

## Perspectives

## Reviewing the Chinese-Specific Reference Amounts Study Conducted by Sun et al., 2022

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The need for region-specific food intake values to accurately estimate food allergen risk is underscored by the recent Ad Hoc Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Consultation on Risk Assessment of Food Allergens (1). A recent study published by Sun et al. in *China CDC Weekly* 2022, titled *A Chinese-Specific Reference Amounts Study with TNO Food Allergen Risk Assessment Models — China, 2022*, critically examines and applies a previously established sensitivity analysis aimed at deriving food intake values for food allergen risk assessment (RA) (2–3). In their examination of Chinese food consumption data, the authors find that “the 95th–99th percentiles of the food consumption distribution per eating occasion for condiments and chocolates are the optimal point estimates for use in deterministic allergen RA, aiming to protect 99% of allergic individuals from allergic reactions due to unintended peanut presence.” This finding significantly deviates from those of Blom et al., which suggested that the 50th–75th percentiles of the food consumption distribution per eating occasion in various global contexts would suffice for achieving a similar safety objective aimed at protecting 95%–99% of allergic individuals from objective allergic reactions due to unintended allergen presence (3–4).

While a more cautious approach to consumption estimations may appear safe from a risk management perspective, such an approach could involve a degree of overprotection that may result in unwarranted restrictions for both the Chinese food-allergic population and the food industry. Achieving a balance between guaranteeing safety and implementing realistic, pragmatic protocols is vital (1). Thus, a risk assessment that incorporates unnecessary high-intake figures may not provide risk managers with the most effective information(5).

Hence, we evaluated the potential causes of the elevated *P*-values discovered in the study by Sun et al. (2). We focused on identifying elements that could significantly augment the sensitivity analysis, ultimately leading to the establishment of a more

robust food intake estimation for China.

Several factors in the data utilized by Sun et al. (2) could be contributing to the observed elevated *P*-values (Table 1), thus likely resulting in an excessively conservative outcome, more so than what was projected when the sensitivity analysis method was initially applied. For instance, the food consumption distribution employed in the study lacks the necessary diversity in comparison to the food consumption distribution from other research, thereby contributing to a less refined point estimate (Table 2). A striking similarity can be seen between the consumption ranges of condiments in China and the Netherlands, hovering between 25 grams to approximately 250 grams within the 50th and 99th percentile of the intake distribution (Table 2).

According to the Dutch National Food Consumption Surveys (DNFCS) (<https://www.rivm.nl/publicaties/diet-of-dutch-results-of-dutch-national-food-consumption-survey-2012-2016>), individual food product consumption is measured per eating occasion at the gram level, which allows for a higher degree of differentiation within the food intake distribution (4). Conversely, the Chinese National Nutrition and Health Survey of 2002 utilizes a different measurement scale in *liang*, resulting in steps of 25 or 50 grams in quantifying food consumption in their survey (2, personal communication Prof. Wu). Consequently, the intake quantity for the P50 to P65 range in the food distribution is the same at 25 grams, with all *P*-values from P75–P90 measured at 50 grams.

This hinders the sensitivity analysis from effectively differentiating between the percentile ranges P50–P65 and P75–P90. Therefore, a food intake distribution with greater differentiation and detail in the consumed amounts might allow for a more highly tuned intake distribution for a food group. Consequently, it may lead to a different optimal point estimate than the one uncovered in Sun et al.’s study (2).

The implications of this research might be further explored through a comprehensive analysis of detailed food consumption data from China. In the absence of such records, comparable information from alternative

TABLE 1. Potential elements contributing to the higher percentiles of food consumption distribution in the sensitivity analysis of Sun et al.'s study (2) compared to Blom et al.'s studies (3–4).

Element	Study by Sun et al. 2022 (2)	Recommended analyses
Characteristics of dietary consumption data	The 2002 food survey dataset, marked by limited differentiation in food consumption amounts (with intervals of 25 or 50 grams), stems from the use of Chinese measurement units known as <i>jin</i> and <i>liang</i> .	The data derived from the food consumption survey can be used to provide a higher degree of specificity, particularly relating to the amounts consumed. This includes detailed information regarding the weight in grams of the product consumed during each eating occasion. Further description of the survey is available in reference (4). In the absence of specific data, conduct a simulation study utilizing more detailed food consumption survey statistics from various countries. This would help to examine whether the incremental steps utilized in the data set of Sun et al. could have potentially resulted in the observed high <i>P</i> -values.
Chosen case study	The point estimate recommendation was derived from the analysis of two distinct food groups.	The analysis was conducted on all food groups identified in a food consumption survey, which typically encompasses between 50 to 60 food groups (3–4).
Threshold dataset	Peanut population ED value distribution of 2014 (6)	The model averaging method developed by (7) is utilized herein, applying ED-distributions to the extended threshold dose datasets for 14 allergenic foods, as discussed in the work of (5).
Safety objective	ED01 of the population distribution for peanut	To use a broader range of ED values (5), including the officially recommended ED05 (8).

Abbreviation: ED=Effective Dose.

TABLE 2. Comparison of intake distribution between the limited differentiation in food consumption amounts from the Sun et al.'s study, and a comparable food group in the Dutch Food Consumption Survey (2007–2010).

Intake distribution percentile	Intake distribution (grams)	
	Reported in Sun et al. (2) for condiments	The “Sauces and Condiments” food group, as reported in the Dutch National Food Consumption Survey 2007–2010 (DNFCS), demonstrated a high degree of differentiation (4)
P50	25	25.3
P55	25	28.4
P60	25	31.6
P65	25	35.5
P70	40	40.1
P75	50	46.1
P80	50	53.7
P85	50	64.0
P90	50	79.1
P95	75	112.4
P97.5	100	149.4
P99	125	205.8
P100	250	733.3

countries could be utilized in conjunction with simulation studies (Table 1).

The original study conducted a sensitivity analysis for the Effective Dose 01 (ED01) of the population ED-distribution; however, the recent FAO/WHO expert consultation advised the use of Reference Doses based on the ED05 of the population ED-distribution (8). In light of selecting a different ED value as the safety objective, sensitivity analysis should be utilized to ascertain the optimal point estimate for the corresponding safety level (3).

This brief review of the study conducted by Sun et al., 2022, aims to facilitate enhanced sensitivity analyses and foster collaborative efforts towards developing Chinese and globally harmonized recommendations for reference amounts for food allergen RA.

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