Review

Emerging risk management metrics in food safety: FSO, PO. How do they apply to the mycotoxin hazard?

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This review focuses on risk management issues applied to mycotoxins and, in particular, the Codex Alimentarius recommendations for microbiological hazards are considered. Mycotoxins are chemical hazards from microbiological origin, thus some parallelisms can be found. Firstly, a revision of main points regarding risk assessment is done. Then, the existing control measures for risk management of mycotoxins are reviewed and ALOP, FSO and PO concepts are introduced. Finally, an example of the application of these metrics is included: the processing of roasted pistachio is considered. The starting point was the maximum levels in Commission Regulation 1881/2006 for total aflatoxins. Having these values in mind, the process steps were individually considered and PCs determined when required. Moreover, according to these PCs, possible PcC and PdC were calculated, using previously published results. The present study demonstrates that the emerging risk management metrics, FSO, PO and PC, might be also applied to the mycotoxin hazard. The example here presented underlines the need for better and more structured information on the impact of the storage and processing steps on mycotoxins accumulation. Moreover, the problem of the impact of uncertainty in checking PO and FSO compliance was brought up.

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Abbreviations: ADI, Acceptable Daily Intake; AFs, Aflatoxins; ALOP, Appropriate Level Of Protection; aw, Water activity; CAc, Codex Alimentarius Commission; CM, Control Measure; DON, Deoxynivalenol; EC, European Commission; EU, European Union; FAO, Food and Agriculture Organization; FB, Fumonisins; FSO, Food Safety Objective; GAP, Good Agricultural Practice; GHP, Good Hygiene Practices; HACCP, Hazard Analysis and Critical Control Point; Ho, Initial level of the hazard; HPO, Hand Pick Out; HT2, HT-2 toxin; I, Increase of the hazard; IARC, International Agency for Research on Cancer; IPSM, Integrated Phytosanitary Management; JECFA, Joint FAO/WHO Expert Committee on Food Additive; m.c., Moisture content; NOAEL, No Observed Adverse Effect Level; OTA, Ochratoxin A; PAT, Patulin; PC, Performance Criteria; PCC, Process Criterion; PMTDI, Provisional Maximum Tolerable Daily Intake; PO, Performance Objective; PTWI, Provisional Tolerable Weakly Intake; R, Reduction of the hazard; RH, Relative Humidity; RASFF, Rapid Alert System for Food and Feed; SCC, Scientific Committee on Food; SPS, Sanitary and Phitosanitary Measures; T2, T-2 toxin; TDl, Tolerable Daily Intake; U, Measurement uncertainty; WTO, World Trade Organization; ZEA, Zearalenone.

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1. Introduction

Food-borne risks to human health can arise from hazards that are biological, chemical or physical in nature. Food safety generally refers to the prevention of illnesses resulting from the consumption of contaminated food (Akkerman, Farahani, & Grunow, 2010).

A key discipline for further reducing food-borne illness and strengthening food safety systems is risk analysis. During the last several decades, risk assessment, risk management and risk communication have been formalized and incorporated into the specific discipline known as food safety risk analysis. This approach has now gained wide acceptance as the preferred way to assess possible links between hazards in the food chain and actual risks to human health, and takes into account a wide range of inputs to decision-making on appropriate control measures. When used to establish food standards and other food control measures, risk analysis fosters comprehensive scientific evaluation, wide stakeholder participation, transparency of process, consistent treatment of different hazards and systematic decision-making by risk managers. Application of harmonized risk analysis principles and methodologies in different countries also facilitates trade in foods (FAO/WHO, 2006).

World Trade Organization (WTO) members are bound by the provisions of the Sanitary and Phitosanitary (SPS) Agreement, which places risk assessment within a coherent SPS system for developing and applying standards for food in international trade. The scope of the SPS Agreement covers risks to human life and health, and requires that WTO members: i) shall ensure that any measure is applied only to the extent necessary to protect human life and health; ii) shall base their measures on risk assessment, taking into account the techniques developed by the relevant international organizations; iii) may implement a measure that is applied only to the extent necessary to protect human health, and takes into account a wide range of inputs to decision-making on appropriate control measures. When used to establish food standards and other food control measures, risk analysis fosters comprehensive scientific evaluation, wide stakeholder participation, transparency of process, consistent treatment of different hazards and systematic decision-making by risk managers. Application of harmonized risk analysis principles and methodologies in different countries also facilitates trade in foods (FAO/WHO, 2006).

Today in place systems like Hazard Analysis and Critical Control Point (HACCP) are developed to manage food safety, based on risk management principles and cover a range of biological, chemical and physical hazards. The basic idea behind a HACCP system is to provide a structured way to identify food safety risks and reduce or eliminate them (Akkerman et al., 2010). Recently the food safety management approach has been completed and developed through the inclusion of other metrics like the Food Safety Objective (FSO) (ICMSF, 1998). The FSO specifies a goal which can be incorporated into the design of control measurements in the food chain corresponding with the maximum permissible level of a hazard in a food at the moment of consumption which leads to an ALOP. Maximum hazard levels at other levels along the food chain are called Performance Objectives (POs) (Codex, 2007). The application of these food safety approaches to the mycotoxin hazard will be discussed in this review.

2. Mycotoxins: chemical hazards

Mycotoxins are natural contaminants in raw materials, foods and feeds. Some mycotoxins can cause autoimmune illnesses, have allergenic properties and some of them are teratogenic, carcinogenic, or mutagenic (CAST, 2003). The conditions for mycotoxin production by fungi vary widely, but in general, it depends on nutrients availability, moisture level, pH, temperature, strain, and presence or absence of specific gases. Therefore, the presence of potentially toxigenic fungi does not imply the presence of mycotoxins. In addition, the finding of mycotoxins does not prove that a particular fungal species was or is present (Fung & Clark, 2004).

Foods associated with fungal alterations are characterized by a low value of water activity (aw) or a low pH value, where fungi may be imposed on the colonization of bacteria and yeasts. Therefore the main food groups contaminated by fungus are cereals and their derivatives, nuts and fruits (CAST, 2003). On the other hand the major mycotoxin-producing fungal genera are Aspergillus, Penicillium, Fusarium and Alternaria. Nonetheless, although thousands of mycotoxins exist, the most important for public health are aflatoxins (AFs), ochratoxin A (OTA), patulin (PAT), fumonisins (FB), zearalenone (ZEA), and trichothecenes.

2.1. Aflatoxins

In relation with the effects produced in the human health, the most dangerous mycotoxins are the AFs. AFs were identified in the early 1960s, and are mainly produced by Aspergillus flavus and A. parasiticus. Crops usually affected are corn, cotton, peanuts, and certain tree nuts (CAST, 2003). Naturally occurring AFs are AFB1, AFB2, AFG1 and AFG2, being AFB1 the most abundant, toxic and carcinogenic (IARC, 2002). AFM1 and AFM2 are respectively the hydroxilation products of AFB1 and AFB2 where M denotes milk or mammalian metabolites. They are found in milk and dairy products in different countries (Cano-Sancho, Marin, Ramos, Peris-Vicente, & Sanchis, 2010; Prandini et al., 2009; Rahimi, Bonyadjan, Rafei, & Kazemeini, 2010). International Agency for Research on Cancer (IARC) classified naturally occurring AFs as human carcinogens based on the evidence from animal studies, epidemiological studies in exposed populations and mechanistic data. In experimental animals, liver is the predominant tumor site in rats, mice, hamsters, trout, salmon, ducks, tree shrews and monkeys. Tumors at other sites, e.g. kidney, have been observed but are much less common (Wild & Gong, 2010). Exposure to AFs is typically by ingestion of contaminated foodstuff. Dermal exposure results in slow and insignificant absorption (Riley, Kemppainen, & Norred, 1985).

2.2. Ochratoxin A

Ochratoxins were identified in 1965. Filamentous fungi belonging to the genera Penicillium, mainly Penicillium verrucosum, and Aspergillus sections Circumdati and Nigri are recognized
as the source of OTA. In the *Circumdati* section *Aspergillus west-erdijkiae* and *Aspergillus steynii* have acquired more relevance than *Aspergillus ochraceus*, considered for a long time as the main source of OTA (Gil-Serna, Vázquez, Sardiñas, González-Jaén, & Patiño, 2011) and in the *Nigri* section, *Aspergillus carbonarius* is the main OTA producer followed by species belonging to the *A. niger* aggregate (Abárca, Accensi, Cano, & Cabañes, 2004). The mainly contaminated crops are cereals, as well as coffee, wine grapes and dried grapes (Coronel, Marín, Cano, Ramos, & Sanchis, 2011; Hussein & Brasel, 2001; Manning & Wyatt 1984). In the group of ochratoxins ochratoxin B and C also exist, however OTA is the most prevalent and relevant fungal toxin. IARC classified OTA as a possible human carcinogen on group 2B based on the evidence from diverse studies (IARC, 2002). Often, a single mycotoxin can cause more than one type of toxic effect. The common organ affected by OTA toxicity in all mammalian species tested is the kidney, where lesions can be produced by both acute and chronic exposure (Harwig, Kuiper-Goodman, & Scott, 1983), although it affects liver, fat, and muscle tissues too (Krogh et al., 1974). Much has been written regarding the possible role of OTA in etiology of these phenomena and detailed reviews on OTA toxicology have been published (Mantle, 2002).

2.3. Fumonisins

FBs were identified in 1988. They are produced by different strains of *Fusarium* and to a lesser extent by *Alternaria*. Recently, *A. niger* has been reported as FB2 producer (Frissvad, Smidsgaard, Samson, Larsen, & Thran, 2007). They affect a wide range of foodstuffs specially maize (Fung & Clark 2004). In total, 16 different types of fumonisins have been isolated and characterized, however, in naturally contaminated samples, FB1 accounts for 70% of fumonisins presence (Plattner, Weisleder, Shackelford, Peterson, & Powell, 1992). IARC classified FB1 as a possible human carcinogen in group 2B based on the evidence from diverse studies (IARC, 2002). Several studies have described the toxic effects of fumonisins in animals like equineleukocenocephalomalacia (ELEM), hepato-toxic syndrome in horses (Butler, 1902; Kellerman, Marasas, Pienaar, & Naude, 1972), and pulmonary edema in pigs (Kriek, Kellerman, & Marasas, 1981). In humans, fumonisins have been associated with an increased risk of esophageal carcinoma in certain areas (Chu & Li, 1994).

2.4. Patulin

PAT was discovered in 1940s in UK, as a possible treatment against flu. Its production has been detected in genera like *Byssoschlamys, Aspergillus* and *Penicillium*, however *P. expansum* is the main responsible of the accumulation of this toxin in food (Betina, 1989). The foodstuffs affected are mainly apples and pears, but also cereals, nuts and roots or rhizomes (Soriano, 2007: chap. 12). Patulin is a common contaminant of apple juice, concentrated juice, puree, and unfermented cider (Cano-Sancho, Marin, Ramos, & Sanchis, 2009a; Stoloff, 1975). Vifias, Vela, and Sanchis (1993) observed that almost 50% of the apples from fruit cold stores with evidences of blue rotted patulin remain. Therefore, wounded apples may be contain and patulin and this shoulbe taken into account when they are used for juices, concentrated juices or subproducts (Baert, De Meulenaer, Kamala, Kasase, & Devlieghere, 2006; Boonzaaijer, Bobeldijk, & van Osenbruggen, 2005; Göklmen & Acr, 1998). Despite it has been classified as Group 3 (IARC, 1999), the chronic toxicity caused by patulin includes neurotoxic, immunotoxic, genotoxic, teratogenic and possibly carcinogenic effects (Hopkins, 1993; Pfeiffer, Groß, & Metzler, 1998; Wichmann, Herbarth, & Lehmann, 2002). Patulin is not found in either alcoholic fruit beverages or vinegars produced from fruit juices, thus it is reported to be destroyed by fermentation. However, patulin survives pasteurization processes that cause only moderate reductions in patulin levels (Harrison, 1989; IARC, 1986; McKinley & Carlton, 1991; WHO, 1990).

2.5. Zearalenone

ZEA is a non-steroidal estrogenic mycotoxin produced by several *Fusarium* species. It is found around the world in a wide number of cereal crops, ZEA producing species are the major causative fungi of head blight of wheat, barley, and maize (Kawashima & Valente Soares Soares, 2006; Kuiper-Goodman, Scott, & Watanabe, 1987; Tanaka et al., 1988) and their food products, such bread, pastry and bakery products (Aziz, Attia, & Farag, 1997). IARC classified ZEA in group 3 (IARC, 2002). ZEA has been implicated in numerous incidents of mycotoxicosis in farm animals, especially in swine, causing infertility, abortion or other breeding problems (Kanora & Maes, 2009; López et al., 1988). Like other mycotoxins, it can be excreted from mammalians which were nourished with contaminated feed as alpha-zearalenol and beta-zearalenol metabolites. It can also be present in the beer made with contaminated grains (Chen et al., 2000).

2.6. Trichothecenes

Trichothecenes are produced mainly by several species of *Fusarium* but also by *Stachybotrys*, *Trichoderma*, and *Trichothecium*. They are the largest group of mycotoxins, consisting of more than 150 chemically-related toxic compounds classified in four groups, HT-2 toxin (HT2), T-2 toxin (T2) and deoxynivalenol (DON) being the most common. They are usual contaminants of cereals like wheat, barley, oats and maize (Cano et al., 2011). Thus, a wide range of cereal-based foods have been confirmed to be contaminated by these toxins ratifying that food processing methods do not completely remove these mycotoxins from the matrix (Hazel & Patel, 2004; JECPA, 2001). Trichothecenes are strong inhibitors of protein synthesis in mammalian cells causing a wide range of toxic effects in animal and humans such as feed refusal, vomiting, diarrhea, hemorrhage, anemia and immunosuppression (Hussein & Brasel, 2001). Compared to some of the other mycotoxins such as AFs, the trichothecenes do not appear to require metabolic activation to exert their biological activity. Although DON is not as toxic as other trichothecenes such as T2 or HT2, this mycotoxin is one of the most common contaminants of cereals worldwide (Jelinek, Pohland, & Wood, 1989; Scott et al., 1989).

3. Risk assessment for chemical hazards

Chemical hazards in foods include food additives, environmental contaminants such as mercury and dioxins, natural toxicants in food, such as glycoalkaloids in potatoes and aflatoxins in peanuts, acrylamide, and residues of pesticides and veterinary drugs. As opposed to microbiological hazards, chemical hazards usually only enter foods in the raw food or ingredients, or through certain processing steps, and the level of hazard present in a food after the point of introduction often does not significantly change. Moreover, health risks may be acute but are generally chronic, and types of toxic effects are generally similar from person to person, but individual sensitivity may differ (FAO/WHO, 2006). In the particular case of mycotoxins, as chemical hazards from microbiological origin, they may increase in concentration through the processing steps, if conditions are conducive for fungal growth.
3.1. Hazard characterization

During hazard characterization, risk assessors describe the nature and extent of the adverse health effects known to be associated with the specific hazard. This includes consideration of mechanistic aspects (e.g., whether the mechanism of action of the chemical observed in often high dose experimental studies is also relevant to human exposure at lower levels). If possible, a dose–response relationship is established between different levels of exposure to the hazard in food at the point of consumption and the likelihood of different adverse health effects. Adverse health effects are usually predicted for long-term exposure to chemicals. For certain chemicals, such as some mycotoxins, marine toxins, pesticides and veterinary drugs, both acute and chronic health effects need to be considered.

In cases where the toxic effect results from a mechanism that has a threshold, hazard characterization usually results in the establishment of a safe level of intake, an acceptable daily intake (ADI), or tolerable daily intake (TDI) for contaminants (FAO/WHO, 2006). Most mycotoxins are considered to act through a non-genotoxic mechanism. This allows the assumption of a practical biological threshold of effect, and consequently the derivation of a tolerable intake level via the determination of a no observed adverse effect level (NOAEL) for a surrogate biological endpoint and the application of factors to ensure the safety. Tolerable intake, which can be expressed in daily, weekly or monthly basis, is an estimate of the amount of a contaminant that can be ingested over a lifetime without appreciable risk.

Estimation of the ADI or TDI (provisional tolerable weakly intake, PTWI) includes the application of default “uncertainty factors” to a no-effect-level or low-effect-level observed in experimental or epidemiological studies, to account for uncertainties inherent in extrapolating from an animal model to humans and to account for inter-individual variability. Safe levels of intake for the more frequent non-genotoxic mycotoxins occurring in food are shown in Table 1.

Toxicological reference values used by different authorities for (genotoxic) carcinogenic chemicals vary. Some are based on a combination of epidemiological and animal data, some may be based on animal data alone, and different mathematical models may be used to extrapolate risk estimates to low doses. These differences can lead to significant variability in cancer risk estimates for the same chemical (FAO/WHO, 2006). As regards AFs, the Scientific Committee on Food (SCF) expressed in its opinion of 23 September 1994 that AFs are genotoxic carcinogens (SCF, 1999).

3.2. Exposure assessment

Exposure assessment describes the exposure pathway or pathways for a chemical hazard and estimates total intake. For some chemicals, intake may be associated with a single food, while for others the residue may be present in multiple foods. Exposure assessment characterizes the amount of hazard that is consumed by various members of the exposed population(s). The analysis makes use of the levels of hazard in raw materials, in food ingredients added to the primary food and in the general food environment to track changes in levels throughout the food production chain. These data are combined with the food consumption patterns of the target consumer population to assess exposure to the hazard over a particular period of time in foods as actually consumed. For chemicals, exposure assessment often uses values at certain points on the continuum of exposure, such as the mean or the 97.5th percentile (FAO/WHO, 2006).

3.3. Risk characterization

The outcome of the exposure assessment is compared to the TDI in order to determine whether estimated exposures to the chemical in foods are within safe limits.

Risk characterization for chronic exposure to chemical hazards does not typically include estimates of the likelihood and severity of adverse health effects associated with different levels of exposure. A “notional zero risk” approach is generally taken and where possible the goal is to limit exposure to levels judged unlikely to have any adverse effects at all.

For example, considering exposure to OTA, it seems to be in most cases quite below the TDI (14 ng kg⁻¹ bw day⁻¹). Nevertheless, some countries appear to be under a more relevant exposure especially if specific group of consumers are considered, as shown for UK population in the range of 1.5–4.5 years, which overpasses the TDI (SCF, 2002).

Regarding PAT exposure reports seem to be quite below the provisional maximum tolerable daily intake (PMTDI) (0.4 µg kg⁻¹ bw day⁻¹). Nevertheless, some countries seem to be suffering from a more relevant contamination, still under the PMTDI, especially in a worst case situations and if specific group of consumers especially small children are considered (SCOOP, 2002).

Exposure to Fusarium toxins studied was found to be considerably below the TDI values. Higher intakes and a transgression of the TDI values were observed for the group of infants and children. Intakes higher than the TDI were noted for the sum of T-2 and HT-2. For DON, the average intake level did not exceed 46.1% of the TDI of 1 µg kg⁻¹ bw day⁻¹. However, for young children the intake might approach the TDI (SCOOP, 2003).

Quantitative risk assessment methodologies have only rarely been applied for chemical hazards thought to pose no appreciable risk below certain very low levels of exposure, probably because the approach described above has generally been considered to provide an adequate margin of safety without a need to further characterize the risk (FAO/WHO, 2006).

In contrast, quantitative risk assessment models have been applied by some governments as well as by international expert bodies (JECFA) for effects that are judged to have no threshold, i.e., for genotoxic carcinogens such as AFs. These models employ biologically-appropriate mathematical extrapolations from observed animal cancer incidence data (usually derived from tests using high doses) to estimate the expected cancer incidence at the low levels typical of ordinary human exposure. If epidemiological cancer data are available, they also can be used in quantitative risk assessment models (FAO/WHO, 2006). Scientific knowledge allows the identification of a practical biological ‘threshold’ experimentally, or the identification of an exposure level that correlates to an acceptable level of risk, via dose–response modeling and quantitative risk assessment.

### Table 1

<table>
<thead>
<tr>
<th>Mycotoxin</th>
<th>Safe level of intake</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTA</td>
<td>PTWI = 100</td>
<td>JECFA (2007)</td>
</tr>
<tr>
<td>FBs</td>
<td>TDI = 2</td>
<td>SCF (2003)</td>
</tr>
<tr>
<td>PAT</td>
<td>PTDI = 0.4</td>
<td>SCF (2000a)</td>
</tr>
<tr>
<td>ZEA</td>
<td>PTDI = 0.2</td>
<td>SCF (2000b)</td>
</tr>
<tr>
<td>DON</td>
<td>TDI = 0.4</td>
<td>SCF (1999)</td>
</tr>
<tr>
<td>T2</td>
<td>PTDI = 0.06</td>
<td>SCF (2002)</td>
</tr>
<tr>
<td>HT2</td>
<td>PTDI = 0.06</td>
<td>SCF (2002)</td>
</tr>
<tr>
<td>NIVALENOL</td>
<td>PTDI = 0.7</td>
<td>SCF (2000c)</td>
</tr>
</tbody>
</table>
AFs exposure has been correlated to human liver cancer. Observations concerning the interaction between hepatitis B infection and AFs suggest two separate AFs potencies; one is apparent in populations in which chronic hepatitis infections are common, the other in populations in which chronic hepatitis infections are rare. Mean potency values for these two groups were chosen, of 0.3 and 0.01 cancers per year per 100,000 population per ng AFs ingested per kg body weight per day, respectively (JECKA, 1999).

4. Risk management

All these toxicological evaluations are the basis for the existing maximum permitted levels of chemical hazards in food. Analysis of the derivation of maximum levels in food differentiates between the duties of the various risk management and risk assessment bodies. The latter evaluate the health effects and intake of a contaminant (including derivation of values for TDI). Risk managers, by setting maximum levels, consider the outcome of the risk assessment process, the concentration of a contaminant in food, socio-economic arguments, the technical feasibility of derived values and other issues. Because setting maximum levels by the Codex Alimentarius Commission (CAC) and European Union (EU) requires the agreement of independent nations, political debate is also an obvious part of the risk management process (Schneider, Ollroge, Clauberg, & Schuhmacher-Wolz, 2007).

Within the EU, the maximum levels legally bind to all member states. By definition, the Codex Alimentarius values only represent recommendations, yet they have attained a prescriptive character due to their acceptance by the WTO as international hygienic standards.

Food safety measures based on risk assessments are generally designed to reduce risks to a target level, and risk managers must determine the degree of health protection they are aiming to achieve. Through good communication with risk managers, risk assessors will likely have examined the relative impacts of different controls on reducing risks, providing the risk managers with objective data that supports decisions on the most appropriate controls. The overriding objective of risk management is to maximize risk reduction while ensuring that the measures employed are efficient and effective and not overly restrictive (FAO/WHO, 2006). Where chemicals are not intentionally used in food production settings, more specific risk management options often are evaluated (e.g. imposing conditions on harvesting, providing information to consumers so that they can voluntarily limit exposure).

Exposure guidelines such as PTWIs can then provide a reference point for maximum safe intake, and risk management measures can be put in place that aim to prevent consumers from exceeding that safe upper limit of exposure. When other risk modeling approaches are used, such as linear modeling for carcinogenic effects, different risk management options may be identified and evaluated, such as banning or severely restricting the presence of the chemical.

4.1. The ALOP concept

The concept of ALOP was introduced in the WTO Agreement on the application of the SPS Agreement in 1995 (WTO, 1995). An ALOP is defined in the SPS agreement as: “The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory”. The purpose of the SPS Agreement was to increase the transparency of SPS-measures. It is the prerogative of individual Member states to determine what constitutes an ALOP that is appropriate for its population (de Swarte & Donker, 2005). The acceptable level of risk is the level adopted following consideration of public health impact, technological feasibility, economic implications, and that which a society regards as reasonable in the context of and in comparison with other risks in everyday life (van Schotteror, 1998).

An ALOP can be expressed in a range of terms, for instance from broad public health goals to a quantitative expression of the probability of an adverse public health consequence or an incidence of disease (de Swarte & Donker, 2005). This concept was initially defined for microbiological hazards. With mycotoxins, often there is no proof of causality between the hazard and an individual case of a food-borne disease because impacts of chemical hazards may be more chronic in nature. On the other hand the TDI concept is based on scientific considerations, which certainly can be taken into account in the ALOP/FSO approach.

Two main approaches are applied to setting an ALOP in selecting risk management options in the mycotoxin case:

- **Notional zero risk approach.** Hazards are kept at levels that equate to a pre-determined “negligible” or “notional zero” risk, based on a risk assessment indicating that such low exposure levels are reasonably certain not to cause harm. This is the approach applied to most mycotoxins. For the majority of mycotoxins no acute effects are observed thus the dose–response relationship cannot be derived. This approach does not produce precise estimates of risk versus dose and cannot model the impact of various interventions in terms of risk reduction. It thus provides an ALOP that is pre-determined by public policy to be “notional zero risk” (FAO/WHO, 2006).

- **Threshold approach.** Risks must be kept below a specific numerical level as pre-determined by public policy; this approach may be used for chemical hazards, particularly carcinogens. A level of risk that is judged acceptable can be defined by public policy, and risk management measures can then be chosen to keep risk below that “threshold,” sometimes referred to as a “virtually safe dose.” The FSO and ALOP are linked by the dose–response relationship which estimates the risk of illness given a specified consumption of a hazard.

The threshold approach is applied to AFs. The 49th Joint FAO/WHO Expert Committee on Food Additive (JECKA) session held in 1999 took as example, an area with low AFs food contamination and with a population having a small prevalence of carriers of hepatitis B: AFs levels based on European monitoring of AFB1 in peanuts, maize and their products were used, and a population with 1% carriers of hepatitis B was assumed. From the potencies given earlier, this yielded an estimated average population potency of 0.013 cancers per year per 100,000 population per ng AFs per kg body weight per day. Based on European monitoring, if all lots with contamination above 20 µg kg⁻¹ are removed and it is assumed that these foods are ingested according to the “European diet”, the mean estimated intake of AFs is 19 ng per person per day. Assuming an adult human weight of 60 kg, the estimated population risk is 0.0041 cancers per year per 100,000 people. If a 10 µg kg⁻¹ hypothetical standard is applied, the average AFs intake is 18 ng per person per day, resulting in an estimated population risk of 0.0039 cancers per year per 100,000 people. Thus, reducing the hypothetical standard from 20 µg kg⁻¹ to 10 µg kg⁻¹ yielded a drop in the estimated population risk of approximately two additional cancers per year per 10⁶ people, well beyond the level of detection. The second example pertained to areas with higher contamination. For these purposes, Chinese data on AFB1 in peanuts, maize and their products were used and areas with a larger population fraction as carriers of hepatitis B (in this case, a population with 25% hepatitis B carriers was assumed). The estimated potency for this
population is 0.083 cancers per year per 100,000 people. Using 20 μg kg⁻¹ and 10 μg kg⁻¹ hypothetical standards and the “Far Eastern” diet, the average estimated intake was 125 ng AFs per person per day yielding an average population risk of 0.17 and 0.14 cancers per year per 100,000 people, respectively. Thus, reducing the hypothetical standard for this population from 20 μg kg⁻¹ to 10 μg kg⁻¹ yielded a drop in the estimated population risk of 0.03 cancers per year per 100,000 people. This is a greater decrease in risk, but still barely detectable (JECFA, 1999; Pitt, 2004).

The major improvements of the ALOP/FSO methodology relating to risk assessment are i) that current risk assessment focuses mainly on life sciences, while ALOP/FSO methodology must also take into account socio-economic and technological consequences of risk management; consequently, in the future, life sciences, social sciences and engineering need to co-operate more closely to develop integrated scenarios for assessing risk management options, and ii) in order to set meaningful ALOPs and consequent FSOs a better knowledge of the impact of a food safety hazard is needed. Epidemiological data can help gain more insight on the impact and to develop models on major sources of infection and public health impact of food-borne illnesses. Often, epidemiological data are not accumulated in a way that it is directly usable in risk assessment. There is clear room for improvement in that respect (de Swarte & Donker, 2005).

4.2. The FSO concept, a food safety management metric

The FSO is the maximum frequency and/or concentration of the hazard in a food at the time of consumption and is preceded by the PO, which is the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption (ICMSF, 2002), that still provides or contributes to the achievement of an FSO or ALOP, as applicable. While Codex considers FSOs only for microbial hazards (the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection) (CAC, 2003), in principle, the concept could apply to other types of hazards as well.

In this context, the agro-food industry would use FSOs as means to co-ordinate risk management in the production process throughout the farm-to-fork production chain (de Swarte & Donker, 2005). In the particular case of mycotoxins, both mycotoxigenic fungi (which is not a biological hazard per se) and mycotoxins, as chemical hazards, should be controlled.

Once an FSO is set, the food industry is responsible for setting up management systems that deliver a level of food safety in compliance to the FSO. Performance criteria (PC) and other metrics on the operational level can be derived by food industry from FSOs by chain-reversal, in effect articulating appropriate food safety standards for individual links in the chain. Such standards as well as particular control measures that government may choose to mandate should be enforced and inspected by (private and public) certification and inspection systems (de Swarte & Donker, 2005).

In the case of a chemical hazard such as mycotoxins, the limits set by a country for mycotoxins in foods can be logically considered also to have the status of a FSO.

Full implementation of the FSO concept calls for a quantitative FSO so that PO and PC can be specified, and a HACCP plan developed. Ideally, all the approaches described above would converge on an appropriate FSO for a food.

4.3. Meeting the FSO

Good hygiene practices (GHP) and HACCP are the primary tools available to control chemical hazards in food operations. Thus, FSOs must be based on a realistic assessment of what can be achieved through GHP and HACCP.

POs are linked to the FSO and, when proposed by governments, can be viewed as a kind of milestones that governments provide as guidance in order to help meet the FSO. For example, Commission Regulation 1881/2006 sets certain maximum limits for cereals and nuts which still have to undergo physical treatments before direct human consumption. However, POs can also be decided on by operational food safety managers as an integral part of the design of the production of a food in a supply chain.

A PC is the effect of one or more control measure(s) needed to meet or contribute to meeting a PO, while a Control Measure (CM) is any action and activity that can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level (it can be products specifications, guidelines on microbial control, hygiene codes, maximum levels, specific information). There are many different types of CM, instigated by regulation or chosen by the industry, the proper functioning of which needs to be monitored and verified by the industry.

A broad range of CM is used in the food continuum from primary production, processing and manufacturing, transport and distribution, storage and retail to preparation and consumption of the food. CM may include a variety of practices applied at various stages (e.g., good agricultural and animal production practices, good hygiene practices during manufacture and processing, good consumer handling practices) (JECFA, 2006).

CM in the food industry regarding mycotoxins may fall into these activities:

- Ensuring control of initial levels of hazards (e.g. avoiding nuts and spices from certain origins, avoiding raw materials from primary producers not adhering to good agricultural practices, establishing requirement specifications with suppliers and requiring verifiable documentation e.g., letters of guarantee or certificates of analysis attesting the status of microbiological, chemical and physical hazards in the incoming raw material, using sampling and analyses, as necessary, and using appropriate methods based on established criteria to reject unacceptable ingredients or products).
- Preventing an unacceptable increase of hazards
  a) preventing contamination, for example adopting GHPs, that minimize mycotoxin contamination from transport, drying and storage facilities establishments or processing equipment and from the aqueous solutions in fruits and nuts, due to poor renovation. GHPs besides minimize product contamination through cross-contamination between raw and processed product; for the particular case of mycotoxins, it is also important to prevent from contamination by mycotoxigenic fungi, which may further develop and produce mycotoxin in subsequent process stages.
  b) preventing fungal growth during transportation, storage and processing, for example, cold storage of apples, adjusting aw in stored cereals, nuts, coffee or spices, adding preservatives in stored fruits and cereals, controlling temperature and moisture/aw in dehydrating fruits, adjusting storage times, use of packaging techniques and materials to protect food from contamination, or implementing effective controls within the food processing environment (e.g., pest control).
- Reducing or eliminating hazards
  a) selecting ingredients (e.g. applying electronic sorters to reject nuts that are likely to contain AFs, culling fruits for fruit juice production that are likely to contain patulin, rejecting rotten grape bunches that are likely to contain OTA, cleaning of cereals will end in separation of moldy
In pistachios, the dominant mycobiota are Aspergillus spp. and Penicillium spp. (Denizel et al., 1976; Doster & Michailides, 1994a, 1994b). In the case of pistachios, the dominant mycobiota are Aspergillus section Nigri, A. flavus and Penicillium spp (Denizel et al., 1976; Fernane, Sanchis, Marin, & Ramos, 2010).

Several studies have reported that Aspergillus spp. causes decay in nuts in different parts of the world, such as California (USA) (Doster & Michailides, 1994b), Iran (Mojtahedi, Rabie, & Lubben, 1979), and Turkey (Denizel et al., 1976). The most important mycotoxins found are the AFB1, B2, G1 and G2 and OTA. In the last ten years (2000–2010) the Rapid Alert System for Food and Feed (RASFF) notified 7191 alerts, border rejections and information regarding mycotoxins, of which 79.60% were for nuts, nuts products and seeds, 37.13% being for pistachio. The most frequent mycotoxins were AFs (2667 notifications), followed by OTA (5 notifications), besides co-occurrence was reported in two cases (RASFF, 2011).

In 2001, FAO published the Manual of the application of the HACCP system in mycotoxin prevention and control, considering two pistachio processing lines after harvest according to the different procedures applied in Asian producing countries. The fast dehulling process line involves fast dehulling (within 24 h after harvest) for preventing staining, floating segregation and quickly drying to 5–6% water content to prevent fungal development. The objective of this line is to reach a good-condition-for-storing product until it is further processed. This process is followed by the major producing countries. Other countries such Turkey or Syria, based on traditional practices, follow slow dehulling process lines, where pistachios are sun dried and stored for months until they are dehulled, segregated by either flotation and drying or by air gravity separators. Subsequent steps are followed by both lines, including sorting, roasting, packaging and storage/shipping (Fig. 1). Pistachios are sorted to remove closed-shell nuts which are sent to other industries for rehydration and mechanical or manual cracking (Campbell et al., 2003). If required, hand sorting could complete other electronic processes for removing stained nuts and others with visible insect damage (Pearson & Schatzki, 1998); finally, very small and insect damaged nuts are sorted. It is known that high AFs levels are found in very small and insect damaged nuts, becoming this final process an important step to reduce mycotoxin contamination (Schatzki & Pan, 1996).

CAC proposed a maximum level of 15 μg kg⁻¹ AFs total in almonds, hazelnuts and pistachios intended for further processing and a level of 10 μg kg⁻¹ AFs total in ‘ready-to-eat’ almonds, hazelnuts and pistachios (CODEX STAN 193–1995). The European Commission (EC) recently amended the Commission Regulation 1881/2006 through Regulation 165/2010, imposing a maximum AFs level in pistachios to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs of 12 μg kg⁻¹ (AFB1), 15 μg kg⁻¹ (total AFs), of 8 μg kg⁻¹ (AFB1) and 10 μg kg⁻¹ (total AFs) for pistachio intended for direct human consumption or use as an ingredient in foodstuffs.

The aim of the present section is to analyze how the PO, PC, Pcc and Pdc concepts can be applied in the case of a pistachio importing and processing company to guarantee FSO compliance regarding AFs. As most of the existing literature deals with AFB1, in some cases extrapolation to total AFs was done. Taking into account the ∑I and ∑R given by the processing steps, food managers must limit the levels of contaminants in the raw materials (Ho) in order
4.3.1.1. Initial level of AF contamination (Ho). In our case the maximum value of Ho is that set by European Commission EC Regulation for total AFs in pistachios to be subjected to sorting, or other physical treatment, 15 μg kg⁻¹. An established Ho value should lead processing companies to accept only those raw material batches which allow compliance with the final PO of the company in the final product. Evidently the Ho established must be achievable from application of Good Agricultural Practice (GAP) and Integrated Phytosanitary Management (IPSM) which seek to reduce the mold spore count in the orchard and reduce the chances of insect attack (Boutrif & Canet, 1998). These practices can assist in limiting mycotoxins formation, but do not guarantee their absence. Therefore if unrealistic low Ho values were required for assuring the FSO, processing steps might need to be redesigned in order to produce a safe product.

4.3.1.2. Increase of AF during storage and processing (\( \Sigma P_I \)). Increase of AFs concentration is linked to aflatoxigenic molds present in pistachio. The only opportunities for this to happen are those in which conducive environmental conditions occur together with an extended period of time: initial storage of pistachio nuts and storage prior or after final packaging. Roasting is expected to kill fungi, thus, mycotoxin formation after roasting is unlikely, unless further fungal contamination occurs afterward.

During storage steps a zero increase of AFs is desirable (Table 2). Provided pistachios are adequately dried and maintained in the dried state during storage, mycotoxin-producing fungi cannot grow. Environmental conditions like temperature, moisture and atmosphere must be controlled; also a regular fumigation can be adequate for pest control during storage. Storage temperature is a main factor on AFs accumulation in pistachio, with a sharp increase at 25–30 °C; maximum AFs levels were found at 20–30% moisture content (m.c.) in pistachios. For AFs prevention, pistachios should be kept under 10% m.c., alternatively they could be stored at a m.c. as high as 25% under cool conditions (<10 °C) (unpublished data).

Moreover, FAO/IAEA (2001) recommended to reach a m.c. of 5–6% after drying and optimum storage conditions of 10 °C or lower and 65–70% relative humidity (R.H.). Moreover for post-processing storage R.H. below 70% and temperature between 0 and 10 °C is recommended depending on expected storage duration. The lower the temperature the longer the storage life.

4.3.1.3. Reduction in AFs levels during sorting and processing (\( \Sigma P_R \)). As absence of mycotoxins in the raw material cannot be guaranteed, relying on inductial processes for a certain AFs reduction is required.

a) Sorting

It is recognized that sorting and physical segregation significantly reduce the AFs content of consignments of nuts. Mycotoxins are mainly linked to moldy nuts, damaged by insects, small, deformed and discolored ones. Removal of pistachio nuts with high contamination by sorting caused a decrease in contamination of 2–4 times in processed pistachios compared to non-processed pistachios (Schatzki, 1995). Park (2002) quantified the physical cleaning, where mold-damaged kernels, seeds or nuts are removed from the intact commodity, may result in 40–80% reduction of AFs. Schatzki and Pan (1996) related the AFs reduction from pistachios previously partitioned by water flotation with the elimination of the stained nuts, which include the scalpers, the eye rejects, the hand pick out (HPO) insects, the HPO dye floaters, and the meat sinkers. Considering that the company imports dehulled pistachios after flotation separation and drying, the company sorts by size and
only removes the meat and the scalpers. The elimination of this part implies a roughly drop of 26% on the AFs content and 2% of the product (Table 2).

b) Roasting

AFs have high decomposition temperatures, ranging from 237 to 306 °C and AFB1 is quite stable to dry heating (Betina, 1989; Rustom, 1997). Although these temperatures are higher from those actually used by the nuts industry, it is usually accepted that the heat treatment decreases the concentration of AFs to some extent. However conflicting results have been published about the effect of the heat treatments on peanuts and pistachios (Ariño et al., 2009; Farah, Martins, & Bachmann, 1983; Lee, Cucullu, Franz, & Pons, 1969; Ozkarsli, 2003; Pluyer, Ahmed, & Wei, 1987; Rustom, 1997; Waltking, Bleffert, & Kiernan, 1968; Yazdanpanah, Mohammadi, Abouhossain, & Cheraghali, 2005). In general the extent of the destruction achieved was very dependent on the initial level of contamination, heating temperature and time. The effects of heat in naturally contaminated peanuts by oven roasting at 150 °C for 30 min caused a 30–45% reduction of AFB1, while in artificially contaminated peanuts treated under the same conditions, the inactivation was 48–61% (Pluyer et al., 1987). Degradation of aflatoxins in peanuts roasted at 150 °C for 30 min increased with the addition of ionic salts in a range from 38%, 41.5% and 47.6% in unsalted peanuts, and salted with 20 μg kg⁻¹ and 50 μg kg⁻¹ respectively (Ozkarsli, 2003). In pistachio, the results regarding degradation of AFs due to roasting are also contradictory. Yazdanpanah et al. (2005) studied the effect of roasting for 30, 60 and 90 min at different temperatures (90, 120 and 150 °C). The milder treatment (90 °C–30 min) reported slightest effect while the most extreme treatment resulted in the degradation of over 95% of AFB1 but the pistachio showed a burned appearance. The roasting process at 150 °C for 30 min showed significant reduction of AFB1 and AFB2 without any noticeable change in taste of sample. Also the rate of reduction was plotted against the initial amount and linear correlation was not found. On the other hand, Ariño et al. (2009) studied the effect of roasting on AFs: four commercial batches of raw pistachios in-shell from Iran were salted (1% salt content) and roasted at 120 °C for 20 min in a roasting industry in Spain. This study did not obtain significant differences in relation with AFs reduction after roasting. However the level of contamination of the starting material was low, ranging from 0.12 to 0.18 μg kg⁻¹.

Analyzing the existing results on the effect of time and temperature in connection with the degradation of AFs, it can be observed that high temperatures (200–400 °C) produce higher mycotoxin reduction (Fig. 2). Moreover lower temperatures need longer exposition time than higher temperatures for obtaining the same reduction percentages. Thus the percentage of reduction depends on temperature, time as well as the initial mycotoxin contamination (Table 2).

4.3.1.4. FSO, PO and uncertainty. The FSO was taken from the maximum levels in EC Regulation 1881/2006 amending by 105/ 2010 for total AFs (10 μg kg⁻¹). Taking into account the information in the previous subsections, the process steps were individually considered (Table 2) and PCs determined when required. Moreover, according to these PCs, possible PCC and PDC were calculated, using

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Table 2

<table>
<thead>
<tr>
<th>Step</th>
<th>PC</th>
<th>PC C</th>
<th>PDC</th>
<th>PO (μg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage</td>
<td>Zero increase</td>
<td>PC achievable by:</td>
<td>–</td>
<td>≤15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;10% mc any T</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;10°C any mc</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>T &lt; 20 °C mc &lt; 20%</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Sorting</td>
<td>26%</td>
<td>Separation of meats and scalpers</td>
<td>–</td>
<td>≤1.1</td>
</tr>
<tr>
<td>Storage</td>
<td>Zero increase</td>
<td>PC achievable by:</td>
<td>–</td>
<td>≤11.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;10% mc any T</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;10°C any mc</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>T &lt; 20 °C mc &lt; 20%</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Roasting</td>
<td>About 30%</td>
<td>150 °C 20 min</td>
<td>–</td>
<td>≤7.77</td>
</tr>
<tr>
<td></td>
<td>About 40%</td>
<td>150 °C 30 min</td>
<td>–</td>
<td>≤6.66</td>
</tr>
<tr>
<td></td>
<td>About 50%</td>
<td>200 °C 20 min</td>
<td>–</td>
<td>≤5.55</td>
</tr>
<tr>
<td>Storage</td>
<td>Zero increase</td>
<td>PC achievable by:</td>
<td>–</td>
<td>≤7.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;10% mc any T</td>
<td>–</td>
<td></td>
</tr>
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<td></td>
<td>&lt;10°C any mc</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>T &lt; 20 °C mc &lt; 20%</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Distribution</td>
<td>Zero increase</td>
<td>PC achievable by:</td>
<td>–</td>
<td>≤7.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;10% mc any T</td>
<td>–</td>
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<tr>
<td></td>
<td></td>
<td>&lt;10°C any mc</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>T &lt; 20 °C mc &lt; 20%</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Consumer</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>FSO ≤ 10 (10-U) (1881/2006)</td>
</tr>
</tbody>
</table>

U – measurement uncertainty.
previously published results. This process can either be done forward, starting from the PO guideline in the raw material, or backward, starting from the FSO to be accomplished in the final product.

The most common measure of uncertainty is variance. The variance of an estimated parameter statistical dispersion, indicates how far from the expected values are. Hence the results should be reported as "$x \pm 2\sigma$" or "$x \pm U$", where $x$ is the result; and $\sigma$ is the standard measurement of uncertainty. The expanded measurement of uncertainty ($2\sigma = U$) gives a confidence level of approximately 95%, assuming normality of the reported results (Eurochem/CITAG, 2000).

For the particular case of mycotoxins, the maximum level as set in the EC Regulation 1881/2006 (FSO) must be over the final product PO to take U into account. EC Regulation (401/2006) states as criterion for acceptance of a lot or sublot that the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and U. According to the performance criteria for AFs analysis (EC 401/2006, recommended RSDV = 21% for a concentration of 10 µg kg$^{-1}$), calculated U would take a value of 4.224 µg kg$^{-1}$. Thus in this case the PO for the final product should take a value of $10 - 4.224 = 5.776$ µg kg$^{-1}$. Thus, in this example, given the recommended value of U, either the PO or the reception of the pistachio should be lower than 15 µg kg$^{-1}$ or the industrial process might need to be redesigned to comply with the maximum level. Considering the current bibliography plus the associated uncertainty, only a final FSO of 10 µg kg$^{-1}$ could be reached if a reduction of 50% was achieved during roasting.

An additional point which has not been addressed in this example is sampling uncertainty. According to Ozay et al. (2007) sampling uncertainty may account for 99.53% total uncertainty, while U would just be 0.09%. At the moment, the EU project Selection and improving of fit-for-purpose sampling procedures for specific foods and risks is running with the aim of evaluating sampling uncertainty for a range of hazards and sampling plans, including AFs in pistachio nuts. The sampling plans for official control are stated by governments, while the food industry might use different sampling plans for their quality control systems.

As a conclusion, for sampling and determination of AFs concentration there is a need to state the PO for the final product lower than the FSO, taking into account the uncertainty value, U (FSO-U = PO). In Australia, one peanut shelling company sorted peanuts until the mean AFs content of samples from any one lot did not exceed 3 µg kg$^{-1}$ (PO): this provided 95% confidence that any lot would meet the 15 µg kg$^{-1}$ FSO (Pitt, 2004).

4.3.2. The need for predictive modeling to reach performance criteria

When seeking for appropriate PC, PCC and PCdC the authors found a lack of kinetic models from where to draw data for both AFs production in pistachio nuts as a function of storage conditions and AFs inactivation as a function of time, temperature, moisture... From this example it is clear that models are required to adequately adjust PcC, PCC and PC especially during the storage and thermal treatments.

Regarding mycotoxins, Garcia, Ramos, Sanchis, and Marín (2009) described two approaches in the mycotoxin production modeling. One modeling approach is preventing mold growth in all the steps of the production and processing of food and thus indirectly prevent mycotoxin production. The other modeling approach involves directly model mycotoxin production as a function of environmental factors in those steps of the process. However this alternative is associated with several disadvantages as high intra-specific variability in mycotoxin production plus a high variability in the mycotoxin production by a given strain in a given substrate. The application of predictive microbiology in risk management may serve to determine the conditions required to avoid the growth of fungi and therefore the production of mycotoxins in steps such as storage and processing.

Likewise, predictive modeling can be also applied to quantify the mycotoxin reduction through certain processing steps. Ideally, decontamination steps, in addition to assuring an adequate wholesome food supply, should: inactivate, destroy or remove the mycotoxins; not produce or leave toxic residues in the food/feed; retain nutritive value and food/feed acceptability of the product; not alter significantly the properties of the product and destroy fungal spores (Kabak, Dobson, & Var, 2006). Moreover, some processing steps may indirectly destroy mycotoxins. In general, factors that may influence the fate of mycotoxins during food processing include the presence of other constituents and enzymes, m.c. of the raw material, processing temperature, pH, pressure, and the mycotoxin concentration (Scott, 1991). All these variables should be explored and their impact on mycotoxins destruction be modeled. This would provide a valuable tool for PC, PCC and PCdC calculation.

5. Conclusions

The present study demonstrates that the emerging risk management metrics, FSO, PO and PC, might be also applied to the mycotoxin hazard. The example here presented underlined the need for better and more structured information on the impact of the storage and processing steps on mycotoxins accumulation. Moreover, the problem of the impact of uncertainty in PO and FSO compliance was brought up.

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References


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