**FRUCOM POSITION ON SUGGESTED POSSIBLE NEW AND REVISED MAXIMUM LEVELS FOR OCHRATOXIN A (OTA)**

FRUCOM, the European federation of the trade in dried fruits and edible nuts, has always followed developments in the EU regulatory approach on Ochratoxin A and has actively participated and expressed its views & concerns in the successive OTA forums organised by the European Commission since 2001. Recently, FRUCOM has also contributed to the EFSA opinion on OTA and organised two mycotoxin forums in dried fruit, nuts and peanuts.

We welcome the opportunity to provide our comments in response to the targeted stakeholder consultation on the suggested possible new and revised maximum levels for OTA in certain foods.

We would like to express our concerns regarding the proposed maximum levels for Ochratoxin A in dried vine fruits, dried figs, dried fruit, pistachios and seeds. In this respect, we wish to stress the importance of taking into close consideration the following elements before engaging into any further regulatory steps.

**Comments on the EFSA opinion which has led to the current stakeholder consultation:**

The CONTAM Panel concluded "that it is **not possible to establish a causal link** of exposure to OTA and adverse effects observed in epidemiological studies in humans". EFSA recognises that "the evidence for a direct interaction of OTA with the DNA is inconclusive", and concedes that an extremely high safety margin, that is "the MOE of 10,000 for substances that are directly genotoxic and carcinogenic **may not be appropriate** in this case because **the evidence for a direct interaction of OTA with the DNA is inconclusive**".

The EFSA opinion states that the most important contributors to the chronic dietary exposure to OTA were 'Preserved meat', Cheese' and 'Grains and grain-based products'. We note in the occurrence table a very high number of samples of dried figs (1936), or 27% of the total number, but a very small number of pork ham (56), despite mean values being similar, or only 15 cheese samples. These data show that the most consumed products are tested at much lower rate compared to dried fruits. We also see that most of the data come from Germany and the Netherlands. **Dried fruit has a very low contribution. Nuts are hardly mentioned** in the opinion.

FRUCOM has asked an expert[1] to investigate the main contributors to high level intakes for infants, toddlers and children. The top five contributing foods to high level (P95) intake in each population group of infants, toddlers and other children were identified:

| Food group | Number of occurrences | % |
|---|---|---|
| Cheese | 46 | 27% |
| Fruit beverages | 35 | 21% |
| Cereal products | 32 | 19% |

1 FRUCOM has investigated the main contributors to high level intakes by applying the use levels provided in Table 3 of the Annex in the CEDEM exposure model (Tennant D R, 2016. Food Additives & Contaminants: Part A, 33:5, 772-781.), which used the same EFSA Comprehensive European Food Consumption Data, also coded at FoodEx levels 2/3.

| | | |
|---|---|---|
| Meat products | 25 | 15% |
| Other | 14 | 9% |
| Dried fruit | 9 | 5% |
| Liquorice | 7 | 4% |

**The principal sources of high-level exposure were cheeses, fruit beverages, cereal products and meat products.**

Data obtained in the Rapid Alert System for Food and Feed (RASFF) portal were used in the exposure assessments. Data reported in RASFF are likely to be from highly targeted samples taken as part of enforcement activities. The high proportion of data originating from Germany and the Netherlands may reflect the existence of national limits in those countries. If sampling is undertaken for enforcement purposes, the results may not reflect typical OTA contamination levels.

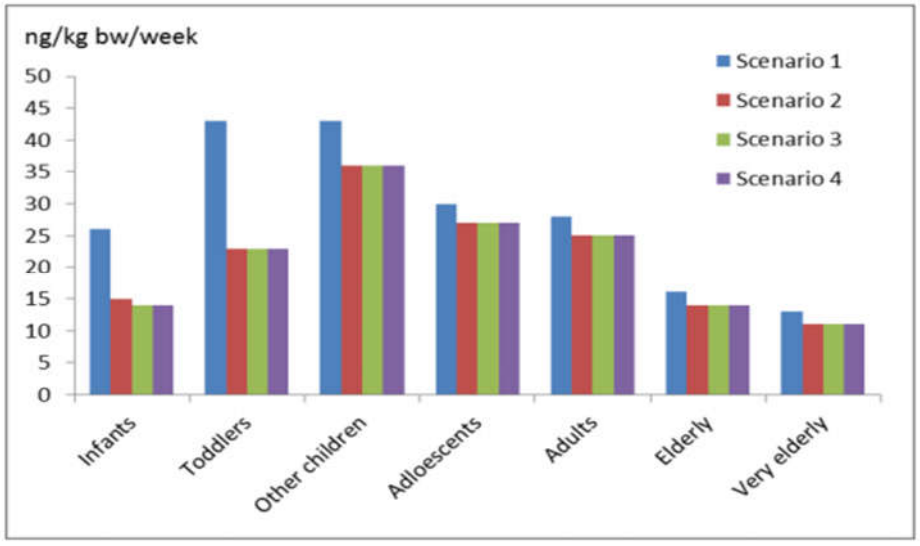
The assessment also recognises **high uncertainty and possible overestimation of the risk**.

Companies in our sector have consistently implemented policies to reduce contamination, which is naturally occurring and is not due to unproper storage or handling.

In the past, FRUCOM commissioned an expert study on the impact on potential consumer exposures to ochratoxin A from the proposed setting of maximum levels for certain dried fruits and nut products, in accordance with EFSA methodology, which was shared with the authorities. The study assessed the potential intakes of OTA under 4 scenarios.

“Estimates of intake based on published OTA occurrence data without applying any maximum limits (Scenario 1) ranged up to 43 ng/kg bw/week for high level consumers. The average contribution of dried fruit, oilseeds and nuts to total intakes from all sources in Scenario 1 ranged from 0.5% for adolescents to 3.3% for toddlers. After applying the current regulatory maximum limits described in Scenario 2, high level intakes ranged up to 36 ng/kg bw/week. Average and high level intakes were on average 36% lower following the application of current maximum limits. The application of additional maximum limits for dried figs and pistachios (Scenario 3) and for other dried fruits, seeds and nuts (Scenario 4) did not result in any further significant reductions in average or high level intakes “(Figure 1).

### Figure 1. Potential maximum high level intakes of OTA under exposure scenarios



Scenario 1 – Data on levels of occurrence based on levels reported in the literature.
Scenario 2 – Data censored using the maximum limits set out in the current Regulation.
Scenario 3 – Data censored using proposed maximum limits for figs and pistachios.
Scenario 4 – Data censored using all current and proposed maximum limits.

**Dried vine fruit (currants, raisins and sultanas), dried figs and dried fruit**

Currently regulatory limits for Ochratoxin A (OTA) cover a range of products including cereals, coffee, wine, grape juice, and spices in addition to dried vine fruit (DVF). The exposure to OTA due to consumption of dried fruit, nuts and seeds is minimal for the vast majority of consumers. In 2006, it was calculated that dried fruit including dried vine fruit were found to contribute only to 3% of overall OTA intake. A maximum level of 10 ppb was introduced for DVF, main product as regards quantity consumed in the category of dried fruit.

Dried vine fruit

Considering the low consumption of DVF compared with other main contributors such as cheese, preserved meat and grain-based products, **we ask the Commission to retain the existing maximum level of 10 ppb for DVF.** The decrease of the maximum level to 8ppb will not have a significant impact on protecting consumer health, but it will negatively impact trade. OTA toxins form at the orchard and therefore yearly conditions prevailing during maturation and drying effect on toxin formation. A maximum level of 8ppb might be difficult to be met for some DVF, for example currants of Mediterranean origin, in a year with unfavourable conditions.

Dried fruits

The consumption of the remaining dried fruits, including dried figs is minimal. The overall consumption of dried fruits by the European population is very low (2.9 g per day according to WHO-GEMS/Food, 2003) and cannot stand comparison with any of the major food products consumed in the EU that are major contributors to OTA exposure. Moreover, the consumption of each type of dried fruit is very unevenly distributed throughout the EU, products' preferences and consumption habits varying strongly from one Member State to the other. This very low consumption of dried fruit other than dried vine fruit by European consumers strongly suggests that consumer exposure to OTA due to these specific products is very minimal. The Aegean Exporters' Associations report on OTA provides further data on import, export and consumption of dried grapes, dried figs and dried apricots of Turkish origin. The report "Turkish dried fruit: ochratoxin A report" is shared with the Commission by the Aegean Exporters' Associations.

In addition to the minimal consumption, most of the dried fruits are treated with additives, such as sorbates or sulphites as preservatives. This effectively prevents mycotoxin (OTA) contamination. Part 2 of annex 1 provides information for OTA in various fruits and pistachios.

For many products, the consumption is minimal. Setting the levels will increase the burden on the operators while not achieving any significant change in consumer protection. Furthermore, in the occurrence data considered in the EFSA assessment, the number of samples for some dried fruits was very low; for dried apples, dried pears, dries mangoes and dried bananas, there were only 11, 5, 4 and 3 samples respectively.

Therefore, we ask the Commission not to set any maximum levels for OTA for dried fruits other than DVF as such limits are unnecessary from a health protection standpoint.

In case that maximum levels are set for dried fruit, we ask the Commission to increase the suggested maximum limit to 10 ppb for some dried fruit (pitted fruit with high moisture content or dried fruit without preservatives). Our data and the feedback we received from our members suggest that some of such products might not comply with the proposed limit of 2ppb (see table 1 & table 2).

Table 1. Data of natural dried apricots

| Product | No. samples | Crop | Positives | Range of positive values | >2 ppb |
|---|---|---|---|---|---|
| Natural apricots | 27 | 2018-2020 | 8 | 0,65 - 13,24 | 4 |
| % | | | 29,6% | | 14.80% |

Aegean Exporters' Associations report concludes that further research and data are required prior to setting up any limits for OTA presence in dried apricots.

Table 2. Data of dried mulberries

| Product | No. samples | Crop/Year | Positives | >2 ppb |
|---|---|---|---|---|
| Dried mulberries | 4 | 2016 | 3 | 0 |
| Dried mulberries | 6 | 2017 | 4 | 0 |
| Dried mulberries | 7 | 2018 | 2 | 1 |
| Dried mulberries | 8 | 2019 | 3 | 0 |
| Dried mulberries | 3 | 2020 | 3 | 1 |

Processed date products

In addition, a limit of 2 ppb will be difficult to be met for further processed dried fruit products. Data collected on dates and date processed products (product composition: 100% dates) show that there is no correlation between the OTA level in the raw material (dates) and the OTA level in the processed date product. All the analytical results of dried dates were below the detection limit while the results for the processed product (made from these dates) were always detectable within a variable range. It should be noted that OTA contamination or OTA development during storage of the dates is very unlikely due to the product characteristics (water activity below<0,75) and the storage conditions (packaging, dry and cold environment, short storage time). Neither can the manufacturing process of date products be a source of OTA formation or OTA contamination.

We believe that the absence of OTA contamination in the analysed dates (raw material) and the presence in extremely variable levels of OTA in the produced product indicates a possible problem in the methodology used for sampling and/or analysis of OTA in dates. OTA contamination is heterogeneous and the analytical results of dried dates does not reflect the real OTA occurrence in dates. An analysis performed by Meyer Science estimated a maximum level for date processed products of 25 ppb based on the 95$^{th}$ percentile of the available data on these products (around 780 samples). Based on the above, we ask the Commission not to set a maximum level for dried dates and date processed products. In case a maximum limit for dates is adopted, we ask the Commission to set a maximum level of 25 ppb[2] for date processed products. More data regarding processed date products and the risk assessment of Meyer Science are enclosed in annex 2.

2 Based on a risk analysis carried out by Meyer Science to estimate an internal standard for maximum OTA levels.

Dried figs

Regarding the proposed maximum levels for dried figs, we believe that setting maximum levels for dried figs is premature due to the absence of an appropriate sampling plan. The existing sampling plan for aflatoxin will create analytical errors when used for figs, due to their size and the distribution of OTA contamination, which is even more uneven than for aflatoxins. This point is further stressed in part 1 of annex 1.

The research on OTA in figs appears to be one of the more comprehensive of the category "dried fruit, except DVF, and nuts". In accordance with the findings, OTA contamination in figs is not linked to inappropriate storage; it is difficult to manage prior to harvest, implementation of GAP had no marked effect on OTA contamination frequency or concentrations, the frequency of OTA varies more than aflatoxins, OTA and black mould relationship is of lower significance. All these factors make it impossible at present to introduce levels as low as reasonably achievable.

A dietary risk assessment was performed by the Department of Risk Assessment under the Turkish Ministry of Food, Agriculture and Livestock (MoFAL) in order to assess the effect of occurrence data and possible levels of 8, 12 ,15 and 20 ppb of OTA in dried figs on public health. The study included adult and toddler groups and considered the consumption data of Turkey. Dietary exposure was calculated for average and high consumption. The outcome of the study is that there is no significant difference between dietary exposure calculated with the possible levels of 8 and 15ppb. It could be concluded that these levels will have a minimal impact on consumer exposure.

Therefore, we ask the Commission not to set a maximum level for OTA on dried figs. If a maximum level is adopted, we ask the Commission to increase the proposed maximum limit to 15ppb. Some data are provided in part 3 and 4 of annex 1.

**Pistachios**

As with dried fruit, the consumption of nuts, including pistachios, is very low and the contribution of pistachios to OTA exposure is minimal. According to the International Nuts and Dried Fruit Council (INC), per capita consumption in Germany is the highest in Europe, with an average consumption of 0.38 kg/year. The most recent EFSA opinion does not refer to tree nuts, including pistachios, as a significant source of dietary exposure to OTA. Therefore, at this time, the setting of maximum levels and the proposed maximum levels for pistachios do not appear to be risk-based, nor do they demonstrate that these levels would result in any additional health benefit. However, they are potentially trade restrictive, which will place an economic burden on suppliers and producers. Further studies are needed to demonstrate the contribution of tree nuts to the dietary exposure to OTA.

The frequency of OTA contamination in pistachios can differ significantly according to the crop year. OTA contamination is associated with insect damage to pistachios. According to our members, there are “good” and “bad” years concerning pest damage. In “bad” crop years, it is expected that the levels of OTA contamination will be higher and, most probably, a higher percentage of the pistachio crop will exceed the proposed maximum limit of 5ppb. There are currently no CODEX maximum levels for OTA for tree nuts. In the EU, only the Netherlands currently applies a *de facto* limit of 10ppb for pistachios. Legislation in the Netherlands does not establish a specific maximum level for OTA in pistachios, but in practice a maximum level of 10 ppb is applied, which is based on the limit of 10 ppb for dried grapes (raisins) in EU legislation. Notably, the Netherlands’ authorities take into account an expanded measurement uncertainty of 50%, which means that the Netherlands’ food safety authorities only take action when the level of OTA in nuts is above 20 ppb. However, this does not indicate that there is an on-going or pervasive number of violative consignments, nor does it support the view that pistachios present any risk to consumers.

The proposed limit of 5 ppb for OTA is significantly lower than the maximum limit for aflatoxins in pistachios, which is a confirmed genotoxic/carcinogenic contaminant as opposed to OTA, and the de facto limit applied by the Netherlands. It is unclear why a significantly restrictive limit for pistachios is being proposed, when no market or risk-assessment data is available to support this level. The EU should provide its risk assessment and verifiable information on the reason for setting the maximum level for OTA in pistachios at the proposed level.

Furthermore, OTA contamination is heterogeneous which means that it does not contaminate every nut. Analysis performed in pairs of pistachio and pistachio paste show that there is no correlation between the OTA contamination levels in pistachios and that in the produced product (pistachio paste). Data are provided in table 4.

Table 4. Data of pistachio and pistachio paste

| Product | Number of samples | <5ppb | >5ppb & <15ppb | >15ppb |
|---|---|---|---|---|
| Pistachios | 10 | 10 | 0 | 0 |
| Pistachio paste | 10 | 2 (20%) | 1 (10%) | 7 (70%) |

In the absence of sufficient and detailed information that demonstrates an obvious need for regulatory measures, **we believe that no maximum limit for OTA for pistachios should be set at this time. If adopted, however, such level should not be set below 15 ppb** and a re-evaluation of the set limit should be undertaken as soon as new scientific evidence becomes available. In addition, pistachio processed products should be excepted if a maximum level for OTA is adopted on pistachios.

The proposed maximum level of 5 ppb for pistachios will cause constraints in pistachios trade and may limit the supply of pistachios to the EU. Therefore, trade facilitation mechanisms, such as those used for aflatoxins, should be available if maximum levels for OTA were to be set. Such an example is the Belgian facility that has recently been authorised for re-working non-compliant pistachios and which was developed by the US pistachio industry in cooperation with the Belgian Federal Agency for the Safety of the Food Chain (FAVV) within the framework of the Pistachio Export Aflatoxin Reporting (PEAR) programme.

<u>In summary, FRUCOM's major concerns on the proposed maximum levels for OTA in all dried fruit and pistachios are:</u>

- The overall consumption of these products in the EU is marginal compared to other food commodities. The resulting OTA exposure of European consumers due to these products is therefore minimal and, all things considered, do not constitute a major threat to consumers' health that would call for stringent regulatory measures.

- OTA maximum levels should only be set provided that a comprehensive and detailed risk assessment clearly demonstrates a reduction of the real risk for European consumers.

- In view of the lack of information on the prevention of OTA contamination of each of these products, their daily intake and the risk of OTA exposure related to their consumption, the setting of a maximum limit for dried fruits, other than DVF, or for pistachios does not seem currently fully justified.

- Any discussions on OTA maximum levels should take account of the existing technical limitations existing for the control of OTA contamination in these products, as well as the sampling protocols

**Based on the above elements, FRUCOM calls on the Commission:**

a) **to retain the maximum level of 10ppb for dried vine fruit**
b) **not to set a maximum limit for dried figs or to set it at 15ppb**
c) **not to set a maximum limit for other dried fruit. We highlight that for some specific types (mulberries, non-sulphured apricots) 2 ppb are insufficient and the level should be 10ppb**
d) **if a maximum level for dates is adopted, to set a maximum limit for date processed product at 25 ppb or above**
e) **not to set a maximum level for pistachios or to not set it below 15 ppb unless scientifically justified. Pistachio processed products should be excepted if pistachio maximum level is adopted.**

# ANNEX 1

**Part 1**

**Practical implementation: difficulties in application of the Regulation 401/2006 on sampling and analysis**

It is stated in the EFSA opinion[3] that OTA that "the random nature of fungal contamination of raw material (such as cereals, fruit and coffee) and thus the uneven distribution of subsequent OTA contamination is a major issue". "In general, literature data on the occurrence of OTA frequently fails to supply adequate detail as to the selection of samples, and *one needs to guard against skewed data if targeted samples e.g. only suspect samples were analysed*".

- Regulation 401/2006[4]sets out the methods for analysis for aflatoxins, which we understand will be used to analyse ochratoxin A. it establishes that for example for figs, which are notorious for uneven distribution of OTA contamination, groundnuts and nuts for consignments up to 15 tons, there should be up to 100 incremental samples taken, aggregated samples of up to 30 kg, mixed, divided into laboratory samples, separately ground finely and mixed thoroughly to achieve complete homogenisation. The same Regulation establishes that if it is not possible to follow above rules, alternative method may be applied, provided it is as representative as possible and is fully described and documented.

- From a practical perspective, these stringent rules are not always being followed in practice at the moment of sampling. Product specific sampling methods are important.

- There is no study that shows aflatoxin sampling will prove the same for OTA since the frequency and levels vary widely according to the product and the year. The sample size of 30 kg can be appropriate if a joint analysis of aflatoxins and OTA is done in one lot. If there is a need to take two 30 kgs from a small lot, then there will be a significant loss. If the sample size is smaller, the accuracy will be in discussion.

- The EU Commission has reminded FRUCOM that it is the Member States' competence to enforce the controls. We doubt however that it is possible and proportionate to carry out testing in line with the existing protocol at border crossings. Non-adherence to sampling protocol will result in false positives, undue rejections and consequently, maintain this product on the special measures with no benefit for the consumer.

- Any reflection on the levels to be set for OTA need to take into consideration the discussion on sampling, and a thorough analysis of the sampling protocols used when exceedances are being reported.

**Part2**

**BRIEF OVERVIEW OF OTA IN VARIOUS DRIED FRUIT AND PISTACHIOS**

**Dried Figs (Ficus domestica)**

There are technical difficulties involved in managing OTA levels in dried figs. We note two major areas of concern, one being the limited consumption and therefore dietary exposure to OTA from consumption of dried figs, and the second being the natural process of the fruit being pollinated by a parasitic wasp, that can inoculate the fruit with *Aspergillus spp.* in doing so.

[3] Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to Ochratoxin A in Food, Question N EFSA-Q-2005-154, p.9

[4] Commission Regulation 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Figs are partially dried on the tree as the dates. OTA starts on the tree even before fig fruits become mature. Aflatoxins start at maturation. OTA contamination in figs is not linked to inappropriate storage and is difficult to manage prior to harvest.

For all fig varieties and for some date varieties the skin is not protective as it is in vine fruit. It is well known that the presence of black mould spots in dried figs does not always indicate high occurrence of OTA. Very roughly around 40 % of black mould are Ochratoxigenic and may produce OTA if all conditions are suitable. The frequency of OTA contamination in figs can differ significantly according to the crop year and to the quality of the products, hot and humid years being more difficult. Important variations of OTA contamination are function of the presence of different ochratoxigenic fungal species and the different virulence between the strains.

In figs, the frequency of OTA varies more than aflatoxins. Aflatoxins may vary between 1-2 % yearly. There is no correlation of OTA/AFLA, therefore the measures currently applied to reduce AFLA contamination will not automatically reduce OTA.

Bright greenish yellow fluorescence and aflatoxin production has a higher correlation and 90 % of fluorescence is on the outside. Moulds may develop inside the fruit cavity and not be visible from the outside. Consequently, moulds cannot be easily sorted out and removed from the lots.

For these reasons, it is widely assumed that some mould contaminated fruit is inevitably to be found, as accounted for in the UNECE specification for dried figs. It is immediately evident that control techniques do not at present exist, and that it is very difficult to envisage how they could be developed.

**Dried Dates (Phoenix dactylifera)**

Dried dates, as the figs, are dried whist still on the palm. This makes these two products different to all other fruit. This again exposes the fruit to insect activity and inoculation of the fruit with *Aspergillus spp.* by insects which can again lead to some OTA residues.

**Dried Stone Fruit (Prunus spp.)**

The key products in this group are **dried apricots** and **prunes**, with a very small amount of Dried Peaches consumed. As such it is the most consumed group of dried fruit after dried vine fruit. All fruit are characterised by a small hard pit. Removal of this part always results in a certain degree of injury to the fruit, and this occurs at a stage where the Aw is in the range at which the ***Aspergillus spp.*** that lead to OTA contamination are active. To counter this the majority of fruit in this group is treated at or before the time of pitting with either Sulphites, or Sorbates as preservatives. The limited results available suggest that this is a very effective control against mycotoxin contamination, and that OTA limits on these fruits are unnecessary from a health protection standpoint.

**Dried Pome Fruit (Malus spp., Pyrus spp.)**

Consumption of dried apple and dried pear are relatively limited in the EU. Again, this material is almost exclusively treated with sulphites and we are unaware of any issue with OTA contamination.

**Dried Tropical Fruit**

These are exclusively produced in developing countries with low levels of infrastructure for testing. Consumption levels are very low. It is also believed from study of distribution routes and marketing materials that most these products are aimed at adult consumers. In this instance, our opinion is that the low consumption rates suggest that even for the most exposed consumers the exposure from this route is extremely low, and the imposition of a regulatory limit would be disproportionate in terms of benefit and cost/ market disruption.

**Preserved and Dehydrated Fruit (Infused pineapples, papaya, mango, cherries, blueberries, cranberries)**

Processed fruit of this type is generally infused with sugar, concentrated fruit juice or similar materials to significantly raise the brix and lower water activity prior to drying. Fresh or frozen fruit is taken in by the factories and processed prior to drying. Consequently, fruit is not subject to conditions suitable for mould growth and mycotoxin formation for a significant period of time. In this instance we see no technical justification for a regulatory limit for OTA.

**Pistachios**

Other separate studies and sampling results referenced below showed limited positive findings. It was concluded that the frequency of OTA contamination in pistachio samples available in the Spanish market is relatively low[5] . Although in Germany[6] some samples tested positive, the German National Institute for Risk Evaluation concluded that it did not expect any negative effects for the consumers.

OTA has been occasionally detected in pistachios. Field research was conducted in 2006 and 2007 on potential OTA producing fungi. Fungi from the potential OTA-producing Circumdati section were found on pistachio hulls and in early split pistachio nuts. Aspergillus ochraceous and A. melleus were the most common Circumdati detected. (This research is available in the research database at www.acpistachios.org)

OTA contamination and increase is unlikely to occur in storage or transport because the fungi require a water activity of >0.8. Pistachios are stored at a moisture percentage of 5-7% which corresponds to a water activity of <0.7. Higher water activities would lead to active mold growth that would render the pistachios unmarketable.

Aspergillus fungi are closely related and species in the different sections are likely to have a similar epidemiology. Consequently, it is reasonable to expect that the OTA-producing fungi behave similarly to the aflatoxin-producing fungi and that OTA contamination is more prevalent in insect-damage nuts. However, due to the rarity of OTA contamination in pistachios, prior research was not extensive enough to conclusively determine OTA epidemiology. In addition, the pistachio-producing areas of California have seen significant changes in the composition of neighboring crops over the last decade and research is likely needed to determine if the relative contamination risk has changed accordingly.

Setting arbitrary limits on pistachios for OTA is not supported by existing research or risk assessments.

**Part 3**

**OCHRATOXIN A INVESTIGATIONS IN DRIED FIGS AND RESULTS**

1. Introduction

The Aegean Exporters' Associations (EIB), closely follow the developments in the European Union, which is the greatest buyer of Turkish dried figs with about 50%. Additionally, the scientific research work/surveys starting from the orchard up to the final product are carried out together with Ege University Faculty of Agriculture (EUZF) since 2005. Samples are taken from processing plants at raw material stage to find out the annual contamination and also data are collected from laboratories for monitoring purposes by the Association.

In dried figs, OTA is mostly formed by *Aspergillus niger* group of black spored moulds. In rarer conditions OTA may also be formed by *Penicillium spp*. moulds. Due to presence of multiple factors, OTA may occur in

5 https://www.ncbi.nlm.nih.aov/pubmed/24779573: A survey of the fungal contamination and occurrence of aflatoxins and ochratoxin A (OTA) in 50 pistachio nut samples collected from commercial stores, Spain; only one sample of pistachio showed OTA contamination at 0.67 pg/kg.

6 http://www.cvuas.de/pub/beitrag_printversion.asp?subid=1&Thema_ID=12&ID=1666&Pdf=No&lang=EN
In 2012 oil seeds (poppy, sunflower, pumpkin, and flax seeds) as well as pistachios and pine nuts taken from the administrative districts of Stuttgart and Karlsruhe were analysed at CVUA Stuttgart for the presence of Ochratoxin A (OTA). A total of 89 samples were analysed.

both hot and dry conditions as well as lower temperatures like 5 oC. Since the fig fruit develops and ripens in summer, the main ochratoxigenic fungi is the drought and heat tolerant black spored Aspergillus group. OTA forms in figs at the fruit development stage before maturity. However, its concentration increases as ripening progresses in fruit and thereafter with drying. Contamination generally occurs during caprification (pollination) and fungi develops within the fruit. On the other hand, every black mould is not ochratoxin producer. Therefore, in dried figs OTA is a contaminant self-induced in nature and the frequency and concentrations may vary with the climatic conditions prevailing during fruit growth, maturation and drying. The levels and frequency may increase with adverse climatic conditions resulting in year to year variations.

2. The results

The results of the surveys carried out by EIB in cooperation with EUZF are presented in the following tables. The method used in analyses being Rhone IFU-2001, Recovery is 90-92% and Limit of Detection is 1 µg/kg.

Table 1. OTA analysis results of the raw material dried fig samples mostly taken at the beginning of the season from the dried fig processing plants between the years 2005-2009 within the scope of the mycotoxin monitoring studies

| | 2005 | | 2006 | | 2007 | | 2008 | | 2009 | |
|---|---|---|---|---|---|---|---|---|---|---|
| OTA (µg/kg) | No.of Samples | % | No.of Samples | % | No.of Samples | % | No.of Samples | % | No.of Samples | % |
| Not detected | 49 | 74,24 | 60 | 78,94 | 20 | 86,95 | 13 | 43,3 | 36 | 76,9 |
| < 10 | 10 | 15,15 | 10 | 13,15 | 1 | 4,34 | 12 | 40 | 5 | 11,4 |
| > 10 | 7 | 10,60 | 6 | 7,89 | 2 | 8,69 | 5 | 16,7 | 3 | 6,9 |
| Total Number of samples | 66 | 100 | 76 | 100 | 23 | 100 | 30 | 100 | 44 | 100 |

**Table 2.** OTA analysis results of the raw material dried fig samples taken from processing plants between the years 2010-2016 (excluding 2012-2014)

| | 2010 | | 2011 | | 2015 | | 2016 | |
|---|---|---|---|---|---|---|---|---|
| OTA (µg/kg) | No.of Samples | % | No.of Samples | % | No.of Samples | % | No.of Samples | % |
| Not detected | 58 | 100 | 41 | 85,41 | 46 | 73,01 | 25 | 45,45 |
| < 10 | - | - | 5 | 10,41 | 8 | 12,69 | 20 | 36,36 |
| > 10 | - | - | 2 | 4,16 | 9 | 14,28 | 10 | 18,18 |
| Total no.of samples | 58 | 100 | 48 | 100 | 63 | 100 | 55 | 100 |

The monitoring was carried out under a project, which targeted occurrence of mycotoxins including OTA. The project ended in 2011 which explains the data gap. However, the Aegean Dried Fruit Exporters' Associations Executive Board decided to continue a monitoring program for Aflatoxins and OTA after 2014. Samples have been randomly taken, analysed and disseminated to the members every year for monitoring purpose. The results are evaluated by the scientific consultants and shared by all members of the Aegean Exporters Association and when necessary with the Ministry of Food Agriculture and Livestock. The data do not point out to the climate change effect.

Table 3. OTA results of the final products of dried figs analysed in accredited laboratories between the years 2012-2016 (private requests)

| | 2012 | | 2013 | | 2014 | | 2015 | | 2016 | |
|---|---|---|---|---|---|---|---|---|---|---|
| OTA (µg/kg) | No.of samples | % | No.of samples | % | No.of samples | % | No.of samples | % | No.of samples | % |
| Not detected | 144 | 80,89 | 156 | 82,97 | 131 | 87,91 | 210 | 81,39 | 259 | 86,62 |
| < 10 | 26 | 14,60 | 25 | 13,29 | 14 | 9,39 | 29 | 11,24 | 32 | 10,70 |
| > 10 | 8 | 4,49 | 7 | 3,72 | 4 | 2,68 | 19 | 7,36 | 8 | 2,67 |
| Total no.of samples | 178 | 100 | 188 | 100 | 149 | 100 | 258 | 100 | 299 | 100 |

**Part 4**

**Data on OTA in dried figs**

**Tables 1,2 and 3 show OTA results in dried figs** (source: Ochratoxin A in Dried Figs, Prof. Dr. Uygun Aksou, Serap Hanci, Dr. Betul Vazgecer, 5/11/2018 )

**Table 1. OTA results of sample taken in different processing plants**

**OTA in figs:** raw samples taken from different regions 2005-2011; 2011-till to date

| Year | Total no of samples | No of samples >10 ppb | No of samples (LOD-10 ppb) | No samples (< LOD) |
|---|---|---|---|---|
| 2005/6 | 66 | 7 | 10 | 49 |
| 2006/7 | 76 | 6 | 10 | 60 |
| 2007/8 | 23 | 1 | 2 | 20 |
| 2008/9 | 30 | 5 | 12 | 23 |
| 2009/10 | 36 | 3 | 5 | 28 |
| 2010/11 | 48 | 2 | 5 | 41 |
| 2011/12 | 58 | 0 | 0 | 58 |
| 2015/16 | 63 | 9 | 8 | 46 |
| 2016/17 | 55 | 10 | 20 | 25 |
| 2017/18 | 52 | 4 | 18 | 30 |

**Table 2. OTA results of private companies**

OTA Database
(Private exporter or importer companies)

| Exporter Company Results | | | | |
|---|---|---|---|---|
| YEAR | Total Number of Samples Analyzed for OTA | Number of Samples > 10 ppb | 10 ppb üzeri OTA tespit edilen analiz sayısı (%) | Max OTA cons. (ppb) |
| 2015 | 1077 | 72 | 2.6 | 54.3 |
| 2016 | 377 | 30 | 12.2 | 39.7 |

| Importer Company Results | | | | |
|---|---|---|---|---|
| YEAR | Total Number of Samples Analyzed for OTA | Number of Samples > 10 ppb | Percent of samples OTA > 10 ppb (%) | Max OTA cons. (ppb) |
| 2015 | 43 | 1 | 0.7 | 10.8 |
| 2016 | 24 | 1 | 2.9 | 34 |

***Column 4 of Exporter Company Results means: percent of samples OTA >10 ppb**

**Table 3. OTA results of laboratories**

OTA Database
(Source: Laboratories, as private requests)

| YEAR | Total OTA analyses (number) | No of samples Nd | % samples nd | No of OTA +samples <10 ppb | Samples < 10 ppb (%) | No of OTA+ samples >10 ppb | Samples> 10 ppb (%) |
|---|---|---|---|---|---|---|---|
| 2012 | 178 | 144 | 81 | 26 | 14.6 | 8 | 4,5 |
| 2013 | 188 | 156 | 83 | 25 | 13.3 | 7 | 3,7 |
| 2014 | 149 | 131 | 88 | 14 | 9.4 | 4 | 2,7 |
| 2015 | 258 | 210 | 81 | 29 | 11.2 | 19 | 7,4 |
| 2016 | 298 | 254 | 85 | 32 | 10.7 | 12 | 4,0 |
| 2017 | 235 | 193 | 82 | 27 | 11.5 | 15 | 6.4 |
| 2018 | 112 * | 104 | 91 | 3 | 2.7 | 5 | 4.5 |

***As of 31/08/2018**

## ANNEX 2

Annex 2 consists of the following documents which are attached to this position paper.

1) Meyer Science: Statement concerning suggested possible new maximum levels for ochratoxin A in dates and processed date products

2) Meyer Science: Risk assessment concerning ochratoxin A (OTA)

**FRUCOM** represents the interests of European traders in dried fruits, edible nuts, honey, processed fruits & vegetables, and processed fishery products. Through its membership, mainly based on 9 national trade organisations in 6 EU Member States (Belgium, France, Germany, Italy, the Netherlands and Spain) FRUCOM represents over 300 companies across the EU and beyond.

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