MINISTRY OF FOOD AND DRUG SAFETY
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Risk Assessment of *Clostridium perfringens* in Paste Group

Introduction

The "paste group" defined in this study is the type of foods including 9 types of similar foods that are classified as "pastes" in the Korea Food Code, such as doenjang (soybean paste), gochujang (hot pepper paste), and cheonggukjang (fast-fermented bean paste). Most solid-state pastes, for the duration of the maturation period, are susceptible to exposure to environments where microorganisms can proliferate, and there is the chance that some of these foods may be eaten uncooked, therefore for such food it is determined that there is possibility that a food poisoning occurrence can transpire. Also, because *Clostridium perfringens* has the feature of forming spores in environments that have been exposed to heat, it is determined that in cases where a sufficient heat-treatment was not applied, if there were any *C. perfringens* present, it would not be completely destroyed. Therefore, it is necessary to verify the safety in such foods by monitoring the possibility of a food poisoning occurrence and examining the contamination level of *C. perfringens* through scientific tests on the paste 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 paste group, and in doing so, establish management standards for *C. perfringens* in the paste group in order to create a system where food poisoning and food related incidents involving the intake of food from the paste group 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. The optimal temperature that supports growth for *C. perfringens* is 43℃ - 47℃, and the optimal temperature for its spores and toxins is 37℃, but it is unable to proliferate at ≤ 15℃ or ≥ 52℃ (Ministry of Food and Drug Safety (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). 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, but its enterotoxin is susceptible to heat and is easily destroyed when heated to 74℃. 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. The incubation period for food poisoning from *C. perfringens* is usually between 7 and 30 hours and symptoms include diarrhea and abdominal pain (McClane 2007). And a high rate of its occurrence was reported in: meats and other high-protein foods, in food stored after being cooked, and in group food services. In Korea, there are about 15 cases of food poisoning each year. Since 2013 the number of occurrences has been on the decline, but there is a large number of patients of food poisoning compared to the number of occurrences. In 2016 it was reported that there were 8 cases of food poisoning, but there were reported 449 patients of food poisoning (MFDS, 2017).

Exposure assessments

For the exposure assessment for *C. perfringens* of the paste group, scenarios were established and carried out over 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 paste

Of a total of 1,097 different doenjang products distributed in Korea, 74 of them were found to have been contaminated with *C. perfringens*. Also, in the results of the estimated initial contamination levels of *C. perfringens* in doenjang, it was found that the initial average contamination level had a mean of 0.25 log CFU/g, 0.02 log CFU/g with 5%, and 0.59 log CFU/g with 95%. In consideration of extreme conditions, the Weibull model was used for the paste where *C. perfringens* has the best survivability, cheonggukjang, and the results of developing a growth and destruction model for *C. perfringens* at a wide range of temperatures (7, 15 20, 25, 30, 35℃) showed that *C. perfringens* in cheonggukjang was sooner destroyed the higher the temperature rose.

Based on the distribution environment study of doenjang and the results of the model predicting the growth and destruction of *C. perfringens* in cheonggukjang, the simulation model was assumed that any *C. perfringens* that was initially contaminated in the paste grew or was destroyed in the distribution and storage process. And the results of the model showed that the destruction of *C. perfringens* was evident in the distribution and storage process of solid-state products, therefore, it was determined for *C. perfringens* to be at low risk. The average intake of doenjang was 12.12 g, based on the estimation of the most suitable model for the intake data of doenjang obtained from the Korean National Health and Nutrition Examination Survey using the @Risk Fitting program.

Hazard characterization

C. perfringens

At present, for the dose-response model for the risk estimation of *C. perfringens*, only the "exponential model, Risk= 1- exp (-r x D) (r, risk parameter = 1.82 x 10^{-11}; D, dose)" was developed by Golden in 2009, and for this risk assessment, Golden's (2009) dose-response model formula was used.

Risk characterization

C. perfringens in paste

Based on the estimation of the contamination of *C. perfringens* per 1 g of the paste group (doenjang) and the intake of doenjang and the distribution of intake frequency obtained from the data of the Korean National Health and Nutrition Examination Survey, the comsumption level of *C. perfringens* per person per day due to the intake of doenjang was estimated. The result of estimating the risk of *C. perfringens* in doenjang via a simulation that utilizes the @RISK program, showed that when doenjang 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 2.84×10^{-9}. Also, because doenjang is usually consumed by cooking it (stews, soups) rather than consuming it in an uncooked state, when taking into considering how *C. perfringens* is destroyed from the heat, the actual risk is determined to be lower than this.

The sensitivity test based on a correlation analysis of the input variables and estimated risks of C. perfringens for solid-state pastes showed that the risk level was positively correlated to the frequency of intake, degree of contamination, and intake amounts, but negatively correlated to warehouse storage time, time on display, and warehouse storage temperature. In particular, there was a high correlation to intake frequency and warehouse storage time, and it was found that these factors had the greatest influence on the risk of C. perfringens to the paste group.

Impact of establishing microbial standards in Korea Food Code

According to the study results, in the general distribution environment for pastes, *C. perfringens* was shown to gradually diminish over time, and it was estimated that there was low risk because most items of the paste group were eventually cooked prior to intake. Therefore, it is considered that the current standard of ≤ 100 per g can be eased.

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.