Risk analysis of mycotoxins by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

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The Joint FAO / World Health Organization (WHO) Expert Committee on Food Additives (JECFA) has been meeting regularly since 1956 to evaluate food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food. To date, the Committee has evaluated more than 1 200 chemicals, including more than 20 contaminants.

JECFA provides scientific advice to the Codex Alimentarius Commission (CAC), primarily through two of its general subject committees, the Codex Committee on Food Additives and Contaminants (CCFAC) and the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). JECFA also provides FAO and WHO member countries with scientific advice on chemicals in food. Because its primary client is CAC, its priorities are generally established by CCFAC and CCRVDF.

To date, JECFA has evaluated three mycotoxins: aflatoxins B, G, and M; patulin and fumonisins. However, governments and CAC are becoming increasingly concerned about the presence of mycotoxins in foodstuffs, as evidenced by the presence of several additional mycotoxins on the CCFAC priority list: fumonisins, trichothecenes and zearalenone for evaluation, and ochratoxin A for re-evaluation. Zearalenone will be evaluated at JECFA's fifty-third meeting in June 1999, but the others are awaiting further data before they are placed on the agenda for evaluation.[1] As with nearly all contaminants, the lack of relevant toxicological and epidemiological data is the primary impediment to the evaluation of most mycotoxins.

OCHRATOXIN A AND PATULIN

The contaminants ochratoxin A and patulin have both been evaluated twice by JECFA. They were re-evaluated at the forty-fourth meeting in 1995, when the previous provisional tolerable weekly intake (PTWI) of 0.1 mg per kilogram of body weight for ochratoxin A was confirmed and a provisional maximum tolerable daily intake (PMTDI) of 0.4 mg per kilogram of body weight was established for patulin. A traditional approach was used in these assessments in that no-observed-effect levels (NOELs) and lowest-observed-effect levels (LOELs) were identified and safety factors were applied to both.

Expression of the tolerable intake on a weekly basis is considered to be appropriate for contaminants that may accumulate within the body over a period of time, as is the case with ochratoxin A. On any particular day, consumption of food containing above-average levels of the contaminants may exceed that day's proportionate share of the weekly tolerable intake. The weekly assessment takes into account such daily variations, with the primary concern being prolonged intake of the contaminant. By contrast, a PMTDI was established for patulin because it does not accumulate in the body and only occasionally is apple juice (the primary route of intake) heavily contaminated.

Levels of ochratoxin A and patulin contamination of foodstuffs and potential intakes of these contaminants were considered by the Committee during their evaluations. However, this information was not included as an integral component of the risk assessment because it was assumed that there is no appreciable risk when intake is below the PTWI or PMTDI.

AFLATOXINS

Aflatoxins were first evaluated at the thirty-first JECFA meeting in 1987. The Committee recognized that aflatoxin B_1 is a well-known potent hepatocarcinogen in all the mammalian species studied, with a wide range of sensitivities. While good data were available on the relationships among aflatoxin levels, duration of exposure and carcinogenicity in animals, the available data on the association between aflatoxin exposure and primary liver cancer in humans were difficult to evaluate because of the large number of uncertainties in these studies, including inadequate data on the dietary intake of aflatoxins, the

[1] JECFA reports are posted on the FAO Web site (www.fao.org / waicent / faoinfo / economic / esn / jecfa.htm).

contribution of hepatitis B virus to the etiology of cancer, and cultural and dietary status and habits. The Committee concluded that the available scientific information was insufficient for determination of the extent to which exposure to aflatoxins contributed to the increased incidence of primary liver cancer in the populations that were studied.

In view of these uncertainties, the Committee was unable to establish a figure for a tolerable intake level. It urged that the intake of dietary aflatoxin be reduced to the lowest practicable levels so that the potential risk could be minimized, and it recommended that efforts should be made to limit the presence of aflatoxins in food to irreducible levels. An earlier Committee meeting had defined an irreducible level as "that concentration of a substance which cannot be eliminated from a food without involving the discarding of that food altogether, severely compromising the ultimate availability of major food supplies".

Subsequent to this evaluation, CCFAC began working on standards for aflatoxin levels in food and feed products, but it has been exceedingly difficult to reach consensus on the maximum levels that should be included in these standards. A major impediment to consensus is that the levels of contamination of foodstuffs vary widely around the world and, with the "irreducible level" recommendation, decisions are made solely on trade grounds.

With respect to trade, the perspectives of delegations differ profoundly. Delegations from countries in which aflatoxin contamination is not prevalent want standards that are based on low maximum levels because they do not wish to see the quality of their food supply degraded. Delegations from countries in which the climatic conditions make aflatoxin contamination a problem naturally wish to have standards in which higher levels of contamination are permitted so that they can trade their products on world markets. In addition, when stringent international standards are used, the populations of these countries are placed at higher risk because products with low levels of contamination are exported, leaving the more contaminated, lower-quality products for domestic consumption.

After a number of years of little progress, CCFAC asked JECFA, at its Twenty-sixth Session in 1994, to provide estimates of the toxicological potency of aflatoxins and to derive estimates of the potential risks for different human populations. In response to this request, aflatoxins B, G, and M were considered at the forty-sixth meeting of the Committee in 1996. However, the evaluation could not be completed at that meeting and it was carried over to the forty-ninth meeting in 1997, when a detailed evaluation was completed (WHO, 1998).

Health risks

The Committee reviewed a wide range of studies, in both animals and humans, that provided qualitative and quantitative information on the hepatocarcinogenicity of aflatoxins. It evaluated the potencies of these contaminants, linked potencies to intake estimates and considered the impact, and overall risks, of hypothetical standards on sample populations.

It was recognized that aflatoxins are among the most potent mutagenic and carcinogenic substances known. Extensive experimental evidence from test species shows that aflatoxins are capable of inducing liver cancer in most of the animal species studied. Most epidemiological studies also show a correlation between exposure to aflatoxin B_1 and an increased incidence of liver cancer, although there is some evidence suggesting that humans are at substantially lower risk from exposure to aflatoxins than test species are. Some epidemiological studies suggest that the intake of aflatoxins poses no detectable independent risk and others suggest that it poses risks only in the presence of other risk factors such as hepatitis B infection.

A number of factors influence the risk of primary liver cancer, most notably carriage of hepatitis B virus which is determined by the presence of hepatitis B surface antigen in serum. The potency of aflatoxin B_1 appears to be significantly enhanced in individuals with simultaneous hepatitis B infection. This interaction makes it difficult to interpret the epidemiological studies and determine the extent to which aflatoxins act as independent risk factors.

The identification of hepatitis C virus is an important recent advance in understanding the etiology of liver cancer. Two studies have investigated interactions among hepatitis C infection, aflatoxins and liver cancer but, so far, the results have been inconclusive. It is estimated that between 50 and 100 percent of cases of liver cancer are associated with persistent infection with hepatitis B and/or hepatitis C.

The Committee considered that the weight of scientific evidence, which includes epidemiological data, studies in laboratory animals and *in vivo* and *in vitro* studies of metabolism, supports the conclusions that aflatoxins should be treated as carcinogenic food contaminants and that their intake should be reduced to levels as low as reasonably achievable.

CARCINOGENIC POTENCY

A number of dose-response analyses have been performed

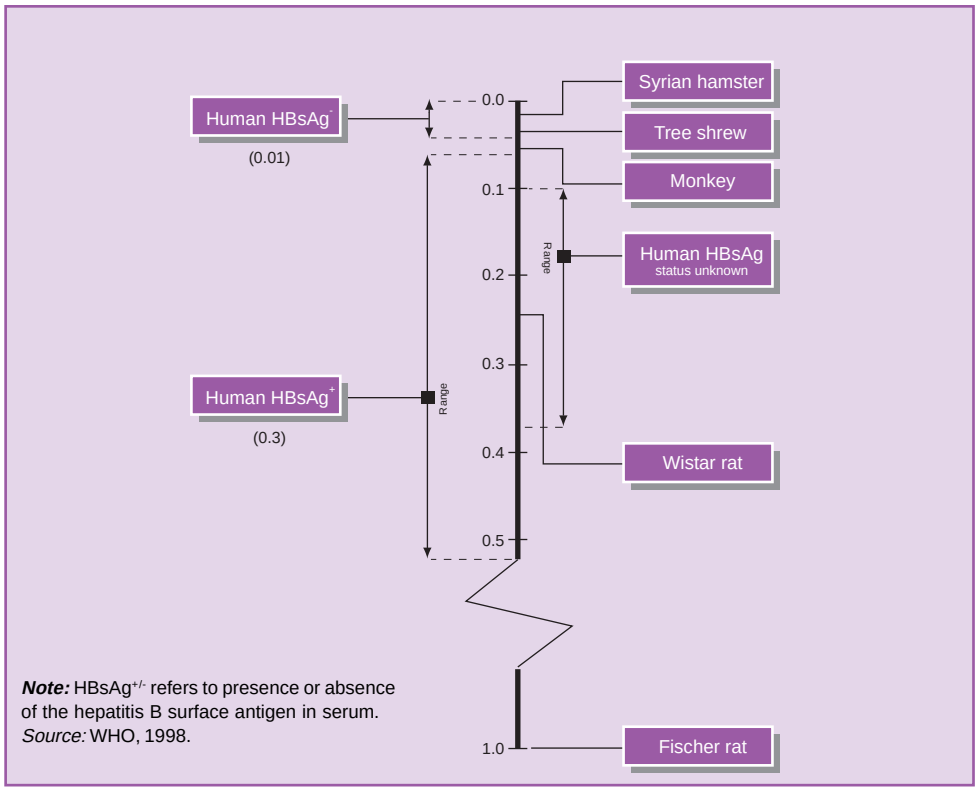
on aflatoxins. However, all of these analyses have limitations, the most important of which are the following:

- All of the epidemiological data from which a dose-response relationship can be determined are confounded by concurrent infection with hepatitis B. The epidemiological data are from geographical areas where the prevalence both of individuals carrying hepatitis B surface antigen and of contamination with aflatoxins are high; the relationship between these risk factors in areas where both of them are low is unknown.
- It is not known how reliable and precise the estimates of exposure to aflatoxins are in the relevant study populations. For example, aflatoxin biomarkers in humans do not reflect their long-term intake.
- The shape of the dose-response curve is also unknown, and this introduces an additional element of uncertainty when choosing mathematical models for interpolation.

Observations relating to the interaction between hepatitis B infection and aflatoxins suggest two separate aflatoxin potencies; one is apparent in populations in which chronic hepatitis infections are common, the other in populations in which chronic hepatitis infections are rare. In analyses based on toxicological and epidemiological data, potency estimates for aflatoxins were divided into two basic groups, potencies applicable to individuals without hepatitis B infection and those applicable to individuals with chronic hepatitis B infection. As can be seen from the Figure, extrapolations of animal data to estimate potencies in humans generally fall within the range of potency estimates derived from the epidemiological data.

In deriving the potency estimates of 0.01 and 0.3 cases per year per 100 000 people, per ng of aflatoxin B_1 per kilogram of body weight per day for hepatitis B surface antigen negative and positive individuals, respectively, the Committee used only those potency estimates from the epidemiological studies that showed a positive association between aflatoxins and liver cancer. Studies in which no association was detected, or in which the association was negative, were not used, leading to an overestimate of aflatoxin potency. Other potential biases included:

- When current levels of intake (measured using biomarkers or dietary surveys) are related to current levels of liver cancer (which is presumed to have a long induction period), historical levels of intake are ignored and, since intakes are likely to have been higher in the past, aflatoxin potency will be overestimated.
- Owing to limitations in the methods used to detect hepatitis B virus, the earliest studies systematically underestimated the prevalence of hepatitis B infection in patients with liver cancer by as much as 20 to 30 percent. This also leads to an overestimation of the relative potency of any other factor, including aflatoxins.
- Histological confirmation of cases of liver cancer is limited in most epidemiological studies, allowing the



Potency estimates for human liver cancer resulting from exposure to aflatoxin B_1 derived from epidemiological and toxicological studies (cancers per year per 100 000 people per ng per kilogram of body weight per day)

possibility that cases of non-primary liver cancer have been included and this too could lead to an under- or overestimation of the aflatoxin potency.

When these biases are taken into account, the values shown in the figure should be viewed as overestimates of the potency of aflatoxins, and it is possible that humans are less sensitive to aflatoxins than the animal species tested in laboratory experiments. Differences in the carcinogenic potency of aflatoxins among species can be partially attributed to differences in metabolism. However, there was insufficient quantitative information available about the competing aspects of metabolic activation and detoxification of aflatoxin B_1 in various species to identify an adequate animal model for humans and to explain the apparent differences in potency among species.

POPULATION RISKS

In a population, the fraction of the total incidences of liver cancer that is attributable to intake of aflatoxins was derived by combining estimates of aflatoxin potency (risk per unit dose) and estimates of aflatoxin intake (dose per person). The frequency and amount of aflatoxin contamination in a number of products were available, and the Committee concentrated on groundnuts, cereals and maize. Many of the data on levels of aflatoxin contamination were derived from non-random samples that appeared to be biased upwards because monitoring studies focus on products that are thought to be contaminated. Some of the data on levels of contamination are not likely to be based on current CAC sampling recommendations for aflatoxins. Accordingly, data on levels of contamination should be interpreted with caution and used only to infer patterns of importance in setting standards and not to provide exact contamination estimates.

Dietary intakes

Mean dietary intakes of aflatoxins for various regions were estimated using regional diets from the Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme combined with data on levels of aflatoxin contamination.

The Committee considered the possible impact of applying two hypothetical standards to aflatoxin contamination – 10 and 20 mg per kilogram. These should not be construed as recommended standards; they were chosen for illustrative purposes only. Governments and CAC should perform this type of analysis for particular standards that are being considered, basing it on their own data on contamination, dietary patterns and prevalence of hepatitis B.

Two examples using these hypothetical standards were developed. In the first example, it was assumed that the level of contamination of food by aflatoxins is low and the proportion of the population that is hepatitis B surface antigen positive is small. Monitoring data from Europe on aflatoxin B_1 levels in groundnuts, maize and their products were used and it was assumed that 1 percent of the population is hepatitis B surface antigen positive. Assuming that these foods are ingested according to the "European diet", the mean estimated intakes of aflatoxins are 19 ng per person per day when a standard of 20 mg per kilogram is applied and 18 ng per person per day with a standard of 10 mg per kilogram. Using the potency estimates shown in the Figure, these intakes translate into estimated population risks of 0.0041 and 0.0039 cancers per year per 100 000 people when standards of 20 and 10 mg per kilogram, respectively, are applied. Thus, reducing the hypothetical standard from 20 mg to 10 mg per kilogram yields a reduction in the estimated population risk of approximately two cancers per year per 1 000 million people.

The second example pertains to areas with higher levels of aflatoxin contamination and a larger percentage of the population carrying the hepatitis B virus. Monitoring data from China on aflatoxin B_1 levels in groundnuts, maize and their products were used, and it was assumed that 25 percent of the population is hepatitis B surface antigen positive. Assuming that these foods are ingested according to the "Far Eastern diet", the mean estimated intakes of aflatoxins are 125 ng per person per day when a standard of 20 mg per kilogram is applied and 103 ng per person per day with a standard of 10 mg per kilogram. Using the potency estimates in the Figure, these intakes translate into estimated population risks of 0.17 and 0.14 cancers per year per 100 000 people when standards of 20 mg and 10 mg per kilogram, respectively, are applied. Thus, reducing the hypothetical standard for this population from 20 mg to 10 mg per kilogram yields a reduction in the estimated population risk of approximately 300 cancers per year per 1 000 million people. These calculations, and the basis for them, are explained in more detail in WHO, 1998 and WHO, 1999.

The differences in population risks between these hypothetical standards are lower than might be expected on a first analysis. However, the results are not surprising when it is considered that, in both cases, the most highly contaminated samples are eliminated, thus greatly reducing average estimated intakes of aflatoxins. The use of standards by all countries should, therefore, be encouraged.

CONCLUSIONS

After reviewing and analysing the data, the Committee came to the following conclusions:

- Aflatoxins are considered to be human liver carcinogens, aflatoxin B_1 being the most potent. Aflatoxin M_1 has a potency approximately one order of magnitude lower than that of B_1.
- The potency of aflatoxins in individuals who carry hepatitis B is substantially higher than in those who do not carry it. Thus, reduction of the intake of aflatoxins in populations with a high prevalence of hepatitis B will result in a greater reduction in liver cancer rates than reduction of the intake of aflatoxins in populations with a low prevalence of hepatitis B.
- Vaccination against hepatitis B will reduce the number of carriers of the virus. The present analysis suggests that reducing the number of carriers would reduce the potency of aflatoxins in vaccinated populations and, consequently, reduce the risk of liver cancer.
- Analyses of the application of hypothetical standards for aflatoxin contamination in food (10 mg or 20 mg per kilogram) to model populations indicate that:
  - populations in which the prevalence of hepatitis B surface antigen positive individuals is low and / or in which the mean intake of aflatoxins is low (less than 1 ng per kilogram of body weight per day) are unlikely to exhibit detectable differences in population risks;
  - populations in which both the prevalence of hepatitis B surface antigen positive individuals and the intake of aflatoxins are high would benefit from reductions in aflatoxin intake.
- Reductions in the intake of aflatoxins can be achieved through avoidance measures such as improved farming and proper storage practices and / or through enforcing standards for levels of contamination in food or feed within countries and across borders.
- When two alternative standards for aflatoxin contamination in food are considered, the higher standard will yield essentially the same risk as the lower standard if the fractions of samples excluded under the two standards are similar. When a substantial fraction of the current food supply is heavily contaminated with aflatoxins, reducing the levels of contamination may result in a detectable reduction in rates of liver cancer. Conversely, when only a small fraction of the current food supply is heavily contaminated, reducing the standard by an apparently substantial amount may have little appreciable effect on health.

FAO and WHO encourage governments and CAC to make use of this evaluation in deciding on the appropriate standards to apply to aflatoxins. Significant resources are required, however, as use of the evaluation requires a significant amount of information at the national level, including monitoring data and information on dietary patterns and the prevalence of hepatitis B in the population. A comforting factor is that risks are significantly reduced when the most highly contaminated samples are eliminated. This can be done without a detailed analysis of the risk, and governments are encouraged at least to take this step if they are lacking the information necessary to make full use of the evaluation carried out by JECFA. ◆

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Risk analysis of mycotoxins by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

The Joint FAO/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) evaluates food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food and provides scientific advice to the Codex Alimentarius Commission (CAC). To date, JECFA has evaluated three mycotoxins: aflatoxins B, G, and M; patulin and fumonisins. Trichothecenes and zearalenone are listed for evaluation at the next JEFCA sessions; and ochratoxin A will be re-evaluated.

In this article, the scientific evidence regarding mycotoxins and liver cancer is assessed and the JECFA conclusions are provided. Aflatoxins are considered to be human liver carcinogens, aflatoxin B_1 being the most potent. Aflatoxin M_1 has a potency approximately one order of magnitude lower than that of B_1. The potency of aflatoxins in individuals who carry hepatitis B is substantially higher than in those who do not carry it. Thus, reduction of the intake of aflatoxins in populations with a high prevalence of hepatitis B will result in a greater reduction in liver cancer rates than reduction of the intake of aflatoxins in populations with a low prevalence of hepatitis B. Vaccination against hepatitis B will reduce the number of carriers of the virus. The present analysis suggests that this would reduce the potency of the aflatoxins in vaccinated populations and, consequently, reduce the risk of liver cancer. Analyses of the application of hypothetical standards for aflatoxin contamination in food (10 mg or 20 mg per kilogram) to model populations indicate that: populations in which the prevalence of hepatitis B surface antigen positive individuals is low and/or in which the mean intake of aflatoxins is low (less than 1 ng per kilogram of body weight per day) are unlikely to exhibit detectable differences in population risks; while populations in which both the prevalence of hepatitis B surface antigen positive individuals and the intake of aflatoxins are high would benefit from reductions in aflatoxin intake.

Reductions in the intake of aflatoxins can be achieved through avoidance measures such as improved farming and proper storage practices and/or through enforcing standards for levels of contamination in food or feed within countries and across borders. When two alternative standards for aflatoxin contamination in food are considered, the higher standard will carry essentially the same risk as the lower standard if the fractions of samples excluded under the two standards are similar. When a substantial fraction of the current food supply is heavily contaminated with aflatoxins, reducing the levels of contamination may result in detectable reductions in rates of liver cancer. Conversely, when only a small fraction of the current food supply is heavily contaminated, reducing the standard by an apparently substantial amount may have little appreciable effect on health. FAO and WHO encourage governments and CAC to make use of this evaluation in deciding on the appropriate standards to apply to aflatoxins. However, this requires a significant amount of information at the national level including monitoring data and information on dietary patterns and the prevalence of hepatitis B in the population.

L'analyse des risques des mycotoxines par le Comité mixte FAO/OMS d'experts des additifs alimentaires (JECFA)

Le Comité mixte FAO/OMS d'experts des additifs alimentaires (JECFA) évalue les additifs alimentaires, les contaminants, les substances toxiques d'origine naturelle et les résidus de médicaments vétérinaires dans les aliments, et donne des avis scientifiques à la Commission du Codex Alimentarius (CAC). A ce jour, le JECFA a évalué trois mycotoxines – les aflatoxines B, G et M – la patuline et des fumonisines; il est prévu que les trichothécènes et la zéaralénone seront évaluées lors des prochaines sessions du JECFA; et l'ochratoxine A fera l'objet d'une réévaluation.

Dans cet article, les preuves scientifiques concernant les mycotoxines et le cancer du foie sont évaluées, et on pourra lire les conclusions du JECFA. Les aflatoxines sont considérées comme des carcinogènes du foie chez l'homme, l'aflatoxine B_1 étant le plus virulent d'entre eux. La virulence de l'aflatoxine M_1 est d'environ un ordre de grandeur inférieur à celui de l'aflatoxine B_1. La virulence des aflatoxines chez les individus porteurs d'hépatite B est nettement plus élevée que chez ceux qui ne le sont pas. Ainsi, la réduction de l'ingestion d'aflatoxines chez les populations qui ont une prévalence élevée d'hépatite B permettra de réduire davantage les taux de cancer du foie qu'une réduction de l'ingestion d'aflatoxines chez des populations qui ont une faible prévalence d'hépatite B. La vaccination

contre l'hépatite réduira le nombre de porteurs du virus. Selon cet article, cela réduirait la virulence des aflatoxines chez les populations vaccinées et donc le risque de cancer du foie. Des analyses de l'application de normes théoriques concernant la contamination des aliments par les aflatoxines (10 mg/kg ou 20 mg/kg) à des populations hypothétiques indiquent ce qui suit: dans les populations où la prévalence d'individus ayant une réaction positive à l'antigène de surface de l'hépatite B est faible et/ou l'ingestion moyenne d'aflatoxines est faible (moins de 1 ng/kg de poids corporel par jour) il est peu probable qu'apparaissent des différences notables du point de vue des risques; alors que chez les populations où la prévalence d'individus ayant une réaction positive à l'antigène de surface de l'hépatite B est forte et où l'ingestion d'aflatoxines est élevée, il y aurait intérêt à réduire l'ingestion d'aflatoxines.

Pour ce faire, on peut prendre des mesures préventives telles que de meilleures pratiques de culture et un entreposage correct et/ou appliquer des normes visant les concentrations de la contamination dans les produits d'alimentation humaine ou animale à l'intérieur des pays et au-delà des frontières. Lorsque deux normes possibles pour la contamination des produits alimentaires par l'aflatoxine sont examinées, la norme supérieure entraînera pour l'essentiel le même risque que la norme inférieure si les fractions des échantillons exclus dans le cadre des deux normes sont similaires. Lorsqu'une part importante des approvisionnements alimentaires courants est fortement contaminée par des aflatoxines, la réduction des niveaux de contamination peut entraîner une baisse sensible des taux de cancer du foie. Inversement, lorsqu'une petite part seulement des approvisionnements alimentaires courants est fortement contaminée, l'abaissement apparemment sensible de la norme peut ne guère avoir d'effet appréciable sur la santé. La FAO et l'OMS encouragent les gouvernements et la CAC à utiliser cette évaluation pour décider de normes appropriées à appliquer aux aflatoxines. Toutefois, cela nécessite de disposer d'une quantité suffisante d'informations au niveau national, y compris des données de surveillance, et des informations sur les schémas alimentaires, et sur la prévalence de l'hépatite B dans la population.

Análisis de riesgos de micotoxinas por el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA)

El Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA) evalúa aditivos alimentarios, contaminantes, sustancias tóxicas naturales y residuos de medicamentos veterinarios en los alimentos y proporciona asesoramiento científico a la Comisión del Codex Alimentarius (CAC). Hasta la fecha, el JECFA ha evaluado tres micotoxinas –las aflatoxinas B, G y M–, la patulina y las fumonisinas; los tricotecenos y la zearalenona serán evaluados en los próximos períodos de sesiones del JECFA; la ocratoxina A será objeto de una reevaluación. En este artículo, se examinan los datos científicos disponibles sobre las micotoxinas y el cáncer de hígado y se ofrecen las conclusiones a que ha llegado el JECFA. Se considera que las aflatoxinas son carcinógenos para el hígado humano, siendo la aflatoxina B_1 la más potente. La aflatoxina M_1 tiene una potencia de un orden de magnitud aproximadamente inferior a la de la aflatoxina B_1. La potencia de las aflatoxinas en individuos que son portadores de la hepatitis B es considerablemente mayor que en los individuos no portadores. Por consiguiente, la reducción de la ingesta de aflatoxinas en poblaciones con una prevalencia alta de la hepatitis B redundará en una reducción de las tasas de cáncer de hígado mayor que la reducción de la ingesta de aflatoxinas en poblaciones con una baja prevalencia de la hepatitis B. La vacunación contra la hepatitis B reducirá el número de portadores del virus. El presente análisis sugiere que si se reduce el número de portadores se reducirá la potencia de las aflatoxinas en las poblaciones vacunadas y por consiguiente el riesgo de cáncer de hígado. Estudios sobre la aplicación de normas hipotéticas para la contaminación de alimentos con aflatoxinas (10 mg/kg o 20 mg/kg) a modelos de población indican que las poblaciones en las que la prevalencia de individuos positivos al antígeno superficial de la hepatitis B es baja y/o en la que la ingesta media de aflatoxinas es baja (inferior a 1 ng/kg de peso corporal al día) no mostrarán probablemente diferencias detectables en los riesgos para la población; las poblaciones en las que tanto la prevalencia de individuos positivos al antígeno superficial de la hepatitis B como la ingesta de aflatoxinas son altas resultarían beneficiadas si se redujera la ingesta de

aflatoxinas. La reducción de la ingesta de aflatoxinas puede conseguirse mediante medidas preventivas como por ejemplo sistemas de cultivo mejorados y prácticas de almacenamiento adecuadas o mediante la aplicación de normas relativas a los niveles de contaminación en los alimentos o los piensos dentro de los países y entre ellos. Cuando se examinan dos normas alternativas para la contaminación de alimentos con aflatoxinas, la norma más rigurosa dará esencialmente el mismo resultado en lo que respecta al riesgo que la norma menos rigurosa si la fracción de muestras excluidas en las dos normas es análoga. Cuando una parte considerable del suministro de alimentos está altamente contaminada con aflatoxinas, la reducción del nivel de contaminación puede dar lugar a una reducción detectable de las tasas de cáncer de hígado. Por el contrario, cuando sólo una pequeña parte del suministro de alimentos está altamente contaminada, puede que la reducción del nivel en una cantidad aparentemente considerable tenga pocos efectos apreciables sobre la salud. La FAO y la OMS instan a los gobiernos y al CAC a que utilicen esta evaluación para decidir las normas apropiadas que han de aplicarse a las aflatoxinas. Sin embargo, ello requiere un volumen considerable de información a nivel nacional, incluidos datos de seguimiento, información sobre hábitos alimentarios y prevalencia de hepatitis B en la población. ◆