



Food and Agriculture
Organization of the
United Nations



World Health
Organization

CALL FOR DATA ON (–)-HYOSCYAMINE, (+)-HYOSCYAMINE AND (–)-SCOPOLAMINE

[Deadline: 31 January 2020](#)

Background

Atropine and scopolamine belong to the class of tropane alkaloids (TA), a group of compounds that are secondary metabolites occurring in several plant families, such as Brassicaceae, Solanaceae and Erythroxylaceae. While there are more than 200 different TA identified in various plants, this call for data focuses on (–)-hyoscyamine, (+)-hyoscyamine and (–)-scopolamine. The racemic mixture of (–)-hyoscyamine and (+)-hyoscyamine is called atropine.

Tropane Alkaloid related incident

Assisting 86.7 million people in around 83 countries each year, the World Food Programme (WFP) is the leading humanitarian organization saving lives and changing lives, delivering food assistance in emergencies and working with communities to improve nutrition and build resilience.

Super Cereal is a flour-type product made of pre-cooked corn, soybean and micronutrients. It is used mainly for pregnant and lactating mothers (PLW), nutritionally vulnerable groups including people living with HIV and tuberculosis (TB), and children above five years old. Annually, WFP distributes approximately 130,000 MT Super Cereal to 4.9 million people with the objective of improving food security and preventing malnutrition.

In March 2019, four people died and 296 were admitted to health facilities after eating Super Cereal in Uganda. A joint investigation performed by Uganda Government, US CDC/FDA, WHO and WFP pointed towards tropane alkaloids, contaminants issued from toxic seeds (i.e. *Datura stramonium*), as the cause of intoxication. WFP took immediate measures on the stock and the implicated supplier, and continue to actively consult with experts, including FAO's Office of Food Safety to manage this risk.

An investigation to identify the source of the issue demonstrated that tropane alkaloids from natural sources, a weed called *Datura stramonium*, in extremely concentration, was the cause, and originated from the harvesting/processing of the soybeans.

Soya is an ingredient in different foods purchased by WFP, and *Datura stramonium* is a known weed for different cereal crops. Therefore, the concern extends beyond Super Cereals for WFP.

Regulatory Framework

There are no applicable international regulations of tropane alkaloids for Super Cereal according to WFP's research to date.

The only known regulatory instrument that set limits on some tropane alkaloids specifically, EU regulation 2016/239, applies to foods aimed at infants and young children. However, it is not clear whether the regulation covers cereal and soybean-based products used by WFP for infants and young children (6 to 59 months of age). WFP's other products, including Super Cereal intended for adults and other vulnerable populations beyond children (5 + years of age). TAs have not previously been addressed by the Codex

Committee on Contaminants in Food (CCCCF) and there is no Codex ML or other Codex risk management measure for these contaminants currently in place.

Due to recent outbreaks of illness with fatalities in Uganda (which was likely caused by food aid contaminated with TAs) and current lack of sufficient regulatory and scientific references for WFP to set operational limits in its food specifications, WFP has requested FAO/WHO for scientific advice to allow the development of appropriate risk management options. In particular, the requested scientific advice to FAO/WHO entails:

- full risk assessment/evaluation of (–)-hyoscyamine, (+)-hyoscyamine and (–)-scopolamine
- based on this, guidance for the development of an operational limit for atropine and scopolamine in the products listed in Table 1, taking into consideration both the food safety for WFP’s beneficiaries, as well as food security, ensuring availability of the right foods to fulfill WFP’s mandate.
- The requested scope for FAO/WHO review includes Super Cereal, Specialized Nutritious Foods for infant and young children (i.e. Super Cereal plus, Lipid-based Nutrient Supplements), applicable grains, pulses and their derived products.

Table 1: List of products for review

Name of product	Main ingredients	Target Group
Super Cereal	Corn/wheat/rice (78.3%), soybean (20%), Vitamins & Minerals (1.7%)	PLW, children above 5 years, other nutritionally vulnerable groups
Super Cereal plus	Corn/wheat/rice (58.3%), soybean (20%), milk powder (8%), Sugar (9%), Veg. Oil (3%), Vitamins & Minerals (1.7%)	Children 6-59 months
Lipid-based Nutrient Supplements	Vegetable oils (30-35%), Sugar, Peanut (or chickpea or extruded corn flour) (10-30%), Soy flour (5-18%) ¹	Children 6-59 months PLW
Certain grains, pulses and their derived products (as specified in column “main ingredients”)	Sorghum* Millet* Wheat* Peas (different types - green, yellow, pigeon, cow, etc.) Rice* Maize* Lentils (different types - red, green, Bengal, etc.) Beans (different types - white, fava, pinto, kidney, pinto, horse, etc.) Soy* Chickpeas* Barley* Buckwheat* Oat* <i>*Both unprocessed and milling products of, such as flours.</i>	General populations

¹ The formulations vary per suppliers, and one supplier can have multiple formulations as well.

Objective of this call

The data will serve as inputs to the development of scientific advice, which shall be provided through an expert consultation that will take place in Rome on 30 March - 3 April 2020.

Request for relevant information

FAO and WHO want to ensure that all available and relevant information and data are collected, and are requesting governments, private sector, the food industry, academia, consumer groups, laboratories, health care providers, environment and biology specialist and any other interested organizations and individuals to submit any available data on the specific areas indicated. These data may be published or unpublished. Reference should be made to related published studies, where applicable.

Deadline for submission of data

Please submit any relevant information by 31 January 2020 in any format (electronic and/or hard copies - electronic submissions are preferred, either via e-mail (if not too large) or on USB key), in any official United Nations (UN) language (English, French, Spanish, Arabic, Chinese, Russian), and with a title and short description of the content in English along with the list of data and information requirements if possible, to Markus.Lipp@fao.org and kpetersen@who.int. If information is not available in an official UN languages, a short summary of the nature of the data should be provided, preferably in English.

CALL FOR DATA

Occurrence and chemical data

1. Levels and patterns of occurrence (and in some cases co-occurrence) of the listed contaminants in raw commodities and finished food products
2. levels of the listed contaminants in animal feed
3. information on carry-over of contaminants from feed to animals for human consumption
4. effects of processing on levels of contaminants in food as consumed and in feed
5. analytical techniques used by investigators or authorities for identifying and quantifying the listed contaminants in foodstuffs and/or human and animal tissues;
6. sampling protocols for the listed contaminants
7. methods available for the prevention and control of the listed contaminants

Please note

Data on occurrence of the listed contaminants in food should be submitted to the GEMS/Food on-line database (<https://extranet.who.int/gemsfood/>).

For more information please refer to the GEMS/Food Electronic Reporting Manual available at the WHO Website – http://www.who.int/foodsafety/chem/instructions_GEMSFood_january_2012.pdf

Toxicological, epidemiological and clinical data

All data relevant to:

1. metabolism and pharmacokinetic studies;
2. short-term toxicity, long-term toxicity studies;
3. epidemiological studies;
4. data and information on disease outbreaks and on sporadic cases - preferably including details about food commodity involved/suspected, and analytical results if any;

5. special studies designed to investigate specific effects, such as the mechanism of toxicity, immune responses, or macromolecular binding;
6. toxic potency of the most studied TAs (–)-hyoscyamine and (–)-scopolamine, but also other tropane alkaloids if data are available;
7. relative potency of TAs; and
8. clinical features and treatment of poison with TAs.

Dietary exposure assessment data

All data relevant to:

1. levels and patterns of human exposure from all relevant sources of TAs;
2. consumption patterns and population groups; and
3. biomarkers of exposure

Risk management measures

All data relevant to prevention and control programmes, including:

1. Existing maximum limits in different foods
2. monitoring;
3. plant species containing on (–)-hyoscyamine, (+)-hyoscyamine and (–)-scopolamine s

Submission of data

Please note that the above lists are not meant to be all-inclusive since it is recognized that other studies may, in some instances, assist in the evaluation.

Procedures for the evaluation of chemicals in food were updated and published by FAO and WHO (Principles and methods for the risk assessment of chemicals in food – Environmental Health Criteria No. 240, available at <http://www.who.int/foodsafety/publications/chemical-food/en/>)

Specific procedural guidelines for food additives are also available from FAO and WHO (see <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/> and <http://www.who.int/foodsafety/chem/jecfa/guidelines/en/index.html>).

All relevant data, both positive and negative, should be submitted. Data should be presented, summarized and referenced in a clear and concise manner.

Confidential and/or unpublished data

FAO and WHO recognize that some of the information and relevant data which are now required may be unpublished or of a confidential nature. With regard to unpublished information and data, this remains the property of the author for subsequent publication by the owner as original material. Unpublished confidential studies that are submitted will be safeguarded in so far as it is possible to do so without compromising the work of FAO and WHO. Specific issues relating to confidentiality should be discussed directly between the information and data owners and FAO/WHO. For these and other issues please contact FAO and WHO at the contacts provided.

This call for data is available at both the FAO and WHO web sites:

<http://www.fao.org/food/food-safety-quality/scientific-advice/calls-data-experts/en/>

<http://www.who.int/foodsafety/call-data-expert/en/>

Correspondence

For more information, please contact:

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References

- Commission Regulation (EU) 2016/239 of 19 February 2016 amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children