Letter to the Editor

Methodology and Application for Health Risk Classification of Chemicals in Foods Based on Risk Matrix*

ZHOU Ping Ping[1,2], LIU Zhao Ping[1,2], ZHANG Lei[1,2,#], LIU Ai Dong[1,2], SONG Yan[1,2], YONG Ling[1,2], and LI Ning[1,2]

The method has been developed to accurately identify the magnitude of health risks and provide scientific evidence for implementation of risk management in food safety. It combines two parameters including consequence and likelihood of adverse effects based on risk matrix. Score definitions and classification for the consequence and the likelihood of adverse effects are proposed. The risk score identifies the intersection of consequence and likelihood in risk matrix represents its health risk level with different colors: 'low', 'medium', 'high'. Its use in an actual case is shown.

The Food Safety Law of the People's Republic of China, which came into force in June, 2009, lays down that 'the State shall establish a food safety risk assessment system to assess the risks of chemical, biological and physical hazards in food and food additives'. Over the past five years, China has launched multiple food safety risk assessment actions, during which risk assessment approaches are gradually applied to food safety field. However, there still exist several crucial scientific questions when we carry out food safety risk assessment, two of which are how to accurately identify the magnitude of risks and how to use uniform and standardized terminologies to objectively describe the degree of risks. It is necessary to adopt a standardized method for health risk classification of chemicals in foods to describe the results of risk assessment. And it is also useful for risk management and risk communication to understand what the degree of risk means. So far, there was no universal methodology for health risk classification of food chemicals. The Risk Ranger tool developed by the Australian Food Safety Centre was in Microsoft Excel spreadsheet software format semi-quantitative model for food product/hazard combination ranking in 2001[1]. Through a cooperative agreement with the U.S. Food and Drug Administration, the Institute of Food Technologists developed iRISK, which was a web-based, interactive risk assessment tool that to enable comparison of microbiological and chemical hazards in foods[2]. For a specific hazard-food combination the model could produce a single metric: a final risk value expressed as annual pseudo-disability adjusted life years (pDALY). However, the methods which were developed by above authors are not suitable for chemicals risk assessment of food safety in China because the parameters are too complex and some of these parameters can't be described due to lack of data. Risk matrix is a qualitative and quantized analytic method. It often is applied to a risk management project to identify risks and management effects for project assessment[3]. As early as 1995, risk matrix was used in Electronic System Center (ESC) of American air force for weapon system research project[4]. Historically, Risk matrix model has been used in engineering, transportation, and environment sciences[4]. To use the risk matrix, we need to build a risk matrix; A risk matrix assigns a unique decision to any risk. It presents a two-dimensional table of decisions. Row of risk matrix corresponds to consequence and column of risk matrix corresponds to likelihood. In present study, this risk matrix model is used to design a risk classification method which could be applied to chemicals risk assessment of food safety in China.

Google (Taiwan) as a search engine used in the risk classification status at domestic and abroad. Retrieve the key words were risk ranking & food; risk classification & food; chemical hazard; risk matrix;

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1. China National Center for Food Safety Risk Assessment, Beijing 100022, China; 2. Key Laboratory of Food Safety Risk Assessment, Ministry of Health, Beijing 100021, China

acute toxicity; genotoxicity; subchronic toxicity; subchronic toxicity; chronic toxicity; carcinogenicity; reproductive toxicity; developmental toxicity; neurotoxicity; immunotoxicity, etc. Retrieve the web sites are: http://www.cnki.net/; http://www.moh.gov.cn; http://www.ncbi.nlm.nih.gov/pubmed; http://www.fda.gov/; http://www.who.int/; http://www.fao.org/index_en.htm; http://www.inchem.org/; http://www.iarc.fr/; http://ec.europa.eu/; http://www.epa.gov/raf/; http://www.standards.co.nz/, etc.

Expert panels were invited to take part to identify and select the most relevant parameters and indicators. A total of 51 experts were from Food Safety Risk Assessment (18), Toxicology (12), Public Health (16), Health Statistics (3), Food Chemistry fields (2). The panel discussed several key questions such as key parameters, indicators system for health risk classification of chemicals in foods and their relative importance. After three expert meetings, the panel followed a holistic approach to evaluate the most important indicators for health risk classification of chemicals in foods and their relative importance.

The chemicals health risk classification of the risk matrix framework and its indicators system are built based on relevant reports in the literature, given risk assessment cases and expert judgment. Codex Alimentarius defined risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food'. Therefore, consequence and likelihood of adverse effects are key parameters used to evaluate a risk in this health risk classification system. A 5 x 5 matrix was chose by expert opinion in this study. To build a risk matrix for health risk classification of chemicals in foods is normally conducted in three steps as following: (1) determining the consequence severity; (2) determining the likelihood of adverse effects when exposure to a hazard; and (3) determining the risk level[4]. In the first step, the consequences that can occur in risk identification and how the consequences will be measured in the risk matrix should be considered. In principle, consequence severity is generally determined by consideration such indicators as hospitalization rate and prevalence rate caused by a hazard in an incident[5]. However, when it comes to chemicals like regular environmental pollutants and food additives, such data as hospitalization rate and prevalence rate is normally not available. In this case, toxicity or severity of adverse effects can be used to measure consequence resulted from a chemical[6]. The severity scores are measured using toxicity of adverse effects of a given chemical including acute toxicity and long-term toxicity should be considered jointly. After reviewing these reports from the web sites mentioned above, we can get existing scientific evidence for acute toxicity and long-term toxicity. Acute toxicity is expressed in 'rat oral lethal Dose 50 (LD_{50})' (represented by 'Ha'). Pursuant to China's GB15193. 3 Acute Oral Toxicity Test (draft for comment), which is currently under revision, acute toxicity may be classified into 5 categories. The categories of acute toxicity are given on a scale from 1 (Lowest) to 5 (Highest) as shown in Table 1[7]. Long-term toxicity (carcinogenicity, mutagenicity, reproductive toxicity, neurotoxicity, chronic toxicity and sub-chronic toxicity are expressed in various toxicity category indicators (represented by 'Hb'). According to International Agency for Research on Cancer (IARC)'s evidence-based principle for weight determination, carcinogens are classified into 5 categories, which are given on a scale from 1 (Lowest) to 5 (Highest) as shown in Table 1; According to the EU criteria for mutagenicity and reproduction classification, mutagenicity and reproduction of chemicals could be classified into three categories (Table 1); According to the Environmental Protection Agency (EPA) criteria, neurotoxicants are classified into four categories (Table 1); According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) classification method for specific target organ systemic toxicity-repeated exposure, substances with specific target organ toxicity are classified into two categories (Table 1). When a compound had a variety of long-term toxicity, we would choose the assignment highest score toxicity indicator to describe the consequence severity according to the risk assessment conservative principle.

In this study, the weight coefficients of acute toxicity and long-term toxicity were determined by expert judgment. Normally, the weight is the same. But in the particular case acute toxicity and chronic toxicity weights will be different, depending on what the assessor to focus more toxic. In other words, the assessor can judge the hazard occurring based on given examples or scenarios. Hence, formula for calculating consequence score of adverse effects was:

Overall Score of consequence=(Score Ha+Score Hb)/2 (1)

Note. A fractional score is rounded up to the nearest integer.