed together.	Operate appropriate stock control systems to ensure that grain subject to positive release is quarantined.	Y – Y CCP		See risk factors 10.1 & 11.1, Table 2. Ensure stock control measures can support functioning traceability system.
29.2	Grain moisture/temperature rises to permit production of *Fusarium* mycotoxin.	Ensure storage units adequately proofed. Minimise moisture migration in stored grain. Maintain grain at low temperatures to minimise grain respiration.	Pre-requisite programme		See Risk factor 11.2, Table 2. Proofing audits, stored-insect pest control, preventive maintenance. Suitable and regular temperature and moisture monitoring.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

30.0 ***Stage B13, Grain Cleaning***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
30.1	Grain cleaning not optimised to remove fines and other heavily contaminated material.	Optimise separation processes.	N N* QCP Evidence suggests that while fines and other damaged grain are a key source of contamination, while their removal can effect significant reductions in fumonisin contamination, the same cannot be applied to other mycotoxins e.g. zearalenone.	Company specification	Specifications ensure good separation of defective material. Appropriate systems in place for the safe disposal of defective material.

Table 4	Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)				
31.0	*Stages B14 & B15, Conditioning & Degerming*				
No.	**Risk Factor**	**Control Measures**	**CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4**	**Critical Limits**	**QA/QC Aspects (Includes Monitoring & Verification)**
31.1	Mill breakdown in conditioning or degerming areas leads to time/moisture conditions which permit *Fusarium* spp. outgrowth and/or mycotoxin production.	See risk factor 13.1, Table 2.	Pre-requisite programme		See risk factor 13.1, Table 2.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

32.0 *Stage B16, Drying*

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
32.1	Grit drying favours localised mycotoxin production, due to dynamics of process or moisture front phenomena.	Use of appropriate dryer technology.	Y -- Y CCP		Determine moisture flow through grit mass to ensure that moisture migration does not promote fungal activity.
32.2	Grit improperly dried and released into finished grain store.	Use of appropriate dryer technology. Non-conforming product segregated and redried.	Y -- Y CCP	< 14.5% (based on risk of ochratoxin A contamination).	Operate appropriate process monitoring systems including grain moisture analyses (monitoring). Consider periodic mycotoxin analyses on basis of risk (verification). Operations to be in accordance with best practice and satisfy evidential requirements of GMP.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

33.0 ***Stage B17 to B21, Particle Reduction***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
33.1	No risk factors identified.				
34.0	***Stages B23, B26 & B22 Finished Product Storage (Mill or Factory) & Blending at Mill***				
34.1	Grit moisture rises to permit production of *Fusarium* mycotoxin.	Ensure storage units adequately proofed. Minimise moisture migration in stored flour.	Pre-requisite programme		See risk factor 15.1, Table 2.
34.2	Wholesome and mycotoxin contaminated grits blended together.	Operate functioning and effective quality assurance system	Pre-requisite programme		Implies failure of all previous quality assurance and control mechanisms.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

35 ***StageB24, Product Transport,***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
35.1	Grit moisture rises due to water ingress, permitting subsequent production of *Fusarium* spp. mycotoxins.	Trucks adequately proofed against water damage of grain.	Prerequisite programme		Trucks operated in accordance with trade association &/or governmental requirements. Extremely wet flour would not flow well on arrival and might be detected and rejected.
35.2	Contamination with residues from previous mycotoxin contaminated material.	Trucks subject to adequate hygiene procedures.	Pre-requisite programme		Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of GMP.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

36.0 ***StageB25, Factory Ingredients. Reception***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
36.1	Product fails to meet specification.	Deliveries are made on basis of certificates of compliance or analysis.	Y -- Y CCP		See risk factor 17.1, Table 2.
37.0	***Stages B27, Cooking & B28 Extrusion***				
37.1	Process temperatures too low to effect thermal degradation of mycotoxins.	Operate at product optimum conditions.	Y -- N Y Y* QCP * Major point of thermal degradation considered to be toasting step (B31)		Monitor temperature on regular basis. Ensure devices for measuring temperature are regularly calibrated within operational range.

Table 4 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)**

38.0 ***Stages B29, Drier and B30, Flaking Mill***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
38.1	No risk factors identified.				
39.0	***StageB31, Toaster***				
39.1	Process temperatures too low to effect thermal degradation of mycotoxins.	Operate at product optimum conditions.	Y -- Y **CCP**	Time x temperature function	Monitor temperature on regular basis. Ensure devices for measuring temperature are regularly calibrated within operational range. Verify efficacy of system by periodic analysis of finished product.

Table 4	Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figures 10 & 11)				
40.0	*Stages B32 to B37 Final processing, packaging and dispatch to retailer*				
No.	**Risk Factor**	**Control Measures**	**CCP or QCP?** (See Figure 2) Q1a Q1b Q2 Q3 Q4	**Critical Limits**	**QA/QC Aspects (Includes Monitoring & Verification)**
40.1	No risk factors identified.				

Table 5 **Hazard/Risk Analysis of EU Maize Processing, From Wet Mill Through to Finished Goods Store – Example, Maize Starch (See also Figure 12)**

41.0 B38, Grain Cleaning

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
41.1	Grain cleaning not optimised to remove fines and other heavily contaminated material.	Optimise separation processes. Operate preventive maintenance systems.	N N* QCP Evidence suggests that while fines and other damaged grain are a key source of contamination, while their removal can effect significant reductions in fumonisin contamination, but the same cannot be applied to other mycotoxins e.g. zearalenone.	Company specification	Specifications ensure good separation of defective material. Appropriate systems in place for the safe disposal of defective material.

Table 5 **Hazard/Risk Analysis of EU Maize Processing, From Dry Mill Through to Consumer – Example, Cornflakes (See also Figure 12)**

42.0 ***StageB39, Steeping***

No.	Risk Factor	Control Measures	CCP or QCP? (See Figure 2) Q1a Q1b Q2 Q3 Q4	Critical Limits	QA/QC Aspects (Includes Monitoring & Verification)
42.1	Concentrations of sulphur dioxide insufficiently high to inhibit fungal activity.	Ensure levels of sulphur dioxide maintained above minimum necessary for inhibition.	Y -- Y CCP	Operating concentrations: 0.1-0.2% sulphur dioxide	Monitor sulphur dioxide concentrations on predetermined basis. Operations to be in accordance with best practice, supported by records of sufficient evidential standard to satisfy requirements of GMP.
43.0	***Stages B40 to B47 Starch Extraction***				
43.1	No risk factors identified.				

4.0 DISCUSSION

4.1 Monitoring and Verification of Critical Control Points

4.1.1 Terminology and Application

Within the HACCP concept, the terms, 'monitoring' and 'verification' have very specific meanings. Leaper (117) defined them as:

Monitoring - *a planned sequence of observations or measurements of CCP control measures;*

Verification - *the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.*

Monitoring therefore gives a 'real-time' assessment of process parameters. It determines whether parameters are within specification and processes are reducing the risk of the hazard occurring to an acceptable level. Real time measurements give either immediate or rapid results and are made either on-line (preferable) or near-line - often by an operative who is not always laboratory trained. In terms of the cereals industry, examples of monitoring would include: measuring grain moisture content at various stages in the process to ensure that that it is sufficiently low not to permit fungal activity (e.g. risk factor 7.1, Table1); checking delivery documentation to control the provenance of grain at primary processor intake (e.g. risk factor 10.1, Table 2) or; measuring the temperatures on cornflake toasters (risk factor 39.1, Table 4). In many cases, proper use of monitoring enables the setting of a range of values which are tolerable, a buffer zone within which remedial actions to the process must be applied and also a critical limit, which if exceeded, requires the blocking of material and possible further treatment (including possible destruction/disposal). One example of this would be crop with an above-specification moisture content being presented to a finished grain store. Here the corrective action would be for it to be dried before being admitted. Monitoring is therefore an essential tool in facilitating the 'prevention is better than cure' concept which underpins quality assurance and enables the safe functioning of JIT systems.

In terms of raw material intake, from a commercial perspective, there is usually a contractual responsibility on the vendor to supply grain in a wholesome condition. In this event, the purpose of assessments on intake is to ensure that this obligation is met. It will be noted that none of the monitoring systems discussed in the previous paragraph actually measures the presence of *Fusarium* spp., still less the presence of their mycotoxins. Approved chemical methods of analysis for mycotoxins currently take days. Rapid analytical kits are now being marketed, which may have applicability to the weighbridge environment. In so doing they will have to satisfy two criteria in particular. These are that a result must be obtained within a short time frame (approximately 25 minutes) and that the methodology used has been agreed by both vendor and purchaser (this assists in minimising disputes in the event of a parcel failing to meet specification). A number of companies have developed in-line detection systems for fungal

contaminated material within a number of high value commodities (including cereals such as rice), using image analysis, however there are currently no commercially available systems which can measure mycotoxin content in 'real time.' Nevertheless there have been reports of the application of Near Infra Red Reflectance (NIR) technology for measuring the mycotoxin content of cereals (152) which might, if successful, have this potential. Currently, therefore, mycotoxin analyses play two key roles, these are in terms of verification/due dilligence and positive release/acceptance procedures.

Within the context of HACCP, the principle of verification is to confirm in absolute terms that the management systems put in place to reduce the risk of a hazard occurring are functioning efficiently. These can only be achieved by periodic analysis of raw materials and product for the mycotoxins concerned. These analyses need to be performed on a representative sample and at an appropriate frequency. Both of these factors will be determined by the nature of the operation. However, it would be expected that if deviations were occurring, the frequency of analyses following the institution of corrective actions would increase until such time as the risk of the hazard occurring was satisfactorily reduced.

4.1.2 Positive Release/Acceptance

Positive release/acceptance invokes the 'guilty until proven innocent' principle and is applied where the risk of the hazard occurring is exceptionally high. In the case of raw materials this could be where its provenance is uncertain, or that they are supplied from an area where the risk of unacceptable contamination is high. In order for a correct decision to be made, it is necessary that the analysis is performed using appropriate methodology by persons of acknowledged competence (e.g. members of an appropriately accredited laboratory) and that it is derived from an appropriate sample.

Sampling

Correct methodology, both in terms of sampling and analytical methodology are essential. Mycotoxin distribution within any grain parcel is likely to be heterogeneous and rigorous sampling regimes need to be developed. In some cases, regimes for particular commodity-mycotoxin combinations have been legislated for, as is the case for ochratoxin A in cereals (75). Currently no such legislation at the European level exists for *Fusarium* spp. mycotoxins.

This topic has recently been reviewed in a general manner by Coker (56). Any sampling regime must ensure that it is representative of the parcel or lot and equations have been developed on which appropriate sampling regimes can be constructed (176). The sampling regime must also address two types of 'risk:'

Producer risk (PR), the probability that the regime will lead to the rejection of material which actually meets specification with regard to mycotoxin contamination;
Consumer risk (CR), the probability of allowing material which exceeds the maximum levels specified, entering into the supply chain.

Both PR and CR are dependent on the sample size as well as the critical concentration (concentration of mycotoxin where a decision to reject a lot is made). It has been shown (56) that as the number of samples increases, both PR and CR decrease, with CR decreasing faster. In contrast, increasing the critical concentration value reduces PR but increases CR. One challenge is that different authorities and/or trades use different sampling regimes with consequently different PR and CR values. One study (197) compared accept/reject decisions using three different regimes. The 'success' (correct decision) rates for the three methods were 95.6, 91.1 and 82.4%. The results also demonstrated the conflicting risks of PR and CR. The least successful scheme in terms of arriving at a correct decision was also the most efficient in rejecting contaminated lots, albeit at the cost of a large number of false positives.

A review (19b) of commonly used sampling methods within the UK cereals' industry at intake has recently been published. It has assessed their utility for various analytes (including mycotoxins) and their suitability for due diligence purposes. In the case of mycotoxins, the author concluded that existing methods for sampling at intake, with regard to the distribution of heterogeneous contaminants such as mycotoxins, were probably inadequate. This could be compensated for at two levels: development of simplified sampling regimes that were 'substantially equivalent' to those already set out in regulations and/or; sampling at a lesser frequency in accordance with regulatory requirements. In both cases sampling and analysis would be considered to be more of a verification- rather than a monitoring- process.

Analytical Methodology

In order to verify critical control points, as well as make decisions concerning the fate of a particular lot or parcel of grain, appropriate methods of analysis are required. The current status of analytical methods for *Fusarium* spp. mycotoxins has recently been reviewed (190). The authors identified a number of challenges with regards to the analysis of grain and grain products for trichothecenes. One of which appears to be poor reproducibility among laboratories. An example of this is in a recently published international ring trial (104), where poor agreement of results between laboratories with between laboratory coefficient of variation values of 32 and 41% was reported. In particular, it was noted that some analytical techniques used, routinely gave higher values over others. One of the reasons for the high inter-laboratory variation given was the absence of a common calibrant. Currently certified reference materials (CRM) have been produced for deoxynivalenol in wheat and maize flours (81). However no such standards are currently available for other mycotoxin - cereal combinations (190). A further problem is the question of the matrix from which the mycotoxin must be extracted. One example of this is work by Solfrizzo *et al.* (181) who have developed new and improved methodologies for the extraction and analysis of fumonisins from cornflakes.

The potential of high inter-laboratory variation poses some interesting challenges to the industry. In particular, these relate to how it sets its own internal specifications within the context of any possible statutory provisions regarding mycotoxin contamination. There are two potential problems which must be addressed:

- Analytical data gained in-house (either from internal or external laboratories) underestimating the amount of mycotoxin actually present in the lot, leading to inadvertent over exposure by the general public;
- Inaccurate analytical data from external sources (e.g. certificates of analyses provided by the vendor or generated by different enforcement agencies). In worst case scenarios this could lead to either unnecessary public exposure or to an unwarranted product recall. In the case of certificates issued by laboratories operated by enforcement agencies, this risk is reduced where the laboratory operates to best practice. For example in the UK, laboratories concerned with enforcement are UKAS accredited and regularly take part in internationally recognised (FAPAS) ring trials.

Application of the HACCP philosophy can assist in reducing the risk of these events happening. This can be achieved at two levels:

- Use of laboratories with demonstrable competence. Such laboratories would have to be accredited under an internationally approved norm and participate in internationally recognised ring trials. Certificates of analysis supplied by third parties (e.g. vendors) from laboratories that cannot demonstrate compliance with these requirements would be considered unacceptable.
- Process specifications have to be derived which set various limit values for mycotoxin contamination. If achieved, these would, initiate corrective action (threshold limit) or result in contaminated material being blocked (critical limit). Bearing in mind that the term, 'Critical Limit' has been defined as, 'a criterion which separates acceptability from unacceptability (117);' at its simplest, the value of any critical limit would be the statutory maximum or that based on recommended action levels, as proposed for deoxynivalenol (12). However application of GMP philosophy which would include the need to operate in accordance with 'Due Diligence,' would suggest that any *commercial* critical limit should actually be lower than any statutory or recommended maximum. This would further reduce the risk of inadvertent use/release of contaminated material which exceeded statutory or recommended levels.

4.2 Farm to Primary Processor

4.2.1 On Farm

Intellectually, as Miedener (130) has pointed out, the only certain route to avoid the hazard of contamination of cereals with *Fusarium* spp mycotoxins is the development of varieties absolutely resistant to infection in the first place. The feasibility of achieving this in the short to medium term is probably low. Risk reduction strategies (which can include the development of cultivars with improved resistance) are therefore the only means by which the problem of *Fusarium* spp mycotoxin contamination of cereals can be managed and the hazard to the consumer contained. The fact that a crop grown in one Member State enjoys relatively low levels

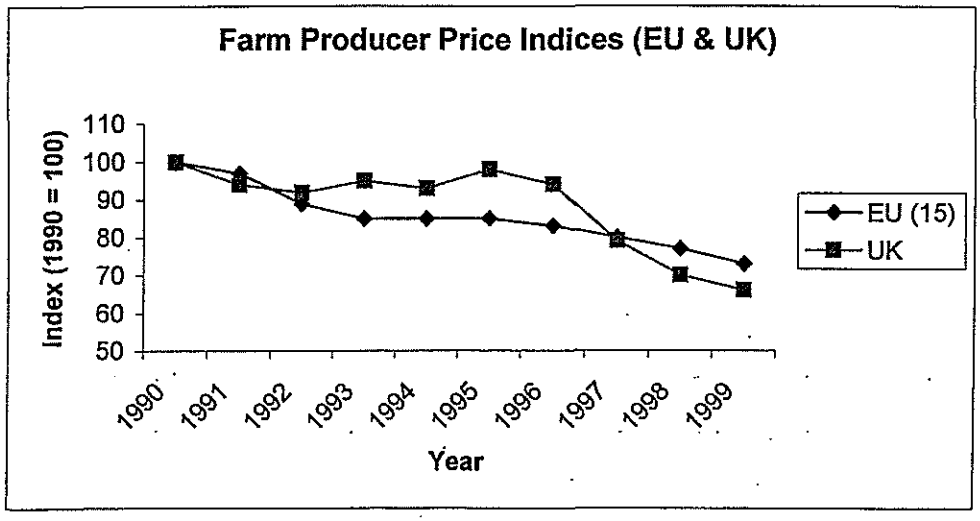
of *Fusarium* spp. mycotoxin contamination should be no cause for complacency. The infecting mycoflora can change, as witnessed, for example, by the changes in the relative numbers of samples of winter wheat infected with *M. nivale* and *Fusarium* spp. over a five year period in UK ear blight outbreaks (17, 88). The same studies also observed an increase in the numbers of potentially toxigenic *Fusarium* spp., in particular *F. graminearum.* This was attributed to weather conditions favourable for fungal infection, changes in tillage practices and the increased use of maize in rotations.

Given that *Fusarium* spp. damage has direct commercial implications for cereals destined for immediate human consumption (e.g. wheat for flour and barley for beer), there are economic drivers that can select against heavily contaminated grain. Evidence for this can be seen in survey data such as that by Pricket *et al.* (153), where the highest levels of contamination were seen in grain destined for animal feed. The significance of the commercial selection process as an adequate control with regard to mycotoxin control is debatable. As the Dutch experience (88) at the end of the twentieth century has shown, it was possible for products made from raw materials of good technological quality to be contaminated with levels of deoxynivalenol, which gave cause for a product recall from the general public.

The use of grain in feed is also of concern. Grain fed to livestock arrives by one of two principal routes: directly to the animals, either within the context of mixed arable/livestock farming or with grain purchased from third parties. Alternatively it can be supplied in the form of a compounded feed. Animal feed is a low-margin operation subject to the constraints of 'Best Cost Formulation' practices. There will thus be even greater pressure for the farmer to minimise costs in terms of production, storage and moisture-management. The significance of this should not be underrated. As discussed in section 1.1, almost 40% of wheat and approximately 60% of coarse crops (principally maize and barley) used in the EU are incorporated into animal rations (16).

Implementation, management and assuring on-farm control of mycotoxin contamination has cost-benefit implications. Consideration of Figure 13, shows that in real terms, farm producer prices both within the UK and the EU as a whole, have fallen (77a). Given developments both within the World Trade Organisation and the Common Agricultural Policy, this trend is likely to continue. One of the consequences of this price reduction is that farmers have to adapt their practices to the new economic circumstances. Some of these adaptations, for example, mono-cropping, alternate growing of wheat and maize, no-tillage cultivation systems and use of fungicides at concentrations below those recommended, are all risk factors in the development of *Fusarium* spp. linked problems. A number of them (e.g. incorrect use of fungicides) can be addressed through appropriately constructed codes of practice enforced by appropriate assurance schemes. In other cases, for example, adoption of no-till systems, compromises will have to be reached between the need to control soil erosion and/or preserve archaeological sites with what are acceptable levels of mycotoxin contamination.

Figure 13 Annual Change in EU Farm Producer Prices, 1990 – 1999 (Based on data taken from reference 77a)



What is also required is that codes of practice and assurance schemes make it clear that dealing with *Fusarium* spp. mycotoxins has both strategic and tactical components. This can be best exemplified by consideration of the role of climate and the farmer's reactions towards it. Consideration of risk factors 3.1 and 3.2 (Table 1) indicate that the farmer must have a strategy or policy in place to deal with weather conducive to mycotoxin formation. Thus if the weather conditions indicate that rainfall and moisture conditions are going to be conducive to infection, depending on the farming regime (organic or not) used, the farmer should have the appropriate fungicides available and ready for spraying in a timely manner. Similarly in cases of drought, spray irrigation should be timed so that it does not coincide with anthesis. An example of the tactical component would be the actual implementation of the strategy. A non-exclusive list of approaches would include timely use of a broad-spectrum fungicide cocktail and its correct application using reliable equipment. While it is relatively common to include such strategic requirements in assurance schemes within manufacturing environments (e.g. crisis management documents), it is less so when dealing with the cultivation of crops.

Those handling raw grain (in particular farmers and third-party stores) therefore need to have appropriate tools to enable them to manage the risk of mycotoxin contamination in a manner which is not only cost efficient but also does not compromise public and livestock health. This needs to be addressed at a number of levels. One of the key challenges facing cereal producers in the northern latitudes in particular is moisture. There is a need not only to be able to determine grain moisture as soon as possible, but also to plan what needs to be done in terms of drying, storage etc. Recent developments in the European Union, have described prototype systems which can measure the moisture content of grain as it is combined (179a). There are also projects underway to develop knowledge based systems (KBS) for managing crops once harvested. One such example is that being developed for malting barley ('Qualigrain,' reference 19a). In this case

the objective is to make available in an easily accessible manner, algorithms which will enable informed decisions to be made as to the fate of barley as it is received by the maltster.

It could be argued that further developments would be helpful, particularly the development of rapid analytical systems which could be used in the field (literally). These would operate at two levels. Either by reliably measuring mycotoxin contamination already present in the crop, or to measure the potential of the crop to be contaminated with *Fusarium* mycotoxins in the future. This could be achieved by analysing for the presence of a specific sequence of DNA encoding for a gene encoding an enzyme involved in mycotoxin biosynthesis such as *tri*5 (66).

Also necessary are systems capable of monitoring for localised fungal activity in stored grain. Current technology only permits continuous measurement of moisture and temperature at predetermined points within a silo. Magan *et al.* (109), using 'electronic nose' technology, have demonstrated that it is possible to detect fungi present in stored wheat by virtue of the volatile compounds that they produce. In addition they (77) have described prototype neural networks capable of integrating data from such devices to arrive at a decision making process regarding the fate of particular batches of wheat. The potential of using the electronic nose as a monitoring device within the concept of HACCP has also been discussed (122). Others (145) have shown that the potential for electronic nose technology to be directly applied to the measurement of deoxynivalenol production in stored barley. In this case, it was shown that a number of volatile fungal metabolites had either a positive (e.g.pentane) or negative (e.g. 1-heptanol) correlation with production of the mycotoxin.

As has been demonstrated in this report, there is now sufficient knowledge concerning the occurrence of *Fusarium* spp. mycotoxins and the factors which can either reduce or aggravate their occurrence. This advice is being translated into guidelines which are readily accessible by the farmer. For example, in the United Kingdom, the Home-Grown Cereals Authority has made available, free of charge on the internet, guidelines for the application of fungicides to combat *Fusarium* ear blight (18) and safe storage of cereals (11). The challenge is to ensure that not only is such guidance is available, but that it is actually implemented, and can be shown to be so. Third party quality assurance schemes have an important role to play in achieving this, providing that they encourage practices which will mitigate mycotoxin occurrence.

4.2.2 Grain Trading

A key element in assuring freedom from mycotoxin contamination is assuring its provenance. This means that appropriate traceability systems have to be in place. For a traceability system to work, it must have three elements:

- A means of identifying any particular parcel of grain as it passes through the supply chain;
- Records giving the history of the parcel;
- Data handling systems to enable access to relevant information.

Ideally this would mean that every grain parcel could be traced back to the farm from where it was produced. For premium cereals this is already occurring in some EU Member States. For example in the United Kingdom, flour mills generally purchase grain produced on farms which are members of a crop assurance scheme. It is incumbent on the farmer (if selling direct) or the grain merchant (if sold through a third party) to declare the membership number(s) of the producing farms on which the grain supplied was grown. The situation becomes more difficult when grain is imported, particularly from outside the Member State. However precedents exist for certain commodities including cereals such as maize and also for soya. These are where there is concern that the crop should not be produced from genetically modified organisms (GMO) and that evidence by way of traceability systems which can be verified by audit are required. Similarly in other foods, for example the German wine industry, computer software ('Weinbuch') exists that makes it possible to trace blended bulk loads through each blending stage (and any other manipulation) back to the individual suppliers of each component.

4.3 Grain Processing

4.3.1 General Comments

A key factor underlying all of the primary processes (flour and maize milling together with malting) reviewed, is that, with the possible exception of maize-starch produced by wet milling, none of the processes are 100% guaranteed to either remove *Fusarium* spp. mycotoxins, or reduce contamination to an acceptable level. In order to produce ingredients with low mycotoxin loading, the processor must ensure that the level of mycotoxin contamination in the raw material is not excessive. They must therefore have a strategy in place for the informed release of grain into the manufacturing system and or the finished product to the customer. Realisation of the strategy must be based on a local risk assessment reflecting the type of grain, its provenance, and the urgency with which it is needed. The later is particularly important where plants operate on a JIT basis. Using HACCP principles it is possible to develop a matrix which could be used by the processor in deciding on what information is necessary to allow grain to be processed. A specimen is shown in Table 6. It must be emphasised that any matrix must reflect local conditions and information shown in Table 6 is by way of example only. As in any risk analysis, contingency plans have to be drawn up in the event of a system failure. These should, where possible, include sufficient holding times so that grain or product can be withdrawn, without the need to execute a product recall involving the consumer.

Operating to JIT principles, presents particular problems regarding the lag time between when material is submitted for analysis and when the results are obtained versus the dynamics of the manufacturing and retail environment. For example in plant-bread manufacture, wheat delivered to a mill on a Monday morning could well have been eaten as bread on the Thursday or Friday of the same week.

4.3.2 Processing

With the possible exception of extreme high temperature processes used in the manufacture of products such as cornflakes, although cereal processing can reduce the mycotoxin load found in the original grain lot, there is no 100% guarantee that the reduction will be sufficient to reduce the amount present sufficiently to avoid a danger to public health.

Generally speaking, any reductive process, such as milling to produce white (< 80% extraction) as opposed to wholemeal (100% extraction) flours will bring about a lowering of the amount of mycotoxin present. However, given that milling does not destroy the mycotoxin (1) and in fact, to one degree or another, concentrates them, the question as to the fate of bran and other by-products produced does arise. This is of particular importance since these materials are often used as raw materials in the manufacture of livestock feed.

4.4 Conclusions

Mycotoxin contamination of cereals is a cause of increasing concern within EU Member States. Mycotoxins produced by the genus *Fusarium* present a significant challenge, since they are, to a large degree formed during the development of the grain. Implementation of focused risk reduction strategies will contribute to ameliorating the occurrence of contamination at unacceptable levels. In terms of a top tier strategy, four needs can be identified:

- Reduced contamination of raw materials - new resistant varieties, better agronomic practices;
- Improved knowledge transfer and application – improved dissemination not only of what information is available but also how benefit can be gained from it;
- GAP and GMP codes to include practices which will reduce the risk of mycotoxin contamination occurring, these codes to be enforced by appropriate supplier quality assurance (SQA);
- Cost effective monitoring and verification systems to ensure compliance.

It is necessary that these strategies should be operated in an integrated and demonstrable manner. Ultimately this means that operations have to be performed using appropriate codes of practice within the framework of a suitable SQA scheme. The later has to be subject to verification by audit and analysis. SQA can operate at either a second party level, (designed and managed by the customer), or at a third party level (designed and managed by an independent body and recognised by the customer). In either case, it is essential that such schemes recognise what factors contribute to mycotoxin contamination and require that participants within the scheme can demonstrate that they are managing those factors in the correct manner.

Table 6 Specimen Risk Assessment Matrix for The Use of Positive Release of Grain By a Primary Processor

Provenance	Risk	Intake Measures (Monitoring)	Verification	Comments
Area known to have low incidence of *Fusarium* ear blight and low mycotoxin contamination (Grain required immediately on JIT process)	Low	Check that delivery documentation permits traceabilty back to farm (e.g. crop assurance scheme registration number). Ensure that all specifications relating to mycotoxin risk are complied with.	Periodic mycotoxin analysis to set schedule. Scheduled evaluation of supplier performance; investigate deviations with view to delisting those with history of non-compliance.	Non-compliance can result in delisting. Grain supplies must come from farms complying with SQA Mycotoxin analyses in accordance with recognised methods.
Insufficient knowledge of area concerned regarding *Fusarium* ear blight and/or mycotoxin contamination (Grain required immediately on JIT process)	Medium/High	Parcel to be supplied with certificate of analysis issued either by vendor or following pre-sample taken by buyer. Ensure that all specifications relating to mycotoxin risk are complied with.	Periodic mycotoxin analysis to set schedule. Scheduled evaluation of supplier performance; investigate deviations with view to delisting those with history of non-compliance.	Non compliance is grounds for concession or rejection. Mycotoxin analyses in accordance with recognised methods. If grain accepted on concession, finished product can only be released on receipt of satisfactory certificate of analysis.
Grain supplied from area known to be at high risk regarding mycotoxin contamination and/or is a variety particularly prone to contamination. (Grain cannot be used for JIT processes)	High	Parcel to be supplied with certificate of analysis (vendor or buyer). Specifications relating to mycotoxin risk must be complied with. Grain or finished product to be held pending confirmation of mycotoxin status by processor.	Scheduled evaluation of supplier performance; investigate deviations with view to delisting those with history of non-compliance.	Non compliance is grounds for concession or rejection. Mycotoxin analyses in accordance with recognised methods. If grain accepted on concession, finished product can only be released on receipt of satisfactory certificate of analysis.

5.0 INFORMATION DISSEMINATION

Oral Presentations to CCFRA Working Parties, Panels & Training Courses (Dr. A.J. Alldrick)

15th March 2001	Dry Goods Manufacturing Microbiology Working Group (CCFRA, Chipping Campden);
11th October 2001	Cereals Milling & Baking Technical Advisory Panel (CCFRA, Chipping Campden);
5th December 2001	Cereal Varieties Working Party (NIAB, Cambridge).
29th October 2002	Managing Mycotoxins – 2002 Update

Participation in Industrial Groups

14th January 2002	Mycotoxin 'Brain Storming Session, 'Groupement des Associations Meunières de Pays de l'UE, Brussels (Mr. C. Anderson)
1st July 2002	
18th November 2002	National Association of British & Irish Millers, Mycotoxin Working
18th December 2002	Party,
20th February 2003	London (Dr. A.J. Alldrick)

Conference Presentations (Dr. A.J. Alldrick)

10th October 2002	Managing the risk of mycotoxin contamination in cereals through use of HACCP and other quality management techniques ICC/IRTAC Cereal Conference 2002, Paris CNIT, La Defense.
17th February 2003	Application of HACCP and other quality management techniques to reduce the risk of mycotoxin contamination in cereals 2nd World Mycotoxin Forum, Noordwijk.
27th June 2003	Reducing the risk of mycotoxin contamination through the application of HACCP and other quality management techniques Mycotoxins in Food Production Systems, Association of Applied Biologists, University of Bath.

Publications

Alldrick, A.J. (2002) Reducing the risk of mycotoxin contamination in cereals. *Food Safety Express* **3** (3) 16.

Alldrick, A.J. (2003) Reducing the risk of mycotoxin contamination through the application of HACCP and other quality management techniques *Aspects of Applied Biology* No. 68 139-146.

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