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Evaluating Persian Adoption of FDA Food Defense Assessment Checklist for Dairy Producing Units in Northeastern of Iran

Ali Barzegar[1], Mahbubeh Abdollahi[2], Abbas Malek[3*]

1. Assistant professor, School of Health and Nutrition, Tabriz University of Medical Sciences, Tabriz, Iran
2. Assistant Professor, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran
3. MSc of Nutrition in Disaster, Student research committee, School of Health and Nutrition, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT

Introduction: In the modern era, it is believed that the use of microbial agents and biological toxins may be harmful to human health. The food industry is a potentially vulnerable target to deliberate contamination, such as the manufacturing units of the dairy industry. The present study aimed to determine the level of food defense preparedness in dairy production units based on the food defense assessment checklist developed by the Food and Drug Administration (FDA).

Methods: This descriptive, cross-sectional study was conducted using the Persian version of the FDA checklist, which was prepared via backward-forward translation and evaluated in terms of face and content validity by a panel of experts. The content validity index (CVI) and content validity ratio (CVR) of all the items were calculated. After localizing the research instrument, 39 dairy producers were enrolled in the study.

Results: After modifying the FDA checklist based on validity assessment and localization, the number of the items reduced from 34 to 31. The level of food defense preparedness in the selected dairy producers in terms of management, human elements, facilities, and operations was estimated at 38.3%, 45.5%, 67.7%, and 92.1%, respectively. The only item that was observed in all the evaluated units was the presence of an initial assessment plan for the adequacy of food security procedures in order to prevent deliberate contamination.

Conclusion: According to the results, the food defense preparedness of large-scale dairy producers was suboptimal and impractical in several items. Therefore, further investigation is required to determine the causes and take proper measures to enhance their level of preparedness.

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Introduction

In recent years, the achievements of the health system have been impressive in the management of the complications caused by disasters. Some of the natural and manmade hazards that have been addressed in the National Program of Public Health Response Operations in Disasters and Emergencies include flood, earthquakes, and droughts (natural events), as well as war, political crises, air pollution, and water- and food-borne disease outbreaks (manmade incidents). The outbreak of water- and food-borne diseases is considered to be a growing global concern, which is defined as the diseases caused by the common consumption of contaminated food or drink with common clinical symptoms (1-3).

Historically, humans have used advanced technologies to their benefits, as well as to serve sinister purposes to kill innocent people. Recent developments have made microbial agents and biological toxins to be converted into lethal weapons that threaten the life and

* *Corresponding author:* Abbas Malek, Student research committee, School of Health and Nutrition, Tabriz University of Medical Sciences, Tabriz, Iran. Tel: 00985137269025; Email: Maleka2@mums.ac.ir

health of humans (4). The turn of the millennium was not the only usher of the new century and was accompanied by new concerns about the safety threats and security of food supplies. In recent years, the safety of food supplies has become a pressing issue for the general population.

Following the events of September 11, 2001 in New York, the awareness regarding terrorist attacks has increased, and concerns have been raised regarding bioterrorism. The United States Department of Agriculture (USDA) defines bioterrorism as the deliberate use of biological or chemical agents to cause damage to the environment. Moreover, the USDA defines food security as food conservation against bioterrorism.

Types of Contamination

Researchers have proposed various targets for attacks and invasions, such as attacking airlines, military, and governmental targets. In the United States, numerous experts believe that the food industry is a soft, yet potentially vulnerable target to deliberate contamination with chemical, biological, radiological, and nuclear defense. The prevalence of several unintentional food contaminations is a consequence of major disruptions in food hygiene due to human errors. Another significant hazard that threatens food supplies is the intentional contamination of foods, which has not been fully recognized. In this regard, those who deliberately commit crimes such as the infecting or damaging of food products are known as aggressors (4-6).

The biological weapons that are produced in various countries are of great importance as they could be applied through water and food, thereby simultaneously threatening national security and public health.

It is critical to distinguish between food safety and food security. Food safety refers to the accidental contamination of food, while food security refers to the deliberate and intentional contamination of food with the purpose of harming and disrupting the community. The respiratory tract and digestive tract are respectively the most common routes of contamination through biological wars. Considering the possibility of using biological weapons in upcoming wars and the efforts of countries to produce these weapons, recognizing these agents and their transmission modes, especially through water and food, is of paramount importance (7-9).

There is an opportunity for bioterrorist activities along the food supply chain from agricultural production to food consumption; this process is known as “from farm to fork”. Pathogenic agents may be used at various stages of food supply, storage, and distribution. If these agents are introduced into the initial stages of food production, their propagation will be further assured.

Biological Agents

Biological agents are divided into two main categories of pathogens and bio-toxins. Pathogen microorganisms are the agents that cause diseases such as anthrax, salmonellosis, brucellosis, cholera, shigellosis, fungal poisoning, staphylococcal infections, and infections caused by *Clostridium perfringens* and *Escherichia coli*. These diseases could be transferred through food and water in bioterrorist attacks.

Botulinum is the most hazardous and fatal bacterial toxin known in nature and could be considered an example of bio-toxins. The lethal dose of botulinum for one person is one nanogram per kilogram of the body weight, and a few kilograms of this pure toxin could easily annihilate all human beings. When added to food and water, botulinum causes no changes in their appearance (color, odor, and taste). As a result, consumers cannot be aware of its presence and the subsequent contamination. For this reason, death due to botulinum contaminants is silent and sudden. Some of the important factors to be considered about this natural toxin are the role of its low doses on in infections and lethality, high resistance in the environment, impossibility of rapid and timely diagnosis, and lack of vaccines against the contamination (8, 10-12).

Unfortunately, some countries are seeking to produce biological weapons through their military, technical, economic, and political power. Despite the international sanctions on the use of biological weapons, evidence suggests that biological agents have been used for military and bioterrorist purposes during the second half of the 19th century. Salmonellosis in

the United States, hepatitis in China, and anthrax in Russia and Zimbabwe are some of the adverse consequences of using biological agents. Evidently, there is still the possibility of using these agents in wars and other human threats in the future (13-15). Individuals with criminal intents may also use the food chain to harm general populations, while food and water may become polluted accidentally as well (16, 17).

Considering the technological advancement in the modern world and fundamental changes in military weapons, using passive defense is essential to the reduction of the casualties and damages caused by modern biological warfare. Defense is defined as the neutralizing or diminishing of the effects of the enemy's aggression and preventing the enemy from reaching its goals. In this context, defense may be active or passive.

Active defense is a tool that requires system management and human users. Passive defense refers to defense without using weapons against the threat. Most countries have a passive defense program to protect national infrastructures against the threats caused by the weapons of mass destruction (18-20). Food defense is a subcategory of passive defense. Protection of food against deliberate or inadvertent contaminations is referred to as 'food defense'. This term has mostly been used in the context of preventing bioterrorist attacks (21).

Contamination at the production level could easily be transmitted to the targeted community. Given the importance of preventing the damages caused by bioterrorism to industrial food production units and due to the high vulnerability of the food industry to deliberate biological contamination, the present study aimed to evaluate the level of food defense preparedness of food production units in terms of management, human elements, facilities, and operations using the localized, validated Persian version of the US Food and Drug Administration (FDA) food defense self-assessment checklist in the dairy industry in Khorasan Razavi province, Iran. The region was selected because it is one of the pillars of the food industry nationwide with massive potential for development.

Material and methods

This descriptive, cross-sectional study was conducted on the dairy production units in Khorasan Razavi province, Iran in 2017. All the dairy producers on the industrial scale were enrolled. Of 46 units, six cases were inactive, and one refused to cooperate in the study. In total, 39 dairy factories were evaluated in terms of defense preparedness against bioterrorist attacks.

The inclusion criteria were the industrialization of the production unit and holding a production license for health products (as well as other necessary approval) from the Iranian Food and Drug Administration. The production units that refrained from completing the informed consent forms, were non-industrial on the workshop scale, and had managers with inadequate scientific and mental ability to answer the questions were excluded from the study.

In order to eliminate the effects of the confounding factors (e.g., potential mistakes of the respondents in completing the checklists due to the lack of national programs for optimizing general knowledge in various populations regarding the subject matter), the researchers carefully enquired four main individuals involved in the study (internal managers, personnel managers, technical managers, and facility officers) before completing the checklists and provided relevant responses through viewing the documents. The study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences, Iran.

The present study aimed to evaluate the food defense preparedness of the subsystems of the dairy production units affiliated to Mashhad University of Medical Sciences. The level of food defense preparedness was evaluated using the FDA standard checklist on dairy processing and production units (appendix). The checklist contained 34 items, which were graded by four options (Yes, No, Not Applicable, Do Not Know). In addition, the checklist consisted of four subscales, including management (items 1-8), human resources (items 9-14), facilities and equipment (items 15-18), and operations and processes (items 19-34).

Considering that the FDA checklist was used for the first time in Iran in the current research, we performed the translation steps and

assessed the content validity and face validity of the checklist prior to the implementation of the study. Initially, the FDA checklist was translated into Persian using the Briclin model for translating and back-translating. To do so, a food industry expert, who was fluent in English and Persian, translated the tool from English (primary language) into Persian (target language). Afterwards, another expert with the same qualities back-translated the translated tool into English without access to the original version (blinded). In case of any contradictions between the items of the original version and translated version, the items were translated into Persian again based on the original version, and another food industry expert, who was fluent in English and Persian, translated the Persian version into English again. The process was repeated four times until there were no contradictions between the original version and translated version.

To assess the face validity qualitatively, the clarity and simplicity of the checklist were reviewed and revised. In addition, the quantitative evaluation of face validity was performed so as to remove the inappropriate items and determine the significance of each item. To this end, the items were scored based on a Likert scale (Very Strong-Very Weak). Mean score of each item was calculated based on the responses of the experts. If the obtained score of each item was more than 1.5, the item would be considered proper and maintained for further analysis.

In the qualitative assessment of content validity, 10 experts in the field of nutrition and food industry provided feedback on the grammatical criteria, proper word use, and placement of the items in the appropriate category, and modifications were made accordingly. After the qualitative evaluation, the content validity index (CVI) and content validity ratio (CVR) were used. To investigate the CVI, each item was analyzed based on the three criteria of simplicity, relevance, and clarity based on a four-point Likert scale (Irrelevant, Partly Relevant, Relevant, and Completely Relevant) by a panel of experts. To evaluate the CVR, the items in the checklist were graded based on a three-point Likert scale. If necessary, modifications were made by the panel of experts.

After localization, the checklist was completed by four participants in each production unit, including an internal manager, a personnel manager, a technical manager, and a facility officer. The production units with moderate or low levels of preparedness were introduced to the Food and Drug Administration affiliated to Mashhad University of Medical Sciences in order to ensure that the necessary measures would be taken by the manufacturing units to reduce their vulnerability to deliberate contaminations (i.e., bioterrorist attacks).

Informed consent was obtained from all the dairy producers, and they were assured of confidentiality terms regarding their personal information. The study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1396.856). Data analysis was performed in SPSS version 16 using frequency and percentage to describe the data.

Results

Qualitative and Quantitative Assessment of Face Validity

At this stage, modifications were made to the checklist based on the comments of the experts. Due to ambiguity and generalization, item 29 was divided into two questions. For the detailed examination of the raw milk transfer chain to accurately investigate the technical officer, items 27 and 28 and the final question were completely modified and rewritten for the Iranian population. In order to clarify the checklist items and reduce ambiguity, the modifications involved the addition of descriptions or deleting parts of items one, two, six, nine, 12, 13, 15, 16, 18, 19, 20, 25, 33, and 34.

Finally, with the two added questions, the checklist contained 36 items, which were quantitatively assessed to confirm their face validity. At this stage, each item was evaluated by a panel of experts based on a five-point Likert scale (Very Weak, Weak, Moderate, Strong, and Very Strong).

After the analysis of the modified checklist, the items with the scores of less than 1.5 were eliminated. As a result, items 13 and 33 were deleted due to low score, and the number of the items in the check list decreased to 34. To avoid repetition, the checklist containing the final

questions after the revisions resulted from the qualitative and quantitative analysis. Evaluations of face and content validity and localization are presented in Tables 2-5.

Qualitative and Quantitative Assessment of Content Validity

The first modification in the checklist after the qualitative assessment of content validity was the removal of the Do Not Know option in the responses. The theoretical basis for this change was that the individual responsible for various departments of a factory should have extensive knowledge of the events and instructions; as such, the Do Not Know option did not suit this purpose. In addition, items one, three, seven, and 21 were rewritten.

Data on CVI and CVR are shown in Table 1. Based on the number of the experts in the panel (n=10) in the present study, as well as the Lawshe CVR table, the minimum acceptable CVR value for the study was estimated at 0.62. Moreover, the CVI score of more than 0.79 was considered appropriate for this criterion. As a result, items two, 16, and 25 were eliminated from the checklist due to inappropriate scoring. The final checklist was used with 31 items for the assessment of the selected dairy production units.

Table 1. CVI and CVR of Items in Persian Adoption of Food Defense Self-Assessment Checklist

Item	CVI	CVR	Item	CVI	CVR
1	1	1	18	1	1
2	0.8	0	19	1	1
3	1	1	20	0.9	1
4	1	1	21	1	1
5	1	1	22	1	1
6	1	1	23	1	1
7	1	1	24	1	1
8	1	1	25	0.6	-0.6
9	1	1	26	1	1
10	1	1	27	0.9	1
11	1	1	28	1	1
12	1	1	29	1	1
13	1	1	30	1	1
14	1	1	31	1	1
15	1	1	32	1	1
16	0.5	-0.8	33	0.9	1
17	1	1	34	1	1

Food Defense Preparedness in Terms of Management

Table 2 shows the findings regarding food defense preparedness in terms of management. Accordingly, all the producers had a program to prevent deliberate contamination, reporting that the recall of their products by the consumers to the manufacturer was impractical (not applicable). On the other hand, the manufacturers had no programs to raise the awareness of the enforcement officials regarding bioterrorist threats or believed that doing so was inapplicable.

Table 2. Data on Food Defense Preparedness in Terms of Management

No.	Item	Yes	No	Impractical/Not Applicable
		N (%)	N (%)	N (%)
1	Presence of an initial assessment plan for adequate food safety procedures (to plan and prevent deliberate contamination in production unit)	39 (100)	0 (0)	0 (0)
2	Developing a product recall strategy (at level of dairy distribution agencies)	0 (0)	0 (0)	39 (100)
3	Providing training on food safety awareness to encourage All staff to be alert about food safety (intentional contaminations, terrorist and criminal acts, and areas that may be vulnerable to such actions) and report on findings to management	37 (94.9)	0 (0)	2 (5.1)
4	Providing appropriate supervision to all staff with access to vulnerable areas of facility (cleaners, seasonal, temporary, contract, and volunteer staff, facilities, maintenance and quality control staff, especially new staff)	7(17.9)	0(0)	32(82.1)
5	Presence of routine security checks in terms of intentional contamination and terrorist and criminal acts in areas of raw and pasteurized milk storage, receiving and storage of food additive supplements, and milk processing and packaging areas of facility or areas that may be vulnerable to such actions	34 (87.2)	0 (0)	5 (12.8)
6	Informing appropriate law enforcement (police force) about threats or suspected criminal/terrorist actions	0 (0)	35 (89.7)	4 (10.3)
7	Review (at least annually) of effectiveness of the food safety plan, use knowledgeable in-house or third-party staff, and revising programs accordingly	0 (0)	39 (100)	0 (0)

Food Defense Preparedness in Terms of Human Elements

Data on the human elements of food defense preparedness are presented in Table 3. Accordingly, none of the items was responded with the "No" option. Similarly, none of the items received a definite answer of "Yes" or "Not Applicable" (100% of the units).

Table 3. Data on Food Defense Preparedness in Terms of Human Elements

No.	Item	Yes N (%)	No N (%)	Impractical/Not Applicable N (%)
8	Obtaining and verifying addresses and phone numbers of all staff with access to raw and pasteurized milk storage, receiving and storage of vitamin supplements, and milk processing and packaging areas of facility (cleaners, seasonal, temporary, and contract staff, maintenance and quality control staff, and volunteer staff)	2 (5.1)	0 (0)	37 (94.9)
9	Having a criminal background check performed by local law enforcement for listed staff	29 (74.4)	0 (0)	10 (25.6)
10	Limited access to raw and pasteurized milk storage, receiving and storage of vitamin supplements, and milk processing and packaging areas of facility to staff that need to enter because of their job functions and only during appropriate working hours	25 (64.1)	0 (0)	14 (35.9)
11	Preventing staff from bringing personal items into raw and pasteurized milk storage, receiving and storage of food supplements, and processing and packaging areas of facility	6 (15.4)	0(0)	33 (84.6)
12	Accompanying all visitors from arrival to exit from unit	31 (79.5)	0 (0)	8 (20.5)

Food Defense Preparedness in Terms of Facilities

Table 4 shows the obtained results regarding the facilities of food defense preparedness. Accordingly, inspecting the bulk-unloading equipment and pumps in the receiving area before use was considered impractical (Not Applicable) by all the dairy production units. Moreover, 94.9% of the units expressed that it would be impractical (Not Applicable) to lock all the entries to the milk house or bulk milk tanks until the time they were unloaded.

Table 4. Data on Food Defense Preparedness in Terms of Facilities

No.	Item	Yes N (%)	No N (%)	Impractical/Not Applicable N (%)
13	Securing all doors, windows, storehouses, roof openings/hatches, vent openings, utility rooms, areas under roof, trailer bodies, tanker trucks, and bulk storage tanks	34 (87.2)	0 (0)	5 (12.8)
14	Inspecting bulk unloading equipment and pumps in receiving area before use	0 (0)	0(0)	39 (100)
15	Locking or sealing all entrances to milk house and bulk milk tanks since unloading	2 (5.1)	0 (0)	37 (94.9)

Food Defense Preparedness in Terms of Operations

The findings regarding food defense preparedness in terms of operation are show in Table 5. Correspondingly, 50% of the items were considered impractical (Not Applicable). In this regard, the item that received most the most positive responses compared to other items was "Use Only Known, Reputable Transportation Companies".

Table 5. Data on Food Defense Preparedness in Terms of Operations

Raw Materials, Nutritional Supplements, and Laboratory Reagents

No.	Item	Yes N (%)	No N (%)	Impractical/Not Applicable N (%)
16	Using only known, appropriately licensed or permitted sources for raw materials, nutritional supplements, and laboratory reagents	0 (0)	0 (0)	39 (100)
17	Establishing delivery schedules for raw materials, nutritional supplements, and laboratory reagents (not accepting unexplained and unscheduled deliveries and investigating delayed or missed shipments)	4 (10.3)	0(0)	35 (89.7)

18	Matching off-loading of incoming raw materials, nutritional supplements, and laboratory reagents in terms of quantity and quality with materials ordered and listed in invoice and document of shipments	0 (0)	0 (0)	39 (100)
19	Investigating shipping documents with suspicious alterations	0 (0)	0 (0)	39 (100)
20	Inspecting incoming raw materials, nutritional supplements, and laboratory reagents for signs of tampering, contamination, damage or counterfeiting upon delivery to dairy unit	0 (0)	0 (0)	39 (100)
21	Inspecting discharge of raw materials, nutritional supplements, and laboratory reagents outside routine working hours	0 (0)	9 (23.1)	30 (76.9)
22	Storage of raw materials, nutritional supplements, and laboratory reagents in secure and enclosed locations and their precise control	4 (10.3)	0 (0)	35 (89.7)
23	Inspection and performing microbial and chemical tests on products at semi-final state (during process and semi-final) by technical officers	11 (28.2)	0 (0)	28 (71.8)
24	Inspection and performing microbial and chemical tests on final product and licensing of its use by technical officers	0 (0)	0 (0)	39 (100)
Labeling				
No.	Item	Yes N (%)	No N (%)	Impractical/Not Applicable N (%)
25	Storing product labels in secure locations (storehouse belongs to packaging requirements)	7 (17.9)	0 (0)	32 (81.1)
26	Destroying labels of outdated or unusable products	0 (0)	0 (0)	39 (100)
Raw Milk				
No.	Item	Yes N (%)	No N (%)	Impractical/Not Applicable N (%)
27	Using only known, authorized (licensed) transportation companies	14 (35.9)	10 (25.6)	15 (38.5)
28	Establishing delivery schedules for raw milk (not accepting unexplained and unscheduled deliveries or drivers and investigating delayed or missed shipments)	0 (0)	0 (0)	39 (100)
29	Acceptance of raw milk shipments with quarantine health certificate from inter-provincial and intra-provincial transportation from Veterinary Organization	4 (10.3)	0 (0)	35 (89.7)
30	Matching amount of received milk with listed amount on shipping documents	0 (0)	0 (0)	39 (100)
31	Inspecting shipments of raw milk incoming outside routine working hours	0 (0)	9 (23.1)	30 (76.9)

Overall Evaluation

Following the localization of the FDA checklist for the Iranian population, the researchers investigated the dairy factories in Khorasan Razavi province. Due to the lack of standards for the scoring of food defense preparedness in the FDA checklist, the results of the current research regarding the dairy production evaluations have been expressed using two different methods in the Results section.

The first method was analysis based on the frequency and percentage of the responses to each of the items, which involved the assessment of each item independently (Tables 2-5). In the second method, we used the geometric mean (Figure 1), as well as the number of the items with the positive response (Yes) in each dimension. In the second method, the dimensions of management and human elements received achieved average to low scores (<0.5), and the dimensions of facilities and operations achieved acceptable scores (>0.5). Due to the lack of standards for the scoring of the FDA checklist, the values obtained in the first method were higher than the second method (geometric means).

The ratio of the positive response (Yes) was used in the overall evaluation, and the findings indicated the proportion of this response in each production unit. Finally, we used the geometric mean to achieve the total score in the studied units and determine whether the units were prepared in terms of food defense (Figure 1). In terms of management and human elements, the selected dairy factories had moderate food defense preparedness (<0.5). On the other hand, higher rates of food defense preparedness were observed in terms of facilities and operations.

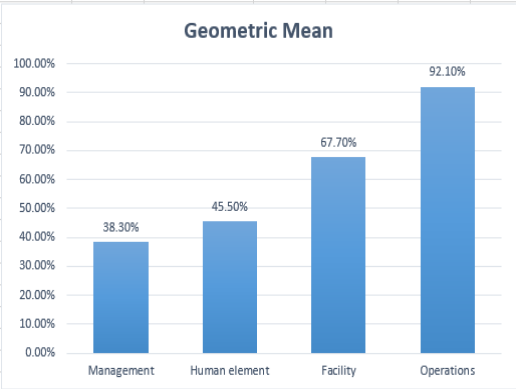

Figure 1. Geometric Mean of Ratio of Items with Positive Response in Each Dimension

Discussion

In the present study, the FDA food defense preparedness checklist was localized for the Iranian dairy industry, as well as their work environments and culture. Similar studies in other countries have also localized such tools, attempting to assess the food defense preparedness of large- and medium-sized production units against bioterrorist attacks (22, 23).

This was the first research to evaluate the level of food defense preparedness in the dairy production companies in Iran. Although it is believed that there are other tools for such assessments, few studies have used the current instrument in this regard. For instance, CARVER plus Shock is a comprehensive vulnerability assessment tool, which facilitates the identification and estimation of economic and psychological impacts throughout the food system. Shock is a combined measure of the health, economic, and psychological effects of bioterrorist attacks on the food industry, and CARVER is an acronym of six words (criticality, accessibility, recoverability, vulnerability, effect, and recognizability) (24).

According to a literature review, CARVER plus Shock and FDA food defense assessment have been used in some countries to examine the vulnerability of intentional food contamination or develop food defense programs. In a study, Kanagawa et al. claimed that the small- and medium-sized food companies that constitute a major part of the food industry in Japan are extremely susceptible to deliberate food contamination (25). Furthermore, they evaluated eight food factories and their facilities based on the FDA checklist of food defense preparedness in dairy processing and production units, as well as the available software, to measure their vulnerability to intentional contaminations using CARVER plus Shock. According to the mentioned research, there was poor awareness regarding food defense and the measures in this regard were also considered inappropriate. As a result, a set of guidelines was developed to help Japanese food companies adopt the essential food defense strategies, which has been used as a reference in taking specific measures.

In another study by Kanagawa et al. (26), a food defense checklist and tentative food defense guidelines against intentional contaminations were developed for food producers and processors. In addition, the checklist was compared to Japan's HACCP Executive Order. As HACCP was approved and applied by Japanese food companies, the researchers also stated that food defense precautions were incorporated into the HACCP. The practicality of the developed guidelines was examined through an oral survey of food factories. In this process, the oral data were collected, and it was concluded that the food defense guidelines were remarkably beneficial to the factories.

In a similar research, Klitz (27) investigated the food defense practices in Montana's northern schools using the FDA food checklist in small retail food units. In the mentioned survey, the majority of the respondents were unfamiliar with the concept of food defense. Moreover, several interviewees believed that food tampering was unlikely in their schools since they considered the employees to be reliable or the location to be insignificant. The results of the present study indicated that the perception of the personnel toward the deliberate contamination of food was unfavorable, and it was essential to train the personnel on the storage and use of the chemicals that may be deliberately added to food.

In a study by Newkirk et al. (28), which aimed to establish a profile of milk-borne diseases and identify the main features of the outbreak of these diseases and the potential indicators of food terrorism, the authors used the data collected by the Center for Disease Control and Prevention (CDC) during 1997-

2006 regarding the diseases caused by milk contamination. In total, 83 disease outbreaks caused by liquid milk had been reported in this period, resulting in 3,621 cases of illness. The number of the patients, location of the outbreak, and etiology of the diseases were indicative of intentional contamination. In 2007, an outbreak of Listeria contaminated pasteurized milk, which seemed to be an unexpected outbreak compared to the outbreak of predicted illnesses.

In this regard, Ashford et al. (29) investigated the role of biological agents in the outbreak of food-borne illnesses during 1988-1999 using the data collected from the reports provided by the US CDC Department of Health Epidemiology Information Service. In the mentioned study, 1,099 outbreaks were observed, in 41 of which the infectious agents were unknown. Furthermore, the researchers stated that these factors were not commonly observed in the CDC reports, and the subsequent diseases were considered to be caused by deliberate exposure if not coincidental.

In a study conducted in 2000 by the University of South Dakota, Frantz (30) examined the extent of the knowledge of food service operators regarding the threats posed by food bioterrorism and the required defense measures. According to the obtained results, three quarters of the respondents had no food defense programs.

In another research by Yoon and Shanklin (31) conducted at Kansas University in the United States, the knowledge of food service managers regarding food bioterrorism and preventive measures was examined using the USDA checklist. The findings demonstrated that adequate knowledge of bioterrorism preparedness resulted in more preventive measures. In the mentioned research, 26.3% of the facilities had responsible individuals for food defense, and the need to train students on the understanding of bioterrorism and preventive measures was highlighted.

Mohtadi et al. (32) compiled a database of chemical, biological, and radio nuclear (CBRN) incidents (n=448) during 1975-2005 to use past incidents to estimate the risk of future incidents on a large scale. The mentioned research was based on the assumption that the past experience of CBRN events is a good predictor of future incidents. They used a statistical method known as the extreme value theory in order to verify the possibility of terrorist attacks affecting large populations. Moreover, they observed that major attacks involving thousands of casualties were more likely to occur with CBRN weapons, claiming that by 2025, a CBRN attack every 20 months would kill 5,000 individuals.

In this regard, Helmuth (33) examined the knowledge regarding the prevention of deliberate food contamination and preventive measures in the food service facilities of the state of Georgia in the United States. In the mentioned study, a checklist was completed by 134 authorized managers of food security in the facilities. According to the findings, although half of the respondents believed that intentional food contamination in the United States was probable, they dismissed the possibility of its occurrence in their system. Therefore, no association was denoted between the perception of the risk of intentional food contamination and preventive measure.

To the best of our knowledge, the present study had an innovative subject nationwide. It is also notable that the issue of food security has not been addressed in the food industry of Iran. Therefore, estimating the food defense preparedness in dairy production units could represent the entire food industry production units, compelling the producers to become aware of the level of their preparedness and vulnerability to deliberate food contamination and bioterrorism attacks. The localized checklist could be used in other provinces as well.

Limitations of the Study

One of the limitations of the current research, as well as the similar studies in this regard, was the mere assessment of food defense preparedness against bioterrorist attacks and deliberate food contamination, which failed to address the other aspects of this investigation, such as the main causes of the inability of food supply and distribution centers in providing defense against contaminating attacks. This limitation may lead the researchers to seek solutions to increase the power of food defense,

which requires the identification of the roots causes of the incapability of producers in providing various items of food defense preparedness. Such assessment could not be carried out in the current research due to the high volume of work from translation to evaluation for the validity confirmation of the research tools and assessing the producers. This aspect of food defense could simply be assessed using the applied checklist.

Conclusion

The concept of food defense is relatively new in Iran, and the existing departments are more concerned with natural disasters (e.g., earthquakes) when it comes to preventing food contamination. Therefore, less attention has been paid to biological threats and bioterrorism in the food industry. Considering the sensitive position of the Middle East in the region, it is recommended that food safety checklists and other effective tools (e.g., CARVER plus Shock) be employed to evaluate the level of food defense preparedness in the food production units with high consumption rates.

According to the results, the food defense preparedness of large-scale dairy producers in the northeast of Iran was inefficient. Moreover, the other international studies in this regard have only described the conditions of food safety without addressing the causes of food contamination. As such, it is suggested that further investigations be performed in order to determine the major causes of intentional food contaminations, taking the necessary measures to enhance the level of preparedness.

Conflict of interest

None declared.

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