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HEALTH HAZARDS, ECONOMIC AND TRADE IMPLICATIONS OF MYCOTOXINS: RELEVANCE TO INDIAN SITUATION

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Introduction

Mycotoxins are toxic metabolites produced by different genera of fungi that can contaminate a wide range of foods and feeds (Table 1). These fungi are ubiquitous and wide-spread at all levels of the food chain. They are present in food produced at all latitudes save the Polar Regions. They are natural contaminants and yet some of the most poisonous toxins known to man. Their presence is considered unavoidable and it is not possible to predict or prevent entirely their occurrence during cultivation, harvest, storage, and processing operations by current good agronomic and good manufacturing practices (Pohland, 1993).

Under favourable conditions of temperature and humidity, these fungi grow on certain foods (grains, cereals, oilseeds, edible nuts, dried fruits) resulting in the production of toxins. In India, nearly 70% of the total production of food grains in India is retained at farm level where the unscientific and faulty storage conditions enhance the chances of fungal attack and thereby mycotoxin production. The decomposers of food grains i.e. fungi, bacteria etc. are always present on food grains in dormant conditions (usually as spores) and grow under favourable climatic and other conditions (1). The fungal growth may cause decrease in germinability, discolouration of grain, heating and mustiness, loss in weight, biochemical changes and production of toxins. All these changes may occur before the responsible fungi could be detected on visual examination (2). The diseases or physiological abnormalities resulting due to ingestion of mycotoxins are known as mycotoxicosis (Goyal, 1988).

Post-harvest seasoning or processing of food does not seem to decrease the toxicity. For example, aflatoxins can be retained in both cake and oil during extraction of oil from nuts. If bio-degradation of the toxins is not complete and if milk cattle consume mycotoxin contaminated feed, part of the toxin is metabolized in the body and secreted in the milk and consumption of this contaminated milk can cause diseases in humans.

The poorest quality grain (if it can be spared) is used for animal feeds. Feed conversion to animal protein is always reduced by the presence of mycotoxins. When contaminated feed are given to farm animals and birds, the toxins seriously affect their production capacity and predispose them to a variety of diseases, thus has economic significance. More seriously, this causes the entry of toxins into

Table 1. Major fungi genera with associated mycotoxins

Fungi Genera	Associated mycotoxins
Aspergillus	Aflatoxins, ochratoxins, cyclopiazonic acid, patulin, gliotoxin, sterigmatocystin,
Penicillium	Ochratoxins, citrinin, patulin, penicillic acid, cyclopiazonic acid, penitrem A, griseofulvin
Fusarium	Fumonisins, moniliformin, zearalenone, zearalenol, , nivalenol deoxynivalenol, T-2 toxin, fusarenon-X, diacetoxyscirpenol, fusaric acid
Claviceps	Ergot alkaloids

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the food chain as the toxic residues remain in meat, milk and egg products. These have been regulated in many developed countries and to a very limited extent in developing countries. However, in many of the developing countries where animals are kept at the individual household level, the chances of contamination of the food from milk, eggs and meat can be higher (Bhat and Miller, 1991). Vital statistics on mycotoxin induced diseases are generally lacking. A wealth of data has been generated based on observations in animals and birds and subsequent extrapolation to human health. The mycotoxins have been demonstrated to induce adverse effects in laboratory and farm animals.

The mycotoxins attract world-wide attention because of the significant economic losses associated with their impact on human and animal health, animal productivity and both domestic and international trade.

Health implications

Exposure to mycotoxins can produce both acute and chronic toxicities ranging from death to deleterious effects upon the gastro-intestinal, nervous, cardio-vascular, respiratory, and uro-genital systems. The ability of some mycotoxins to compromise the immune response and, consequently, to reduce resistance to infectious disease is now widely considered to be the most important effect of mycotoxins, particularly in developing countries. In addition to direct risks to humans from consumption of mycotoxin-contaminated grains, there are indirect health risks to those who consume animal products containing residues of carcinogenic mycotoxins. The Centre of Excellence in Pathology, College of Veterinary & Animal Sciences, Kerala Agricultural University, Thrissur has made over decades of contribution to the science of mycotoxicology in domestic animals. Consumption of mycotoxin contaminated feed by livestock is the potential for economic losses from animal health and productivity problems. Aflatoxins in feed are known to be associated with liver damage in animals, reduced milk and egg production, poor weight gain, and recurrent infections due to immunity suppression. The young of any particular species are most vulnerable, but the degree of susceptibility varies by species (Bhat, 1999).

Aflatoxin, the most commonly occurring and well studied mycotoxin is classically known for its multifaceted effects on man and animals. The actual effect of the toxin depends on the level and duration of exposure. If consumed in very high quantities, it induces instant (acute) liver damage (hepatotoxin) but can also act as a mutagen (an agent causing damage at genetic level) on multiplying cells. In addition, it has immunosuppressive properties (one which increases susceptibility to diseases). Although more difficult to directly associate with mycotoxin contamination, an equal, or perhaps even greater, food safety concern than acute illness is the long-term effects of lower-level mycotoxin consumption, particularly the risks of cancer and immune deficiency. Aflatoxin B_1 was placed on the list of known human carcinogens by the International Agency for Research on Cancer (IARC) in 1988, and other mycotoxins are suspected or known to be carcinogenic or to have other adverse health consequences. Aflatoxins are a particular concern for populations with a high incidence of hepatitis B because the relative rate of liver cancer in people with hepatitis B is up to 60 times greater than normal when those people are exposed to aflatoxin (Richard et al., 2003). Aflatoxins have also been implicated in human diseases including liver kwashiorkor (a protein-energy malnutrition of children), Indian childhood cirrhosis and certain occupational respiratory diseases. While the exact cause-effect relationship has been established for only a few diseases, speculation about the role of mycotoxins in the aetiology of various illnesses has been based on circumstantial evidence. In India, the acute diseases for which there is evidence are the aflatoxic hepatitis in 1975, entero-ergotism in 1976 and deoxynivalenol mycotoxicosis in Kashmir in 1987 (Tandon, 1993). A common feature of all these outbreaks has been the involvement of staple foods such as corn, wheat or pearl millet, following unseasonable rains or drought during either the growing season or harvest.

Exposure of farm animals and economic losses

A vast majority of outbreaks in farm animals have been caused by aflatoxin, fumonisins and zearalenone and to a lesser extent by ochratoxin and ergot alkaloids. Farm animals most affected by mycotoxins are poultry, swine, dairy cattle and horses. Production losses can occur even at low levels of exposure to mycotoxins in feed. A combination of mycotoxins may pose a greater production loss than each of these mycotoxins separately. The economic losses have been associated in terms of reduced productivity, such as lowered egg production, reproductive effects, susceptibility to infections resulting in increased morbidity and finally mortality. Losses also could occur due to mycotoxin residues in milk, eggs, meat, etc.

The actual cost of these losses has been estimated only for some outbreaks. A case study in India of an outbreak of aflatoxicosis in 11,465 layers and 5,000 pullets in a poultry farm revealed that an 18 day exposure of poultry to the contaminated feed containing 600 ìg/kg AFB1, contributed mainly from groundnut cake, resulted in a loss of about 10% of the initial investment (Sudershan et al., 1996.). The major loss was observed to be due to a drop in egg production followed by mortality in birds and additional expenditure on the protein source. The balance was accounted for by medical and other miscellaneous expenditures.

An outbreak of fumonisin mycotoxicosis occurred in India in 9 700 laying hens leading to 10% mortality and 20% reduction in egg production due to fumonisin contamination in feed. Analysis indicated fumonisin levels up to 8.5 mg/kg and aflatoxin B1 up to 0.1 mg/kg (Prathapkumar et al., 1997).

Regulations and International legislations on mycotoxins

The knowledge that mycotoxins can have serious effects on humans and animals has led many countries to establish regulations on mycotoxins in food and feed in the last decades to safeguard the health of humans, as well as the economical interests of producers and traders. Setting mycotoxin regulations is a complex activity, which involves many factors and interested parties. According to FAO (2004), several factors, both of a scientific and socio-economic nature, may influence the establishment of mycotoxin limits and regulations. These include: availability of toxicological data; availability of data on the occurrence of mycotoxins in various commodities; knowledge of the distribution of mycotoxin concentrations within a lot; availability of analytical methods; legislation in countries with which trade contacts exist; and ?need for sufficient food supply. The first two factors provide the necessary information for hazard assessment and exposure assessment respectively, the main ingredients for risk assessment.

Risk assessment is the scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to food-borne hazards; it is the primary scientific basis for the establishment of regulations. The process consists of hazard identification, hazard characterization, exposure assessment and risk characterisation (Berg, 2003).

International legislation on foods and feeds is established by Codex Alimentarius Commission, (CAC), supported by the FAO/WHO (Berg, 2003; FAO, 2004). Currently 168 countries are members of Codex Alimentarius. Within the CAC, the Codex Committee on Food Additives and Contaminants (CCFAC) derives maximum limits (standards) for additives and contaminants in food, which are decisive in trade conflicts. The CCFAC develops standards based on a procedure that follows the principles of risk analysis as far as possible, according to rules and methods laid down in the Codex Procedural Manual as well as the Codex General Standard for Contaminants and Toxins in Food. The body responsible for the risk assessment component of the Codex Alimentarius risk analysis process is JECFA (Joint Expert Committee on Food Additives). JECFA provides the Codex Alimentarius with scientifically based assessment of the toxicity of food additives, veterinary drug residues and contaminants such as mycotoxins, and to establish safe levels for human consumption both on a world wide and regional basis. The evaluation of toxicological data carried out by JECFA normally results in the estimation of a Provisional Tolerable Weekly Intake (PTWI) or a Provisional Tolerable Daily Intake (PTDI). The use of the term "provisional" expresses the tentative nature of the evaluation in view of the paucity of reliable data on the consequences of human exposure at levels approaching those with which JECFA is concerned. In principle, the evaluation is based on the determination of a No-Observed-Adverse-Effect-Level (NOAEL) in toxicological studies. and the application of an uncertainty factor. The uncertainty factor means that the lowest NOAEL in animal studies is divided by 100, 10 for extrapolation from animals to humans and 10 for variation between individuals, to arrive at a tolerable intake level (FAO, 2004). This hazard assessment approach does not apply for toxins where carcinogenicity is the basis for concern as is the case with the aflatoxins. Assuming that a no-effect concentration limit cannot be established for genotoxic compounds, any small dose will have a proportionally small probability of inducing an effect. Imposing the absence of any amount of genotoxic mycotoxins would then be appropriate, if these toxins were not natural contaminants that can never completely be eliminated without outlawing the contaminated food or feed. In these cases, JECFA does not allocate a PTWI or PTDI. Instead it recommends that the level of the contaminant in food should be reduced so as to be As Low As Reasonably Achievable (ALARA). The ALARA level is defined as the concentration of a substance that cannot be eliminated from a food without involving the discard of that food altogether or without severely compromising the availability of major food supplies.

In the mycotoxin area, CCFAC established standards for total aflatoxins in unprocessed peanuts, aflatoxin M1 in milk and patulin in apple juice in 2003. A draft standard has been developed for ochratoxin A in wheat, barley, rice and derived products, and proposed standards for DON in cereals are currently under discussion. The CCFAC has, apart from its goal to develop standards (Maximum Limits) where necessary, also develops Codes of Practice in which principles and advice about practical measures to control mycotoxins during cultivation, storage and processing are assembled. Examples of these include the codes of practice developed for: i) the reduction of aflatoxin B_1 in raw materials and supplemental feedstuffs for milk producing animals; ii) prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages and iii) the prevention and reduction of mycotoxin contamination in cereals including annexes on ochratoxin A, zearalenone, fumonisins and trichothecenes (FAO, 2004).

In addition to information about toxicity, exposure assessment is another main ingredient of the risk assessment. Reliable data on the occurrence of mycotoxins in various commodities and data on food intake are needed to prepare exposure assessment. In most of the JECFA reviews of mycotoxins, the analytical data on the levels of contamination were often inadequate from developed countries and non-existent for developing countries (FAO, 2004).

Impact of international tolerance limits on trade and economy

Although attempts have been made to quantify the economic impact of mycotoxin contamination of feeds and foods, the magnitude of the problem is too great, and the ramifications too far reaching to make reliable estimates. The economic losses annually are quite likely in the billions of dollars world wide. In 1985, the Food and Agriculture Organisation (FAO, 1990) estimated that 25% of the world's food crops are contaminated annually with mycotoxins. Numerous reports focusing on different countries/regions, commodities, toxins, and cost categories (e.g., costs of regulations, testing, production loss, trade losses) offer some indication of these losses. In some cases, developing countries have experienced market losses due to persistent mycotoxin problems or the imposition of new, stricter regulations by importing countries. According to FAO estimates, the direct costs of mycotoxin contamination of corn and peanuts in Southeast Asia (Thailand, Indonesia, and the Philippines) amounted to several hundred million dollars annually, with most of the losses accounted for by corn (Bhat, 1999).

In an attempt to harmonize the current tolerances for aflatoxin which exist in different countries, the working group on mycotoxins of the WHO/FAO and CCFAC proposed a maximum limit of 15 ìg/kg for total aflatoxins in raw groundnuts based on a sample size of 20 kg (Bhat et al., 1996). The potential economic problems associated with a level of 10 ìg/kg and the public health implications of a level of 15 as compared to10 ìg/kg for aflatoxins in foods are two main issues in the setting of maximum levels for aflatoxins in groundnuts intended for further processing. Many countries consider the level of 15 ìg/kg to be a reasonable limit that could be achieved by producer countries thus facilitating international trade, and consider that a lower level would constitute a trade barrier due to the finding of the JECFA evaluation that this may not offer significant improvement for public health. However, genotoxic properties of aflatoxin, uncertainties in risk assessment, the ALARA principle, and inadequate data on the effect of a level of 10 ìg/kg on the availability of groundnuts on the world market, support continued consideration of the lower level.

A situation can be envisaged from a multi-centric national study in India on aflatoxin contamination in maize and groundnut. The study indicated that 21% of the contaminated groundnut samples available in the Indian market have to be considered as unfit for human consumption as they contain Aflatoxin B1 above the Indian permissible limit of 30 ìg/kg (Bhat et al., 1997). If the Codex proposed limit of 15 ìg/kg were to be applied then it would result in the rejection of 37% of the groundnuts. If the limits were lowered to 10 ìg/kg a much larger percentage of the samples would be rejected. Similarly, 26% of maize samples exceeded the Indian tolerance limit of 30 ìg/kg. On the basis of Codex levels 47% of the samples would have to be rejected (Van Egmond, 1999).

Trade Regulations should be brought into harmony with those in force in other countries with which trade contacts exist. Strict regulative actions may lead importing countries to ban or limit the importing of commodities such as certain food grains, which can cause difficulties for exporting countries in finding or maintaining markets for their products. For example, the stringent regulations for aflatoxin B_1 in animal feedstuffs in the EU (Commission of the European Communities) led European animal feed manufacturers to switch from groundnut meal to other protein sources to include in feeds; this had an impact on the export of groundnut meal of some developing countries (Bhat, 1999). The distortion of the market caused by regulations in importing countries may lead to export of the less contaminated foods and feeds leaving those inferior foods and feeds for the local market. Some countries apply different limits for aflatoxins in certain products depending on the destination. The regulatory philosophy should not jeopardize the availability of some basic commodities at reasonable prices. Especially in the developing countries, where food supplies are already limited, drastic legal measures may lead to lack of food and to excessive prices.

The World Bank has published a study on impact of the adoption of international food safety standards, and the harmonization of standards, on global food trade patterns (Wilson and Otsuki, 2001).

Current member countries of the Association of Southeast Asian Nations (ASEAN) comprise Brunei Darussalam, Cambodia, Indonesia, the Lao People's Democratic Republic, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Viet Nam. Most of these countries have specific regulations for mycotoxins. Whereas harmonized regulations are obviously not (yet) established by ASEAN, an ASEAN Task Force on Codex Alimentarius has taken a common position to support the 0.5 ìg/kg level for aflatoxin M1 in milk (ASEAN, 1993)

The Food and Agriculture Organization has anticipated that by the year 2010 some 120 countries are expected to have known mycotoxin regulations (FAO. 2004). Regulations have become more diverse and detailed with newer requirements regarding official procedures for sampling and analytical methodology, and the issue of measurement uncertainty has entered the regulatory discussions. These developments reflect the general concerns that governments have regarding the potential effects of mycotoxins on the health of humans and animals. At the same time, harmonization of tolerance levels being undertaken for goods moving in international commerce. This harmonization is a slow process because of the different views and interests of those involved in the process. Whereas harmonized tolerance limits would be beneficial from the point of view of trade, this would not necessarily be the case from the point of view of (equal) human health protection around the world. Risks associated with mycotoxins depend on both hazard and exposure. The hazard of mycotoxins to individuals is probably more or less the same all over the world (although other factors sometimes play a role as well such as hepatitis B virus infection in relation to the hazard of aflatoxins). Exposure is not the same because of differences in levels of contamination and dietary habits in various parts of the world. National governments or regional communities should encourage and fund activities that contribute to reliable exposure assessment of mycotoxins in their regions. The availability of inexpensive, validated and easily performed analytical methodology and the application of Analytical Quality Assurance are basic ingredients to come to meaningful data on occurrence, and their development must therefore be stimulated.

Regulatory control measures on mycotoxins especially aflatoxins had been initiated by several countries in order to protect the public health and to promote trade at national and international levels (Van Egmond, 1999). There is a lack of uniformity in the limits fixed by various countries. A tolerance limit of 30 parts per billion (ppb) aflatoxin in all foods has been fixed in India and 120 ppb for feeds ((FAO, 2004), while the limits of 0 to 50 ppb has been fixed at international level depending upon the country and commodity. On the basis of studies conducted by the National Institute of Nutrition, Hyderabad in India, a 30 ppb tolerance level for deoxynivalenol in wheat and wheat products has been proposed.

The stringent levels of mycotoxin regulation enforced by importing countries impose a heavy burden on international food trade. The world volume of agricultural products like maize, groundnuts, copra, palmnuts and oil seed cake which are some of the high risk commodities for aflatoxins is about 100 million metric tonnes of which the share of developing countries is over 20 million metric tonnes. The Indian export of 850 thousand tonnes of agricultural commodities and their by-products valued at 100 million US dollars in 1976 have been reduced to 200 thousand tonnes valued at 20 million dollars in 1986 due primarily to the problem of aflatoxins (FAO, 1990, 2004). The trend is continuing at the wake of globalisation. The magnitude of the problem is likely to escalate in the context of the recent ASEAN-(Association of South East Asian Nations) treaty. Loss in foreign exchange to these extents is highly significant for a developing country like India. There have been examples of commodities like chilies exported from India being rejected by Japan, Europe and middle east countries because of aflatoxins (Bhat, 1999; Wilson and Otsuki, 2001). As a comparison to India, the export commodities from Asia region which received attention in the past because of problems of aflatoxin contamination include maize and tapioca in Thailand, groundnut in Indonesia, palm kernels in Malaysia, copra in Sri Lanka, Philippines, pistachio nuts in Iran, and almonds in Afghanistan. Generally, as a consequence of stringent quality specifications, best of the commodities (free of aflatoxins) are exported while sub-standard commodities not acceptable to the foreign buyers are circulated within the country. This situation exacerbates the risk to human and animal health.

The economic cost of including such substandard commodities in the diet of livestock is substantiated in a several case studies in poultry farm in India. As a result of feeding poultry with groundnut cake having 0.7 ppm of aflatoxin the egg production declined as much as 27%. Unfortunately unlike developed countries these studies remain unpublished. In fact, a calculation of the cost burden over a three week period including those of reduced egg production, mortality of birds, additional expenditure on alternate protein sources, medical and analysis expenditure amounted to 3145 US dollars which is over 10% of the initial investment of the poultry farm (FAO, 1990). Apart from the losses mentioned above there are costs incurred by inspection, sampling and analysis before and after shipments; losses attributable to compensation paid in case of claims; farmer subsidies to cover production losses; research, training and extension programme costs; costs of detoxification etc. When combined, these costs may be staggering (Bhat and Miller. 1991).

Prevention and control

Some efforts have been made to reduce the extent of toxins in food and feeding stuff. In addition to the broad categories such as detoxification of foods for example by ammonia process; development of mycotoxin resistant strains and also good agronomic practices such as avoiding water stress, minimising insect damage, appropriate drying techniques, maintaining proper storage facilities and taking care not expose the grains or oil seeds to moisture during transport and marketing, a coordinated research effort involving a multidisciplinary approach is essential.

The Association of South East Asian Nations (ASEAN: http://www.aseansec.org) has a built-in system to monitor food safety and security. The problem of mycotoxins in developing countries is known to ASEAN for over a couple of decades. The 'Grains Working Group' of the ASEAN has developed strategies and action-plan for research and development on fungi and mycotoxins. They recommended certain guidelines for minimising the harmful effects of mycotoxins to human and animal health. These are highly relevant to the Indian situation and probably to many other developing countries in the tropics. The recommendation of ASEAN pertains to four basic areas (Beardall, 1994; ACIAR, 1995) and are listed below.

1. Advocacy: To address the mycotoxin problem in a creative manner (through the use of well prepared briefings suitable for non-technical people) to senior government managers and political decision makers. This process of addressing the issue should involve the health, agriculture/animal husbandry, and trade constituencies. The expected outcome of this would be support for an integrated set of policies to educate farmers, manage toxin concentrations in commodities brought into urban areas as well as to export markets, and appropriate regional and domestic research and development.

2. Education: Production of appropriate information, education, and communication packages to be distributed at all levels/sectors in the food/feed industry with a view to putting in place mycotoxin management strategies. It also stresses the need to strengthen the information exchange both within and between countries.

3. Research and Development: The need to carry out research and development to support the implementation of any mycotoxin prevention programme.

4. International Assistance: Continued support of international assistance from agencies such as the FAO/WHO/IAEA etc. in the form of regional workshops, preparation of reference manuals, networking with other countries, and establishing/maintaining data bases.

Hazard Analysis and Critical Control Point (HACCP) principles as envisaged by the FAO/WHO are thus likely to be among the most effective means of lowering risks and economic losses, especially since prevention of mycotoxin contamination is widely considered more practicable than decontamination (Park et al . 1999). However, an effective long-term strategy for controlling and monitoring mycotoxin risks in developing countries most susceptible to the problem may require technical assistance from public agencies and improved adherence to quality control measures and HACCP principles by the private sector also.

Conclusion

Public health officials are confronted with a complex problem: mycotoxins, and particularly the carcinogenic mycotoxins, should be excluded from food as much as possible. Since the substances are present in foods as natural contaminants, however, animal and human exposure cannot be completely prevented, and exposure of the population to some level of mycotoxins has to be tolerated. Despite the dilemmas, mycotoxin regulations have been established during the past decades in many countries, and newer regulations are still being drafted.

In order to ensure safe food supply free from naturally occurring contaminants, a continuous surveillance of high-risk food commodities for contamination by selected mycotoxins have to be carried out. This also involves monitoring the human and livestock population groups for diseases attributable to mycotoxins. The financial and human investments in this endeavour would be returned in terms of better human and animal health as well as reduced economic losses. The need for controlling mycotoxin associated impact in Indian livestock industry has renewed significance in the context of globalisation and ASEAN-treaty.

The regulations enacted for mycotoxins in food and feed, and those under development, should be the result of sound cooperation between interested parties, drawn from science, consumers, industry and policy makers. Only then can realistic protection be achieved. Weighing the various factors that play a role in the decision making process to establish mycotoxin tolerances is therefore of crucial importance.

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