MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evalution

Risk Assessment of *Clostridium perfringens* in Sauce Group

Introduction

Most of sauces may have been: pasteurized before distribution, but it is possible to be contaminated due to an insufficient job of heat-treatment or pasteurization during processing. And sauces are thought to be sensitive to microbial contamination because this food item tends to be eaten in an uncooked state. Compared to other food-borne pathogens, *Clostridium perfringens* has high infectious dose, so it is classified as a low risk food-borne pathogen. It can be present for a long period in food as a spore before causing food poisoning. Therefore, because it is necessary to verify its safety by conducting monitoring and scientific tests on *C. perfringens*, this study seeks to utilize the results based on an assessment of *C. perfringens* risk in the sauce group to reestablish the standards and to reduce the risk of a food poisoning occurrences. The "sauce group" in this study is defined as a group of foods including sauces (sauce, dressing, etc.), mayonnaise, ketchup, and others among the types of foods in the Korea Food Code. The data for one food type under extreme conditions from the type of food of the sauce group for each stage of the risk assessment was collected and used to ultimately create the calculated risk that covers the risk of all food types belonging to the sauce group.

Statement of purpose

The purpose of this risk assessment is to suggest a plan for risk management through a risk analysis for *C. perfringens* in the sauce group, and in doing so, suggest a scientific basis for establishing quantitative standards for *C. perfringens* in the sauce group, and systematically create a system where food poisoning and food related incidents caused by the intake of *C. perfringens* in sauces can be prevented.

Hazard identification

C. perfringens

As a gram-positive bacterium of an obligatory anaerobe *C. perfringens* is 3×9 μm in size, has no flagellum and forms spores. It can be found in natural environments (soil, rivers, runoff), and is widely distributed in the intestinal tracts and feces of both humans and animals and in food. The spores of this bacteria can survive for extended periods in the places it has contaminated (Ministry of Food and Drug Safety (MFDS), 2015). Since it can exist in the intestinal tracts of healthy individuals, in order to diagnose a case of food poisoning from *C. perfringens* a minimum measurement of 10^6 or more spores per 1 g of feces should be found within 48 hours of occurrence. (MFDS, 2015). Because *C. perfringens* produces *C. perfringens* enterotoxin (CPE) in the process where vegetative cells form spores and causes food poisoning, it can be classified by 5 types of bacteria depending on the toxin production: type A, B, C, D or E (McDonell, 1980). Of the five types, the most cases of food poisoning involve type A, food poisoning involving type C is very rare and causes necrotizing enterocolitis (Bates and Bodnaruk, 2003). However, its enterotoxin is susceptible to heat and is easily destroyed when heated to 74℃. The optimal temperature that supports growth is 43℃ - 47℃, and the optimal temperature for its spores and toxins is 37℃, but it is unable to proliferate at ≤ 15℃ or ≥ 52℃ (MFDS, 2015). It can grow at a pH of 5.0 - 9.0, with the optimal pH range being 6.0 - 7.0; the optimal pH range for the production of toxins is 6.5 - 7.3 (MFDS, 2015). It can also grow under anaerobic conditions, and even do so at a water activity of 0.930 - 0.970 (NZFSA, 2001). In Korea, there are about 15 cases of food poisoning occurring each year. The trend over the past 5 years showed the number of occurrences decreasing after increasing. But, compared to the number of food poisoning occurrences reported, there was a large number of patients of food poisoning. When taking into account the fact that the most common facilities where food poisoning occurrences took place were restaurants, schools, and snack shops near schools in that order, it could be determined that food poisoning caused by *C. perfringens* often occurs in environments where there is institutional food service.

Exposure assessments

For the exposure assessment for *C. perfringens* of the sauce group, scenarios were established and carried out across a total of 4 stages: (1) transport from the point of production to the point of sale, (2) pre-sale storage, (3) display, and (4) intake by consumers.

Exposure assessment for *C. perfringens* in sauce group

Since all the samples of the 250 sauces of the sauce group being distributed in Korea tested negative for *C. perfringens*, a beta distribution and a formula suggested by Sanna (2004) were utilized to estimate the results, which showed that the initial average contamination level had a mean of -3.65 log CFU/g, -4.69 log CFU/g with 5%, and -2.92 log CFU/g with 95%. The results of fitting Baranyi model as the growth and destruction model for *C. perfringens* for the sauce group that were drawn from a wide range of temperatures (4, 15, 25, 35℃), showed that *C. perfringens* had a tendency to grow quickly when temperatures rose until the point that excessive temperature destroyed it.

Based on the results of the distribution environment study of the sauce group and the growth and destruction model, data collected on the degree of the contamination level study, the distribution environment, amount of intake, intake frequency, and growth and destruction model were utilized to create a simulation in line with the scenario (point of production-sales warehouse-display-consumption) established in this risk assessment. While the sauce group was in the distribution stage, the average degree of contamination estimated was verified to have gradually increased from –3.65 log CFU/g to –0.902 log CFU/g.

On the basis of the "intake of the sauce group and the intake pattern study", the results of calculating the amount of ketchup intake showed that intake of this sauce was the highest with a mean intake of 11.69 g.

Hazard characterization

C. perfringens

For the dose-response model for the risk estimation of *C. perfringens*, the Exponential model, Risk=1-exp (-r × D) (r, risk parameter = 1.82×10^{-11}; D, dose) was used.

Risk characterization

C. perfringens in Sauce group

The result of estimating the risk of *C. perfringens* in the sauce group via a simulation that utilizes the @RISK Excel spread sheet, showed that when the sauce group was consumed after undergoing an established distribution stage, the likelihood of a food poisoning occurrence from *C. perfringens* per person per day was estimated to have a mean of 2.78 x 10^{-4}.

The results of the risk estimation for *C. perfringens* for the sauce group showed that when the sauce group was consumed after undergoing a distribution stage, the likelihood of a food poisoning occurrence from *C. perfringens* per person per day was estimated to have a mean of 2.78 x 10^{-4}. The results of analyzing the risk of *C. perfringens* through a sensitivity analysis showed that the level of risk is positively correlated to warehouse storage time and temperature, initial degree of contamination, and shelf-time when displayed and other variables. In particular, warehouse storage time, was a standout showing the greatest positive correlation.

Impact of establishing microbial standards in Korea Food Code

The current sauce group (sauces) is being managed in a way ensuring that is negative from *C. perfringens*. The results of this study are for cases where is assumed that the food is contaminated with very miniscule amounts of bacteria (-3.65 log CFU/g), therefore it does not mean the current sauce group is at risk. Yet, when considering extreme conditions in sauces where *C. perfringens* can grow fast, the possibility for a food poisoning occurrence is estimated to have a mean of 2.78×10^{-4}, which is higher compared to other foods, therefore the current "negative" standard is determined to be appropriate.

Gaps in the data

This risk assessment uses results that are evaluated under some assumptions using limited data; therefore, it should be re-evaluated if additional data become available. It is considered necessary to continuously perform risk assessment to establish scientific and reasonable standards and specifications, taking into account factors such as, among others, the risk and exposure frequency.