

Unit on Biological Hazards and Contaminants (BIOCONTAM)

Acute health risks related to consumption of raw apricot kernels and products thereof

Joint EFSA- EFET-BfR document
(Agreed on 22 April 2015)

This joint document reflects the common understanding of EFSA, EFET and BfR on the divergence between the scientific opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) on the acute health risks related to the presence of cyanogenic glycosides in apricot kernels and products derived from apricot kernels and previous assessments from EFET and BfR on this issue

1. Procedural background

Article 30 of Regulation 178/2002¹ stipulates that EFSA should identify potential sources of divergence between its scientific opinions and those issued by other bodies carrying out similar tasks and to cooperate with a view of either resolving the divergence or preparing a joint document clarifying the contentious issues and identifying the relevant uncertainties in the data.

On 1 March 2016 the EFSA CONTAM Panel adopted a Scientific Opinion on the acute health risks related to the presence of cyanogenic glycosides in apricot kernels and products derived from apricot kernels. Following adoption, on 7 March EFET and BfR were informed about potential divergences. On 10 March 2016, EFSA sent a letter to EFET and BfR in which the assessment elements diverging from the previous risk assessments of EFET² and BfR³ on the risks of consumption of apricot kernels were presented in detail. These are (i) differing acute reference doses (ARfDs) for cyanide and (ii) differing amounts of apricot kernels (or apricot kernel material) that can be consumed safely.

In their response from 15 April 2016, EFET thanked EFSA for the opportunity to clarify potentially contentious issues regarding the EFSA risk assessment, agreeing with the ARfD for cyanide as derived by EFSA, but retaining their recommendation of a maximal daily consumption of two apricot kernels for adults.

In their response from 24 March 2016, the BfR welcomed the opportunity to give their views on the EFSA opinion, however, disagreed with the ARfD for cyanide as derived by EFSA and

¹Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, 1-24.

²http://www.efet.gr/images/old_efet/gpikramiqdala.pdf

³<http://www.bfr.bund.de/cm/349/two-bitter-apricot-kernels-per-day-are-the-limit-for-adults-children-should-refrain-from-consuming-apricot-kernels-together.pdf>

in consequence, also with the amount of apricot kernels (or apricot kernel material) that could be considered as safe as described in the EFSA opinion.

2. Critical risk assessment elements

In the EFSA Opinion, a bioavailability study in which 12 healthy adult volunteers consumed cyanogenic foods (Abraham et al., 2016) was used to derive an ARfD for cyanide. Instead of using the peak blood level and associated cyanide dose from a single individual, as was done in the evaluation of BfR, EFSA used the mean cyanide dose of 0.105 mg/kg bw that resulted in a mean blood concentration of 20 µM in women consuming either bitter apricot kernels or cassava for derivation of an ARfD. This concentration is the threshold for cyanide toxicity as cited by Rumack et al., 1983 but which is associated with considerable uncertainty. Applying an uncertainty factor of 1.5 for toxicokinetics (because appreciable interindividual differences in peak cyanide levels are unlikely to occur and therefore the full default value of 3.16 is not required) and the standard uncertainty factor of 3.16 for variation in toxicodynamics, resulted in establishment of an ARfD of 20 µg cyanide/kg bw.

Using the highest cyanide concentration in apricot kernels reported in the literature (3.8 mg/g cyanide per apricot kernel, Yildirim and Askin 2010) the maximum quantity of kernels that could be consumed without exceeding the ARfD would be 0.06 g for toddlers and 0.37 g for adults, respectively. The ARfD would already be exceeded by consumption of one small kernel in toddlers, while adults could consume three small kernels. However, consumption of less than half of a large kernel could already exceed the ARfD in adults.

2.1. EFET position as laid down in their letter of 15 April 2016

EFET noted that in the opinion of the EFET Scientific Council a Provisional Tolerable Daily Intake (PMTDI) was derived, while an ARfD was established by the EFSA CONTAM Panel. Taking into account that the fact that maximum levels of cyanide in blood are reached very quickly and that removal of cyanide is rapid as well and that under normal conditions eating apricot kernels would correspond to an acute intake, the derivation of an ARfD is acceptable for EFET.

EFET acknowledges that concentration of cyanogenic glycosides in apricot kernels and size of apricot kernels vary and that insufficient data on consumption are available but notes that although scientifically valid, using kernel size estimates as a parameter in the assessment (as done by EFSA) might in some cases lead to unclarities for consumers. EFET retains its recommendation of a maximum of two apricot kernels per day for adults (as done in their assessment) as this is clearer than the respective text in the EFSA opinion that differentiates between "small", "medium" and "large" kernels and would retain also the recommendation that pregnant/lactating women should not consume such kernels at all.

2.2. BfR position as laid down in their letter of 24 March 2016

Using the mean cyanide concentration resulting from consumption of cyanide containing foods in the study from Abraham et al. (2016) and applying a safety factor of 1.5 to account for individual variability in toxicokinetics of cyanide (as was done by EFSA) would result only

in a minor difference in the value for the ARfD when comparing with the BfR approach where the highest cyanide level obtained in a single individual was used and no safety factor was applied.

The main difference between the ARfD as derived by EFSA (20 µg cyanide/kg bw) and that of BfR (75 µg cyanide/kg bw) results from EFSA's application of the default safety factor of 3.16 to account for variations in toxicodynamics. Application of such a factor is not necessary since the blood level of 20 µM cyanide cited as a toxicity threshold for cyanide (Rumack, 1983) and considered in the BfR assessment, already contains several elements of conservatism. The missing necessity of the use of a safety factor for toxicodynamics is supported by the fact that the equivalent cyanide dose of the female participants in the study from Abraham et al. (2016) was more than 5-times higher than the EFSA ARfD value of 20 µg/kg bw but did not lead to any clinical symptoms.

Individuals consuming apricot kernels daily in quantities of at least 10 per portion and up to 90 per day did not experience subjective symptoms and despite the wide spread advertisement of apricot kernels as dietary supplement in the internet, only very few poisoning cases are reported in Germany. If consumption of more than one-half of a large kernel or three small kernels would indeed be associated with a health risk, a lot more poisoning cases would occur.

In view of BfR, consumers cannot assess the size of apricot kernels, and any kernels a person likes to eat may be of large size. Therefore, BfR recommends adults not to eat more than two apricot kernels per day which is identical with the recommendation of EFET.

3. Conclusion from EFSA

With regard to the comments from EFET, EFSA appreciates that EFET acknowledges that using kernel size estimates as a parameter in the assessment (as done by EFSA) might lead to unclarity for consumers. EFSA notes in this context that the estimated consumptions of apricot kernels that could lead to possible exceedances of the ARfD in adults and children reported in the EFSA opinion are aimed at supporting risk managers in taking an informed decision on possible risk management measures. They are not primarily focussed as recommendations for the general public or consumers. With respect to the recommendation issued by EFET regarding the consumption of apricot kernels and specifically vulnerable groups the EFSA CONTAM Panel considered the established ARfD sufficiently protective to cover potential acute effects in individuals of all population groups.

With regard to the comments from BfR, EFSA notes that the study of Abraham et al. (2016) was conducted with a small number of healthy adult volunteers and the absence of information of cyanide specific data on individual sensitivity (i.e. covering specifically susceptible individuals in the population). Therefore, EFSA retains its position with regard to application of the default uncertainty factor for toxicodynamics and consequently the ARfD of 20 µg cyanide/kg bw. BfR also reports, that over the last years, they have been informed about individuals consuming considerable amounts of apricot kernels without experiencing subjective symptoms. In this context it has to be noted that EFSA's risk characterisation is based on measured occurrence values of cyanide in and weights of apricot kernels as reported in the literature, comparing potential exposures with the ARfD. Therefore the conclusions with regard to the amount of raw apricot kernels (or corresponding kernel material) that can safely be consumed are retained. Moreover, in the literature, toxicity in

humans is reported from consumption of 20 or more kernels in adults and of 5 or more kernels in children.

References:

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