

# RECOMMENDATIONS

**COMMISSION RECOMMENDATION (EU) 2015/976**  
**of 19 June 2015**  
**on the monitoring of the presence of tropane alkaloids in food**  
**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) The Scientific Panel on Contaminants in the Food Chain ('Contam') of the European Food Safety Authority (EFSA) adopted an opinion on tropane alkaloids in food and feed <sup>(1)</sup>.
- (2) The most studied tropane alkaloids are (-)-hyoscyamine and (-)-scopolamine. Atropine is the racemic mixture of (-)-hyoscyamine and (+)-hyoscyamine of which only the (-)-hyoscyamine enantiomer exhibits anticholinergic activity.
- (3) The presence of tropane alkaloids in genus *Datura* is well known. *Datura stramonium* is widely distributed in temperate and tropical regions and for this reason seeds of *Datura stramonium* have been found as impurities in linseed, soybean, sorghum, millet, sunflower and buckwheat and products thereof. The *Datura stramonium* seeds can not be easily removed from sorghum, millet and buckwheat by sorting and cleaning.
- (4) More occurrence data are needed on the presence of tropane alkaloids in food. There is also a need to understand the agricultural conditions under which tropane alkaloids occur in agricultural commodities.
- (5) It is therefore appropriate to recommend the monitoring of the presence of tropane alkaloids in food,

HAS ADOPTED THIS RECOMMENDATION:

1. Member States should, with the active involvement of food business operators, perform monitoring for the presence of tropane alkaloids in food, and particularly in:
  - cereals and cereal-derived products, in particular (in order of priority):
    - buckwheat, sorghum, millet, maize and buckwheat, sorghum, millet and maize flour,
    - cereal-based food for infants and young children,
    - breakfast cereals,
    - grain milling products,
    - grains for human consumption,
  - gluten-free products,
  - food supplements, teas and herbal infusions,
  - legume vegetables (without pods), pulses and oilseeds and derived products.
2. The tropane alkaloids to be analysed are at least atropine and scopolamine and, if possible, to analyse the hyoscyamine enantiomers separately and also other tropane alkaloids.

<sup>(1)</sup> EFSA Contam Panel (EFSA Panel on Contaminants in the Food Chain), 2013. Scientific Opinion on Tropane alkaloids in food and feed. *EFSA Journal* 2013;11(10):3386, 113 pp. doi:10.2903/j.efsa.2013.3386.

3. In order to ensure that the samples are representative for the sampled lot, Member States should follow the sampling procedures laid down in Commission Regulation (EC) No 401/2006 <sup>(1)</sup>.
4. The method of analysis to be used for monitoring is preferably high performance liquid chromatography — mass spectrometry/(mass spectrometry) (HPLC-MS/(MS)) or, if HPLC-MS/(MS) is not possible, gas chromatography — mass spectrometry (GC-MS).

The Limit of Quantification (LOQ) for atropine (racemic mixture of hyoscyamine enantiomers) and scopolamine should be preferably below 5 µg/kg and not higher 10 µg/kg for agricultural commodities, ingredients, food supplements and herbal teas and should preferably be lower than 2 µg/kg for finished foods (e.g. breakfast cereals) and 1 µg/kg for cereal-based foods for infants and young children.

5. Member States, with the active involvement of the food business operators, should perform investigations to identify the agricultural conditions resulting in the presence of tropane alkaloids in food in case significant levels of tropane alkaloids are observed.
6. Member States should ensure that the analytical results are provided on a regular basis and by the latest by October 2016 to EFSA in the EFSA data submission format in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed <sup>(2)</sup> and the additional EFSA's specific reporting requirements.

Done at Brussels, 19 June 2015.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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<sup>(1)</sup> Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12).

<sup>(2)</sup> <http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm>