

# Imported food risk statement

## Tetrodotoxin and pufferfish

**Scope:** Tetrodotoxin in pufferfish. This includes whole or portions of pufferfish that are fresh, frozen, dried or canned.

### Recommendation and rationale

Do tetrodotoxins in imported pufferfish present a potential medium or high risk to public health:

Yes

No

#### Rationale:

- Tetrodotoxin (TTX) is an extremely potent hydrophilic neurotoxin that accumulates in pufferfish species.
- Serious illness and deaths are regularly reported in previously healthy adults as a result of TTX ingestion.
- Pufferfish flesh or *fugu* is a food delicacy in Japan, where Government certification is required for commercial sale. Nevertheless, TTX intoxications still result in serious food poisoning and death in Japan. Significant training is necessary to enable an individual to remove the toxic organs from pufferfish without contaminating the edible portions with TTX.
- TTX intoxications have occurred in Australia; however, these have occurred where pufferfish have been caught recreationally and then consumed.
- Small quantities of pufferfish are being imported into Australia for human consumption.

### General description

#### Nature of the toxin:

Tetrodotoxin (TTX) is an extremely potent hydrophilic neurotoxin produced by aquatic microorganisms. TTX can biomagnify through aquatic food chains to achieve high concentrations in aquatic heterotrophs such as pufferfish, octopus, crab, starfish, flatworm, frogs, toads and newts<sup>1</sup>. At least 30 analogues of TTX have been described, and many of these have also been shown to have toxic potential<sup>2</sup>.

TTX is the causative agent in pufferfish poisoning events. Pufferfish is a food delicacy in Japan (known as *fugu*) and other populations in East Asia. Pufferfish species consumed as food belong to fish families within the order *tetraodontiformes*, predominantly from the family *Tetraodontidae* and to a lesser extent *Didontidae*<sup>3</sup>. Other common names include globefish, blowfish, balloonfish, swellfish, toadfish and porcupine fish.

Pufferfish acquire TTX and analogues exogenously through the ingestion of other TTX-bearing food organisms such as starfish, marine gastropods, bivalves and flatworms. In ocean pufferfish species, the liver and ovaries generally have the highest toxicity, followed by intestines and skin. In freshwater species, TTX levels are generally higher in the skin.

Pufferfish for human consumption must be prepared by carefully removing the organs where TTX has accumulated<sup>3</sup>. This is a specialist process, where product intended for consumption can easily become contaminated with TTX or confused with tissue abundant in TTX.

TTX is odourless and heat-stable, and is not diminished by cooking, rinsing, cleaning or freezing<sup>2,3</sup>. Batch testing imported product may be of limited value to safeguard against TTX contamination, as the processing of an individual fish is the primary method of eliminating TTX from consumed product.

## General description

### Adverse health effects:

People affected by TTX show symptoms that may include:

- numbness or tingling around the mouth, face or extremities
- unsteady walking, weakness and clumsiness
- slurred/unclear speech
- dizziness/vertigo or double vision
- drop in blood pressure
- slow and irregular heartbeat
- difficulty breathing, swallowing
- paralysis, leading to unconsciousness
- deaths are regularly reported in previously healthy adults as a result of TTX ingestion.

The onset of symptoms associated with TTX is variable and dependent on the amount of TTX consumed. Effects can be observed within minutes or, in less severe cases, hours<sup>4</sup>. Treatment for TTX poisoning is primarily limited to managing severe symptoms until the toxin can be cleared naturally<sup>1</sup>.

### Consumption patterns:

No data for *fugu* consumption is available for Australian consumers. No information on *fugu* consumption was captured by the 2011-2012 Nutrition and Physical Activity Survey<sup>5</sup>.

*Fugu* is a delicacy in Japan where preparation requires significant training and is subject to Government certification<sup>3</sup>. Nevertheless, TTX intoxications still result in serious food poisoning and death<sup>6</sup>.

### Surveillance information:

Between October 2021 and March 2022, approximately 190 kg of pufferfish *fugu* was imported into Australia from Japan<sup>5</sup>.

### Illness associated with consumption of tetrodotoxins in pufferfish

Poisonings from ingestion of TTX in pufferfish have occurred in Australia. However, these events have occurred where recreational fishers have caught and eaten pufferfish species without understanding the associated risks of toxicity<sup>7-9</sup>.

## Standards or guidelines

### Australia and New Zealand

Schedule 19-5 of the Australian New Zealand Food Standard Code does not specify a maximum level (ML) for TTX.

**Codex** – There are no Codex Standards available that establish a ML for TTX in pufferfish for human consumption.

**Japan** – Japan has a maximum regulatory limit of 20 MU/g, corresponding to 2 mg/kg TTX equivalents, that is permitted in *fugu*<sup>1,2</sup>.

**Europe** – There are no maximum limits established by the European Commission for tetrodotoxin<sup>10</sup>. However, Regulation (EC) No 853/2004 states that: 'Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*'<sup>11</sup>.

## Management approaches used by overseas countries

**New Zealand** – Imported pufferfish in New Zealand is classed as a Food of High Regulatory Interest. Product can be imported from Korea when accompanied by an official certificate and TTX must be undetectable in the product<sup>12</sup>.

**Japan** – Only select pufferfish species are permitted for sale<sup>3,13</sup>. A chef must be adequately trained and hold a Government issued permit before they can prepare *fugu*<sup>13</sup>.

**United States** – Commercial importation of pufferfish into the United States is heavily restricted by the US Food and Drug Administration (FDA) and product can be detained without physical examination. Personal importation is prohibited<sup>14</sup>.

<sup>5</sup> Information supplied to FSANZ by the Australian Government Department of Agriculture, Fisheries and Forestry.

An agreement was reached between the Japanese Ministry of Health and Welfare and the US FDA to permit importation of a single species of pufferfish, *Takifugu rubripes*, for special occasions and subject to specific criteria<sup>14,15</sup>.

This risk statement was compiled in: June 2022

## References

- 1 Lago J, Rodríguez LP, Blanco L, Vieites JM, Cabado AG. Tetrodotoxin, an Extremely Potent Marine Neurotoxin: Distribution, Toxicity, Origin and Therapeutical Uses. *Mar Drugs* 2015; **13**: 6384–406. <https://doi.org/10.3390/md13106384>.
- 2 Katikou P, Gokbulut C, Kosker AR, Campàs M, Ozogul F. An Updated Review of Tetrodotoxin and Its Peculiarities. *Mar Drugs* 2022; **20**. <https://doi.org/10.3390/md20010047>.
- 3 Oshiro N, Kuniyoshi K, Yamamoto S, et al. High Levels of Tetrodotoxin in the Flesh, Usually an Edible Part of the Pufferfish *Takifugu flavipaterus*, Caused by Migration from the Skin and the Regional Characteristics of Toxin Accumulation. *JMSE* 2021; **9**: 1312. <https://doi.org/10.3390/jmse9111312>.
- 4 Ahasan HAMN, Mamun AA, Karim SR, Bakar MA, Gazi EA, Bala CS. Paralytic complications of puffer fish (tetrodotoxin) poisoning. *Singapore Med J* 2004; **45**: 73–74.
- 5 ABS. National Nutrition and Physical Activity Survey, 2011–12. Canberra 2014.
- 6 Noguchi T, Arakawa O. Tetrodotoxin – Distribution and Accumulation in Aquatic Organisms, and Cases of Human Intoxication. *Mar Drugs* 2008; **6**: 220–42. <https://doi.org/10.3390/md20080011>.
- 7 Field J. Puffer fish poisoning. *J Accid Emerg Med* 1998; **15**: 334–36.
- 8 Isbister GK, Son J, Wang F, et al. Puffer fish poisoning: a potentially life-threatening condition. *Med J Aust* 2002; **177**: 650–53. <https://doi.org/10.5694/j.1326-5377.2002.tb04999.x>.
- 9 Tibballs J. Severe tetrodotoxic fish poisoning. *Anaesth Intensive Care* 1988; **16**: 215–17. <https://doi.org/10.1177/0310057X8801600216>.
- 10 Knutsen HK, Alexander J, Barregård L, et al. Risks for public health related to the presence of tetrodotoxin (TTX) and TTX analogues in marine bivalves and gastropods. *EFSA J* 2017; **15**: e04752. <https://doi.org/10.2903/j.efsa.2017.4752>.
- 11 European Parliament. REGULATION (EC) No 853/2004. Rome 2004. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004R0853&from=EN> (accessed April 2022).
- 12 Ministry for Primary Industries. Food Notice: Importing Food. Issued under the Food Act (2014). Wellington, New Zealand 2021. <https://www.mpi.govt.nz/dmsdocument/10685-Food-Notice-Importing-Food> (accessed May 2022).
- 13 Antonelli P, Salerno B, Bordin P, et al. Tetrodotoxin in live bivalve mollusks from Europe: Is it to be considered an emerging concern for food safety? *Compr Rev Food Sci Food Saf* 2022; **21**: 719–37. <https://doi.org/10.1111/1541-4337.12881>.
- 14 U.S. Food and Drug Administration. Import Alert # 16-20. Guidance to FDA field personnel. [https://www.accessdata.fda.gov/cms\\_ia/importalert\\_37.html](https://www.accessdata.fda.gov/cms_ia/importalert_37.html) (accessed April 2022).
- 15 U.S. FDA. Exchange of letters between Japanese Ministry of Health and Welfare and the U.S. Food and Drug Administration. Import Conditions for Japanese Puffer Fish. <https://www.fda.gov/international-programs/cooperative-arrangements/fda-japan-exchange-letters-regarding-puffer-fish> (accessed April 2022).