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ANALYSIS OF PUBLIC HEALTH RISK OF MYCOTOXINS GETTING INTO THE FOOD CHAIN, WITH SPECIAL REGARD TO AFLATOXIN AND OCHRATOXIN CONTAMINATION OF PAPRIKA MARKETED IN HUNGARY

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1. Background of the research and its objectives

A number of toxic compounds of natural origin threaten human health. Mycotoxins have the greatest importance among them due to their public health and worldwide economic influence. Acute and chronic toxic, potent carcinogenic effects and frequent occurrence in various commodities make aflatoxins (AF) and ochratoxin A (OTA) the most dangerous mycotoxins types. Their risk to human health varies according to continent, region, country depending on the level of contamination of foodstuffs, consumption patterns and population's health condition (other illnesses, nutrition, resistance etc.). All of the above mentioned facts make necessary the introduction of risk assessment on national level for evaluation of the level of risk to the population's health.

The internationally accepted method for determination and mitigation of public health risk is Risk Analysis. The dissertation follows the classic principles of Risk Analysis, namely Risk Assessment, Risk Management, Risk Communication applying them to AF and OTA contamination of paprika marketed in Hungary.

Most studies do not concern spices among the significant sources of AF and OTA intake because of their small proportion compared to other food ingredients in the diet. The role of paprika in exposure to mycotoxins due to the high paprika consumption in the Hungarian diet was highlighted in the media when high level contamination with AF and OTA was detected in paprika in 2004. Complex analysis of the food investigation data and the scientific assessment of risk related to the event have not been conducted yet.

This study intent to describe and assess the risk of the Hungarian population from mycotoxins contamination of paprika and to give recommendation for prevention based on worldwide and Hungarian data, scientific statements and consideration of the Hungarian events in 2004.

The objectives of this study were to answer the following questions:

- What are the characteristics of the distribution and occurrence of mycotoxins in the samples?
- How high is the exposure of the population to aflatoxins and ochratoxin A from paprika?
- Does the risk to Hungarians defer from that to Europeans and if it does, why and in what extent?
- What factors affect the national risk assessment?
- Does the present legislation and control system in Hungary and in the EU ensure the appropriate protection of consumer's health?

- What measures are needed to improve the situation in Hungary?

2. Materials and methods

Complete risk analysis was carried out by following the steps of Risk Assessment, Risk Management and Risk Communication for evaluation the case of contamination of paprika with mycotoxins in Hungary in 2004.

The exposure assessment was performed using national food contamination and consumption data.

The AF and OTA contamination of paprika was assessed by comparative analysis of the results provided by two governmental and one private accredited laboratory for the period of the years of 2000 - 2006 for AF and 2004-2005 for OTA. For risk assessment, data with specified contamination level or LOD (Limit of Detection) were only used. Qualitative results reported as “acceptable” or “not acceptable” have not been considered.

The average, maximum, minimum, median, and standard deviation of mycotoxins concentration were calculated, and the proportion of samples above LOD and legal limits (non-compliances) were determined. The evaluation was carried out by using MS Excel software. Results were compared according to laboratories and years.

For food consumption data, the Hungarian paprika consumption was assessed based on a representative national survey carried out in 2003 and evaluated by the National Institute for Food Safety and Nutrition. The results were compared to the GEMS/Food consumption data for the European region, other data (from FAO, USDA etc. sources) and the data on consumption per capita from the Hungarian paprika sales statistics.

Risk Characterization was carried out by comparing the results of the abovementioned calculations with the European data and considering the characteristics of the Hungarian population’s health condition.

Data for the evaluation of the risk management and risk communication was collected from governmental sources, reports, laboratories, press, media, Internet, scientific papers and interviews with officials, representatives of the paprika industry and consumers.

3. Results

3.1. Occurrence and distribution of mycotoxins contamination in paprika

Neither AF nor OTA shows a normal distribution in paprika samples. The distribution is continuous but not symmetrical and it is extremely skewed towards the high contamination

levels. The distribution dominated by samples with very low contamination or even below the limit of detection, but on the other hand there were batches with extremely high contamination (maximum level of was AFB_1 96,28 μg/kg, OTA 284 μg/kg), and the calculated mean contamination level was increased by the highly contaminated lots.

The mean OTA contamination value could be decreased by more than 50 % by elimination of the 5% of the highest contaminated lots. Both harmful mycotoxins, AF and OTA were present together in 48.1% of total paprika samples, and moreover, in 5.1% of samples both mycotoxins were found above the official tolerable limit. However, there was no correlation between the concentrations of the two types of mycotoxins occurring in the same sample. According to our study, the ratio of the most potent carcinogen AFB_1 to the *total* AF was between 62-83%, and there was good linear correlation between them.

Studying the mean contamination on yearly basis, it can be stated, that batches highly contaminated with aflatoxins were placed on the market in 2004, whose contamination level exceeded the average of the previous years. The average of AFB_1 was 0.76 μg/kg in 2000-2003 and it increased to 2.48 μg/kg with a total AF of 3.96 μg/kg by 2004. After the implementation of drastic measures the average fell significantly in 2005, and it was similar (0.79 μg/kg) to those observed prior the event of 2004.

The contamination of paprika with OTA is of importance too. The average contamination was at the national limit of 10 μg/kg both in 2004 (10.23 μg/kg) and 2005 (10.04 μg/kg). No decline of OTA concentration could be observed yet in 2005.

3.2. Exposure of population to AF and OTA from paprika

The Hungarian consumption of paprika is at least four times higher than the European average (1.3 g/day – 0.3 g/day). Based on the Hungarian paprika consumption data (1.3 g/day) the average AFB_1 intake from paprika was 0.98 ng/person from 2000 to 2003 and increased to 3.25 ng/person in 2004. The exposure calculated from the Hungarian data was 0.017 ng/day/bwkg between 2001- 2003 and 0.54 ng/day/bwkg in 2004. This exposure level from paprika alone amounts to 5-10 % of total AFB_1 intake from all relevant food sources of some other European countries. Exposure of big eaters or consumers of highly contaminated lots could exceed several times the average European intake from all sources. According to ALARA (As Low As Reasonable Applicable) principle there is no safe or tolerable level of intake of AFB_1, so the lowest possible level should be reached. Comparing the AF contamination level of paprika to other food items, the pistachio proved to be the highest contaminated product. Apart from pistachio, paprika and spice mixtures and foods containing

paprika were the most contaminated products with AF. $AFB_1$was found even in meat products containing paprika as ingredient.

The daily OTA intake from paprika was 13 ng/person/day i.e. 0.22 ng/kgbw/day in 2004. Comparing this level of exposure to some other European countries, the OTA intake solely from paprika is equal to 10-20 % of total OTA intake from all relevant food sources in those countries. The worst case scenario is where a large eater consumer consumes from one of the most contaminated batches leading to a daily intake as high as 24 ng/kgbw/day (148 ng/kgbw/week) solely from paprika. The EFSA estimated a maximum tolerable weekly intake of 120 ng/kgbw/week for OTA in 2006. The EFSA study did not considered spices among possible sources of OTA. In contrast, the comparison of the OTA contamination level of paprika with other food items revealed that paprika contained the highest contamination in Hungary. High OTA contamination was detected even in foods, and meat products prepared with paprika as ingredient.

Based on the results it can be stated that paprika, and ready-to-eat meals with high paprika content have important role in exposure of Hungarians to mycotoxins, AF and OTA. The reasons are the higher paprika consumption than the European average and the high contamination of paprika with AF and OTA. In 2004 11% and 19% of consumers ate foods containing paprika which exceeded the official tolerably limit for AFB_1 and OTA, respectively.

4. Conclusions and recommendations

4.1. Conclusions

4.1.1. National risk assessment: conditions and obstacles

Due to the fact that the dietary preferences of Hungarians defer significantly from the European average, national risk assessment necessary and reasoned. For the national risk assessment there is an urgent need for reliable food consumption data on national level for every food categories. Likewise, exact food contamination data are needed from representative sampling plans. The national patterns and customs of purchasing, preparing and consuming food are of importance as well. In Hungary the paprika consumption results in continuous and regular mycotoxins intake, as a commercial package of paprika lasts for weeks for a family, or for months in cases where the paprika bought in big quantity was used for preparation of home-made sausages or other products. For those persons who bought from

the highly contaminated lots, the risk is manifold. The national risk analysis should take this phenomenon into account.

The accurate execution of risk assessment and the comparison with other food categories were hindered by the inaccuracy of the Hungarian data collection, management and registration and the lack of planned systematic monitoring and exact Hungarian food consumption data. There are only few data on other important food categories that are possible sources of mycotoxins, e.g. cereals, so the total AF or OTA intake on national level could not be estimated. However, it can be stated that paprika is one of the mostly contaminated food for both AF and OTA and that the contamination is characteristic for the processed products containing paprika such as meat products, ready-to-eat meals and spice mixtures as well.

4.1.2. Effectiveness of risk management in consumer's health protection

The legislation in European Union regarding mycotoxins is the strictest one all over the world. The maximum tolerable limit for AFB_1 is 5 μg/kg, for total AF it is 10 μg/kg in spices. There is no limit for OTA in EU for paprika so far. However, Hungary has national limit of 10 μg/kg OTA for spices as well. In 2004 during the paprika scandal the risk management was characterized by initial uncertainties, delayed or inefficient measures followed by sudden drastic decisions resulting in communication crisis in food safety. Although the measures and the communication had some controversial features, the decision proved to be efficient and the average AF contamination level of paprika fell back to that of before the special events. The risk management and communication stressed only the presence of AF while the similar level of OTA was not really considered. The fact that the contamination with OTA did not reduce yet in 2005 suggests that this phenomenon has to be studied further to explore the reason and to establish prevention measures.

4.1.3. Public health situation as an influencing factor

AF and OTA may contribute to the risk of development of chronic liver diseases and cancers. The health risk is already significantly higher in Hungary than the European average with a morbidity rate that is 7.5 times higher from chronic liver diseases and 2.5 times higher from cancers.

4.2 Recommendations

4.2.1. Recommendations for risk assessment

- In order to achieve objective and authentic assessment of exposure of population to mycotoxins national monitoring system for mycotoxins based on representative official

sampling should be introduced. This monitoring system shall cover all possible sources including paprika and all potent mycotoxins including AF and OTA as well.

- The analysis for monitoring purpose should be carried out with the use of the most sensitive methods available and give accurate results reporting the LOD/LOQ (Limit of Detection /Limit of Quantification) too. The results shall be recorded and stored in such a way, that they can be retrieved for analysis and evaluation at national level.
- National risk assessment needs reliable food consumption data, the collection of them must be planned and started as soon as possible.
- Accurate data are needed on contamination of paprika with mycotoxins harvested in Hungary. The possibility of mycotoxins production in paprika in relation to the changes in climate should be assessed. The level of contamination of paprika with OTA and the possibility of contamination with high amount of toxin under the Hungarian climate shall be investigated.
- Further investigations are needed on the co-existence of mycotoxins and their interactions including molecular inter-action mechanism, degradation and route of excretion.

4.2.2. Recommendations for risk management

- Establishment of limit for OTA in the European Union shall be initiated and a consistent national position should be represented based on the Hungarian results.
- The prevention and control shall have the greatest importance in risk management.
- The official and the in-house control should be enhanced, especially for the imported products.
- Guidelines for the Good Agricultural Practices and Good Manufacture Practices shall be developed, published and their application shall be required in order to decrease contamination.
- The primary responsibility of food business operators shall be stressed.
- The control of suppliers and of supplied/imported batches prior to use are important tools in prevention.
- Screening batches in order to exclude the extremely high mycotoxins contamination is efficient tool to decrease the average mycotoxins intake. Rapid tests, simple, less sensitive laboratory methods could be applied in official control and by the manufacturers for screening the highly contaminated lots. Analysis for AFB_1 alone is sufficient for conformity check. These suggestions contribute to cost-efficiency and time-saving, thus beneficial for promoting the protection on public health.

- Reliable analytical results shall prove the high quality and the low contamination level of Hungarian paprika. The internal quality assurance system and the strict official control must assure the traceability. It needs clearly defined data on the origin of the products.
- Strict control is needed for preventing the blending of highly contaminated lots with low contaminated products. Although this is prohibited in EU, technology of paprika-processing makes it easy to carry out.

4.2.3. Recommendations for risk communication

- The important and explicit role of proper risk communication in prevention and crisis management should be stressed. Communication strategy should be elaborated for avoidance of panic and for better understanding of necessary measures. Special attention is needed for the authentic communication concerning the unavoidable presence at very low concentration of highly toxic contamination in the food chain.
- Results of monitoring tests shall be available for experts and the citizens must be informed in a proper form.
- The media shall be informed through plain, understandable and authentic press releases.
- If researches prove the high quality and low mycotoxins content of Hungarian paprika, the results have to be shown as an advantage in marketing communication in order to restore the reputation and market position of this national product.

5. New research results

1. I proved by exact calculation that paprika lots highly contaminated with aflatoxins and ochratoxin A were marketed in Hungary in 2004. As a consequence, the mean level of AFB_1 contamination (2.48 μg/kg) exceeded manifold the average mean level of previous years, with maximum as high as 96.28 μg/kg. The mean OTA concentration was also high (mean: 10.23 μg/kg; max: 284 μg/kg). Based on the special Hungarian paprika consumption pattern, which is significantly higher than that is in the European Union, the mycotoxins contamination imposes an increased risk to the Hungarian consumers, especially extreme exposure derived from the consumption of the highly contaminated lots.

2. The characteristic of the distribution of mycotoxins in paprika was analyzed. It has been found that the distribution is not normal, not symmetric although continuous and it

is extremely skewed towards the high contamination levels with the majority of low-contaminated samples below or around the limit of detection.

3. Both AF and OTA were present in 48.1% of paprika samples with 5.1% above legal limits. Though no correlation could be established between their concentrations, the frequent co-existence of these highly toxic substances justifies special attention in the assessment of their risk.

4. The ratio of AFB_1 to total AF was analyzed, and close correlation was established with R^2=0.959. AFB_1 adds up to more than 50% of total AF (63-82%). According to this finding the analysis for AFB_1 solely would be sufficient for compliance tests, as lots complying with the 5 µg/kg AFB_1 limit would also comply with the 10 µg/kg limit for total AF.

5. It was demonstrated that the paprika is a significant source of intake of AF and OTA in Hungary, which amounted to 5-10% of the average of the European intake in case of AF and 10-20% of that of OTA in 2004. This fact has not been considered in international risk assessments so far.

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