

The Liver of the Aquacultured Japanese Pufferfish¹⁾ (Natural Toxins)

Summary

Food Safety Commission of Japan

Pufferfish is categorized as one of foods which contain or are covered with toxic or harmful substances or are suspected to contain or be covered with such substances” in Article 6, Item (ii) of the Food Sanitation Act (Act No. 233 of December 24, 1947). The issue, however, stipulates in the proviso “that this shall not apply to cases where the Minister of Health, Labour and Welfare (MHLW) specifies that such articles involve no risk to human health”. Based on the proviso, the pufferfish species and the edible parts, which involve no risk to human health, were specified in the notice titled “New Rules for Measures to Secure Sanitation Regarding Pufferfish”. Currently, the liver of Japanese pufferfish (Takifugu rubripes, hereinafter referred to as “Torafugu”) is not included in the notice, thus shall not be sold based on Article 6, Item (ii) of the Act. A proposal to add the liver of Torafugu as a food which involves no risk to human health, as one of the cases stipulated in the proviso, was submitted to the MHLW. In response to the request from MHLW, Food Safety Commission of Japan (FSCJ) conducted a risk assessment on the liver of Torafugu that is aquacultured and served to the customer under the controlled procedures proposed by Saga prefecture and a business operator in the prefecture (hereinafter referred to as “the specified operator”). The proposed procedures are: 1) Torafugu is aquacultured on land under the control of the specified operator. 2) Using a HPLC-FL method, TTX level of a part of liver tissue from every Torafugu fish is determined. 3) Only the liver showing below the detection limit of TTX will be served exclusively in the restaurants managed by the specified operator. FSCJ conducted the risk assessment mainly from the view points; 1) toxicating mechanisms of Torafugu, as well as hazards and risk control points in the on-land aquaculture, 2) validity of the HPLC-FL method for TTX analysis, 3) reliability of the sampling part for TTX-level determination, 4) acceptability of exclusive determination of TTX. Based on the current findings and data in the documents submitted, FSCJ concluded that the safety of the liver of Torafugu aquacultured on land through the proposed procedures could not be secured, even with the determination of TTX in the individual liver.

Conclusion in Brief

Pufferfish poisoning is attributed mainly to tetrodotoxin (TTX) contained in this fish. The incidences of pufferfish poisoning including fatal cases are reported almost every year in Japan. Pufferfish is categorized as one of “articles²⁾ which contain or are covered with toxic or harmful substances or are suspected to contain or be covered with such substances” in Article 6, Item (ii) of the Food Sanitation Act (Act No. 233 of December 24, 1947). Therefore, pufferfish shall not be sold³⁾.

The Article 6, Item (ii) of the Act, however, stipulates in the proviso “that this shall not apply to cases where the Minister of Health, Labour and Welfare (MHLW) specifies that such articles involve no risk to human health”. Based on the proviso, the pufferfish species and the edible parts, which involve no risk to human health, were specified in the notice⁴⁾ titled “New Rules for Measures to Secure Sanitation Regarding Pufferfish”. Currently, the liver of Japanese pufferfish (Takifugu rubripes, hereinafter referred to as “Torafugu”) is not included in the notice, thus shall not be

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sold based on Article 6, Item (ii) of the Act.

A proposal to add the liver of Torafugu as a food which involves no risk to human health, as one of the cases stipulated in the proviso, was submitted to the Ministry of Health, Labour and Welfare. In response to the request from the Ministry of Health, Labour and Welfare, Food Safety Commission of Japan (FSCJ) conducted a risk assessment on the liver of Torafugu that is aquacultured and served to the customer under the controlled procedures proposed by Saga prefecture and a business operator in the prefecture (hereinafter referred to as “the specified operator”). Documents used for the assessment include “The proposal for making the liver of aquacultured Torafugu edible” by Saga prefecture and the specified operator, related documents submitted by the specified operator, and various published materials.

The proposed procedures are as follows: 1) Torafugu is aquacultured on land⁵⁾ under the control of the specified operator. 2) Using a HPLC-FL method, TTX level of every Torafugu liver is determined. Liver tissue for TTX determination is sampled from an area of the liver, called “R4”⁶⁾. 3) Only the liver showing below the detection limit of TTX will be served exclusively in the restaurants managed by the specified operator.

FSCJ conducted the risk assessment mainly from the following view points; 1) toxicating mechanisms of Torafugu, as well as hazards and risk control points in the on-land aquaculture, 2) validity of the HPLC-FL method for TTX analysis, 3) reliability of sampling area (“R4”) for TTX-level determination, 4) acceptability of exclusive determination of TTX.

The results are as follows:

1) Considering the fact that toxicating mechanisms have not yet been fully revealed, the hazard and the point to be controlled could not be identified. FSCJ thus could not secure the safety of the liver of Torafugu aquacultured on land through the proposed procedures.

2) The proposed HPLC-FL method has never been validated as an inspection method for food safety of Torafugu. Moreover, no actual data obtained from the proposed HPLC-FL method is available on “R4” of the liver of Torafugu aquacultured on land under the control of the specified operator.

Therefore, findings and documents submitted by the specified operator do not allow FSCJ to judge the proposed method for determination of toxic substances is appropriate to secure the food safety of the liver of Torafugu aquacultured on land under the control of the specified operator.

3) Although the toxic potency in “R4” was described to be relatively high in the proposal document, no convincing anatomical- or physiological-basis to support such a deflecting intra-organ distribution of the toxic substance was available. Even a conflicting report exists to show that the distribution

of toxic potency in the liver of Torafugu varies largely.

Based on the submitted documents, FSCJ recognized that the safety of the whole piece of liver of Torafugu aquacultured on land through the proposed procedures is not secured by sampling “R4” for the determination of TTX level using the HPLC-FL method.

4) In the proposal, TTX is the only substance to be analyzed. Occurrence of TTX-related substances possessing a comparable toxicity, however, is undeniable in the liver of Torafugu aquacultured on land. In addition, toxicating mechanism of pufferfish with paralytic shellfish poisons (PSP) is yet obscure. Thus a possible accumulation of PSP in the liver of Torafugu aquacultured on land should be considered.

Hence, FSCJ is unable to judge that specifying only TTX for the analysis is appropriate for securing the safety of the liver of Torafugu aquacultured on land.

Based on the current findings and data in the documents submitted, the safety of the liver of Torafugu aquacultured on land through the proposed procedures could not be secured, even with the determination of TTX in the individual liver. The proposal requests to shift the current administrative measure to the new one, in which non-detectable level of liver TTX in instrumental analysis allows the conventionally inedible part of pufferfish to be sold. Prior to such change in the administrative measure, actual data from instrumental analysis of liver TTX should be accumulated, which is similar to the case of the change in the administrative measure on diarrhetic shellfish toxin⁷⁾. Further, the effect on human health needs to be considered based on more detailed toxicological data including the lethality and other effects.

- 1 The Japanese pufferfish are aquacultured and served to the customer under the controlled procedures proposed by Saga prefecture and the specified operator.
- 2 “article” means foods.
- 3 The article 6 of the Food Sanitation Act provides “shall not be sold (including cases of being delivered but not being sold to many and unspecified persons; the same shall apply hereinafter), or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of marketing.”
- 4 The notice is “Kan-Nyu No. 59 dated December 2, 1983,” which was issued from the then Director-General of Environmental Health Bureau, Ministry of Health and Welfare.
- 5 According to the proposal, the seawater used for on-land aquaculture is taken from the 50 meter offshore, where the depth is about 10 meter, at about one meter above the bottom through pipes. The seawater is filtrated and sterilized with a water purification system prior to use.
- 6 “R4” is one of the sampling scheme of 10 parts from a liver, which is shown in Appendix 3 of the risk assessment document. “The liver of the aquacultured Japanese pufferfish”.
- 7 The reference is available at <http://www.fsc.go.jp/fscjis/attachedFile/download?retrievalId=kya20130827309&fileId=502>.