

SCIENTIFIC OPINION

Statement on recent scientific information on the toxicity of Ochratoxin A¹

EFSA Panel on Contaminants in the Food Chain^{2,3}

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ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to assess recent scientific information on the toxicity of ochratoxin A and, if necessary, to update its opinion on ochratoxin A in food adopted on 4 April 2006 by the Scientific Panel on the Contaminants in the Food Chain (CONTAM Panel). Five publications, most of which were from one research group, were submitted to the European Commission. The CONTAM Panel noted that four of these publications address the possible co-exposure to ochratoxin A and aristolochic acid of the human population in areas previously identified as having a higher prevalence of Balkan Endemic Nephropathy, the etiology of which has not yet been established, and the pathologies related to these two substances. In addition, a new method of analysis for multiple mycotoxins was presented in one of the papers, including data from breakfast cereals from the French retail market. The links to the respective abstracts are provided in the Appendix. The CONTAM Panel acknowledged the additional scientific information presented in the publications provided by the requestor. The Panel concluded that the nature of the information provided by these papers was not relevant to the overall assessment of the risks related to food contamination with the mycotoxin ochratoxin A, and as a consequence neither contradicts nor changes the conclusions drawn in the EFSA's opinion on ochratoxin A in food. An update of the opinion on ochratoxin A, on the basis of the submitted papers, is therefore not necessary.

KEY WORDS

Ochratoxin A, food, nephropathy

1 On request from the European Commission, Question No EFSA-Q-2010-00038, adopted on 19 May 2010.

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SUMMARY

The European Food Safety Authority (EFSA) was asked by the European Commission to assess recent scientific information on the toxicity of ochratoxin A and, if necessary, to update its opinion on ochratoxin A in food adopted on 4 April 2006 by the Scientific Panel on the Contaminants in the Food Chain (CONTAM Panel). Five publications, most of which were from one research group, were submitted to the European Commission. The CONTAM Panel noted that four of these publications address the possible co-exposure to ochratoxin A and aristolochic acid of the human population in areas previously identified as having a higher prevalence of Balkan Endemic Nephropathy, the etiology of which has not yet been established, and the pathologies related to these two substances. In addition, a new method of analysis for multiple mycotoxins was presented in one of the papers, including data from breakfast cereals from the French retail market. The links to the respective abstracts are provided in the Appendix. The CONTAM Panel acknowledged the additional scientific information presented in the publications provided by the requestor. The Panel concluded that the nature of the information provided by these papers was not relevant to the overall assessment of the risks related to food contamination with the mycotoxin ochratoxin A, and as a consequence neither contradicts nor changes the conclusions drawn in the EFSA's opinion on ochratoxin A in food. An update of the opinion on ochratoxin A, on the basis of the submitted papers, is therefore not necessary.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	3
Background as provided by the European Commission.....	4
Terms of reference as provided by the European Commission.....	4
Evaluation.....	4
1. Introduction	4
2. Assessment of recent scientific information on the toxicity of ochratoxin A.....	4
References	5
Appendix	6
Abbreviations	7

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

The Commission received in April 2009 a letter from the Law Firm “Philippe and Partners” (ref. COM500689/DOH/CHU) mentioning that the maximum levels of ochratoxin A established by Commission Regulation (EC) 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in food⁴ should be modified. The reason given for this request is that the conclusions of the opinion of the Scientific Panel on Contaminants in the Food Chain from EFSA on ochratoxin A in food,⁵ on which EU legislation on ochratoxin A is based, are contradicted by recent scientific publications.

Given that some of the publications referred to in the letter have been published after the adoption of the scientific opinion, EFSA is requested to assess the provided scientific information and to consider, if an update of the scientific opinion is necessary.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Art. 29 (1) of Regulation (EC) N° 178/2002, the European Commission asks the European Food Safety Authority to assess the provided scientific information on ochratoxin A and, if necessary, to update the opinion of the Scientific Panel on Contaminants in the Food Chain from EFSA on ochratoxin A in food.

EVALUATION

1. Introduction

Ochratoxin A is a mycotoxin that occurs following fungal invasion in a variety of plant products such as cereals, pulses, beans, beer, wine, grapefruit juice, cacao products, spices and nuts as well as in some animal-derived products. Exposure of experimental and farm animals to ochratoxin A results in characteristic renal pathologies. The risks for consumers associated with the dietary exposure to ochratoxin A have been evaluated by the previous Scientific Committee on Food (EC, 1996, 1998), the Joint FAO/WHO expert Committee on Food Additives (JECFA) in 1991 (FAO/WHO, 1991), 1995 (FAO/WHO, 1995) and 2001 (FAO/WHO, 2001) as well as more recently by European Food Safety Authority’s (EFSA) Panel on Contaminants in the Food Chain (CONTAM Panel) which adopted its opinion on ochratoxin A in food on the 4th of April 2006 (EFSA, 2006). The outcome of the EFSA opinion was a threshold-based approach using the lowest observable effect level of 8 microgram per kg bodyweight (b.w.) for early markers of renal toxicity in pigs (the most sensitive animal species) and applying a composite uncertainty factor of 450 for the uncertainties in the extrapolation of experimental data derived from animals to humans as well as for intra-species variability. Based on this assessment, a tolerable weekly intake of 120 ng/kg b.w. was derived for ochratoxin A.

2. Assessment of recent scientific information on the toxicity of ochratoxin A

Five publications, most of which were from one research group, were submitted to the European Commission. The CONTAM Panel noted that four of these publications address the possible co-exposure to ochratoxin A and aristolochic acid of the human population in areas previously identified as having a higher prevalence of Balkan Endemic Nephropathy, the etiology of which has not yet been established, and the pathologies related to these two substances. In addition, a new method of analysis

⁴ OJ L 364, 20.12.2006, p. 5.

⁵ Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to ochratoxin A in food, adopted on 4 April 2006, The EFSA Journal (2006) 365, 1-56. Available from http://www.efsa.europa.eu/en/scdocs/doc/contam_opej365_ochratoxin_a_food_en.pdf.

for multiple mycotoxins was presented in one of the papers, including data from breakfast cereals from the French retail market. The links to the respective abstracts are provided in the Appendix.

The CONTAM Panel acknowledged the additional scientific information presented in the publications provided by the requestor. The Panel concluded that the nature of the information provided by these papers was not relevant to the overall assessment of the risks related to food contamination with the mycotoxin ochratoxin A, and as a consequence neither contradicts nor changes the conclusions drawn in the EFSA's opinion on ochratoxin A in food. An update of the opinion on ochratoxin A, on the basis of the submitted papers, is therefore not necessary.

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APPENDIX

Below are given the links to the abstract of the reviewed papers, if available:

- Arlt VM, Ferluga D, Stiborova M, Pfohl-Leszkowicz A, Vukelic M, Ceovic S, Schmeiser HH and Cosyns JP, 2002. Is aristolochic acid a risk factor for Balkan endemic nephropathy-associated urothelial cancer? *International Journal of Cancer*, 101, 500-502. No abstract available.
- Molinie A, Faucet V, Castegnaro M and Pfohl-Leszkowicz A, 2005. Analysis of some breakfast cereals on the French market for their contents of ochratoxin A, citrinin and fumonisin B1: development of a method for simultaneous extraction of ochratoxin A and citrinin. *Food Chemistry* 92, 391-400. Abstract available from http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T6R-4D7K2R3-3&_user=3324955&_coverDate=09%2F30%2F2005&_alid=1342500190&_rdoc=1&_fmt=high&_orig=search&_cdi=5037&_docanchor=&view=c&_ct=12&_acct=C000060275&_version=1&_urlVersion=0&_userid=3324955&md5=843422062b6494012141a151c415e92f.
- Pfohl-Leszkowicz A, 2008. Chapter 7. Formation, persistence and significance of DNA adduct formation in relation to some pollutants from a broad perspective. In: *Advances in Molecular Toxicology*. Vol 2. Fishbein JC (Ed), Elsevier B.V., 183-239. This review is a book chapter.
- Pfohl-Leszkowicz A, 2009. Ochratoxin A and aristolochic acid involvement in nephropathies and associated urothelial tract tumours. *Arhiv Za Higijenu Rada i Toksikologiju*, 60, 465-483. Abstract available from <http://www.ncbi.nlm.nih.gov/pubmed/20061248?dopt=Citation>.
- Pfohl-Leszkowicz A, Tozlovanu M, Manderville R, Peraica M, Castegnaro M and Stefanovic V, 2007. New molecular and field evidences for the implication of mycotoxins but not aristolochic acid in human nephropathy and urinary tract tumor. *Molecular Nutrition & Food Research*, 51, 1131-1146. Abstract available from <http://www.ncbi.nlm.nih.gov/pubmed/17729220>.

ABBREVIATIONS

b.w.	body weight
CONTAM Panel	Panel on Contaminants in the Food Chain
EFSA	European Food Safety Authority
JECFA	Joint FAO/WHO expert Committee on Food Additives