This document is the English translation of "食中毒統計作成要領." The Ministry of Health, Labour and Welfare offers this translation as a service to a broad international audience/readers. While the ministry has attempted to obtain translation that is as faithful as possible to the Japanese version, we recognize that the translated version may not be as precise, clear, or complete as the original version. The official version of this document is the Japanese version. Since December 28, 1994 (Rev. March 29, 2013)

## Methods for creating statistics on food poisoning

I. Purpose

This statistic serves to create a report on the food poisoning case, etc. based on systematic investigations in order to understand accurately the occurrence status of patients of food poisoning and the deaths caused by food poisoning and to find out the complicated status of such occurrences, then ultimately to obtain basic materials for the sanitary administration in a broad sense, but in particular, for food sanitation measures.

#### II. Scope of investigation

- 1 Diseases and patients to be covered
  - (1) Food poisoning
  - (2) Patients of food poisoning or those who are suspected to be so. (hereinafter, a "person poisoned by food, etc."), or those who died of food poisoning.
- 2 Timing and place to understand the target, and the entire flow of the investigation
  - (1) Physician

When a physician has diagnosed a person poisoned by food, etc. or the suspected ones, or has examined a corpse thereof, they shall notify the director of their nearest health center of this fact by writing, calling, or orally within 24 hours.

- (2) Health centers
  - A) Understand the target

Understand the target based on the notification by a physician.

When an official of health centers, etc. finds persons poisoned by food or deaths that have not been notified yet, they shall have the primary physician who have examined the person poisoned by food, etc. or the corpse thereof make a notification. In the case that there is no primary physician, an official of a health center who has a medical license shall notify after a diagnosis.

B) Transfer of the notification slip

"Nearest health center" which receives notification from a physician shall transfer a copy of said notification slip immediately to the director of the health center that is responsible for the location of the person poisoned by food, etc., if it is out of jurisdiction of the former health center.

Note: "Present location" of the person poisoned by food, etc. means where the health center can conduct a food poisoning investigation on the patients with an aim to find out the cause of food poisoning.

That is, "present location" of the person poisoned by food, etc. means:

If the person poisoned by food, etc. is at a place of residence or where they live at the time of investigation then it is the place of residence or their address;

If they are staying at an inn or hospitalized at the time of investigation, then it is the inn or hospital where they are staying.

#### C) Create a Questionnaire on food poisoning

The health center that received a notification or a transferred notification slip shall create "the Questionnaire on food poisoning" (Form No.1) (hereafter, "the questionnaire").

D) Transfer the questionnaire

When the home/business operator/facility, etc. that caused the food poisoning is located in the jurisdiction of the health center that is not the one that created the questionnaire, said questionnaire shall be transferred to the director of the health center that controls where said home/business operator/facility, etc. is located as soon as it has been created.

E) Create the Report on the food poisoning case

The health center supervising the location of the home/business operator/facility, etc. that caused the food poisoning shall investigate the persons poisoned by food, etc. and the deaths in their jurisdiction, and the causal home/business operator/facility, etc., then create "a report on the food poisoning case" (Form No. 14 of the Ordinance for Enforcement of the Food Sanitation Act (hereinafter, "the Ordinance")) (hereinafter, "the case report") based on their comprehensive examination that considered the investigation results and the questionnaire.

(3) Prefectures, cities with health centers and special wards

Prefectures, cities with health centers and special wards (hereinafter, "prefectures, etc.") shall compile case reports reported by health centers that they supervise, and create "a report on the investigation results of the food poisoning case" (Form No. 15 of the Ordinance).

#### III. Implementing organization

- 1 At the Ministry of Health, Labour and Welfare, the Office of Foodborne Disease Surveillance, Inspection and Safety Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau shall develop plans, then statistics shall be created by the office and the Food sanitation divisions of the Regional Bureau of Health and Welfare.
- 2 At the prefectures, etc., the sanitation lead departments and health centers shall conduct the investigation.

At health centers, a close collaboration shall be made under the leadership of the director of the health center by receiving support from relevant organizations, etc., and the officials of the center (those who are responsible for the food sanitation, for example) shall perform the investigation.

#### IV. Form of the notification slip and the questionnaire

1 Form used for notification by physicians The notification of the persons poisoned by food, etc. (Form No. 1-1) 2 Form used for investigation by the director of health centers The questionnaire on food poisoning (Form No. 1)

3 Form used for the report by the director of a health center, Prefectural governors, mayor of cities with health centers, and those of special wards (hereinafter, "Prefectural governors, etc.")

- (1) Report on food poisoning case (Form No. 14 of the Ordinance)
- (2) Form of the invoice
  - A) The invoice that the director of health centers uses to send the Report of the food poisoning case to Prefectural governor, etc. (Form No. 2)
  - B) The invoice that Prefectural governor, etc. uses to send the compiled report to the Minister of Health, Labour and Welfare (a report on the investigation results of the food poisoning case) (Form No. 15)
- V. Notice on investigation
  - 1 Understand the persons poisoned by food and the deaths, and organize the notifications
    - (1) When receiving a notification from physicians by phone or face-to-face, the health center that received it shall create a notification of the persons poisoned by food, etc.
    - (2) The transfer of the notification of persons poisoned by food, etc. can be done by phone, fax, or other appropriate electronic methods.
  - 2 Create the questionnaire
    - (1) When conducting an investigation which requires to create a questionnaire, the investigation shall be performed in the following order regardless of whether the questionnaire needs to be transferred or not.
      - A) The persons poisoned by food and deaths
      - B) Physicians who diagnosed the persons poisoned by food or investigated their dead bodies
      - C) The home, business operators, facility, etc. which are associated with the food poisoning
    - (2) When receiving the notification or transferring the copy of the notification slip, investigation shall be done on the persons poisoned by food or the death, physicians who made the notification, or the home, business operator, facility, etc., that is associated with said food poisoning immediately, then a questionnaire shall be created within 14 days from the receipt of notification.
    - (3) Regarding the case when the causal food is suspected to have been taken abroad or during onboard, the arrival airport shall be treated as the location of the home, business operators, facility etc. causing the food poisoning except when they are domestic and identified. When creating the questionnaire, the location shall be selected in accordance with the following; the case in which the causal food is suspected to have been taken abroad or on foreign airplanes ie, "abroad"; the case in which the causal food is suspected to have been taken on Japanese airplanes ie, "in Japan".
    - (4) Transfer of the questionnaire shall be done in accordance with the following;
      - A) In the case the poisoning has happened in multiple places in Japan except onboard, and they are presumed to be the same food poisoning case in terms of their causal food and disease agent; it is completely impossible to presume the causal home, business operator, facility, etc. and the persons poisoned by food and deaths have

been identified in the jurisdiction of multiple health centers -- It shall be transferred to the director of the health center that has the largest number of persons poisoned by food and deaths in the prefecture, etc. with the largest number of persons poisoned by food and deaths.

- B) The director of health center that received the transferred slip shall conduct an investigation on the unknown items and complete them.
- (5) The health center that created or received the questionnaire shall organize and keep the completed ones, and use them for preventing or planning measures for food poisoning.
- 3 Create the case report

The case report shall be created by the health center that supervises the location of the home, business operator, facility etc. that caused the food poisoning. The case in which the food taken abroad or on board is suspected to be the cause shall be handled in accordance with the previous paragraph 2 (3).

Regarding the case which happened in multiple places in Japan except on board, and when they are presumed to be the same food poisoning case in terms of their causal food and disease agent but it is completely impossible to presume the causal home, business operators, facility, etc, the report shall be created as follows. All of the persons poisoned by food and deaths that have been identified in the jurisdiction of a single health center -- It shall be created by the said health center; The persons poisoned by food and deaths that have been identified in jurisdictions of more than one health centers; It shall be created by the health center that has the largest number of the persons poisoned by food and deaths in the prefectures, etc. with the largest number of the involved persons poisoned by food and deaths.

#### 4 Reporting procedures

(1) Submission procedures

As soon as the food poisoning investigation has been finished, the director of health centers shall create a case report and submit two copies of it to the Prefectural governor, etc.

(2) Correction to reports

If the case report submitted needs to be corrected, the director of health centers shall notify Prefectural governor, etc. immediately.

#### VI. Guidelines for reporting the investigation items

1 Guidelines for completing the questionnaire

The items investigated for the creation of the questionnaire after the notification of persons poisoned by food and deaths from physicians need to be the ones to find out the suspected causal food including the when, where, how and who ate what food, and what the symptoms of the patients like. This investigation should be conducted by food sanitation officials systematically on the inspection status of the causal substances as well.

Note: In the following sections, "patients" shall be replaced with "persons who are suspected to have had food poisoning" or "death" as appropriate.

# Health center code Write the code of the health center that initiated the investigation.

Case number at health center	The health center that completed the questionnaire must write the case number in the year.
Patient number	The health center that completed the questionnaires must write the patient number in the year.
Investigation initiation date	Write the date when the investigation was initiated.
Items in column A (1) Name	Write the name of the patient.
(2) Address	Write the place of residence of the patient. If patient was hospitalized, write the place of the patient before hospitalization.
(3) Gender	Circle the applicable number.
(4) Occupation	The occupation of the patient shall be written in detail in accordance with "Handbook on demographics statistics on occupation and industry".
(5) Date of birth	Circle the applicable name of era, then write the date of birth and the age at the time when food poisoning happened.
(6) Place of onset	Write the place where the patient developed the disease. In the case that the patient developed the disease in a car, on a vessel or on board and was diagnosed as food poisoning after leaving it, the place of onset shall be the first point where the patient left those vehicles.
(7) Name of causal food	The name of the causal food shall be written in detail as much as possible based on a comprehensive determination in accordance with items including "(16) Microbiological and chemical test", "(19) Investigation of causal food", etc. In any of the food taken in the meals such as catered box lunch, school lunch, or course meals that is identified (including presumed; the same applies hereinafter) as the cause of food poisoning and the causal food is identified, for example, as rolled egg, write as "Rolled egg (catered lunch box)". If the causal meal was identified but the causal food is still unknown, write "Unknown" with the meal name in brackets, for example, "Unknown (catered lunch box)". Even if both the causal food and meal are unknown, do not leave it blank but write "Unknown".

(8) Type of causal food	Write the type of causal food in accordance with the classification in "Appendix 1". If the causal food is written as, for example, "Boiled fish and fish sausage (catered lunch box)", write the type of the food for each of "boiled fish" and "fish sausage", as "fish and seafood, etc." and "fish-paste product" respectively. If the causal food is written as "Unknown (school lunch)", "Unknown (course meals), "Unknown (catered lunch box)", etc., classify them under "15 Other".
(9) Place where the causal food was had	Write the facility, etc. where the causal food was eaten.
(10) Cooking at place of intake	Circle the applicable number for cooking activity at the place above (9) from cooked, not cooked, and unknown.
(11) Cooking method at place of intake	If you circled "1:Cooked" in above (10), circle the number applicable to the cooking method.
(12) Detection	If the first notification of the patient was made by a physician, circle "1: Physician", and if the notification of the food poisoning case was made by somebody other than a physician via face-to-face meeting, phone, or postal mail, etc., circle the applicable number about the informant. Please note that "4: Relevant person" means families or care takers of the patient, food sanitation inspectors, etc.
(13) Notification	<ol> <li>For "Date of notification", write the date when the physician first made the notification if it was made by phone or face-to-face meeting, or when it was posted if it was made via postal mail.</li> <li>For "Date of acceptance by a health center", write the date when the (nearest) health center received the notification of occurrence from a physician.</li> <li>For "Physician's name", write the name of the physician who made the notification.</li> <li>For "Physician's address", write the address where the physician who made the notification works at. For example, if the physician works for a hospital, etc., write the address.</li> </ol>

(14) Diagnosis	1) For "Date of First visit", write the date when the physician diagnosed the patient for the first time, or
	examined the corpse thereof.
	2) For "Date of diagnosis", write the date when the
	physician clinically diagnosed the disease as food
	poisoning.
	3) For "Place of diagnosis", write the address of the facility
	where the diagnosis was made.
	If the diagnosis was made in a home visit, write the place
	where the patient was located on the day.
	4) For "Method of diagnosis", circle the applicable number
	on the base for diagnosis on the patient. If more than two
	methods were used for the diagnosis, circle all of the
	applicable ones.
	1 Clinical determination: Diagnosed based on clinical
	determination
	2 Bacteriological test: Diagnosed based on
	bacteriological test of blood, fecal matter, urine, etc.
	<ul><li>collected from a living body.</li><li>3 Testing of chemicals: Chemicals were detected from</li></ul>
	3 Testing of chemicals: Chemicals were detected from blood, fecal matter, urine, etc. collected from a
	living body as a disease agent.
	4 Autopsy: Diagnosis was made based on appearance
	observation as a result of autopsy as well as
	determination based on detection of bacteria or
	chemicals, structure test, pathological test, etc.
	5 Animal test
	6 Other
(15) Onset situation	1) "Date & Time of intake" shall be the date and time when
	the causal food was eaten.
	2) "Date & Time of onset" shall be the date and time when
	the patient developed the disease.
	3) "Incubation period" shall be the duration from when the
	patient had the causal food until the onset.

(16) For "Test" column, circle the applicable one for the test Microbiological and conducted using "Yes" or "No".

chemical test	For "Results" column, write the name of the bacteria, for example, Salmonella spp., Staphylococcus aureus, Norovirus, etc., as well as their type such as serotype, phage type, genotype, toxin type, and so on if anything was detected. When any chemicals were detected, write the name of the substance. If the detected bacteria or chemical was determined as the cause of the food poisoning, circle the name of the detected substance. If the test result was negative or unknown, for example, in case of the test for vomit, write as follows; ex) Bacteria test (-), chemicals (Unknown).
17) Symptoms and Order of onset	For each of the symptoms, circle the applicable answer using "Yes" (observed) or "No" (not observed). If you choose "Yes" (observed) for diarrhea and vomit, circle the applicable number for each and write the number of times per day. For fever onset, write the highest temperature. For other items, circle the applicable answer using "Yes" (observed) or "No" (not observed). Moreover, for the symptoms that the patient developed,
(18) Outcome	write the order of development in brackets and the number. Circle the applicable number and write the appropriate date. When the patient was found to be dead through an interview, etc., confirm the fact by asking the physician who wrote the certificate of death or investigated the dead body, then circle "Death".
(19) Investigation of causal food	<ol> <li>Menu of the food taken before the case         <ol> <li>If the causal food is identified, write the date and time (breakfast, lunch, dinner) when the menu including the causal food was eaten, and the details of the menu. For example, when sliced raw tuna is identified as the causal food, write the entire menu eaten with the sliced fish such as miso soup, rolled egg, etc.</li> <li>When the causal food is unknown but the menu including the causal food can be almost presumed, write the date and timing (breakfast, lunch, dinner) when it was taken and the details of the menu.</li> <li>When more than two meals are presumed as the causes, write the causal meals along with the time course with details of those menus and the date and timing (breakfast, lunch, dinner) when</li> </ol> </li> </ol>

	they were taken.
	<ul> <li>(4) In the case of above (2) or (3) and the presumption is ambiguous, write all of the intake status of possible suspicious snacks, etc. in "2: Other food and drinks". In this case, "(7) Name of causal food" and "(8) Type of causal</li> </ul>
	<ul><li>food" shall be written as "Unknown".</li><li>(5) If the presumption of the causal food or meal is</li></ul>
	not possible, write (Unknown) without leaving it blank.
	<ul> <li>(6) If the box meal was included in the detail of the menu, write "Box meal (boiled fish, steamed fish paste)", for example.</li> </ul>
	2 Other food & Drinks
	When meals other than breakfast, lunch, or dinner described in "1: Menu of the food taken before the case", that is a midnight angely or speely are believed to be the
	that is, a midnight snack or snacks are believed to be the causal food apparently, write the date of the intake and the name of the food or the details of the menu in accordance with the above 1-(2), (3), and (4) if the causal food is determined to be categorized under "2: Other food and
(20) Measures	drinks". Write the measures taken against the food business operators, etc. based on the Food Sanitation Act, for example, "Disposal of materials or other dispositions", "Prohibition or suspension of operation", "Rescission of the license", "Accusation", etc. When the food was contaminated at home or the food poisoning was caused by a toxic food taken at home, the Food Sanitation Act is not applicable to the food. However, if a food sanitation official taught any disposal method of the food, write the details.
(21) Note	When the food poisoning was caused by food additives, apparatus or containers or packaging, write so with special notes, if any.
Items in column B	
(1) Location of causal home/business operator/facility	When the home/business operator/facility that caused the food poisoning case is located in Japan, choose "1: In Japan" and write the name of the said prefecture/city/town. If the causal facility is definitely located in Japan but the
	detailed location is unknown, choose "1: In Japan" and write "Unknown" in the "Prefecture" column. If it is located abroad, choose "2: Abroad" and write the name of said country/city.

	If it is unclear whether it is located in Japan or abroad, circle "3".
	However, like the food poisoning caused by paralytic shellfish poison, in the case that the cause of food poisoning is the place where "fish and seafood" were picked up and is difficult to write the exact location as it is in the ocean, complete the place where said fish and seafood were landed, and specify the picking water area in "(9) Other". If the causal business operator is an ambulant vendor and the cause of food poisoning is associated with his/her location, write the address of the location; if it has nothing to do with his/her location, leave this blank and draw a diagonal line across the box "(1) Location of causal home/business operator/facility".
(2) Name of causal business operator/facility	Write the name of the office/school/hospital/shop/ restaurant/factory, etc. that is sufficiently presumed to have caused the food poisoning. If the cause of food poisoning was at home, write "Home" and add the name of householder in brackets. If it was in an airplane of a Japanese airline, write the company name, its registration number, and flight number.
(3) Type of causal home/business operator/facility, etc.	Write the type of home/office/school/hospital/shop/ restaurant/factory, etc. which caused the food poisoning in accordance with "(4) Type of causal home/business operator/facility, etc." of the case report, and add details in brackets. For example, if it was at a sushi or soba restaurant, write "Restaurant (sushi restaurant)" or "Restaurant "soba restaurant", and if it was at a childcare center or nursing home, write "Office (food service facility (childcare center))" or "Office (food service facility (nursing home)).
(4) Classification of Food poisoning	f Circle the number applicable.

<ul> <li>(5) Disease agent</li> <li>(6) Status of patient or death</li> <li>(7) Status of causal home/business operator/facility, etc.</li> </ul>	Write the disease agent that is determined to be the cause of the food poisoning case. If the disease agent is bacteriogenic, write the name of the bacteria, such as Salmonella spp., Staphylococcus aureus, Clostridium botulinum, Vibrio parahaemolyticus, pathogenic Esherichia coli, Clostridium perfringens, Bacillus cereus, Yersinia enterocolitica, Campylobacter jejuni/coli, Non-O1 Vibrio cholerae, and when the sserotype, etc. has been identified as well, add the type such as serotype, phage type, genotype, toxin type, etc. If the disease agent is viral, write the name such as Norovirus. When it was caused by a parasite, write the name of the parasite such as Kudoa, Sarcocystis, or Anisakis/Pseudoterranova, or the species name such as Kudoa septempunctata if it is identified. If it is due to other parasite, write the name such as Cryptosporidium, etc. In the case it is a chemical substance, write the name of inorganic substance, inorganic compound, or organic compound such as methanol, calcium arsenate, parathion, etc. As regard natural toxins, specify whether it is of animal origin or botanical origin. Write the number of people who ate the causal food, and those who developed the disease, and add the number of patients who died as duplicate. As regard sanitation status of the home/business operator/facility, etc. that caused the food poisoning case, circle the applicable number in each question. Please note that questions about cooking location shall be replaced with those on a kitchen in case of home and a production facility in case of a food factory. As for questions on cleanliness, water discharge, presence of flies, circle the applicable number based on judgment of cooks.
(8) Status of causal handler	At the causal home/business operator/facility, etc., if the food handler is to be blamed as the cause of contamination, circle the number applicable. If the cause of contamination has nothing to do with the food handler, draw a diagonal line across the box "(8) Status of causal handler".
(9) Other	Write an important notice, for example, it was the food poisoning caused by misuse of pesticide, etc.

2 Notes on completing the questionnaire

- (1) In case of a mass outbreak of food poisoning caused by common causal food and disease agent, the common ground listed in column B must be written on the first patient only and there is no need to complete this for each of the patients. In this case, the questionnaire on the first patient shall be kept as the cover.
- (2) Do not leave all investigation items as blank by writing "Unknown" for unknown questions, "Not investigated" for questions which have not been investigated, and "None" for questions that ask for any presence but not appropriate.
- 3 Guidelines for filling the case report

Health center code	Write the code of the health center that completed the case
	report.

Case number at the Prefecture, etc. shall write their case number in the year. prefecture, etc.

Case number at the Health centers shall write their case number in the year. health center

(1) Location of When the home/business operator/facility that caused the food poisoning case is located in Japan, choose "1: In Japan" and write the name of said prefecture/city/town.

facility If the causal facility is definitely located in Japan but the detailed location is unknown, choose "1: In Japan" and write "Unknown" in the "Prefecture" column.

If it is located abroad, choose "2: Abroad" and write the name of said country/city.

If it is unclear that it is located in Japan or abroad, circle "3".

However, like the food poisoning case caused by paralytic shellfish poison, in case that the cause of food poisoning is at the place where "fish and seafood" was picked up and is difficult to write the exact location as it is in the ocean, complete the place where said fish and seafood were landed, and specify the picking water area.

If the causal business operator is an ambulant vendor and the cause of food poisoning case is associated with his/her location, write the address of the location; if it has nothing to do with his/her location, leave this blank and draw a diagonal line across the box "(1) Location of the causal home/business operator/facility".

(2) The first patient Write the date of onset and the date when a health center received the notification.

(3) Name of causal business operator/ facility	Write the name of the office/school/hospital/shop/ restaurant/factory, etc. which is sufficiently presumed to have caused the food poisoning case. If the cause of the food poisoning case is a home, just write "Home". If it is a Japanese airline, write the company name, its registration number, and flight number.
(4) Type of causal home/ business operator/ facility, etc.	Circle the number applicable to the type of home/business operator/facility, etc. which caused the food poisoning case. "(10) Place for picking" means the case in which the cause of contamination exists at the place of picking and it has nothing to do with any facility; for example, when harmless shell turns toxic in seawater only during a specific period. Therefore, food poisoning which is not related to the point of picking, for example, natural toxic poisoning such as that caused by "puffer fish" or "poison mushroom" shall be exempted.
(5) Name of causal food	Copy the name of food written in "(7) Name of causal food" on the Questionnaire on food poisoning.
(6) Type of causal food	Circle the number applicable to the causal food in accordance with the classification shown in Appendix 1. If the name of causal food written in the column is, for example, "Boiled fish and fish sausage (catered lunch box)", circle the number appropriate for the type of each of the "boiled fish" and "fish sausage", respectively. If the description in the name of causal food column is "Unknown (school lunch)", "Unknown (course meals), "Unknown (catered lunch box)", etc., classify them as "15 Other".
(7) Determination of causal food	Circle the number applicable as to whether it is "Confirmed" or "Presumed" regarding the determination of the causal food. If more than two causal food are identified, circle the number applicable for whether it is "Confirmed" or "Presumed" on each of the top three causal food. When "16: Unknown" is selected in "(6) Type of causal food", write the type number of causal food as just "16", and then there is no need to circle any of confirmed or presumed.
Type number of causal food	Write the number circled in "(6) Type of causal food" column.

Confirmed	Circle the number listed here when the disease agent is detected or causal food is clearly identified by epidemiological studies, etc.
Presumed	Circle the number listed here when the causal food is presumed as a result of epidemiological studies.
(8) Place of food intake	Copy the place of food intake that is written in "(9) Place where the causal food was had" on the questionnaire.
(9) Type of place of food intake	Circle the number applicable to the facility, etc. where mainly the causal food was eaten. If the causal food was eaten at more than 2 locations, choose the facility where the largest number of patients did, or the location that is considered to be the most important epidemiologically when those are equal among groups, then circle the number that is applicable to the chosen one.
(10) Cooking at place of food intake	Circle the number applicable for whether cooking was done at the place mentioned in "(9) Type of place of food intake" or not.
(11) Disease agent	Write the name of disease agent of the food poisoning based on the results written in "(16) Microbiological and chemical test" of the questionnaire. If bacteria have been confirmed as the disease agent and any information about it such as serotype has been identified, write the name of the bacteria and its serotype, phage type, toxin type, etc. In the case of a virus and when its genotype has been identified, write the type in addition to the name of virus.
(12) Type of disease agent	Based on the results written in "(16) Microbiological and chemical test" of the questionnaire, circle the number appropriate as the type of disease agent of the food poisoning in accordance with the classification shown in Appendix 2.
(13) Test status	<ul> <li>Write the status based on the results written in "(16) Microbiological and chemical test" of the questionnaire.</li> <li>Write the results of the test by classifying the type of "Testable materials" into "Substances collected from the patient", "Food", "Apparatus, containers and packaging" and "Other".</li> <li>In this case, "Apparatus, containers and packaging" shall contain the swab samples collected from them.</li> </ul>

Test conducted Based on the description in "Test" column on the questionnaire, confirm whether the test was conducted or not on each type of the testable materials, then circle the number applicable as either "1: Yes" or "2: No" on the case report. Presence of disease As for the type of testable materials on which the test was agent conducted, circle the number applicable from among "3: (required only when Present" or "4: No" on the case report based on the any tests are description under "Test" column on the questionnaire. conducted) In this case, if the test was conducted on any of "blood", "fecal matter", "urine" or "vomit" of the testable materials written on the questionnaire, "1: Yes" should be chosen in "Test conducted" on "substances collected from the patient" or "substances collected from others" on the case report. If the bacteria or chemical substance detected was written or any of their name was circled on any of "blood", "fecal matter", "urine" or "vomit" of the testable materials written on the questionnaire, "3: Present" should be chosen in "Presence of the disease agent (must be completed only when the test is conducted)" on "substances collected from patient" or "substances collected from others" on the case report. (14) Status of Write the number of patients who developed diseases from among those who consumed the causal food, who died from patient/death/eater among the patients developing the disease, and who ate the causal food. Those numbers shall be written by age group and by gender based on age as of the occurrence day of food poisoning. Transfer Write the name of prefecture, etc. and health centers which transferred the questionnaire, and the number of sent slips. Even if the transferred questionnaire was sent from more than four prefectures, etc. or health centers and it is not possible to write all of their names in the column, use the note column or margin to write all of their names and the number of questionnaires received. Note The case that was caused by food additive, apparatus or container and packaging, or which have been continued from the previous month shall be noted as such. Other than the above, write special notes, if any.

# VII. Task of the Prefecture, etc.

1 Screening

Review the details written in case reports submitted by the director of health centers. If there is need for correction, contact the director of health centers immediately and check.

# 2 Submission of case report

(1) Submission of a case report

Review written details while checking the number of case reports received from the director of health centers with that mentioned on the invoice (Form No. 2). If there is a need for correction, notify the director of health centers immediately and have them correct it. (Correction in the previous sentence shall be done by the food sanitation lead division.) Of the two copies submitted, one shall be kept and the other shall be compiled to create a report on the investigation results of the food poisoning case.

## (2) Registration of case number

The case report shall be given a serial case number that term starts from January 1st and ends on December 31st, and the number shall be written in "Case number at the prefectures, etc." column.

## 3 Delivery procedure

(1) Create & Submit a Report on investigation results of the food poisoning case

The report on investigation results of the food poisoning case shall be submitted to the Office of Foodborne Disease Surveillance of Inspection and Safety Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare by the prescribed date with the report of the food poisoning case received within the month attached.

At the same time, registration on the Food Sanitation Synthetic Information Processing System shall be done as well.

(2) Submission deadline

A report on investigation results of the food poisoning case shall be submitted to the Minister of Health, Labour and Welfare by the 10th of the following month of receiving a report of the food poisoning case.

# (3) Correction of reporting

If the report on investigation results of the food poisoning case submitted or the case report attached needs to be corrected, correction report should be made by using Form No. 15 or Form No. 14 of the Ordinance each time. (For details, see IX Reporting for Correction.)

# VIII. Guideline for Screening (The case report)

Health center code Is a code (4 digits) given to each health center? Are there any contradictions with "(1) Location of the causal home/business operator/facility"? The wrong code shall be corrected by the appropriate health center code.

Case number at the prefecture, etc.	Is an annual serial number given by the prefecture, etc.? Is there no duplicated number? The cases having the same number and details shall be handled as a single case. If only case numbers overlap but details are different, the number on one case shall be corrected to the following number.
(1) Location of the causal home/ business operator/ facility	Is it specified whether it is located in Japan or abroad? If the causal facility is definitely located in Japan but the location details are unknown, make sure that "1: In Japan" is chosen and noted as "Unknown" under the "Prefecture" column.
(2) The first patient	Is the date of onset earlier than the date of acceptance by a health center? If not, the date shall be corrected upon confirmation.
(4) Type of the causal home/ business operator/ facility, etc.	Make sure that there is no contradiction on the type and name of the causal home/business operator/facility.
(5) Name of the causal food	Is the name described in detail?
(6) Type of the causal food	The relationship between the name of the causal food and the causal food Do "(5) Name of the causal food" and the classification made in (6) Type of the causal food correspond? If the name of the causal food written is more detail than the applicable classification of type of causal food, leave it as is when there is no contradiction, and correct it to the option that is appropriate to the causal food when there is apparent conflict. A) For example, when name of the food is "grilled fish" but type is classified as "Processed fish and seafood 5: Other", correct it to "Fish and seafood 3: Other". B) When name of the causal food is unknown but the causal meal was identified, and the description is like "Unknown (catered lunch box)" and the type is classified as "16: Unknown", the classification shall be corrected to "15: Other".

(7) Determination Is either "Confirmed" or "Presumed" selected on all the of the causal food items circled in "(6) Type of the causal food"?

When type of the causal food is classified as "16: Unknown", neither of "Confirmed/Presumed" will be selected.

(9) Type of the sonly one option selected?

- place of food intake If more than two options are selected, choose the place where the largest number of patients ate the food, or the place that is considered as most important epidemiologically when the number of patients is equal among all places, then circle the number that is applicable to the chosen one.
- (11) Disease agent Are all of the details identified (serotype, phage type, genotype, toxin type, etc., as well as name of the disease agent) and written?
- (12) Type of the A The relationship between type of the causal disease agent home/business operator/facility and disease agent

If the case is applicable to all of the following, the cause of poisoning is a subject that contains a toxin in its own body does not mean that it was contaminated at the place of picking. Therefore, the answer for (4) Type of the causal home/business operator/facility, etc. shall be corrected to the type of facility, etc. which failed in handling the food; (4) The type of causal home/business operator/facility is classified as "10: Place of picking"; (12) Type of disease agent is classified as "20 Poisonous plant"; (6) Type of causal food is classified as "25 Poisonous animal"; (6) Type of causal food is classified as "2 Puffer fish."

B The relationship between type of the causal food and disease agent

When in "(13) Test Status", "2: No" is selected or nothing is checked on all of "Substances collected from patient", "Substances collected from others", "Food", "Apparatus, containers and packaging" and "Other", and "(6) Type of the causal food" is "2: Puffer fish", is "25: Poisonous animal" selected in (12) Type of disease agent? Similarly, in case of "11: Mushrooms", is "24: Poisonous plant" selected as disease agent? If other option is selected, correct the type of disease agent to "25: Poisonous animal" or "24: Poisonous plant".

(13) Test status	When in "Test Status", "1: Yes" is selected on each of "Substances collected from patient", "Substances collected from others", "Food", "Apparatus, containers and packaging" and "Other", is either of "3: Present" or "4: No" is circled in "Presence of disease agent (must be completed only when the test is conducted)"? If nothing is selected (in the case the test was done but disease agent is unknown), correct it to "4: No". If "2: No" is selected in "Test conducted" and either of "3: Present" or "4: No" is circled in "Presence of disease agent (must be completed only when the test was conducted)", delete the answer and leave it with nothing chosen.
(14) Status of th patient/death/eater	<ul> <li>As for the number of eaters, patients, and deaths, if the formula (the number of eaters) &gt;= (the number of patients)</li> <li>&gt;= (the number of deaths) is not seen, reinvestigation shall be conducted.</li> <li>Is the total number of patients equal to the sum of the number of patients by gender (sum of male/female) or by age group? If not, correction shall be made upon reinvestigation.</li> <li>Is the number of deaths (duplicated) equal to the sum of the number of deaths by gender (sum of male/female) or by age group? If not, correction shall be made upon reinvestigation.</li> </ul>
Transfer	When the questionnaire was transferred, is everything completed?

# IX. Reporting for Correction

1 General correction method

(1) Correction method for numbers and letters

Reporting on corrections shall be made by writing reported numbers (letters) only at below for the part that needs correction "in blue or black ink" and correct the numbers (letters) above there "in red ink". In this case, special attention is required for the following which are A - E.

- A) Do not strike out the incorrect description with a diagonal line or double lines.
- B) When correcting the item reported in blank, write "0" below the box "in blue or black ink", and add the correct number above "in red ink".
- C) When canceling the reported number, write the figure below the box "in blue or black ink", then add the correct number (for example, "0" when it results in zero) "in red ink".
- D) When correcting numbers, pay careful attention to different written figures in red or in blue.
- E) The figures written "in blue or black ink" are the ones that have been already reported in reports of correction. Therefore, the figures submitted shall be organized and kept

so that the immediate base figures are understood accurately even if multiple corrections are required.

(2) Method for correcting circled items

When correcting items of the selected encircled numbers, the circle reported shall be crossed out "in blue or black ink", then the correct number "in red ink" shall be circled.

- 2 Correcting the case report
  - (1) In case the submitted case report needs to be corrected, Form No. 14 of the regulation shall be used each time and noting "Correction" at the top right margin "in red" in the submission.
  - (2) The following items shall be written "in blue or black" in the submission and corrected appropriately.

A: Health center code, B: Case number at the prefectures, etc., C: Case number at the health center, D: "(1) Location of the causal home/business operator/facility", E: "(2) Date of onset of the first patient and Date of acceptance by health center"

(3) When a prefecture, etc. receive the report on corrections from a health center, corrected documents are kept at the prefecture, etc. first, then a report on corrected items are made to the Ministry of Health, Labour and Welfare. Careful attention should be paid in this case, because mistakes often happen when figures corrected by a health center are reported to the Ministry of Health, Labour and Welfare directly.

# X. Submission of the questionnaires, etc.

The followings are number of copies and deadlines for the questionnaire, etc. to be submitted by Prefectural governor, etc. and by the director of health centers.

Type of the questionnaire, etc.			The director of health Prefectural governor, centers etc.				
			1	G 1	etc.	C.	0.1.4
		Create	Storage	Submit	Create	Storage	Submit
Form No. 1	Questionnaire on food poisoning	1	1	-	-	-	-
From No. 14	Report of food poisoning case	3	1	2	-	1	1
Form No. 2	Invoice	2	1	1			
From No. 15	A report on the investigation results of food poisoning cases				2	1	1
		poisoni be crea immed comple poisoni investig submitt	iately at tion of ing case gation a ted to th	e shall fter the a food nd ne vernor,	investig of the f case sh submitt Office Disease of Insp Safety Departr Environ Health Safety, Pharma Safety Environ Health Ministr Labour by the followi compil report of poisoni	ted to the of Food e Survei ection a Division ment of nmental and Foo aceutica	esults soning le borne llance nd n, od 1 , alth, elfare, the th by n the cod that

Type by lood p	
Fish and Seafood	
1. Shellfish	Shellfish and those cooked or processed
2. Puffer fish	Puffer fish and those cooked or processed
3. Other	Fish and seafood other than 1. and 2., and those cooked.
	Whale is included in this category.
Processed fish and seafood	
4. Fish paste product	Steamed fish paste, Satsuma-age, Chikuwa, Gobomaki
	(burdock root rolled by fish paste), Naruto-maki,
	Sumaki, fish ham, fish sausage, Hampen, etc.
5. Other	Processed food made from fish and seafood listed in
	above 3 except fish paste shown in 4. Smoked fish, dried
	fish (Mirin-boshi, Hoshi-mono, Bushi, etc.), semi-dried
	fish (Shirasu-boshi, Namari-bushi, etc.), salted fish
	(including Tarako, Sujiko, Shiokara), Tsukuda-ni,
	Tsukemono (Japanese pickles; Kasuduke, Misoduke, and
	so on), etc.
6. Meat and its product	Meat innards and poultry, and those cooked or processed.
7. Egg and its product	Egg of birds, and those cooked and processed including
	mayonnaise).
8. Milk and its product	Milk of mammals (except human), and those cooked or
	processed.
9. Grain and its product	Grain (expect beans) and similar food, and those cooked
	or processed. Snacks and alcohol are not excluded.
	Buckwheat flour, rice cake, cooked rice, Fu (dried bread-
	like pieces of wheat gluten), Shiratama (dumplings made
	from rice flour), Sake-kasu (sake lees), soy sauce, miso
	paste, bread (except sweet ban), etc.
Vegetable and its product	
10. Bean	Beans and those cooked or processed
	Fruits are not included.
	Daizu-kasu (bean lees), Unohana, tofu, soy milk,
	Abura-age, Natto, Shimi-dofu, raw bean paste, etc.
11. Mushroom	Mushrooms and those cooked or processed.
12. Other	All vegetables, fruits, and those cooked or processed
	except above 10 & 11. Confectionery and alcohol are not
	included.
13. Confectionery	Confectionery except chilled sweets.
	Bean snacks (butter peanuts, Goshiki-mame, etc.),
	rice crackers (Senbei, Arare, etc.), rice cakes (Daifuku-
	mochi, Kashiwa-mochi, etc.), Manju, Dorayaki, cakes,
	Castella, cream puff, potato chips, popcorn, biscuits,
	sweet bun (Azuki-bean roll, cream bread, and so on), etc.
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Appendix 1 Type by food poisoning causing food

15. Other	Cooked or processed food made from more than two food materials (any that are primary food), therefore it is unknown which is the causal food, for example, croquette, gyoza, steamed Chinese dumplings, cooked meat and vegetables, etc. All food not applicable to any of above 1. to 14. Alcoholic drinks, chilled sweets, seaweed, and those cooked or processed. Food additives, apparatus and containers and packaging.
16. Unknown	containers and packaging.

Cla	ssification of the disease a	gent of food poisoning
1	0.1 11	
1	Salmonella spp.	
2	Staphylococcus aureus	
3	Clostridium botulinum	
4	Vibrio parahaemolyticus	
5	Shiga toxin producing	
~	Escherichia coli	
6	Other pathogenic	
_	Escherichia coli	
7	Clostridium perfringens	
8	Bacillus cereus	
9	Yersinia enterocolitica	
10	Campylobacter jejuni/coli	
	Non-O1 Vibrio cholerae	
	Vibrio cholerae	
	Shigella	
	Salmonella Typhi	
15	Salmonella Paratyphi A	
16	Other bacteria	Aeromonas hydrophila, Aeromonas sobria, Plesiomonas shigelloides, Vibrio fluvialis, Listeria monocytogenes, etc.
17	Norovirus	
18	Other virus	Sapporo virus, Rotavirus, Hepatitis A virus, Hepatitis E virus, etc.
19	Kudoa	Kudoa septempunctata
20	Sarcocystis	Sarcocystis fayeri
21	Anisakis/Pseudoterranova	Nematode which is referable to Anisakis or Pseudoterranova
22	Other parasite	Cryptosporidium, Cyclospora, lung fluke, Spiruria, Cestoda, etc.
23		Inorganic substances including methanol, histamine, arsenic, lead, cadmium, copper, antimony; inorganic compound including arsenate, arsenate lime; organic mercury, formalin, parathion, etc.

Appendix 2 Classification of the disease agent of food poisoning

24	Poisonous plant	Toxic sprouts of potatoes (solanine), toxic components of
		raw ginkgo and raw Japanese plum (cyanide), toxic
		components of lycoris (lycorine), components of Coriaria
		japonica (Coriamyrtin, tutin), toxic components of Datura
		metel (atropine, hyoscyamine, scopolamine), toxic
		components of aconite and aconitum (aconitine), toxic
		components of poisonous mushroom (muscarine,
		amanitin, phalline, lampterol, etc.), root toxin of
		Phytolacca acinosa (phytolaccatoxin), seed of Calystegia
		japonica (pharbitin), and other toxic components
		contained in plants naturally.
25		Puffer fish toxin (tetrodotoxin), ciguatera toxins, paralytic
		shellfish poison (PSP), diarrhetic shellfish poison (DSP),
		tetramine, neurotoxic shellfish poison (NSP), domoic
		acid, and other toxic components contained in animals
		naturally.
26	Other	
27	T. T 1	
27	Unknown	