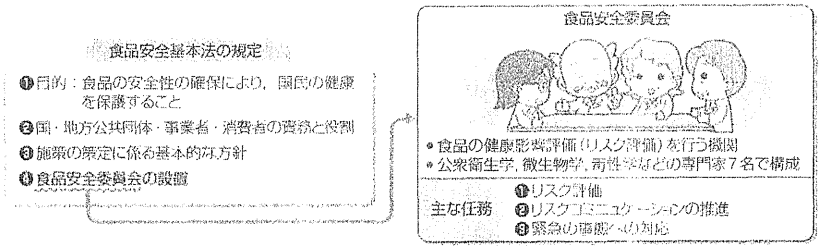
食品安全基本法

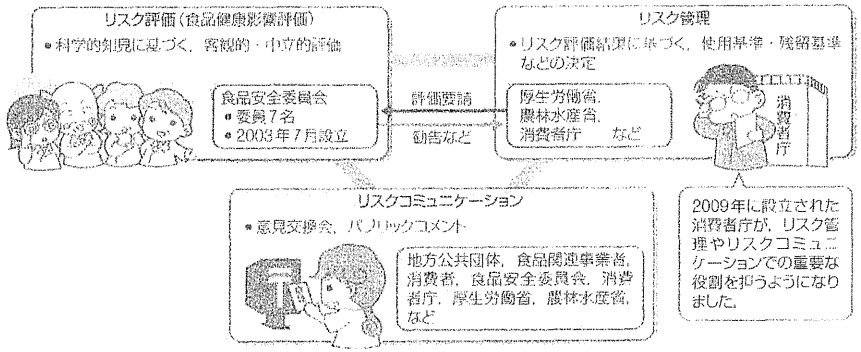
牛海綿状脳症（BSE），国内では使用が許可されていない食品添加物の使用など，食品の安全性を揺るがす事件が相次ぎ，消費者の不安が高まってきたことから，食品の安全性の確保により，国民の健康を保護することを目的とした『食品安全基本法』が2003年7月に施行された．



食品のリスク分析

リスク分析とは，どんな食品にもリスクがあるとの前提で，リスクを科学的に評価し，適切な管理を行い，リスクを最小限にすることを重視する考え方をいう．リスク評価，リスク管理，リスクコミュニケーションの3要素からなる．

リスク分析の3つの要素



食品中の放射性物質

2011年の東日本大震災に伴う原子力発電所事故により，厚生労働省は同年3月より食品中の放射性物質の基準値を設定しました．当初の基準値は「飲食物摂取制限に関する指標」に基づいて緊急的に設定された値でしたが，その後，より一層の安全確保の観点から見直しが行われ，2012年4月に新たな基準値が設定されました．

新たな基準では，年間被曝線量の上限を従来の5mSvから1mSvに引き下げたほか，食品を「一般食品」および

放射性セシウムの基準値

食品群	基準値（Bq/kg）
一般食品	100
乳児用食品	50
牛乳	50
飲料水	10

牛海綿状脳症（BSE）

BSEは感染性プリオン蛋白質によって起こる牛の病気で，感染した牛の肉骨粉を別の牛の飼料に用いることで感染が拡大します．1986年にイギリスで初めて確認され，その後世界中に広がっていきました．また1994年頃から若年者においてvCJD（変異型クロイツフェルト・ヤコブ病）が多発するようになり，これはBSEからの感染とされています．

日本では，2001年2月にBSE発生国からの牛肉の輸入が禁止されました．しかし同年9月にBSEに罹患した牛が初めて発見されたことから，食用として処理されるすべての牛を対象としたBSE検査が全国一斉に開始されました．翌年には牛の肉骨粉の飼料への使用の禁止などを定めた『牛海綿状脳症対策特別措置法』が制定され，BSEに罹患した牛肉を流通させないシステムが確立されました．

近年では，世界のBSE発生数は激減しており（1992年：約37,000頭 → 2011年：20頭），日本においても検査体制や輸入条件の緩和が図られています．

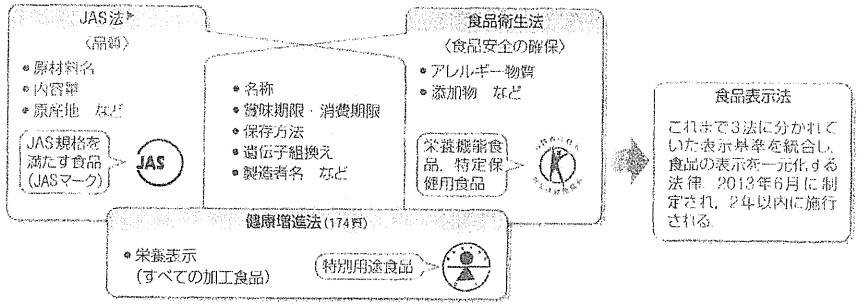
・牛海綿状脳症（BSE）：bovine spongiform encephalopathy　・変異型クロイツフェルト・ヤコブ病（vCJD）：variant Creutzfeldt-Jakob disease

食品の表示

表示の種類

・食品の表示は，消費者が食品を選ぶ際の基準となる重要なものである．食品包装には原材料名や賞味期限，保存方法などの基本事項をはじめ，栄養成分，遺伝子組換えやアレルギー物質含有の有無など，あらゆる表示がなされている．
・主な法律に『食品衛生法』『JAS法』『健康増進法』などがある．さらに2013年『食品表示法』が制定された．
・食品の表示制度に関しては，2009年度より消費者庁および消費者委員会が業務を担当している．

食品表示に関する法律とその規定内容



表示事項

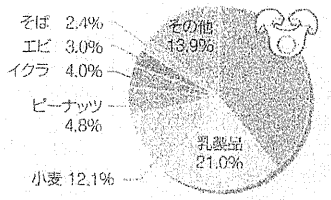
・表示のほとんどは『食品衛生法』および『JAS法』で定められている．また原材料名中のアレルギー物質を含む食品に関する表示は『食品衛生法』で定められている．

食品表示法・食品衛生法・JAS法の基本的表示事項に基づく加工食品の例

名称	スナック菓子
原材料名	じゃがいも（遺伝子組換え），植物油，チーズ，食塩，乳化剤（大豆を含む），調味料（アミノ酸等），香料，パプリカ色素，酸化防止剤（エリソルビン酸Na） 食品添加物とそれ以外を区別し，重量の多いものから順に記す
内容量	62g
賞味期限	2012.02.11
保存方法	直射日光の当たるところ，高温多湿のところでの保存は避けてください 未開封の期限におけるもの
原産国	アメリカ 国内で製造されたものの場合は不要
輸入者	メディック食品株式会社 東京都港区南青山×-×-× 国内で製造されたものの場合は製造者または加工者

アレルギー物質を含む食品の表示（『食品衛生法』）

特定原材料の7品目（表示を義務化するもの）	特定原材料に準ずる20品目（表示を推奨するもの）	
・えび	・あわび	・大豆
・かに	・いか	・鶏肉
・小麦	・いくら	・バナナ
・そば	・オレンジ	・豚肉
・卵	・キウイフルーツ	・まつたけ
・乳	・牛肉	・もも
・落花生	・くるみ	・やまいも
	・さけ	・りんご
	・さば	・ゼラチン
	・カシューナッツ	・ごま



資料：食品アレルギーの発症・重症化予防に関する研究

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Association between first airborne cedar pollen level peak and pollinosis symptom onset: a web-based survey

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Cedar pollinosis in Japan affects nearly 25 % of Japanese citizens. To develop a treatment for cedar pollinosis, it is necessary to understand the relationship between the time of its occurrence and the amount of airborne cedar pollen. In the spring of 2009, we conducted daily Internet-based epidemiologic surveys, which included 1453 individuals. We examined the relationship between initial date of onset of pollinosis symptoms and daily amount of airborne cedar pollen to which subjects were exposed. Approximately 35.2 % of the subjects experienced the onset of pollinosis during a one-week interval in which the middle day coincided with the peak pollen count. The odds ratio for this one-week time interval was 4.03 (95 % confidence interval: 3.34–4.86). The predicted date of the cedar pollen peak can be used to determine the appropriate date for initiation of self-medication with anti-allergy drugs and thus avoid development of sustained and severe pollinosis.

Keywords: seasonal allergic rhinitis; web-based survey; population surveillance; pollinosis; cedar

Introduction

Pollinosis involving immunoglobulin E (IgE)-mediated immediate-type hypersensitivity is an important issue in many countries because of the high rates of morbidity associated with the condition (D'Amato et al. 2007). One meta-analysis revealed that pollinosis has a morbidity of 24.5 % in the general population in Japanese urban cities (Kaneko et al. 2005). However, the morbidity is increasing along with environmental changes, which increase the severity of pollinosis. The social and public health impacts of the condition are highly significant because of the reduction in productivity caused by prolonged symptoms, which can persist for > 2 months (Crystal-Peters et al. 2000; Okubo et al. 2005).

In Japan, *Cryptomeria japonica* (Japanese cedar) is a major representative pollen allergen. This species was planted in large numbers after 1945 because of the increased demand for timber following World War II. Cedar pollen begins to form in July and is almost fully developed by November when the cedar tree enters a dormant state. Cedars awaken from their dormancy and start to flower in early February (Kawashima & Takahashi 1999). The scattering of cedar pollen is determined by conditions appropriate for high levels of flowering as well as by weather conditions that enable the pollen to become airborne (Kawashima et al. 1998). The amount of airborne cedar pollen is affected by several variables, including the number of sunlight hours, wind speed and direction, and humidity (D'Amato et al. 2005). When the season begins, only small amounts of cedar pollen are generated, and these are then dispersed by strong winds. At the peak of flowering, large quantities of pollen become airborne, and when these are dispersed by strong winds they may cause pollen storms. The released cedar pollen floats in the atmosphere for long periods and is dispersed over great distances (Okamoto et al. 2009; Awaya & Murayama 2012). Therefore, the daily amount of airborne cedar pollen fluctuates during the allergy season and is influenced by weather conditions (Takasaki et al. 2009).

Epidemiological surveys of pollinosis are usually conducted using patient questionnaire surveys that show trends, but these surveys cannot clarify prevalence (Okuda 2003). Clinical diagnostic techniques, including IgE assays, can provide definitive diagnoses to support information gleaned from patient symptom surveys (Sakashita et al. 2010). However, total morbidity cannot be determined by surveys involving patients treated at medical facilities, because many patients do not seek medical attention when their symptoms are mild, especially early in the allergy season. Therefore, general population surveys on pollinosis are necessary. Once pollinosis occurs, symptoms persist for the duration of the season (Sasaki et al. 2009). Identification of the initial date of pollinosis is necessary to clarify its characteristics and to take appropriate countermeasures. To this end, daily observations are necessary. The Internet is useful for conducting such daily epidemiological investigations (Sugiura et al. 2010, 2011). The first epidemiological survey using the Internet was published in 1996, and others have followed (Bell & Kahn 1996). A benefit of this method is that both individuals who seek medical care and those who do not can be included (Tilston et al. 2010). Internet surveys of the population with and without allergic rhinitis have been conducted using citizens registered with Internet survey companies (Long 2007; Sharp & Seeto 2010). However, most were cross-sectional surveys conducted after the season onset.

In 2007, we developed a web-based daily symptom surveillance method known as the WDQH or Web-based Daily Questionnaire for Health (Sugiura et al. 2010, 2011). Surveys using the WDQH enable the discovery of infection outbreaks and are used to investigate the effects of environmental factors on health conditions in the population (Sano et al. 2013). In the present study, we conducted a survey on pollinosis using the WDQH. The survey was conducted during the spring, prior to the onset of cedar pollinosis symptoms.

The objectives of this study were to evaluate the feasibility of a web-based epidemiological survey of pollen diseases, to determine the daily morbidity and initial date of pollinosis onset, and to clarify the relationship between pollinosis and the amounts of airborne cedar pollen.

Methods

Survey method

The daily survey was conducted between 1 February 2009 and 30 March 2009, and involved 1453 residents of Tokyo, Japan; the study was approved by the Research Ethical Committee of Nara Medical University (No. 220). The study population comprised individuals and their families who ordered food using the Internet and who

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were members of the Japanese Consumers' Co-operative Union (CO-OP). The survey involved the CO-OP because the cooperative is interested in promoting the health of its members. At the time of the study, there were 1 million CO-OP members among Tokyo's population of 12.3 million. The participants were recruited through banner advertisements on the CO-OP home page. Participants were rewarded points equal to 100 yen (1 USD = 89 yen at the time of the survey) as a reward for registering. Written informed consent was obtained from all participants. Although there was no monetary reward for responding to the survey, responders gained access to the survey results via a link on the home page, and a short essay about daily health.

Upon registration, respondents provided their CO-OP registration number as well as the sex and age of themselves and their family members. On the survey dates, the investigators sent an email reminder to each respondent. The subjects were given a maximum of 3 days to fill out the questionnaire for each survey day. The contents of the daily surveys involved "yes" and "no" questions asked of each family member regarding 19 symptoms or signs characteristic of infections and allergies (Sugiura et al. 2011).

The study also looked into the medical conditions of all members of families with the representative of each family answering questions on the home page.

In the present study, we analyzed the data acquired for the following five symptoms: runny nose, itchy eyes, sneezing, slight fever, and high fever. Pollinosis symptoms were defined as the simultaneous presence of rhinitis and conjunctivitis in the absence of both slight and high fevers to rule out infectious disease.

To simplify the current survey, respondents were asked to report the presence or absence of pollinosis symptoms, but not their severity. This is because our study was not specific for pollinosis and included questions relating to other infections and allergies; the questions were simplified for ease of daily input.

Data regarding cedar pollen abundance are publicly available on the Internet. We accessed the pollen observation system of the Tokyo Metropolitan Government (TMIPH) and obtained data on daily 24-h airborne cedar pollen levels at Suginami-ku – an urban area, the central area where the subjects lived – from 1 February 2009 to 30 March 2009. The daily amount of airborne cedar pollen is calculated hourly by measuring the pollen-specific fluorescence in 1 m^3 of air obtained using an aspiration pump (KP-1500, Kowa Inc., Nagoya, Japan), which is set up at a height of 12 meters above the ground. This result is reported in real time.

Data analysis

The daily incidences of runny noses, sneezing, and itchy eyes were calculated, and the data were plotted on an epidemiological curve on which the *X*-axis represented the date and the *Y*-axis the number of cases. All pollinosis symptoms were plotted on the same graph and compared with the amounts of airborne cedar pollen. We followed each individual during the entire period, and the initial date of pollinosis symptom onset was identified. The daily number of people experiencing the initial onset of pollinosis symptoms was also calculated.

The odds ratio (OR) of the χ^2 test of pollinosis symptoms was determined before and after the date on which the maximum level of airborne cedar pollen was noted to evaluate the risk of the first pollen exposure. In addition, binary logistic regression analyses were performed to confirm the increases in the initial onset of pollinosis symptoms during a one-week interval with the middle day coinciding with the peak amount of airborne cedar pollen. To correct for inter-subject correlations in the daily survey (among

the same subjects during the study period), a generalized estimating equation method was used. For these analyses, the presence or absence of the initial onset of pollinosis symptoms was designated as the dependent variable, and the independent variable was defined as the one-week interval in which the middle day coincided with the peak amount of airborne cedar pollen. In addition, to adjust for confounding factors, sex and age were included as independent variables. The statistical analyses were performed using SPSS version 19.0 (SPSS, Chicago, IL, USA).

Results

A total of 1453 individuals were enrolled in the survey, which represents an excellent participation rate (96 %) given the number of initial responders exhibiting interest. Over 58 investigation days, the average daily response rate was 40.1 % ± 5.0 %.

The time-course analysis of the daily airborne cedar pollen concentrations revealed a clear relationship between the peak incidence and the severity of allergic responses (Figure 1). The pollen count stood at 34 m^3 day on 1 February, the day when the study began. No recognizable correlation existed between prevalence and the pollen count

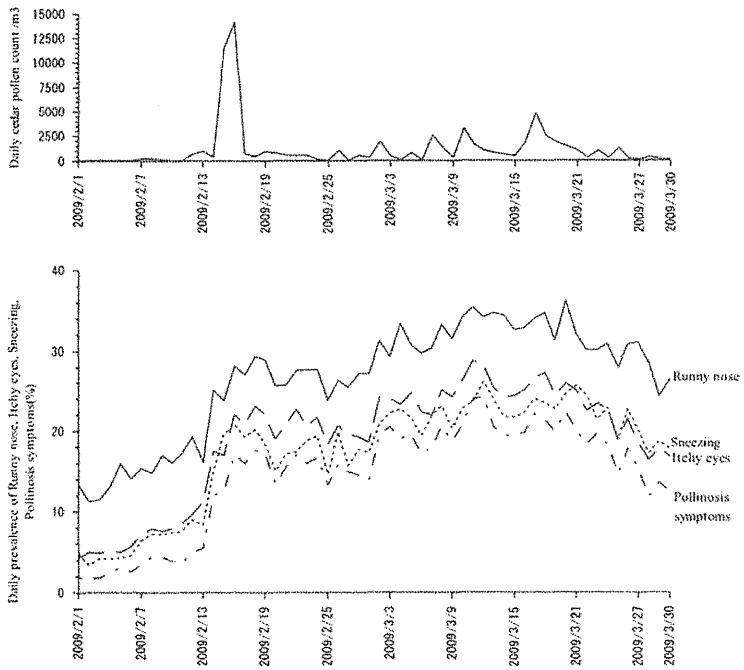

Figure 1. Daily prevalence of patients with individual pollinosis symptoms and daily cedar pollen count.
Notes: Pollinosis was defined as rhinitis together with conjunctivitis in the absence of fever.

over the entire period. The first peak in airborne cedar pollen levels was associated with a dramatic increase in the percentage of subjects reporting all four parameters. We considered a correlation between pollen peaks and subsequent symptoms. The Pearson product-moment correlation coefficient had a value of 0.518 ($p < 0.001$), showing a weak positive correlation.

The percentage of affected subjects remained elevated until the second peak in airborne cedar pollen levels, which was detected during the third week of March. Following the second peak in cedar pollen levels, the symptoms started to subside and continued to do so until the end of the survey period. These data show that allergic reactions were initiated by the first peak in cedar pollen levels and persisted throughout the entire season, even when the cedar pollen levels returned to near the baseline levels.

The number of persons reporting the initial onset of pollinosis symptoms gradually increased and reached a maximum on 16 February, coinciding with the maximum amount of airborne cedar pollen. A cumulative frequency distribution showed that on 12 February, four days before the airborne cedar pollen peak, 21.2 % of the subjects reported the onset of pollinosis symptoms. During the first week (13–19 February), which included the maximum amount of airborne cedar pollen on 16 February, 35.2 % of the patients reported the initial onset of pollinosis symptoms. The cumulative number of persons with an initial onset of pollinosis symptoms by 19 February, three days after the airborne cedar pollen peak, was 56.4 % (Figure 2).

The OR of the χ^2 test for pollinosis symptoms before and after the date of the maximum amount of airborne cedar pollen was 4.66 (95 % confidence interval, 4.22–5.16). A binary logistic regression, which was performed using a generalized estimating equation method, revealed that the OR during the first week of the initial maximum pollen peak vs. the other days, adjusted for sex and age, was 4.03 (95 % CI, 3.34–4.86). Women were more sensitive to pollen levels than men, and the most sensitive group included those between the ages of 20 and 40 years (Table 1).

Discussion

Our findings confirm the feasibility of using a web-based epidemiologic survey of pollen-related conditions to determine the relationship between peak pollen levels and allergic responses. The first peak in the airborne cedar pollen level was associated with a dramatic increase in the initial onset of pollinosis symptoms. However, we clearly showed the persistence of symptoms after pollen levels returned to close to the baseline, and no recognizable correlation existed between prevalence and the pollen count over the entire period. This is a pattern peculiar to Japanese cedar pollinosis, in contrast to European hay fever (Berger et al. 2013).

The subjects resided in densely populated areas of Tokyo. However, Japanese cedar pollen travels even from a remote plantation 100 km away and differs greatly from plant allergens in other countries in that large amounts of it affect patients when blown in by strong winds during blooming in the spring. The quantity defined as "extremely high" is approximately 1000/m^3. A pollen count of 14 times this value was observed in this investigation on the day with the highest count.

We clearly showed that once the subjects had a response to the initial peak in pollen release, they reported symptoms of pollinosis until the end of the season. Thus, the allergic reactions were primed by the first surge in airborne cedar pollen levels and remained elevated for weeks before slowly declining at the end of the season. The large amounts of pollen initially observed caused prevalence to spike at first and then increase

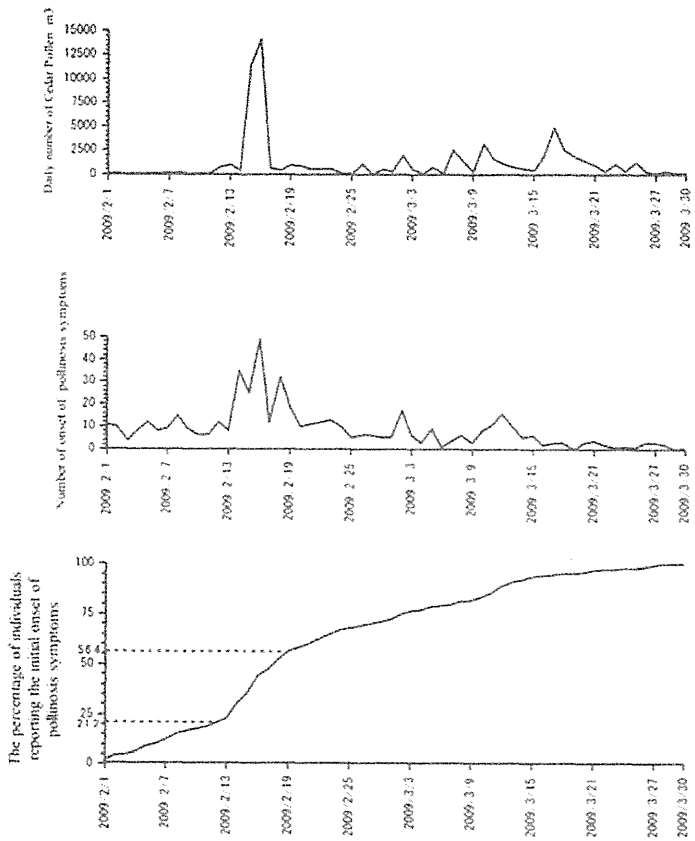

Figure 2. Daily percentage of individuals reporting the initial onset of pollinosis symptoms and the amount of airborne cedar count.

at a slower pace despite a decline in the pollen count. Furthermore, we revealed that there are two phases in the relationship between the pollen count and prevalence. The first is the priming phase associated with the large amounts of pollen initially observed. The logistic regression analysis showed that the initial airborne peak in cedar pollen levels influenced the number of subjects experiencing the incidence of pollinosis. Most subjects who were susceptible to developing severe pollinosis in the Tokyo area were affected by this first peak in airborne cedar pollen levels. The second phase is a period after the initial blip in the pollen count disappears. A reanalysis conducted under the conditions after the initial peak in the pollen count disappeared revealed the existence of a positive correlation between the pollen count and the number of individuals who developed pollinosis symptoms. The second phase, despite a lower daily pollen count, saw a higher prevalence than the first phase. After pollen has dispersed and been scattered in large quantities, it remains in the trees for a few days and can become a source

Table 1. Results from the two-term logistic regression analyses: comparison of the first week with the initial maximum cedar pollen peak and the rest of the pollen season.

	Odds		95 % CI	
	Number	Ratio	Lower limit	Upper limit
One week of the initial maximum cedar pollen peak vs. the subsequent pollen season		4.03	3.34	4.86
≥ 60 years	73	1.99	1.08	3.66
≥ 40 to < 60 years	474	2.48	1.54	3.99
≥ 20 to < 40 years	399	2.67	1.65	4.33
≥ 15 to < 20 years	105	2.1	1.24	3.58
≥ 10 to < 15 years	138	2.3	1.36	3.9
≥ 5 to < 10 years	128	1.88	1.08	3.27
Reference: < 5 years	136			
Women vs. men		1.26	1.08	1.47

for later scattering. In addition, because individuals are in a sensitive state, they are primed for symptomatic reactions, even if the amount of pollen does not increase markedly. This explains the lack of a correlation between prevalence and the pollen count over the entire period. These findings are new and have never been reported in previous research.

Prophylactic administration of anti-allergy drugs before the initial peak in airborne cedar pollen levels would be beneficial for individuals who normally experience seasonal pollen allergies. Therefore, the identification of the initial peak in the airborne cedar pollen level is of paramount importance.

The population in the current study was already symptomatic when the onset of pollinosis was detected at the beginning of the season. However, the present study demonstrated that most subjects reported the onset of pollinosis when a large amount of pollen was present. During the days before and after 16 February (13–19 February), when the level of airborne cedar pollen reached its maximum value, 35.2 % of the subjects reported the initial onset of pollinosis symptoms. This finding indicates that the initial large amount of airborne cedar pollen caused seasonal pollinosis in many citizens. By 19 February (3 days after the maximum level of airborne cedar pollen), 56 % of the subjects (the cumulative total number of subjects from the initial date) had reported the onset of pollinosis symptoms. Another study on the relationship between cedar pollinosis onset and cedar pollen count in patients seeking care at medical facilities found that there was a distinct initial peak of onset (Dejima et al. 1992). Because that study was a patient-based study, only seriously ill individuals were included; however, even small amounts of pollen scattering were believed to induce reactions.

Medek et al. (2012) reported a daily symptom investigation of 42 hay fever patients and the pollen relationship with the daily climate using a web-based survey. Their study clarified the daily nasal rhinoconjunctivitis symptoms of patients and the pollen load via a web investigation. Moreover, the present study demonstrated that web-based surveys can be used to determine these patterns in the general population, and such surveys are presumably easier and faster to use and administer than paper-based questionnaires; they may also help to determine the initial onset of symptoms. Another advantage of using an Internet survey is that epidemiological data can be gathered early in the season to

develop better preventive measures. The fast-growing social and economic burden of pollinosis in Japan calls for an improvement in preventive measures to better inform the population of the onset of airborne cedar pollen exposure. Because patients seeking medical attention present with severe symptoms, the present study used an Internet-based survey to ensure that patients with mild symptoms were also included in the population study. This approach allowed us to identify the onset of mild symptoms within the allergy season, and to identify the citizens most at risk of developing severe and persistent pollinosis symptoms.

A logistic regression by age group showed that the age range included subjects between 20 and 40 years of age who represented a highly sensitive population in this Tokyo-based investigation. Young children are normally very susceptible to allergies, and this is a major concern for clinicians. A breakdown of the data analysis of those < 20 years of age (data divided into 5–10, 10–15, and 15–20 year age groups) revealed that pollen symptoms were also present in individuals aged 5–10 years. This supports previous data published after an investigation of allergies among primary school-aged children in Tokyo (Futamura et al. 2011).

An Internet survey has several advantages over conventional paper surveys. Generally, the amount of data acquired is greater in epidemiological surveys performed using the Internet than in conventional paper surveys (Schleyer & Forrest 2000; Ekman et al. 2006). Another advantage is the inclusion of subjects with mild and early symptoms who do not normally seek care at medical facilities (Bell & Kahn 1996). Of note, however, is that baseline information is not available for these studies. In our present survey, there was a high response rate, the symptoms of pollinosis were reported every day, and sufficient data were available for reliable statistical analyses. Regarding the response rate and sampling, the average online survey response rate was 39.6 % according to a meta-analysis performed of 68 surveys. We would consider therefore that the survey had a satisfactory response rate for an online survey conducted daily (Cook et al. 2000).

A limitation of this study was that the analysis was only based on the data from 2009. Therefore, similar studies should be conducted over several seasons. Another limitation was that the number of patients who used oral anti-allergic drugs might have been underestimated. Therefore, in future studies, questions regarding the use of anti-allergic drugs may need to be included. This study discusses incidence based solely on reports on cedar pollen-related symptoms. Although confirmation through a blood test is essential to avoid a false-positive result, we could not perform blood tests in conjunction with an epidemiological study because of the Personal Information Protection Law (Okamoto et al. 2009) in Japan. Despite this limitation, our web-based survey proved to be suitable for documenting trends associated with cedar pollinosis in Tokyo.

In conclusion, aiming to identify the initial day of onset of pollinosis, this Internet survey clarified the statistical significance of airborne pollen quantity and pollinosis symptoms. The first peak in the airborne cedar pollen level was associated with a dramatic increase in the initial onset of pollinosis symptoms. This finding can be used to predict the appropriate date for the initiation of self-medication with anti-allergy drugs and thus avoid the development of sustained and severe pollinosis (Gotoh et al. 2011).

Acknowledgments

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(Department of Public Health, Health Management and Policy, Nara Medical University School of Medicine) for the data analyses, and the Tokyo Metropolitan Government for providing data on the cedar pollen levels.

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Developing a National Food Defense Guideline Based on a Vulnerability Assessment of Intentional Food Contamination in Japanese Food Factories Using the CARVER+Shock Vulnerability Assessment Tool

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Abstract

The awareness of food terrorism has increased following the September 11, 2001 terrorist attacks in New York City, United States, and many measures and policies dealing with this issue have been established worldwide. Suspected deliberate food-poisoning crimes have occurred in Japan, although they are not regarded as acts of food terrorism. One area of concern is that the small- to medium-sized companies that dominate Japan's food industry are extremely vulnerable to deliberate food poisoning. We conducted a literature research on food defense measures undertaken by the World Health Organization and in the United States and Europe. Using the Carver+Shock vulnerability assessment tool, eight food factories and related facilities in Japan were evaluated and we found the level of awareness of food defense to be low and the measures inappropriate. On the basis of this evaluation, we developed a set of guidelines that Japanese food companies can use to help develop their food defense strategies and to serve as a reference in considering specific measures.

Introduction

Following the September 11, 2001 terrorist attacks in New York City, United States, the awareness of terrorism has increased worldwide. Recently, concerns have risen regarding food terrorism, such as bioterrorism and agroterrorism. The World Health Organization (WHO) defines food terrorism as "an act or threat of deliberate contamination of food for human consumption with biological, chemical and physical agents or radionuclear materials for the purpose of causing injury or death to civilian populations and/or disrupting social, economic or political stability" (WHO, 2008). If a harmful substance is mixed directly into the production and processing of food, the ensuing human and economic damage will expand along the food chain, and identifying the cause becomes difficult.

Food safety is maintained by food security measures to secure a stable food supply and food safety measures to prevent the unintentional contamination of foods with harmful substances, such as bacteria and toxins. The U.S. Food and Drug Administration (FDA) defines food defense as "the effort to protect food from intentional acts of adulteration where there is an intent to cause public health harm and economic disruption" (Fig. 1) (FDA 2003, 2005, 2007).

Criminal food poisoning has occurred in Japan, in which foods were intentionally contaminated with harmful substances, such as in the Glico-Morinaga case, the Wakayama curry-poisoning case, and the frozen dumpling poisoning case (detailed below). However, even after those incidents, no major efforts were made to implement food defense strategies in Japan owing to the small number of such cases. Consequently, the awareness of food defense is still low. Because of these issues and the fact that most of the food factories in Japan are small family-owned businesses, a research group focusing on the awareness of food bioterrorism (led by Tomoaki Imamura, professor of Nara Medical University) was established in 2005; this followed a request by the Ministry of Health, Labour and Welfare, which is

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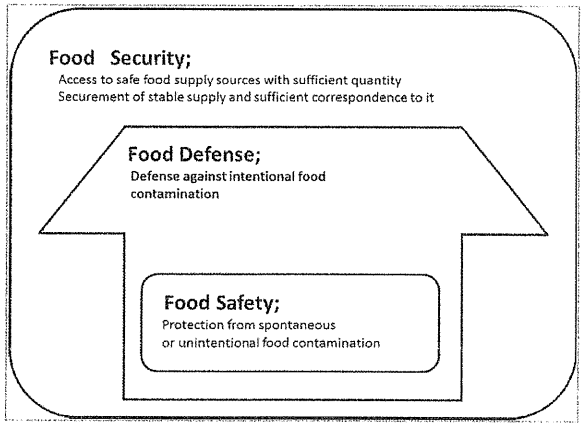

FIG. 1. Relationship among the three elements of food.

responsible for food safety. The research group evaluated the vulnerability of food factories in Japan and attempted to develop national food defense guidelines.

Review of Global Resources Applicable to Developing a National Food Defense Strategy in General and Specifically for Japan

The WHO set up the Working Group on the System for Terrorist Threats to Food in 2002 and produced the Recommendation for Counteracting Terrorist Threats to Food. In 2003, the WHO published "Terrorist Threats to Food."

In the United States, the FDA published the "Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" in March 2003. The US Strategic Partnership Program Agroterrorism (SPPA) Initiative was set up in 2005. The SPAA has explored various measures for assessing and increasing awareness of threats to the food supply. In 2007, a vulnerability assessment tool—the "CARVER+Shock"—was established and made accessible on the Web. CARVER+Shock presents details about the general vulnerability of processed foods and agricultural products as well as terrorism countermeasures. The FDA has also established a website exclusively for food defense at http://www.fda.gov/food/fooddefense/, and it provides the Food Defense Plan Builder (FDA, 2007; Taylor, 2008).

The International Organization for Standardization (ISO) established formal international food defense standards by publishing several guidance documents: the ISO 22000 "Food Safety Management Systems—Requirements for Any Organization in the Food Chain" in 2005 (International Organization for Standardization, 2005), and ISO/TS 22002-1:2009 "Prerequisite Programmes on Food Safety—Part 1: Food Manufacturing" was published in 2009 (International Organization for Standardization, 2009). These efforts were supported by similar documents published by the British Standards Institution to include PAS96 ("Defending food and drink. Guidance for the deterrence, detection and defeat of ideologically motivated and other forms of malicious attack on food and drink and their supply arrangements") and PAS223:2011 ("Prerequisite programmes and design requirements for food safety in the manufacture and provision of food packaging") and PAS221:2013 ("Prerequisite programmes for food safety in food retail—Specification") (British Standards Institution, 2013).

Lastly, in addition to the above resources, the Asia-Pacific Economic Cooperation (APEC) held the Counter-Terrorism Task Force in 2013 (APEC, 2013). Together, these efforts emphasize that global food defense measures are gradually progressing and, given greater awareness to the global food safety and food manufacturing communities, further global harmonization efforts should continue.

Examples of Food Terrorism Acts That Have Occurred with Japanese Food Factories

Food terrorism acts in Japan

In Japan, three well-known cases of intentional food contamination have occurred in the last 30 years.

The Glico-Morinaga case involved hydrocyanic acid–contaminated products that were distributed to retail stores from 1984 to 1985 and were manufactured by major confectionary companies (Ezaki Glico and Morinaga). This terrorism act plunged both the Japanese stock market and Japanese citizens into a panic. Unfortunately, no one was arrested for these crimes, but an outcome of this case was that it made food company managers realize that a minor terrorist attack could cause damage economically and it could erode consumer confidence in the food industry in its ability to provide safety from food damage (National Police Agency, 2000).

In the Wakayama curry-poisoning case in 1998, 4 people died and 63 people suffered from abdominal pain and vomiting after eating curry that was probably mixed with arsenious acid and distributed at a local summer festival. This case led to a sharp decrease in curry sales in Japan. The perpetrator was arrested and

the prosecution showed evidence that the terrorism act was part of an "act of revenge" that was carried out against this person's neighbors (Decision of Supreme Court of Japan, 2009).

The frozen dumpling poisoning case started at the end of December 2007. The food poisoning was believed to have been caused by frozen dumplings contaminated with methamidophos from a food production factory in China and imported and sold in Japan. The subsequent health damage occurred across the country, notably Chiba and Hyogo prefectures. The results of an investigation determined that three complaints about abnormal taste and odor had been reported for the same product in Miyagi and Fukushima prefectures after October 2007, before the health damage occurred. This case indicates that precautions need to be exercised against the contamination of food for both domestic and imported products (Japanese Consumer Co-operative Union, 2008, MHLW, 2008).

Foodborne outbreaks involving enterohemorrhagic *Escherichia coli* O157:H7 (EHEC) and *Staphylococcus aureus* (SA) have occurred in Japan. The EHEC outbreak took place in 1996, in the city of Sakai, and involved 9523 schoolchildren who ate fresh radish sprouts that were associated with school lunches; there were 3 deaths in this group. The SA outbreak took place in Osaka in 2000 and was associated with contaminated reconstituted raw milk and milk powder. Together these outbreaks indicate that large-scale bioterrorism events and foodborne outbreaks can arise quickly and expand rapidly, causing widespread illness (Michino *et al.*, 2000; MHLW and Osaka City, 2000). Table 1 summarizes the major foodborne disease events that have occurred in Japan during 1984 to 2008.

Specific characteristics associated with food factories in Japan

Food factories in Japan implement comprehensive sanitation management and production processes, which incorporate the Hazard Analysis Critical Control Point (HACCP) and risk management tools according to ISO 22000. The sanitation standards for Japan's food production processes are made on the premise that employees would not act with malicious intent, reflecting the high moral character of the Japanese. This has led to a situation where the security of food factories is not strict. For example, food factories lack fences or walls so as not to provoke a sense of unease among neighbors, and it is widely known that worker identity confirmation or running background checks on newly hired employees is legally prohibited. However, it is difficult always to hire new employees based on the recommendations of older employees. Thus, the extreme vulnerability of Japan's food industry to malicious contamination causes concern. The validity of CARVER + Shock has not yet been demonstrated in Japan.

TABLE 1. CASES OF INTENTIONAL POISONING OF FOOD AND LARGE-SCALE FOOD POISONING IN JAPAN

1984	March	Glico Morinaga case Intimidation of food companies by placing their products containing poison in stores
1996	July	Diarrhea in group of schoolchildren in city of Sakai (number affected, 9523; deaths, 3) Cause: enterohemorrhagic *Escherichia coli*
1998	July	Wakayama curry-poisoning case (number affected, 63; deaths, 4) Cause: arsenious acid
2000	June	Food poisoning case by Osaka factory of Snow Brand Milk Products Co., Ltd. (number affected, 13,420) Cause: *Staphylococcus aureus* (enterotoxin)
2008	January	Frozen dumpling case (deaths: 0, number affected, 10) Cause: agricultural chemical contained in dumplings produced and imported from overseas

Materials and Methods

Evaluating vulnerability of food factories in Japan

Eight domestically representative food-related facilities (six facilities, including factories for milk, packed lunches, *natto* fermented soybeans, other beverages, and a large facility that attracts many customers; and two distribution facilities) were assessed for vulnerability. For this study, different types of food production factories were selected from among partner factories of the Japanese Consumers' Co-operative Union.

We selected food factories located chiefly in the suburbs of Tokyo, such as Saitama and Chiba prefectures, for our survey. The CARVER + Shock tool and the checklist for food factories, which was prepared with reference to the FDA's "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance," were used for the assessment. In carrying out the assessment, many specialists in such areas as food sanitation administration, medicine, chemistry, and agriculture visited the food facilities.

Measures for food defense in Japan

Measurement of cost effectiveness

Setting costs. We conducted an economic assessment in a survey on costs with a number of specialty traders on condition of confidentiality. Expense was scored using the following classification. We investigated hardware measures for equipment and facilities as well as maintenance and management. The total expense for initial cost (annually converted) and annual operational costs were calculated and scored. The costs were scored as follows: 5 (very high), 4 (high), 3 (somewhat low), and 2 (low).

Software measures involved measures by employees' inspection and a review of operational processes. Costs for hiring new employees or subcontracting were assessed as long-term cost (4 points) and short-term cost (2 points). Costs for increased work associated with implementing internal measures were assessed as long-term increase (3 points) and short-term increase (1 point).

Setting effects. The effects were classified as follows, with those exerting a greater effect being accorded a higher score:

1. Measures considered to have been conducted to meet minimum social demands (6 points)
2. Measures leading to the halting of culpable activities (directly, 5 points; indirectly, 4 points)
3. Measures contributing to minimizing damage (directly, 3 points; indirectly, 2 points)
4. Measures contributing to improving ease and reliability (1 point)

Establishing the recommendation level for checklist items and guideline development. With each measure, the total score of the expense was subtracted from the total score of the effects, and the recommendation level was established according to those calculated levels. Recommendation level A (the highest) was given for 9–11 points in software measures and 7–8 points in measures for equipment and facilities. Recommendation level B was accorded for 6–8 points in software measures and 5–6 points in measures for equipment and facilities. All other cases received recommendation level C (the lowest). Members of the research group (which included specialists in various fields) made an expert judgment to determine the priorities in considering the cost-effectiveness and feasibility at food facilities.

On the basis of the recommendation level, the Guideline for Food Defense (for Food Factories) was established and an explanation provided. To validate the practicality of the developed guideline, we conducted a survey among representatives of the six food factories.

Results

Results of vulnerability assessment of food companies in Japan

In this survey, our research group members visited eight factories to directly interview factory representatives, and obtained answers from all the factories. At each factory, 5 to 10 quality-assurance monitors were interviewed, and they responded about their factory's measures. Our assessment of the Japanese food factories showed a lack of security measures against the deliberate introduction of foreign matter. Additionally, the awareness was extremely low.

We found that implementing the CARVER + Shock tool would require both the cooperation of specialists in various fields and greater effort by food companies. We believed it would be difficult for Japan's small-scale food companies to conduct a vulnerability assessment with the CARVER + Shock tool because of human factors and the economic burden.

We confirmed the vulnerability assessment using the checklist for food factories in Japan in terms of five fields: *management*; *human factors—staff*; *human factors—public*; facility; and operations (Table 2). We found that it would not be realistic to implement the food defense measures detailed in the checklist owing to human factors and financial restrictions.

Development of Guideline for Food Defense (for Food Factories)

On the basis of the results related to cost-effectiveness and assessment at the food facilities, we set two priority levels. "Measures that need to be implemented preferentially" covered 34 items: management (4 items); human factors—staff (5); human factors—public (5); facility (14); and operations (6). "Desirable measures that should be implemented where possible" covered six items: management (one item), human factors—staff or public (one), and facility (four). Based on these results, the Guideline for Food Defense (for Food Factories) (hereafter, the guideline) was established and consisted of 40 items (Table 3).

TABLE 2. RESULTS OF VULNERABILITY ASSESSMENT USING THE CHECKLIST FOR FOOD FACTORIES IN JAPAN

Management	• Procedures for reporting inside and outside the company in the case of suspected intentional food contamination, and collection, storage, and disposal of products not decided. • Employee work situation and content needs to be understood accurately. • Education about food defense not conducted.
Human element (staff)	• Confirmation of identification when recruiting employees is insufficient. • Return of uniform, name tag, ID badge, key (key card) when an employee is transferred or leaves the company not conducted thoroughly. • What goods can be brought into production spots is not decided.
Human element (public)	• Methods allowing visitors access not decided. • Goods introduced by persons in charge of facility maintenance and areas where they can be taken not decided. • Reception area for mail and delivery service not decided.
Facility	• Regular confirmation of goods within facility insufficient. • Sites where harmful substances may be intentionally added not understood. Anticrime measures and management of keys during nonoperational hours not established. • Intruder prevention measures from outside, such as regular exchange of keys and changes in secret identification code, insufficient. • Storage places for test materials (reagents for examination and positive samples, etc.) and for harmful substances and storage methods not established. • Intruder prevention measures for water wells, tanks, and distribution facilities and monitoring need to be conducted. • Setting of access rights in computers and data-processing records not stored.
Operations	• Consistency between delivered products and quantities of materials or raw materials and ordered products and quantities sufficiently confirmed. • If signs or traces of intentional food contamination (e.g., loss or increase in stock, shortfall in delivery amounts) are found, a system for inspection and reporting not established.

After trial implementation of the guideline, the representatives of the food facilities expressed the view that some specific measures may not have been readily understood. To that end, we prepared an explanation of the guideline to be used as a reference for particular measures. The explanation provides specific information, including a response plan for deliberate or accidental food contamination, coping with an increase in stock or final products and a tool for determining such an increase, report production by security personnel, training programs for employees, and selection standards for purchasing pesticides.

Discussion

Since the Rajneesh case in 1984, when the *Salmonella* was sprayed onto a salad bar, the awareness of food terrorism has been recognized. Among the various forms of terrorism, food terrorism can be carried out relatively easily. In particular,

TABLE 3. "MEASURES THAT NEED TO BE IMPLEMENTED PREFERENTIALLY" AND "DESIRABLE MEASURES THAT SHOULD BE IMPLEMENTED WHERE POSSIBLE" IN THE GUIDELINE

	Specific measures
Measures that need to be implemented preferentially:	
Management	Achieving an ideal working environment
	Understanding the working situation and work content of employees
	Making employees aware of the threat of deliberate food contamination or handling
	Establishing response plans and handling and disposal methods for collected products
Human element (staff)	Points of concern at recruitment
	Arrangements for collecting uniform, ID badge, key (key card) or other materials if an employee is transferred or leaves the company
	Goods taken into the factory or uniforms worn in certain areas
	Management of time when employees start and stop work
	Making an identification and recognition system for employees
Human element (public)	Confirmation of presence or absence of visitor appointments and places inside factory that visitors can access
	Employees accompanying visitors
	Confirmation of identity and reason for visit
	Restricting access within factory
	Setting up areas where vehicles and packages/baggage may be brought in.
	Designation of reception place for mail or delivery services
Facility	Thorough management of fixed number and position of goods used inside factory
	Being aware of sites where harmful substances may be deliberately introduced and exploring food defense measures
	Anticrime measures at nonoperational times
	Establishment of management method for keys
	Intruder preventive measures by regular exchange of keys and changes in security code
	Management of contact points between the factory and outside
	Storage places for research materials (test agents, reagents)
	Restricting access to research facilities (tests, test rooms)
	Establishment of storage and disposal methods of toxic substances, etc.
	Structuring inspection and reporting system on occurrence of loss, etc.
	Establishment of selection standards and storage methods for pesticides
	Confirmation of results of safety tests for well water
	Restricting access to important data systems, such as computer process control system
	Storage of records related to data processing
Operations	Confirmation of labels and packaging of delivered materials
	Supervising freighting and dropping off of delivered materials and shipping products
	Confirmation of the consistency of quantities of delivered products
	Loss and increase in stock
	Excess or shortfall with delivered amounts (loss or increase)
	Structuring an inspection and reporting system whenever such signs as intentional food contamination are found
	Common sharing of contact places where products are delivered
Desirable measures that should be implemented where possible:	
Management	Concretization of reporting content of results of guard duty and patrols
Human element (staff)	Being aware of places at the site where each employee is present
Facility	Intruder prevention measures, such as fences
	Monitoring outside the factory buildings and monitoring for toxic substances, materials, and raw materials stored or on used at the site by patrol guards and cameras
	Confirmation of locking, etc.

food terrorism countermeasures have been introduced following the increased fear worldwide since the 9/11 attacks in 2001.

International trends in food defense

In the United States, where the development has been greatest, efforts have been made so that food companies can implement vulnerability assessment and food defense measures (FDA 2003, 2005, 2007; Taylor, 2008; USDA, 2008a,b). Food defense measures have been explored by other countries and by international organizations, such as the WHO and APEC (WHO, 2003; APEC Counter-Terrorism Task Force, 2013; USDA, 2007). In practical terms, however, food companies need to execute their own food defense measures.

In the frozen dumpling poisoning case, health damage occurred through a poisonous substance that had been mixed into a product from overseas. The harmful foods were not detected even though sampling inspections at quarantine stations had been carried out. Food defense measures are very necessary both for foods produced domestically and those imported from overseas. Food defense measures are required not only within production facilities but throughout the distribution process until the products reach consumers (Celaya *et al.*, 2007; Soon *et al.*, 2012, 2013; Martini Rodrigues and Salay, 2012; Dioguardi *et al.*, 2010; Costa Dias *et al.*, 2012; Sueli Cusato *et al.*, 2013; Domenech *et al.*, 2013).

Comparison of food defense between Japan and overseas

Our vulnerability assessment indicated that the awareness among food companies in Japan about the awareness from terrorism or criminal conduct was extremely low; many food companies need to improve their measures against the deliberate introduction of foreign matter. In Japan, 36.9% of food companies had taken measures concerning the possibility of food terrorism and 60% had not (Satomura *et al.*, 2007). Moreover, 60% of the latter companies considered the possibility of food terrorism to be low.

Food defense measures conducted by food companies in Japan include countermeasures against intruders, checking raw materials, security management of transportation, company personnel being present when receiving or shipping products, and confirmation of products within 3 h before shipment or after receipt. Conversely, measures that are not being implemented include restrictions for personnel entering different workplaces, restrictions on vehicles bringing in and taking out products, and random inspections of products brought to the company (Satomura *et al.*, 2007).

Our vulnerability assessment indicated that the awareness among food companies in Japan about the awareness from terrorism or criminal conduct was extremely low; many food companies need to improve their measures against the deliberate introduction of foreign matter.

Because of human factors and the economic burden, it is not feasible to implement a vulnerability assessment using the CARVER + Shock tool and recommending the food defense measures listed in its checklist—as is done in the United States—in Japan's many medium- and small-scale food companies. To promote an awareness of the importance of food defense among Japan's food companies, it is necessary to present measures that the companies can easily implement in terms of priority. Thus, mindful of cost-effectiveness and following expert judgment, we triaged the measures listed in the checklist for food facilities and established a guideline for measures that are of prime importance and those that should be implemented where possible.

The practicability of the guideline was examined at the various food companies in this study. To increase the effectiveness of the guideline, we provided an explanation and also addressed the points of concern with HACCP. Opinions heard during interviews at the companies became reflected in the guideline, so we may assume that the guideline will be helpful for food companies wanting to engage in specific food-defense measures. Viewpoints relating to food defense were added to the points of concern with HACCP, with which Japan's food companies are very familiar, and specific measures were indicated in the guideline. As a result, we may expect that the awareness of food defense will increase even among small-scale food companies in Japan and that they will make progress in adopting specific measures.

In Japan's many family-run, middle- and small-scale food companies, it will be necessary to educate employees about food defense. However, special consideration will have to be given to preserving the relationship of mutual trust between employers and employees.

The purpose of the guideline is not to force food factories to implement various measures: as far as possible, it is to bring to the attention of Japan's food traders, who have a low awareness of food defense, the necessity of measures in this area. We consider it useful to embrace the notion of food defense as part of routine sanitary control and sanitary education to prevent both food terrorism and the criminal mixing of harmful matter into food.

If Japanese food companies establish food factories overseas, sanitation standards are exported along with the manufacturing equipment. However, in addition to sanitation standards, it is desirable that the idea of food defense also spreads. Because there are only a few countries in which vulnerability assessment is conducted by specialists, as in the United States, the guideline established for medium- and small-scale food factories in Japan may be useful as a reference for food companies overseas in applying food defense measures.

Conclusions

This investigation revealed that there is a low awareness of food defense among Japanese food companies, and further measures need to be taken in this area. The guidance document was established by our research group to bring the necessity of measures for food defense to the attention of food companies in Japan and help them implement specific measures. With this guideline as a reference, we expect food defense measures among Japan's food companies to improve.

Disclosure Statement

No competing financial interests exist.

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食品汚染防止に関するチェックリストを基礎とした食品防御対策のためのガイドラインの検討

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目的　世界的に人為的な食品汚染についての関心が高まるに伴い，G8では専門家会合が開催されたり，米国では多くの対策・方針案等が策定されている。しかし，日本では，食品企業の食品テロに対する認識が低く，その脆弱性が危惧されている。今回我々は，日本の食品企業に食品防御対策を普及させるためのガイドライン等を作成した。

方法　すでに作成されている食品工場用チェックリストに示されている食品防御対策について，費用対効果を考慮した「推奨度」を整理した。その推奨度（費用対効果の高い対策順）を基に，「食品防御対策ガイドライン（案）」を作成し，食品工場に対して聞き取り調査を実施した。また，食品防御の観点から，食品工場用チェックリストやガイドラインと「総合衛生管理製造過程承認制度実施要領（日本版HACCP）」を比較した。

結果　推奨度を基に試作したガイドライン（案）に対する食品工場への聞き取り調査を踏まえて，「食品防御対策ガイドライン（食品製造工場向け）」とその解説を作成した。また，食品企業に普及させるために，HACCPにおける食品防御の観点からの留意事項を作成した。

結論　食品防御対策を普及させるためには，食品事業者が使用しやすいガイドラインが有用と考えられた。

Key words：食品汚染，食品防御，食品汚染防止に関するチェックリスト，食品防御ガイドライン，CARVER＋Shock，HACCPの留意事項

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Ⅰ　はじめに

2001年の世界同時多発テロ以降，世界各国で食品テロの危険性が高まっている。さらに，日本では，食品の期限表示の偽装問題や，中国産冷凍餃子による健康被害の発生により，「食品」の安全に対する関心が高まっている。

日本の食品工場等では，従来から食品衛生の観点から，食品の原材料の受け入れから製造・出荷までのすべての工程において，危害の発生を防止するための重要ポイントを継続的に監視・記録する衛生管理手法であるHazard Analysis Critical Control Point（HACCP）手法を取り入れた総合衛生管理製造過程[1)]の導入や，HACCPの食品衛生管理手法をもとにした食品安全マネジメントシステムの国際規格であるInternational Organization for Standardization（ISO）22000[2)]に則ったリスク管理が実施されている。しかし，「悪意」をもった食品への毒物の混入には，極めて脆弱であることが危惧されている。

米国では，2003年3月に，食品・薬品を中心に化粧品や玩具，タバコなど，消費者が接する機会の多い製品の認可や違反取締を行う食品医薬品局（Food and Drug Administration; FDA）がGuidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance（食品セキュリティ予防措置ガイドライン「食品製造業，加工業および輸送業」編）を作成し，食品の製造から輸送過程における食品防御の考え方や対策を示している[3)]。さらに，2007年6月には，施設運営者が脆弱性の可能性を特定でき，製品や施設運営の防御強化に役立つようデザインされた脆弱性評価手法である「CARVER＋Shock法」を開発し，Web上で公開している[4,5)]。「CARVER＋Shock法」とは，Criticality（危険性），Accessibility（アクセス容易性），Recuperability（回復容易性），Vulnerability（脆弱性），Effect（影響），Recognizability（認識容易性）の6つの特性とその衝撃度から名付けられたものである。しかし，「CARVER＋Shock法」による評価を実施するには，多くの専門家の協力が必要となり，それに伴う費用も高額となることから，中小零細規模の食品企業が多い日本にその評価手法を適応することは極めて困難と考えられた。

我々は，2005年度から，厚生労働科学研究として，「食品によるバイオテロの危険性に関する研究（研究代表者：今村知明奈良県立医科大学教授）」の研究班を設置し，海外の食品防御に対する取り組みを調査するとともに，日本の食品工場の脆弱性を評価し，具体的な食品防御対策を検討してきた[6,7)]。具体的には，米国の取り組み等を参考に，食品企業が悪意を持った食品への汚染を防御するための対策（食品防御対策）の必要性に気づき，必要な対策を検討する上で参考となるように，「食品工場における人為的な食品汚染防止に関するチェックリスト（以下「食品工場用チェックリスト」）」や，「食品に係る物流施設における人為的な食品汚染防止に関するチェックリスト（以下「物流施設用チェックリスト」）」をすでに作成している[6,8,9)]。しかし，約100項目からなるこれらのチェックリストを用いて食品工場等の脆弱性を評価する場合には，一定の知識と時間が必要となる。さらに，チェックリストに挙げられたすべての対策を実施するにも，多額の費用がかかるなどの課題があった。そのため，日本の食品企業に食品防御対策を普及させるために，チェックリストに挙げられた対策に優先順位をつけ，食品企業が利用しやすい簡便なガイドライン等の作成が必要と考えられた。

こうした背景を踏まえ，すでに作成されている食品工場用チェックリスト[8)]から，費用対効果を考慮した「対策推奨度」を整理するとともに，その推奨度を基に「食品防御対策ガイドライン（食品製造工場向け）（以下「ガイドライン」という」やその解説を作成した[10,11)]。さらに，食品企業が具体的に食品防御対策を検討するために，食品事業者になじみの深い「総合衛生管理製造過程承認制度実施要領（日本版HACCP）（以下「日本版HACCP」という）」[J1)]とチェックリストや作成したガイドラインを比較し，食品防御の観点から必要と考えられる対策を検討し，「食品防御の観点を取り入れた場合の総合衛生管理製造過程承認制度実施要領（日本版HACCP）［別表第1承認基準］における留意事項（以下「HACCPの留意事項」という）[12)]としてまとめた。

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Ⅱ　方　　法

1.　チェックリスト項目別の費用対効果の測定と対策推奨度の整理

食品工場用チェックリスト[8)]は「組織マネジメント」（21項目），「人的要素（従業員）」（19項目），「人的要素（部外者）」（5項目），「施設管理」（22項目），「経営運営」（27項目）の5分野，計94項目から構成される。食品工場用チェックリストに列挙された対策の中から，費用対効果の高い対策を抽出するため，項目別に効果の大きさと必要な費用の多さからそれぞれ得点化を行い，費用対効果を推定した。さらに，その結果を用いてチェックリスト項目の対策推奨度を整理した。

1)　費用対効果の測定

(1)　費用の設定

食品工場の広さや構造，立地条件，取り扱っている食品等の特性により食品防御対策の効果や費用も異なる。また，その費用には，単価情報や積算方法が含まれることから，公開しないことを条件に，文献7の研究班員（以下，「研究班員」）が，複数の専門業者の協力を得て費用に関する聞き取り調査を行い，以下の分類で得点化した。

①ハード対策（施設整備による対策）

新たな設備の設置費用や維持管理費用等を調査し，初期コスト（年換算）と年間運用コストの凡その金額を算出し，得点化した。

金額の得点化は，極めて高額（5点），高額（4点），やや低額（3点），低額（2点）とした。

②ソフト対策（従業員等による点検作業や作業方法の見直しによる対策）

- 新たな対策の導入による新規雇用や外注のコスト
  継続的なコスト；4点
  短期的なコスト；2点
- 内部対策の実施に伴う業務量の増加
  継続的な増加；3点
  短期的な増加；1点

(2)　効果の設定

チェックリストに挙げられた対策の実施による効果を以下のように分類し，効果の大きい対策を高得点とした。

①社会的要請として最低限行っておくべきと考えられる対策（6点）

②犯行実施の抑止への寄与；直接的（5点）/間接的（4点）
③被害の最小化への寄与；直接的（3点）/間接的（2点）
④安心・信頼の向上に寄与（1点）

2）チェックリスト項目の対策推奨度の整理

各対策による効果の総得点から，費用の総得点を引き，その大小により推奨度を整理した。ソフト対策では9～11点，ハード対策では7～8点を推奨度A（最も高い）とし，ソフト対策では6～8点，ハード対策では5～6点を推奨度B，それ以外を推奨度C（最も低い）とした。さらに，各種専門家から構成される研究班員による専門家判断（エキスパートジャッジ）を行い，優先度を判断した。

2. ガイドライン（案）の作成と食品工場への聞き取り調査

食品企業が効率的に食品防御対策を実施できることを目的に，推奨度A，Bとして抽出された防御対策を基に，「ソフト対策」，「ハード対策」に分けて，「最も推奨される対策」，「実施が望まれる対策」を列挙し「ガイドライン（案）」を試作した。

試作したガイドライン(案)を基に，研究班員が，乳製品・調味料・パン・食肉加工品の4か所の食品工場を対象に，聞き取り調査を行った。

具体的には，ガイドライン（案）に示された，優先度の高い対策である人的要素（従業員等）や施設管理，経営運営等の食品防御対策の実施状況を確認した。また，ガイドライン（案）に示された食品防御対策と業務の効率性確保における課題，対策を実施する上で障害となる要因だけでなく，食品防御に対する意識や，食品工場を運営する上で留意している点なども調査した。

これらの聞き取り調査の結果を踏まえて，再度，研究班員による検討を行い，ガイドライン最終案を作成した。

3. HACCPの留意事項の検討

日本で広く使用されている食品の衛生規範である「日本版HACCP［別表第1承認基準］」には，食品防御の考え方は含まれていないが，承認基準として，製造又は加工の工程に関する文書，施設の図面，危害の発生を防止するための措置，改善措置の方法，記録，管理体制等に関する基準が定められている。このため，日本の食品工場で食品防御の考え方を普及させ，具体的な対策が実施できるようにするために，日本版HACCPと食品工場用チェックリストや作成したガイドラインを比較し，食品衛生管理と併せて食品防御対策を検討する場合に必要となる考え方を検討し，「HACCPの留意事項」として整理した。

4. 倫理面への配慮

本研究において，特定の研究対象者は存在せず，倫理面への配慮は不要である。なお，本研究で得られた成果はすべて厚生労働省に報告しているが，一部テロ実行の企てに悪用される恐れのある情報・知識については，非公開としている。

Ⅲ 結　果

1. 費用対効果からみた推奨される対策とガイドライン（案）の試作

費用は平均3.0点（最高9点，最低1点），効果は平均8.4点（最高15点，最低1点）であった。

効果の点数が最も高い対策は，施設管理対策の一つである「敷地内における警備員の巡回やビデオ監視」であったが，費用も同様に最も高い点数を示した。逆に費用の点数が低い対策としては，人的要素(従業員等)に含まれる適切な従業員管理の徹底や，工場内のアクセス制限，経営運営や施設管理対策である商品や試薬等の管理基準等の作成であった。

推奨度Aとして，ソフト対策12項目，ハード対策3項目，推奨度Bとして，ソフト対策42項目，ハード対策8項目が抽出された。抽出された推奨度に基づき，「ソフト対策」，「ハード対策」に分けて試作されたガイドライン（案）に示された対策を表1に示す。

2. 食品工場への聞き取り調査の結果

推奨度を踏まえて試作したガイドライン（案）を基に4か所の食品工場に対して聞き取り調査を行った。

組織マネジメントに関しては，食品工場からは，従業員に対する食品防御に関する監督・教育は，逆に従業員に好ましくない情報を与えてしまうこと，会社が従業員を信頼していないというメッセージとして受け取られてしまう可能性があること等の懸念が示された。その一方で，多くの工場では，風通しの良い職場環境づくりや，メンタルヘルス対策等はすでに実施されていた。

人的要素（従業員等）に関しては，私物，医薬品等の持ち込みは，多くの食品工場では制限しているが，逐一のチェックはなされていなかった。従業員の職制・職能別の工場内施設別（工程別）のアクセス権は，業務の効率性を阻害しない様に留意する必要があるのと意見が聞かれるとともに，アクセス権の設定は，施設面の対策に含まれるとの意見が多く聞かれた。

人的要素（部外者）に関しては，部外からの来訪者の荷物（車輌への積載品も含む）の検査が行われ

表1　抽出された推奨度に基づき，「ソフト対策」，「ハード対策」に分けて試作されたガイドライン（案）に示された対策

最も推奨される対策	実施が望まれる対策
【ソフト対策】	
○組織マネジメント	
• 人為的な食品汚染の脅威や，実際の発生時の対応策にかかる計画の策定（A1） • 回収された製品の取扱い方法と廃棄方法の策定（A2）	• 「人為的な食品汚染」に関する観点を含んだ食品汚染対策の手続きや，それに必要となる安全評価の実施（B1） • 人為的な食品汚染を行わせない従業員の監督体制の構築（B2） • 人為的な食品汚染行為に脆弱な箇所の安全性を日常的な確認（B3） • 製品回収の基準の策定（B4） • 警備保障会社職員（もしくは社内の警備担当者）の業務内容の確認・報告（B5）
○人的要素（従業員等）	
• 従業員の採用・勤務 • 従業員の異動・退職時などの制服や名札，IDバッジの回収（A3），鍵（キーカード）の回収（A4）。 • 職能・時間に応じた施設内アクセスエリアの制限（A5）と，すべてのエリアに無制限にアクセス可能な従業員の認識・特定（A6） • 従業員の異常な健康状態や欠勤の把握（A7）	• 工場内へ持ち込む私物の制限（B6） • 工場内への医薬品の持ち込み制限（B7） • 私物の持込みエリアの制限（B8） • 人為的な食品汚染行為等やその脅威に対する内容を含んだ職員訓練プログラムの実施（B9） • 人為的な食品汚染に対する予防措置の重要性に関する定期的な意識喚起（B10）
○人的要素（部外者）	
	• 疑わしい・不適切なあるいは通常でない物品や行動，車両，荷物の検査の実施（B11） • 訪問者に対しての社員の同行の義務付け（B12） • 訪問理由の確認（B13） • 訪問者の身元の確認（B14）とその方法（B15） • 訪問者の食品取扱い/保管エリア/ロッカールームへのアクセスの制限（B16）
○施設管理	
• 汚染物質を一時的に隠すことができる場所，死角・暗がりになる場所等の洗い出し・安全確認（A8）	• 鍵の管理方法の策定（B17） • 工場内部と外部との結節点の安全確認（B18）と施錠（B19） • 非稼動時の安全確認（B20） • 立入禁止区域への入口の安全確認（B21） • 研究施設（検査・試験室）へのアクセス制限（B22） • 研究材料（検査薬・試験薬）の保管場所および保管方法の決定（B23）およびアクセス制限（B24） • 試薬の紛失等に関する事態の調査・通報の体制の構築（B25） • 不要な試薬の安全な廃棄（B26） • 有毒物質等の在庫量（B27）とその定期的な確認方法（B28）・保管方法（B29），保管場所へのアクセス制限（B30） • 殺虫剤の選定基準（B31）と保管方法の策定（B32） • 研究材料や有毒物質等の在庫の紛失やその他の事態の発生状況の調査や，発生時の通報体制の構築（B33）

表1　抽出された推奨度に基づき，「ソフト対策」，「ハード対策」に分けて試作されたガイドライン（案）に示された対策（つづき）

最も推奨される対策	実施が望まれる対策
○経営運営	
• 在庫の紛失や増加，その他の事態の調査や通報の体制の構築（A9） • 納入先における最終製品の在庫の紛失や増加，その他の事態の調査や通報の体制の構築（A10） • コンピューター処理制御システムや重要なデータシステムへのアクセス許可者を制限（A11） • 従業員の異動・退職時等におけるコンピューターアクセス権の削除（A12）	• 資材や原材料等の受領前の，納入資材等のラベルや包装の形態の確認（B34） • 納入資材の積み下ろし作業の監視（B35） • 納入製品・数量と，発注製品・数量との整合性の確認（B36） • 納入資材の人為的な食品汚染行為等の徴候・形跡の調査や通報の体制の構築（B37） • （井戸水を利用している場合）井戸水の安全性検査の結果の変化への注意（B38） • 出荷製品の荷受人の把握（B39） • 最終製品に対する苦情（B40）や健康被害情報（B41）が寄せられた場合の調査や通報の体制の構築 • コンピュータのデータ処理に係る履歴の保存（B42）
【ハード対策】	
○人的要素（従業員等）	
• 従業員の職位や特性に応じた明確な識別・認識システムの構築（A1） • 定期的な暗証番号の変更や鍵の取替え（A2）	• 敷地内に存在する者の所在の把握（B1）
○施設管理	
• 敷地内を走行する車両に対する駐車許可証，アクセスキー，通行許可証のいずれかの発行（A3）	• フェンス等による敷地へのアクセス制御（B2） • 敷地内における警備員の巡回やビデオ監視（B3） • 敷地内にある有毒物質等の所在や保管量を把握，監視（B4）
○経営運営	
	• 保管中の納入資材や使用中の資材の監視（B5） • 井戸，給水栓，貯蔵施設の安全性確保（B6） • 井戸水を利用している場合，水，およびその関連施設を塩素殺菌する設備の監視（B7） • 出荷した製品の積荷の位置を常時確認可能な体勢の検討（B8）

（参考文献7より筆者要約）

ていないことや，原材料や資材等の搬入のための運送業者以外にも，比較的頻繁に宅配業者が出入りしていることも判明した。部外からの来訪者への社員の同行については，初めての場合は同行するが，顔馴染みには同行しないことや，身元の確認は，集団での来訪者の場合は代表者のみで，一人ひとりは詳細に確認していないケースがほとんどであった。部外からの来訪者にはグループ会社や委託業者等も含まれるため，一律に社員の同行の有無の線引きは難しいとの指摘があった。

施設管理については，暗証番号の変更や鍵の取替えは，ほとんど行われていない現状が把握された。保管中の有毒物質や納入資材は，出納表等で使用量を管理されていることや，保管場所が使いやすいよう製造現場に近いことが一般的であった。

経営運営については，原料や資材等の数量が入荷時に増加していた場合，増加分の具体的な特定方法の事例は聞き取ることができなかった。出荷製品の出荷時の荷姿は確認しているが，出荷製品数が当初予定数より予期せず増加した場合，その増加分の特定が困難である現状が把握された。また，大項目名である「経営運営」の意味が難解との意見もあった。

表2　食品防御対策ガイドライン（食品製造工場向け）の概要

食品防御対策ガイドライン（食品製造工場向け）
―意図的な食品汚染防御のための推奨項目―

1.　優先的に実施すべき対策

■組織マネジメント
- 働きやすい職場環境の醸成と，自社および自社製品への愛着や責任感の高揚
- 意図的な汚染が疑われる事態発生時の原因究明や情報公開のための勤務状況や業務内容の把握と，従業員等への意識付け
- 製品の異常の早期発見のための苦情や健康危害情報等の確認，意図的な食品汚染発生時の社内外への報告，製品の回収，保管，廃棄等の手続きの策定

■人的要素（従業員等）
- 採用時の可能な範囲での身元確認，各種証明書や資格等の原本確認
- 異動・退職時等に制服や名札，IDバッジ，鍵（キーカード）の返却，識別・認識システムの構築，新規採用者の認知
- 製造現場内への持ち込み可能品リストの作成と遵守の確認
- 従業員等の異常な言動，出退勤時間の著しい変化等の把握

■人的要素（部外者）
- 訪問者の身元・訪問理由・訪問先等の確認と従業員の同行
- 訪問者の車両のアクセスエリア，荷物の持ち込みエリアの設定
- 工場内を単独行動する訪問者の持ち物の確認，不要物持ち込みへの留意
- 郵便，宅配便の受け入れ先の設定，建屋内への立ち入り，資材・原材料や製品への接近への留意

■施設管理
- 不要物，利用者・所有者が不明な物の定常的な確認
- 食品に直接手を触れることができる工程や従事者が少ない場所等，意図的に有害物質を混入しやすい箇所の把握と，防御対策の検討
- 非稼動時における防犯対策
- 鍵の管理方法の策定，定期的な鍵の取替え・暗証番号の変更等による外部からの侵入防止対策の実施
- 工場内部と外部との結節点の特定と対策の実施
- 工場内の試験材料（検査用試薬・陽性試料等）や有害物質の保管場所の設定，管理・保管方法・在庫量の確認方法等の策定と，在庫品紛失等発生時の通報体制の構築
- 殺虫剤の選定基準および管理・保管方法の策定
- 井戸，貯水，配水施設への侵入防止措置や浄化関連設備へのアクセス管理・監視の実施
- コンピューター処理制御システム等へのアクセス許可者の制限，異動・退職時等のアクセス権解除，データ処理履歴の保存

■入出荷等の管理
- 資材や原材料等のラベルや包装の確認，意図的な食品汚染行為等の兆候・形跡発見時の調査や通報の体制の構築
- 資材や原材料等の納入作業および製品出荷作業の監視
- 納入製品・数量と，発注製品・数量との整合性の確認
- 保管中の在庫の紛失・増加，意図的な食品汚染行為等の兆候・形跡，納入量過不足（紛失や増加）等が判明した際の調査や通報体制の構築
- 納入製品の荷受先の確認方法の共有

2.　可能な範囲での実施が望まれる対策

■組織マネジメント
- 警備・巡回結果の報告内容の明確化

■人的要素（従業員等）
- 敷地内の従業員等の所在の把握

■施設管理
- 敷地内への侵入防止対策
- 警備員の巡回やカメラ等による工場建屋内外，資材や原材料，有害物質，施錠確認等

（文献11より筆者要約）

表3　HACCPにおける食品防御の観点からの留意事項に記載された内容

- 食品防御対策の責任者の選任
- 出入り口，原材料納入口，製品出荷口などの外部との結節点の監視や施錠等の防犯体制
- 部外者との接点の有無や監視状況
- 持ち込み品の検査
- 機械器具の配置による死角
- 従業員の職制に応じた立入可能エリアや，図面へのアクセス制限
- 作業手順や作業標準に従った配置や動線からの逸脱など，作業員の行動のモニタリングや作業員同士の相互監視等による投入行為の抑制
- 人為的な異物投入の可能性の恐れがある工程や原因物質の特定
- 従業員や関連する部外者への食品防御に対する教育の実施
- 従業員の休憩室や，薬品庫・工作室・工務室等異物の保管場所と製造現場との隔離やアクセス管理
- 設備や機械器具の保守点検時の工程外の改修の有無の確認
- 殺虫剤等の選定や管理
- 使用水やその設備等の管理
- 不適格品の再利用や廃棄等の取り扱い方法や，回収製品の保管や廃棄方法の策定
- 記録保管時の盗難や部外者への漏出への注意

（文献12より筆者要約）

ガイドラインの構成については，ソフト対策とハード対策に分けることが困難な対策もあることから，優先度で記載すべきとの意見や，ガイドラインのみでは，食品企業が採るべき具体的な対策が分かりづらいとの意見が多く聞かれた。

3.　食品防御対策ガイドライン（食品製造工場向け）の作成について

聞き取り調査の結果を踏まえて，各種専門家から構成される研究班員による検討を行い，ソフト対策とハード対策に分けずに，最終的には，「優先的に実施すべき対策」，「可能な範囲での実施が望まれる対策」の2段階からなる「食品防御対策ガイドライン（食品製造工場向け）」[10]が作成された。

チェックリストやガイドライン（案）では，人的要素（従業員等・部外者）や経営運営に含まれていた対策の内，設備や施設に関係する対策は「施設管理」にまとめるとともに，大項目名の「経営運営」は，最終案では「入出荷等の管理」に改められた。

その結果，ガイドライン最終案には，「優先的に実施すべき対策」としては，組織マネジメント（4項目），人的要素（従業員等）（5項目），人的要素（部外者）（5項目），施設管理（14項目），入出荷等の管理（6項目）の計34項目が，「可能な範囲での実施が望まれる対策」としては，組織マネジメント（1項目），人的要素（従業員等）（1項目），施設管理（4項目）の計6項目が列挙された。

完成したガイドラインの概要を表2に示す。

また，ガイドラインが食品工場の現場における対策を強制するものではなく，「可能な範囲での対策の必要性の気付きを得る」ためのものであるとの趣旨・目的を説明文に明記した。

さらに，ガイドラインのみでは，食品企業が採るべき具体的な対策が分かりづらいとの意見を踏まえて，食品企業が具体的に食品防御対策を検討する上で参考となるようガイドラインの［解説］[11]を作成した。解説には，人為的な食品汚染に対する対応計画の作成，警備担当者からの報告内容，人為的な食品汚染に対する職員訓練プログラム，殺虫剤購入時の選定基準，在庫や最終製品の増加時における対応方法や増加分の特定方法等について，具体的な内容を分かりやすく記載した。

4.　HACCPにおける食品防御の観点からの留意事項

「日本版HACCP」と，食品工場用チェックリストやガイドランと比較した結果，日本版HACCPの承認基準に，食品防御の観点からの留意事項を追記することが，日本の食品企業が食品防御対策をとる上で有用と考えられた。具体的には，製造又は加工の工程に関する文書，施設の図面，危害の発生を防止するための措置，改善措置の方法，記録，管理体制について，それぞれ食品防御の観点からの留意点が追記された。

ガイドラインの参考資料として公表されている「HACCPの留意事項」[12]に記載された内容の概略を表3に示す。

Ⅳ　考　　察

2001年の9.11世界同時多発テロ以降，WHOの「食品を介するテロの脅威に対するシステムに関するワーキンググループ」の開催や，「食品テロの脅威に対抗するためのWHOへの勧告」，Terrorists Threats to Food（食品テロの脅威への予防と対応のためのガイダンス）の作成，米国での『食品セキュリティ予防措置ガイドライン”食品製造業，加工業および輸送業”編』の作成や，食品テロに対する脆弱性評価手法としての「CARVER＋Shock法」の開発，アジア太平洋経済協力（APEC）や経済協力開発機構（OECD）におけるテロ対策委員会の開催など，世界的に食品テロ対策の重要性が高まっている[13〜15]。

その一方，日本では，食品企業の60％は食品テロを想定しておらず，さらにその内の60％は食品テロの可能性は低いと考えているなど，食品テロに対する認識が低いことが指摘されている[16]。我々が国内8か所の代表的な食品関連施設（牛乳，弁当，納豆，清涼飲料，大規模集客施設等工場6か所，物流施設2か所）を対象に試行した“CARVER＋Shock法”による脆弱性評価の結果からも，テロや犯罪行為（人為的な異物混入等）に対する食品工場のセキュリティ対策の実施状況はかなり低く，とくにセキュリティ対策の基本である，現場におけるテロや犯罪行為に対する危険性の認識は，極めて低いものであった[6]。

こうしたことから，日本の食品企業の食品テロに対する認識を高め，具体的な対策を検討することが喫緊の課題となっていた。

我々はすでに，FDAの『食品セキュリティ予防措置ガイドライン“食品製造業，加工業および輸送業”編』を参考に，「組織マネジメント」，「人的要素（従業員等）」，「人的要素（部外者）」，「施設管理」，「経営運営」の5分野，計94項目に渡る「食品工場用チェックリスト」と，「組織マネジメント」，「人的要素（従業員等）」，「人的要素（部外者）」，「施設管理」，「経営運営」の5分野，計98項目からなる「物流施設用チェックリスト」を作成し，食品工場や食品の物流施設での食品防御対策の重要性の気付きを促してきた[6,7]。その結果，これらのチェックリストが，大手スーパーや生協等が納入業者に対して使用を促している実態や，倉庫内で勤務する従業員に対して厳格な持ち込み品検査，X線検査を実施している大規模倉庫を有する大手小売業者があることが研究班会議で報告されている[7]。その一方，中小零細規模の食品企業の多い日本において，米国と同様の脆弱性評価の実施や，チェックリストに列挙された対策を推奨することは食品企業の人的要素や経済的な負担を考慮すると現実的ではなく，食品企業が実施しやすい対策を，優先順位をつけて示すことが必要と考えられた。

このような現状を踏まえて，食品工場用チェックリスト項目の対策推奨度を検討し，それを踏まえた「ガイドライン（案）」を作成し，食品企業へのヒアリングを通じて，その実用性を確認し，その意見を踏まえて，「優先的に実施すべき対策」，「可能な範囲での実施が望まれる対策」の2段階からなる「ガイドライン」が完成した。推奨度を検討したことで，チェックリストで示された100項目近い対策が，ガイドラインでは40項目に集約された。さらに，分かりやすい解説を作成したことで，より具体的な対策の検討に資することが期待できる。

日本の食品企業が行っている食品防御対策としては，侵入者対策や原材料のチェック，輸送時の安全管理，搬出入時の職員の立会い，商品の入出荷の際の3時間内の確認は実施されているが，職員の職種による立ち入り先の制限や，搬入・搬出車の封印，搬入品の抜き取り検査は行われていないと言われている[16]。

中小零細規模が多く，家族経営的な食品企業が多い日本においては，従業員への食品防御に関する教育等を実施する場合には，労使の信頼関係を悪化させない特段の配慮が必要と考えられた。今後，食品防御対策を進めるには，食品企業に馴染みの深いHACCPに食品防御の観点を追加し，具体的な対策を実施することが最も効果的と考えられた。

今回作成されたガイドライン[10]や解説[11]，HACCPの留意事項[12]を参考に，日常的に行っている衛生管理や，衛生教育の一環として，「食品防御の考え方」を取り入れていくことが有用であろう。

Ⅴ　結　　論

食品企業で食品防御対策を普及させるため，費用対効果を測定し，対策の推奨度を踏まえた，実効性・実用性の高い「ガイドライン」とその解説を作成するとともに，食品事業者になじみの深いHACCPに沿った食品防御の観点から留意事項を示した。

ガイドラインは，食品工場に食品防御対策を強制するものではなく，「可能な範囲での対策の必要性の気付きを得る」ためのものである。ガイドラインとその解説や，「HACCPの留意事項」を併用しながら，多くの食品企業が食品防御対策の必要性や具体的な対策を検討されることが期待される。

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Tentative food defense guidelines for food producers and processors in Japan

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Key words : food contamination, food defense, food defense checklist for food producers and processors, food defense guidelines, CARVER＋Shock, HACCP

Objectives With increasing global interest in intentional food contamination, expert meetings have been held by the G8, while the U.S. government has proposed policies for preventing food terrorism and intentional contamination. However, Japan has no food defense policy, and some food companies are concerned about an impending terrorism and contamination crisis.

Methods We developed a Food Defense Checklist for Food Producers and Processors and published the details on the website. We also developed tentative Food Defense Guidelines for Food Producers and Processors on the basis of the checklist. In this study, we tested the usability of the guidelines through a hearing survey regarding food plants. We also compared the checklist with the implementation manual for the approval system of Comprehensive Sanitation Management and Production Process (the Japanese equivalent of the HACCP).

Results We organized the comments gleaned from the hearing survey and provided a detailed explanation of the guidelines. As the HACCP has been adopted by Japanese food companies, we included both precautionary measures and the HACCP perspective in the explanation regarding the rapid dissemination of information.

Conclusion The guidelines are useful for Japanese food companies, and it is important to disseminate knowledge on this topic and implement food defense measures.

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