

Supporting document 1

Poisoning incidents from hydrocyanic acid (HCN) in apricot kernels and regulation of HCN in general foods internationally (at Approval) – Proposal P1016

Hydrocyanic Acid in Apricot Kernels & other Foods.

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1 Poisoning incidents from consumption of HCN in apricot kernels in other countries

Raw apricot seeds contain cyanogenic glycosides which cause poisoning and death when eaten raw and in sufficient amounts. Cases of poisoning from apricot seeds have been reported in the medical literature since the 1960s. The first reported cases of cyanide poisoning due to apricot seed ingestion were nine children in Turkey in 1957 (Sayre, 1964) which included two deaths. Twenty-four cases of cyanide poisoning in children were also reported in 1981 in Gaza with three deaths due to apricot seed ingestion (Lasch, 1981).

1.1 Canada

There have been a limited number of reports of adverse symptoms experienced by Canadians who have consumed apricot kernels. Sometimes, but not always, these reports result from the consumption of apricot kernels for medicinal or natural health purposes, the use of which has not been evaluated or approved by Health Canada.

In Canada one man died in 2000, after consuming 20 to 40 gelatin capsules containing crushed bitter almonds (apricot kernels) on a daily basis over a 3 months period of time, as an alternative to cancer treatment. Two women were hospitalized after consuming bitter apricot kernels, one in June 2005 and one in May 2009.

The most recent Canadian poisoning incident occurred in May 2009, when a woman was hospitalised following the consumption of approximately 40 apricot kernels in a short period of time. This event prompted the posting of an advisory on Health Canada's Advisory and Warnings website (<u>http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/ 2009/2009 101-eng.php; http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/13308a-eng.php</u>.

Additionally, in 2009, Health Canada published a fact sheet on its Food and Nutrition website about cyanide in bitter apricot kernels (<u>http://www.hc-sc.gc.ca/fn-an/pubs/securit/2009-apricots-abricots/index-eng.php</u>).

Canada considered that consumer and industry education on the potential health risks associated with the consumption of large numbers of bitter apricot kernels was an appropriate method of communicating health risks at that time. The following excerpt from Health Canada's website presents Health Canada's opinion and consumer advice pertaining to bitter apricot kernels:

It is the opinion of Health Canada that apricot kernels should not be consumed for medicinal or natural health purposes. There is a concern about the potential health effects associated with large numbers of bitter apricot kernels being consumed on a regular basis, particularly by young children. Health Canada advises adults of the general population who do eat bitter apricot kernels as flavouring to consume no more than three bitter apricot kernels per day, ground and mixed with other foods.

1.2 United Kingdom

In 2006, the UKFSA Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)¹ expressed concern that, when ingested, bitter apricot kernels can produce cyanide.

¹ http://tna.europarchive.org/20111116080332/cot.food.gov.uk/pdfs/tox-2006-13.pdf

The COT therefore considered a safe intake is equivalent to one to two kernels a day <u>www.food.gov.uk/news/newsarchive/2006/apr/apricot</u>.

1.3 Europe

Between 2005 and 2008, 15 notifications on cyanide in apricot kernels were transmitted through the Rapid Alert System for Food Feed (RASFF) database of the European Commission. The reported levels ranged approximately between 300-2500 mg/kg.

In order to make a notification under the RASFF system and protect public health and safety, Article 14(2)(a) of Regulation No (EC) 178/2002 is used which makes it an offence to sell or possess for sale food which is unsafe or injurious to health.

1.4 USA

Apricot kernels have long been recognized as a potential source of cyanide poisoning due to their cyanogenic glycoside (amygdalin) content. The most recent poisoning incident in the USA was in 2014 where an individual reported consuming apricot kernels and having symptoms such as dizziness, panting and convulsions.

The USA does not have any formal limits on HCN in foods. It previously took a case-by-case approach and if the product was marketed as food, they looked at it from the perspective of whether it contains excessive levels of cyanide that may render the food injurious to health and enforced on that basis. Their general advice in the past was that almond pastes and pastes made from other kernels should contain less than 25 ppm (mg/kg) of HCN naturally occurring in the kernels.

Currently, the USA considers apricot kernels to be "laetrile" (also known as amygdalin) and detain it as a new drug under relevant import legislation <u>Import Alert 62-01</u>.

1.5 Hong Kong

In 2014 the Department of Health in Hong Kong issued a warning against consuming raw apricot seeds due to a case of poisoning in a 26 year old male. The patient developed abdominal pain, vomiting, dizziness and headache about two hours after consuming a self-prepared drink containing raw bitter apricot seeds http://www.chp.gov.hk/en/view_content/37324.html.

2 Regulation of hydrocyanic acid internationally

Maximum Limits (MLs) for HCN have been established in a few countries for cassava and cassava derived foods including ready-to-eat cassava chips/crisps and these apply to a limited range of products (Annex 1).

2.1 Codex

The Codex Alimentarius Commission has developed and published standards for Sweet Cassava)², Bitter Cassava³, Edible Cassava Flour⁴ and Gari ⁵(a product obtained from processing cassava tubers) (also spelt as 'garri') and specifies levels for hydrocyanic acid in the General Standard for Contaminants and Toxins in Food and Feed⁶. The key aspects of these standards are:

- sweet cassava is defined as a raw product containing less than 50 mg/kg of 'hydrocyanic acid'
- edible cassava flour is defined as a product suitable for direct human consumption and the level of 'total hydrocyanic acid' in the flour must not exceed 10 mg/kg
- for gari, another product for direct human consumption, the 'total hydrocyanic acid' must not exceed 2 mg/kg as free hydrocyanic acid
- the Codex Standard for Bitter Cassava (300-2010) defines bitter varieties of cassava as those containing more than 50 mg/kg of cyanides expressed as hydrogen cyanide (fresh weight basis). In the absence of a Codex maximum level for hydrogen cyanide for bitter cassava in the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), it permits the setting of an acceptable maximum level on a safety basis by the national legislation of the importing country pending the outcome of the future work of the Codex Committee on Contaminants in Foods on cyanogenic glycosides.
- Labelling provisions in the standard for sweet cassava require a statement that cassava must be peeled and fully cooked before being consumed.

The labelling requirements for bitter cassava to alert consumers to risk of consumption are:

- cassava must not be eaten raw
- cassava shall be peeled, de-pithed, cut into pieces, rinsed and fully cooked before consumption
- cooking or rinsing water must not be consumed or used for other food preparation purposes.

2.2 Japan

In Japan, HCN levels in food are regulated under the Ministry of Health Notification No.370, 1959) Codes and standards of food products and additives.

The standards for grain and pulse are as follows:

- No detectable level of HCN is allowed in Adzuki bean and other pulses
- No greater than 500 ppm (mg/kg) of HCN for *Phaseolus lunatus* (e.g. Butter bean; Paigya; Lima bean etc.) soy bean; pea; broad bean and peanut.

² Codex Standard for Sweet Cassava (Codex STAN 238-2003)

³ Codex Standard for Bitter Cassava (CODEX STAN 300-2010)

⁴ Codex Standard for Edible Cassava Flour (CODEX STAN 176-1989)

⁵ CODEX Standard for Gari (CODEX STAN 151-1989)

⁶ Codex Standard for Contaminants and Toxins in Food and Feed (Codex Standard 193-1995)

In addition, there are labelling requirements for pulses which contain HCN under Paragraph 1, Article 19 of the Food Sanitation Act (Cabinet Office Ordinance No. 45, 31 August 2011).

2.3 European Commission

In the EU, Annex II of Directive 88/388 on flavourings sets the following maximum permitted levels of HCN in foodstuffs and beverages to which flavourings or other food ingredients with flavouring properties have been added: 1 mg/kg in foodstuffs, 1 mg/kg in beverages, with the exception of 50 mg/kg in nougat, marzipan or its substitutes or similar products, 1 mg percent of alcohol in alcoholic beverages and 5 mg/kg in canned stone fruit (EEC 1998).

There have been 3 opinions from EFSA on HCN:

- Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on hydrocyanic acid in flavourings and other food ingredients with flavouring properties⁷
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to cyanogenic compounds as undesirable substances in animal feed⁸
- Ethyl carbamate and hydrocyanic acid in food and beverages Scientific Opinion of the Panel on Contaminants⁹.

2.4 UK

In the UK, HCN levels in food are regulated under *The Flavourings in Food Regulations* 1992 <u>http://www.legislation.gov.uk/uksi/1992/1971/schedule/2/made</u>.

The following levels for HCN are permitted for foods to which flavourings have been added:

- 50 mg/kg in nougat, marzipan, a nougat or marzipan substitute or a similar product
- 5 mg/kg in tinned stone fruit
- 1 mg/kg per 1% alcohol in alcoholic drinks.

Otherwise, the HCN content of food is not specifically regulated except under the terms of the Food Safety Act 1990 which make it an offence to sell or possess for sale food which is injurious to health.

3 References

Codex Standard for Edible Cassava Flour (1989). Codex Stan, 176 (1): 1-4

Codex Standard for Sweet Cassava (2005). Codex Stan, 238-2003.

Codex Standard for Bitter Cassava (2010). Codex Stan, 300-2010.

Codex Standard for Gari (CODEX STAN 151-1989)

Codex Standard for Contaminants and Toxins in Food and Feed (1995). Codex Stan. 193-1995

EEC (1988) Council Directive 88/388/EEC of 21 June 1988 on the approximation of the laws of the member States relating to flavourings for use in foodstuffs and to source materials for their production. Official Journal of the European Communities, 15.7.1988, L184/61-67.

⁷ <u>http://www.efsa.europa.eu/en/efsajournal/pub/105.htm</u>

⁸ http://www.efsa.europa.eu/en/efsajournal/pub/434.htm

⁹ http://www.efsa.europa.eu/en/scdocs/doc/Contam_ej551_ethyl_carbamate_en_rev.1,3.pdf

Lasch E, El Shawa R. Multiple cases of cyanide poisoning by apricot kernels in children from Gaza. *Pediatrics.* 1981; 68: 5-7

Sayre JW, Kaymakcalan S. Cyanide poisoning from apricot seeds among children in central Turkey. *N Engl J Med*.1964. 270:1113-1115.

Annex 1 – National Standards and/or requirements for cassava in food

Country	Food	Level of HCN (mg/kg)	Other information
Brazil	Multimistura	5	Multimistura is composed of 5% cassava leaves, bran of wheat and rice, corn and wheat flours and other ingredients
Indonesia	Cassava Flour Mocaf (modified cassava flour)	40	
Philippines	Dried cassava chips and granules	10 (total HCN on a dry weight basis)	Refers to total hydrocyanic acid which includes the hydrocyanic acid which may be enzymatically released from a cyanogenic glycoside as well as any free or unbound hydrocyanic acid in cassava, expressed as milligrams of hydrocyanic acid per kilogram of cassava by-products (mg/kg)

Sources

Brazil. Resolução RDC n.53 de 15/06/2000. Regulamento Técnico para Fixação de Identidade e Qualidade de Mistura à base de Farelos de Cereais. Aprovado pelo Decreto 3.029, de 16 de abril de 1999. Diário Oficial da União. 2000 19 jun.

Philippine National Standard for dried cassava chips and granules PNS/BAFPS 29:2010 ICS 67.080.