A Risk Analysis Framework for the Long-term Management of Aflatoxins in Milk

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Abstract—*Balanced diets are gaining importance and milk & milk products have a significant position in that. However, they may also be a source of natural food contaminants that can cause disease. There is an increasing awareness in terms of safety concerns, emerging risks and challenges. Milk and dairy product's contamination with aflatoxin M1 is important problem worldwide especially for developing countries. The presence of the mycotoxins in milk and milk products is highly hazardous for the children, infants and pregnant ladies. This paper presents a framework for transparency, traceability and information flow for management of dairy supply chain networks as prevalent in India. The paper analyses complexity of dairy products as well as processes in terms of both intrinsic and extrinsic factors. For regulatory authorities the risk of consumers from mycotoxins in milk needs to be determined (risk assessment) and evaluated for the risk minimisation (risk management and risk communication). The strict protocols have reduced the contamination of AFM1 in milk and dairy products in developed countries so the same can be adopted by the Indian authorities. Furthermore adopting good harvesting practices, improving analytical facilities, monitoring and implementing strict regulations would avoid or reduce these natural contaminants in milk and ensure the safety of milk and milk products as human food.*

1. INTRODUCTION

The health of population for any country is concomitant to their food-producing ecosystems. The access to safe and wholesome food is a basic requirement for the good health. Balanced diets are gaining importance and milk & milk products have a significant position in that. India is the largest milk producing country in the world, with 137.7 million tonnes of milk produced in 2013-14 [1]. Milk and milk products are highly nutritious food containing many macro- and micronutrients. However, they may also be a source of natural food contaminants that may cause disease. The contamination of the dairy products with aflatoxins is a serious issue, especially for developing countries [2]. The presence of the mycotoxins in milk and milk products is highly hazardous for the children, infants and pregnant ladies. In India about 65% of the milk is unprocessed and directly consumed. In India the unorganized sector processes about 22 per cent of the total 35 per cent of milk processed. The unorganized processors, comprising of small dairies and halwaiis, mainly deal with production of the traditional Indian dairy products and sweets [3, 4]. The unorganized dairy processors, lack investments, equipment and technology necessary for producing high quality dairy products meeting international safety, packaging and transparency standards [3, 5]. These products normally have short life, packed in normal conditions and are sold across the counters [6]. These can be a potential source of hazards for the consumer.

This study is primarily an attempt to highlight the current food safety issues with reference to mycotoxins in the dairy industry at national and international levels. The Scientific data and research in this domain in India is scant; therefore, paucity of literature pertaining to mycotoxin's safety status in milk appears to be a virtual constraint to further elucidate the issue. The study evaluates and develops framework based on the gaps in infrastructure and risk-based approach in the both implementation and enforcement.

2. METHODOLOGY

This paper follows a field study approach and presents findings from studies of various dairy supply chains in India. The conFig. uration of dairy supply chains is almost similar throughout India and the variables in this regard find a great amount of similarity. The analysis is done taking into account the background of Indian conditions and regulatory authorities. During the primary analysis the focus group comprised of academicians, bureaucrats and people associated with dairy supply chain, namely, dairy farmers, milk collectors, processors, distributors as well as retailers and the consumers.

3. AFLATOXINS

Aflatoxins (AFs) are toxic fungal metabolites produced primarily by Aspergillus flavus and Aspergillus parasiticus, but also by Aspergillus nomius, Aspergillus pseudotamarii, Aspergillus ombycis, Aspergillus ochraceoroseus and Aspergillus australis [7]. Aflatoxin B1 (AFB1), aflatoxin B2 (AFB2), aflatoxin G1 (AFG1) and aflatoxin G2 (AFG2) are the major classes of AFs [8]. A range of agricultural products and animal fodder are significantly affected by their presence

[9, 10]. Aflatoxin B1 is the most toxic, carcinogenic, teratogenic and mutagenic class of AFs [11] and is listed as a group I carcinogen by the International Agency for Research on Cancer [12, 13]. The hepatic microsomal mixed-function oxidase system in liver metabolizes Aflatoxin B1 (AFB1) to AFM1 [14]. The excretion of AFM1 starts 12–24 h after the first AFB1 ingestion, which then increases to reach a peak after a few days. The cessation of intake of contaminated feed results in fall of the AFM1 concentrations to undetectable levels after 72 h [15].

3.1 Aflatoxin M1 and its toxicity

Approximately 0.3-6.2% of AFB1 is converted into metabolized AFM1 and excreted in milk, depending on factors such as the genetics of the animals, seasonal variation, the milking process and the environmental conditions [16]. There is positive correlation reported between childhood aflatoxin exposure and growth stunting [17]. Aflatoxins are one of the major etiological factors for hepatocellular carcinoma [6]. It has been calculated that about 27% of the hepatocellular carcinoma cases reported in Southeast Asia are aflatoxin induced [18]. The mutagenic potential of AFM1 is less than AFB1 [19] but still because of the toxic and carcinogenic it is in Group1 [6].

3.2 AFM1 in milk and dairy products

In general it has been observed that aflatoxins are stable during heat-treatments [20-23]. Oruc [24] found that the toxin is stable during cheese storage and ripening. Bakirci [25] has found 13% higher level of AFM1 in yogurt samples as compared to bulk-tank milk samples, but the difference of AFM1 level was not statistically significant. Purchase [26] and Kabak [27] have indicated reductions of up to 32% in AFM1 during heat treatments, while Galvano *et. al.* [28] have indicated that AFM1 is heat stable. In general, aflatoxins are stable during heat treatment [2]. Therefore, to minimize the health risks associated with these toxins, most countries have implemented regulations [29].

3.3. Regulations on aflatoxin M1 in milk and dairy products

The international regulations for the maximum limit for AFM1 in milk and dairy products range from 0 to 1.0 mg/kg are shown (Table 1). The EU limits the total AF levels to no more than 20 mg/kg in lactating dairy feeds and 0.05 mg/kg in milk. Practically, the regulatory limit is defined as the concentration of AFM1 in milk equivalent to 1.7% (range from 0.8 to 2.0%) of the concentration of total AFs in dry matter. Cattle consuming a diet containing 30 mg/kg AFs will excrete milk containing AF residues above the 0.5 mg/kg level [30]. The regulatory limits for AFs in food vary from 0 to 50 mg/ kg [31]. According to the United States regulations, the AFM1 levels should not exceed 0.5 mg/kg. However, the Codex Alimentarius set 50 ng/kg as the regulatory limit and for infant milk and follow-on milk, no more than 0.025 mg/kg is allowed [32]. Similarly, in Austria and Switzerland, the maximum level is only 10 pg/mL for infant food. The tolerance level for AFM1 in milk varies from 0.005 μg in Europe to 0.5 in US. The European Commission [EC] has established a maximum admissible level of 0.05 μg/kg for AFM1 in milk [33]. The maximum permitted limit under Codex Alimentarius Regulations [34] and under the mandatory regulations of India, The Food Safety and Standards Act 2006 [35] for milk is 0.5 μg/kg. This difference in the maximum permitted limits has a direct effect on global trade.

4. FRAMEWORK OF INDIAN DAIRY AND RISK ANALYSIS

India is a tropical country with climatic conditions favourable for the growth of aflatoxigenic fungi. Factors such as prolonged drought, high temperatures, substrate composition, storage time and conditions play an important role in fungal growth and the synthesis of AFs [36]. Siddappa *et. al.* [37] from India reported a mean AFM1 level that ranged from 0.1 to 3.8 mg/L in milk. These levels of AFM1 were comparatively high and would be a serious health hazard for consumers. The extensive variations in AFM1 levels among different studies conducted in South Asia could not only be related to climatic and geographic differences but also due to differences in feeding systems, farm management practices, and analytical methods [38]. During the summer, especially in South Asia, fresh animal feed such as pasture, grass, weeds and green fodder is available. However, due to the shortage of fresh green feed during the winter, more concentrated feeds consisting of wheat, corn and cotton seeds are used. Furthermore, green fodder and hay preserved as silage under inadequate storage conditions may be attacked Aspergillus fungi, and subsequently, AFs may be produced [39-41].

Fig. . 1 depicts the flow of contaminants from the product to the consumer. There are qualitative and quantitative changes in the residues along the line of transport. The conversion of AFB1 to the AFM1 is typically considered a detoxification process because the in vivo carcinogenicity of AFM1 is approximately only 10% of that for AFB1. Furthermore, using in vitro metabolic activation, AFM1 only has 10% of the mutagenicity of AFB1 [42]. The dairy supply chain in developing countries such as India are quite different in terms of small production units and multiplicity of the stakeholders involved with reduced concepts of traceability and verifiability for the consumer [43]. Fig. . 2 depicts the complexity of the dairy supply chain in the India involving complementary supply chains which are interlinked sequentially and/or parallel with precedence relationships for production of number of dairy products. Thus, quality and safety of dairy products depends upon the entire supply chain as the product quality at every stage depends upon product and processes quality at preceding or intermediary stages. The risk analysis model can be utilized by the scientific panel of experts covering aspects like program review, incident reports, inspection results, international scenario, etc. Risk analysis covers the three important aspects: risk assessment; risk management and risk communication. Fig. . 3 shows the framework of risk analysis for the mycotoxins. The samples for the risk assessment can be animal feed, milk and in some advanced cases the consumer samples. Considering the complexity of the authorities in India, these issues require a more extensive application of this framework. The public private partnership is another area which will help in achieving effective control. Development of cost effective testing kits for milk analysis will be a milestone for small establishments. Involvement of academic institutions for testing and facilitation in knowledge building will help them to achieve milk safety.

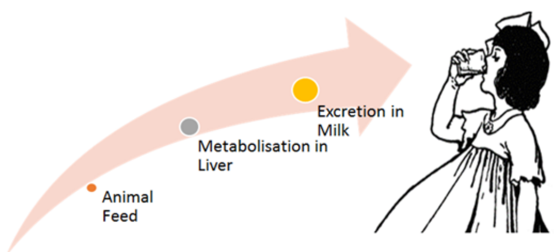

Fig. 1: The route of Aflatoxicosis from farm to humans

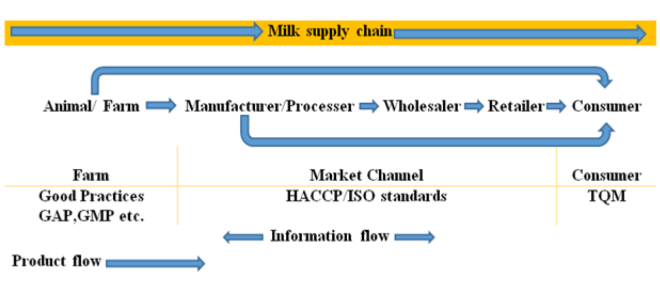

Fig. 2: The Milk supply chain in India and stake holders

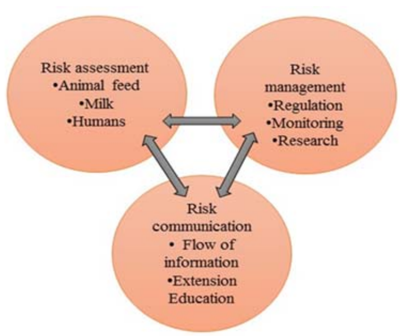

Fig. 3: The risk analysis framework for the dairy industry (Case of mycotoxins)

The process should have interlinks between other ministries like Ministry of Agriculture and Ministry of Health so as to bring the stakeholders on a common platform and to avoid the multiplicity of agencies. This will further facilitate and hasten the process of achieving the objectives of food safety. It is recognized that one of the most effective methods to ensure absence of AFM1 in milk is to monitor the AFB1 in the livestock feed. While developed countries regulate the content of AFB1 in cattle feed, thus ensuring the content of AFM1 within permissible limits in milk and milk products, excepting for China, there are no mandatory limits in India and other Asian countries for cattle feed.

5. CONCLUSION

Aflatoxin M1 in milk and dairy products could be a risk to human as well as animal health. High contamination in feed may result in a significant AFM1 level in milk when animals are fed with highly contaminated foodstuffs. This study shows the importance of continuous aflatoxin level monitoring in animal feed and the necessary implementation of strict regulations. The most popular method for AFM1 analysis in milk and dairy product is HPLC. However, analytical methods that can simultaneously detect and quantify a broad number of mycotoxins in milk with low limits of detection and quantification are needed to reduce analytical costs and to allow more frequent monitoring of mycotoxins in milk. In short, adopting good harvesting practices, improving analytical facilities, and implementing strict regulations would avoid or reduce these natural contaminants in milk and ensure the safety of milk and milk products as human food.

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