FSA survey of PAs in certain foodstuffs

In this guide

71. In 2014, in response to the EFSA Panel's 2011 recommendation that 'ongoing efforts should be made to collect analytical data on occurrence of PAs in relevant food and feed commodities [to inform future safety evaluations]' (EFSA, 2011), the FSA commissioned a survey to measure the levels of PA in teas, herbal infusions, plant-based food supplements and honey (FSA, 2014). The data collected as part of this survey were submitted to EFSA for their 2017 evaluation (summarised in the following paragraphs).

72. Fifty-five samples of tea from C. sinensis (common black and green teas), 70 samples of herbal infusions, 45 samples of plant-based supplements and 54 samples of honey were analysed in this study. The samples were purchased from a range of national supermarkets, smaller retailers, health/natural/organic food stores and UK internet/mail order retailers between February and March 2014. The analytical results for PAs (detected by liquid chromatography with tandem mass spectrometry) are presented in Table 1.

Table 1– Analytical results of the FSA pyrrolizidine alkaloids survey in teas, herbal infusions, plant-based foods and honey carried out in 2014 (FSA, 2014).

Type of tea	Total no. of samples	No. of samples in which PAs were detected	0-100 (µg/kg)	100-500 (µg/kg)	500-1,000 (µg/kg)	1,000 – 3,000 (µg/kg)	>3,000 (µg/kg)	Range (µg/kg)
Teas (black, green and Earl Grey)	55	11	6	4	Not detected.	1	Not detected.	LOQ – 1,170
Herbal infusions	70	35	9	12	8	4	2	LOQ - 52,508*
Plant-based supplements	48#	5	2	3	Not detected.	Not detected.	Not detected.	LOQ – 344
Honeys	54	35	29	6	Not detected.	Not detected.	Not detected.	LOQ – 251

Abbreviations: LOQ – Limit of quantification.

*The highest levels were from borage and comfrey infusions which are known to contain high levels of PAs.

#Three of the samples could not be tested.

73. As it was evident that PAs were present in teas and herbal infusions as a result of contamination from PA containing weeds, more rigorous quality control and good agricultural practices including better weed control, harvesting and processing are being put in place to minimize PA levels.

74. The FSA has been working with the producers of teas, herbal infusions, plant-based supplements, and honey in identifying measures that will reduce levels of PAs in these foods. The Food Business Operators (FBOs) have identified and implemented good agricultural practices in the growing and harvesting of the plant material used in the production of these products. FBOs have shown that subsequent testing, since 2014 when this work was carried out, of these foods has indicated that the mitigatory measures have been successful in reducing the levels of PAs. The FSA will continue to monitor the levels of PAs in food (FSA, 2014).

75. The samples used in this report were collected in early 2014 and should not be considered representative of what is available on the market now. The findings of this report have led to positive changes in agricultural practices and recent industry results continue to show a reduction in PA levels. The results have been fed into the EFSA dataset and have been used in discussions on managing the risks associated with the presence of PAs in food and feed at European level (FSA, 2020).

EFSA 2017 PAs evaluation

76. In 2017, the EFSA CONTAM Panel established a new reference point for PAs, based on the increase in incidence of liver hemangiosarcoma in female rats. The reference point of 237 µg/kg (benchmark dose lower confidence limit for 10% extra tumour incidence above background (BMDL10) with a was calculated for riddelliine, a specific PA, with a BMDU10) of 548 µg/kg (benchmark dose upper limit), using a control group and five different doses with a measured endpoint of hemangiosarcoma.

77. The EFSA CONTAM Panel concluded that there is a possible concern for human health related to the exposure to PAs, in particular for frequent and high consumers of tea and herbal infusions. Specifically, for green tea, exposure levels calculated from various data sets compared to the reference point of 237 µg/kg bw per day resulted in margin of exposure (MOE) values varying from 98,750 to 2,838 in adult consumers (EFSA, 2017). An MOE of 10,000 is of potential concern.

78. Furthermore, the EFSA CONTAM Panel noted that “consumption of food supplements based on PA-producing plants could result in exposure levels too close (i.e., 100 times lower) to the range of doses known to cause severe acute/short term toxicity” (EFSA, 2017).

79. The EFSA Panel concluded, that whilst the levels of 1,2-unsaturated PAs present in green tea products were not sufficiently high to be responsible for non-neoplastic hepatotoxicity alone, their presence in green tea products could not be ruled out as a contributing factor (EFSA, 2017).

Uncertainties

80. The EFSA Panel considered several uncertainties with respect to exposures, biological and toxicological effects. These are detailed in the EFSA opinion (EFSA, 2018), and include considerations such as natural variation in chemical composition (due to plant variety, growing environment, season, age of leaves and manufacturing conditions), and the potential presence of hepatotoxic contaminants such as PAs.

81. In addition, due to the limited dose-response data after daily EGCG exposures of up to 800 mg/day in humans, there is uncertainty regarding the starting point for the derivation of a health-based guidance value for the general population. There is an uncertainty as to whether serious liver effects may develop after long-term use of GTEs; and the mechanism(s) leading to both the dose-dependent hepatotoxicity of EGCG and the mechanism(s) leading to idiosyncratic hepatotoxicity to EGCG (EFSA, 2018).

EFSA discussion and conclusion

82. EFSA concluded that catechins from green tea prepared in the traditional way of infusion, or reconstituted drinks giving the equivalent composition of catechins as that of green tea infusions, were, in general, safe; however, the Panel at the time were unable to determine a dose of EGCG from GTEs that would be considered safe. The EFSA Panel made the following recommendations:

- Studies to be carried out determining a dose-response of hepatotoxicity of GTCs and examine inter and intra species variability.
- As pyrrolizidine alkaloids in green tea preparations including food supplements could contribute to hepatotoxicity, maximum limits should be established.
- Labelling of green tea products (particularly food supplements), should include catechin content and EGCG proportion.