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中文摘要

多氯戴奧辛、多氯夫喃、與多氯聯苯可持久性存在環境中，人類的主要暴露途徑為呼吸、飲食、接觸等。戴奧辛可影響實驗動物的生殖發育，流行病學研究指出戴奧辛會引起人類的癌症與多種不良健康效應，國際組織針對戴奧辛訂定可容許攝取量或癌症斜率因子，有許多研究探討各國人群的暴露風險，然而國人的戴奧辛暴露與其健康風險尚未被充分了解，本計畫之目的為評估各群組國人之每日戴奧辛總暴露量並描述其健康風險。本研究依循風險評估基本架構：危害鑑定、劑量反應評估、暴露評估、及風險特徵描述進行，探討 17 種多氯戴奧辛/夫喃與 12 種有類戴奧辛作用的多氯聯苯(簡稱戴奧辛)，以世界衛生組織的toxic equivalency factors計算毒性當量。在暴露評估步驟，結合國內空氣、食物、與土壤之戴奧辛濃度資料以及國人的飲食攝取量、飲水量、呼吸速率、及土壤攝取量，估計各群組國人之戴奧辛暴露量，進而計算各群組國人戴奧辛暴露佔Joint FAO/WHO Expert Committee on Food Additives (JECFA)的provisional tolerable monthly intake (PTMI)之百分比，並且以US EPA的斜率因子試算癌症風險。本研究採用simple distribution與Monte Carlo simulation兩種方法估計暴露量與風險。研究結果顯示：在所有性別-年齡組別的一般民眾或焚化廠附近居民，其平均總戴奧辛暴露皆低於 28 pg WHO-TEQ/kg bw/month，佔PTMI的 40%以下；在一般民眾，93%-98% 的戴奧辛暴露來自飲食；而焚化廠附近居民，其 86%-95% 的戴奧辛暴露來自飲食，4.5% - 14%來自空氣。以simple distribution與Monte Carlo simulation兩種方法所得結果相近。當以US EPA的斜率因子估算癌症風險時，所有性別-年齡組別的致癌風險皆超過 1×10^{-5}，與以JECFA的方法估計之風險差異很大。本研究以JECFA方法所得的結果顯示台灣民眾的戴奧辛暴露在可容許範圍，且無明顯的致癌與非致癌風險。然而，有 2.5%的民眾、或是 6.5%的小於 13 歲者其戴奧辛暴露超過PTMI，應設法降低其飲食戴奧辛暴露量。再者，本研究受限於其他各類食物的戴奧辛濃度資料不足，可能低估民眾的總戴奧辛暴露量。

關鍵詞：暴露評估、健康風險評估、多氯戴奧辛、多氯夫喃、風險特徵描述

Abstract

Polychlorinated dibenzo-para-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs) are ubiquitous and persistent in the environment. Previous studies suggested that long-term exposure to dioxins increased the risk of cancer and various adverse health effects in human. The purposes of this study were to estimate daily intake of dioxins and to assess the health risk from dioxins for the populations in Taiwan. This study evaluated the effects of 17 PCDDs/PCDFs congeners and 12 coplanar PCBs and used the term “dioxins” to represent them. Exposure assessment includes estimation of daily intake of dioxins from inhalation, ingestion of food and water, and soils for the general population and residents near waste incinerators. The estimated daily intake was compared with the provisional tolerable monthly intake (PTMI) established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The US EPA cancer slope factor was used to estimate the upper-bound cancer risk. Simple distribution and Monte Carlo simulation methods were applied to estimate exposures and risk. The results showed that for 14 age-sex group in the general population or in residents near waste incinerator, means of total intake for dioxins were less than 28 pg WHO-TEQ/kg bw/month. The mean %PTMI values were under 40%. In the general population, 93%-98% of the daily dioxin exposure was contributed to diet. Among residents near waste incinerators, 86%-95% of their dioxin exposure was contributed to diet and 4.5% - 14% to inhalation. Results of the Monte Carlo simulation showed that the mean %PTMI ranged from 25% to 36 % for 10 age-sex groups in the general populations. The estimated cancer risk, using the US EPA slope factor, was greater than 1×10^{-5} in all age-sex groups, which was contradictory to risk estimated by the JECFA approach. The study results imply that means of exposures to dioxins for the general population are well within the tolerable intake and there is no appreciable risk for both cancer and non-cancer effects when JECFA approach was used. However, 6.5% of subjects aged younger than 13 years had exposure greater than PTMI. Measures should be taken to reduce exposures in these subjects. Furthermore, this study could underestimate the exposures due to lack of dioxin concentration data for all food groups.

Keywords: exposure assessment; risk assessment; PCDDs; PCDFs; risk characterization

Background and Significance

Polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) are emitted mainly from combustion processes, waste incineration, metal smelting, paper pulp bleaching, and polychlorinated biphenyl and chlorophenols production (Brouwer et al., 1998; WHO 2002). Polychlorinated biphenyls (PCBs) were manufactured in the past for a variety of industrial uses, such as electrical insulators or dielectric fluids (WHO 2002). PCDDs, PCDFs, and PCBs are ubiquitous and persistent in the environment and bio-accumulate in adipose tissues (WHO 2002).

TCDD is toxic for experimental animals at extremely low doses (US EPA 2004; WHO 2002). The potential cancer and non-cancer effects of PCDDs, PCDFs and PCBs have been extensively investigated in animal studies and epidemiological studies. Animal studies showed that TCDD and related compounds had developmental and reproductive toxicity at low dose (WHO 2002). Previous epidemiological studies suggested that long-term exposure to TCDD increased the risk of cancer (US EPA 2004; Bertazzi et al., 2001; Flesch-Janys et al., 1998; Steenland et al., 1999), increased chloracne, elevated liver gamma glutamyl transferase levels, and altered testosterone levels in adults (US EPA 2004). Other effects, such as circulatory, pulmonary, neurological, and immunological effects, were inconsistently reported in epidemiological studies (US EPA 2004). The International Agency for Research on Cancer has classified TCDD as the Group 1 carcinogen (McGregor et al, 1998). The National Toxicology Program of the US Department of Human Health Service has classified TCDD as “known to be human carcinogens” in its Eleventh Report on Carcinogens (US DHHS, 2005).

Several national/international organizations have conducted risk assessment for PCDDs, PCDFs and coplanar (or dioxin-like) PCBs and either established guidance values or derived cancer slope factors for cancer risk. In 1998, the World Health Organization (WHO) has established a tolerable daily intake (TDI) of 1-4 pg toxic equivalent (TEQ)/kg body weight (bw)/day, based on the evaluation of the most sensitive effects in animal studies (van Leeuwen et al., 2000). In 2001, the Scientific Committee on Food (SCF) of the European Commission has adopted a tolerable weekly intake (TWI) of 14 pg TEQ/kg bw/week, based on new animal studies of the most sensitive effects of TCDD on developmental endpoints (SCF 2000, 2001). In 2001, the Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Expert Committee on Food Additives (JECFA) has evaluated the most sensitive effects of TCDD and established a provisional tolerable monthly intake (PTMI) of 70 pg/kg bw/month (JECFA 2001; WHO 2002). In its exposure and human health reassessment of TCDD, the US Environmental Protection Agency (EPA) derived a cancer slope factor of 1×10-3 per pg TEQ/kg bw/day as an estimator of upper-bound cancer risk (US EPA 2004).

Scientists have conducted risk assessment for dietary and/or non-dietary exposures to PCDDs, PCDFs, and/or dioxin-like PCBs for the general populations or special groups in several countries. The WHO, JECFA, and/or the EPA approaches were used in these assessments, and daily intake of dioxins was directly calculated by food consumption and concentrations of PCDDs, PCDFs, and/or dioxin-like PCBs in food (Charnley and Doull 2005, Llobet et al., 2003, Mayer 2001). Moreover, different sources of dioxins were considered in the exposure assessment. The results showed that daily intake of varied among age-sex groups within a population.

People and media in Taiwan have expressed substantial concern for dioxins in food supply and the environment as well as the potential health risk from consumption of dioxins-contaminated food, especially after the duck egg dioxins incident happened in Chang-Hua County in 2005. Health risk assessment has being recognized as an important tools and used by the governmental regulatory agencies in Taiwan. The total daily intake of PCDDs, PCDFs, and dioxin-like PCBs from various sources as well as the health risk for the for the population in Taiwan are not well understood.

Specific Aims

The purpose of this study was to assess the exposure and health risk of PCDDs, PCDFs, and dioxins-like PCBs for the population in Taiwan. The specific aims were (1) to extensively review international risk assessment methods, (2) to estimate daily intake of PCDDs, PCDFs, and dioxins-like PCBs for the general population and special groups of population in Taiwan, (3) to assess the health risk from daily intake of PCDDs, PCDFs, and dioxins-like PCBs for the general population and special groups of populations in Taiwan using the WHO JECFA approach, and (4) to evaluate the cancer risks from exposure to PCDDs, PCDFs, and dioxins-like PCBs using the US EPA cancer slope factor.

Methods

This study followed these four steps in the human health risk assessment: hazard identification, exposure assessment, dose-response assessment, and risk characterization (NRC 1983, 1994) in conducting the risk assessment and extensively reviewed the methodology for risk assessment of TCDD and related compounds. This study evaluated the effects of 17 PCDDs/PCDFs congeners and 12 coplanar PCBs congeners with dioxin-like effects and use the term “dioxins” to represent these 29 congeners. The 1998 WHO toxic equivalency factors (TEFs) (Van den Berg et al., 1998) was used to derive total WHO toxic equivalent (WHO-TEQ) for these 29 PCDDs, PCDFs, and PCBs.

Data of Intake Rates

For food consumption rates, this study used the 24-hour dietary recall data from the Nutrition and Health Survey in Taiwan (NAHSIT) 1993-1996 (Taiwan DOH 1999) and from our recent survey of residents from three cities in Taichung county. People were categorized into 14 age-sex group: male and female, <13 years, 13-16 years, 16-19 years, 19-31 years, 31-51 years, 51-64 years, and >64 years.

Regarding the water consumption rate, inhalation rate, soil ingestion rate, and soil dermal contact rates, this study collected data and reports for the Taiwan population or subgroups. If the existent data were not available or adequate for the purpose, data from other populations were applied for these intake rates. For example, the US EPA has published the *Exposure Factors Handbook,* which summarizes statistical data on human behaviors and characteristics affecting exposure to environmental contaminants, recommends exposure factor values for use in exposure assessment (US EPA 1997).

Data for Concentrations of Dioxins

The concentrations of 29 PCDDs, PCDFs, and PCBs congeners in various food items, especially from animal origins, have been measured in nation-wide surveys and in the First Taiwan Total Diet Study 2003-2004. We mainly used the data from the total diet study, which determined dioxins levels in food in the as-consumed status. As for the levels of dioxins in soil and air, we have collected these data for communities near or away from waste incinerators in the past few years and used that data for population living near waster incinerators. In late 2006 and early 2007, the Taiwan EPA has monitored ambient air dioxin levels for 62 stations around the island (Taiwan EPA 2007). Results from the EPA's general air monitoring stations were used to present the air dioxins concentration for the general populations.

Simple Distribution and Probabilistic Modeling for Estimation of Daily Intake

Two approaches were applied to estimate exposure or daily intake for each studied population group: the simple distribution method and the probabilistic modeling method. First, the mean (standard error) and median as well as the 95th percentiles of the daily intake levels for dioxins from ingestion, inhalation, and dermal contact will be estimated for the general population, different age-sex groups of the general population and people livings near waste incinerators. Statistical software SAS version 8.2 (SAS Institute, Cary, NC) and, if necessary, SUDAAN version 9 (RTI International, Research Triangle Park, NC) will be applied to compute the mean, standard error, and 95% confidence intervals for each study groups, taking into account sampling design and sampling weights when nationwide survey data are used. Second, when data are available for probabilistic modeling, we will use the Monte Carlo simulation approach to generate the distributions of daily intakes for each population groups (Barraj et al., 2000) using Crystal Ball 2000 software (Decisioneering, Inc. 2004).

Dose-Response Assessment

JECFA has evaluated the most sensitive effects of TCDD and established a PTMI of 70 pg/kg bw/ month (JECFA 2001; WHO 2002). The US EPA used an approach different from that of JECFA and assumed a non-threshold cancer effects and suggested a cancer slope factor of 1×10^{-3} per pg TEQ/kg bw/day as an estimator of upper-bound cancer risk for both background intakes and incremental intakes (US EPA 2004).

Risk Characterization

This study mainly used the JECFA approach and compared the estimated daily intake (converted to monthly intake) with the PTMI of 70 pg TEQ/kg bw/month and calculate the %PTMI for each population groups with different scenarios. A %PTMI below 100% implied no appreciable risk for both cancer and non-cancer effects (WHO 2002). Contribution of each exposure pathway as well as each food group to the daily intake were assessed for each population groups. If possible, the proportion of subjects with dioxins exposure exceeding PTMI were estimated for each population group. Furthermore, the probabilistic modeling was conducted to generate the distributions of %PTMI and the certainties that distribution of %PTMI was below 100% for each population groups, using Crystal Ball 2000 software. In addition, the US EPA cancer slope factor of 1×10^{-3} per pg TEQ/kg bw/day and was used to estimate the cancer risk.

Results

This study used the following data for estimating exposures to dioxins for the population in Taiwan: (1) dietary intake data for ingestion rate of various food items – the 24-hour dietary recall data of 5834 people aged 13-64 years from the Nutrition and Health Survey in Taiwan 1993-1996 and the 24-hour dietary recall data of 1588 people aged 0.1-90 years from our survey of residents in three cities in Taichung county, 2006-2007; (2) water consumption data from our recent survey of 1588 residents in three cities in Taichung county, 2006-2007; (3) food dioxins concentration data from the first Taiwan Total Diet Study, 2003-2004; (4) default values for inhalation rate (in m^3/kg bw/day) and soil ingestion rate (in mg/kg bw/day) from the California EPA or Taiwan EPA; (5) air concentrations of dioxins: Taiwan EPA's ambient air dioxins monitoring data (N = 104 from the 52 general air monitoring stations) collected during late 2006 to early 2007 for the general population and the air dioxins data for areas near waste incinerators and analyzed by our team during 2001-2007 (N = 542); (6) soil concentrations of dioxins for areas near waste incinerators and analyzed by our team during 2002-2007 (N = 368); (7) tap water concentrations of dioxins analyzed by our team in 2004 (N = 13).

For all 14 age-sex group in the general population, the means of total intake (from food, water, air, and soil) for PCDDs/PCDFs/coplanar PCBs were less than 28 pg WHO-TEQ/kg bw/month when either dietary consumption data was used. The mean %PTMI values were under 40%. The youngest age groups had higher intake of dioxins than the older age groups.

For all age-sex groups, about 93%-98% of the daily dioxin exposure was contributed to diet. Up to 6% of daily dioxin intake was contributed to inhalation of dioxins in the ambient air. For our recent surveyed population in Taichung county, 2.5% of all subjects, and 6.5% of subjects aged under 13 years had %PTMI greater than 100%. The main source of dietary dioxins exposure was the dairy products among the younger age groups.

Among population living near a waste incinerator, the means for total intake (from food, water, air, and soil) of PCDDs/PCDFs/coplanar PCBs were less than 27 pg WHO-TEQ/kg bw/month when either dietary consumption data was used. The mean %PTMI values were under 40%. For 14 age-sex groups, about 86%-95% of the daily dioxin exposure was contributed to diet and 4.5% - 14% of daily dioxin intake was contributed to inhalation of dioxins in the ambient air. Dioxin exposures from tap water consumption and soil ingestion contributed to less than 0.01% of total exposures.

Results of the Monte Carlo simulation using the national diet survey data showed that the mean %PTMI ranged from 25% to 36 % for 10 age-sex groups in the general populations. The certainty levels for having PTMI<70 pg WHO-TEQ/kg bw/month ranged from 93.8% to 97.5% for these groups.

When the cancer slope factor (1×10^{-3} per pg TEQ/kg bw/day) derived by the US EPA was used to calculate the upper-bound cancer risk, the estimated cancer risk was greater than the acceptable risk of 1×10^{-5} in all age-sex groups either for the general population or for people living near waste incinerators.

Discussion

In this study, the mean exposures to PCDDs, PCDFs, and PCBs from food, water, air, and soil were less than 40% of the PTMI for different age-sex groups in the general population or in residents near waste incinerators. The results imply that means of exposures to dioxins for the general population are well within the tolerable intake and there is no appreciable risk for both cancer and non-cancer effects (WHO 2002). However, when the US EPA cancer slope factor was used to calculate cancer risk, the estimated risk was much higher than the acceptable risk of 1×10^{-5} in all age-sex groups. This phenomenon has been reported by other researchers. In a study by Foran et al. (2005), both WHO TDI and EPA cancer risk estimates were used to derive the consumption advice for salmon. The study results showed that daily intake of dioxin-like compounds at the lower end of the WHO TDI (i.e. 1 pg TEQ/kg bw/day) resulted in upper-bound cancer risks exceeding 1×10^{-5} (Foran et al., 2005). It appears that when both JECFA's and EPA's approaches were used to estimate risk, the results could be conflicting and difficult to interpret. The National Research Council (2006) has reviewed EPA's 2003 draft reassessment of the risks of dioxins and dioxin-like compounds and has recommended the EPA to provide risk estimates using both nonlinear and linear methods to extrapolate below points of departure. Therefore, this study would mainly use the JECFA's PTMI to estimate risk.

This study used both simple distribution and the Monte Carlo simulation methods to estimate the mean (and median, 95% confidence interval, and the distribution of) exposures to PCDDs, PCDFs, and PCBs for different age-sex groups of the population. The results were similar from both approaches. However, the certainty levels for having exposure<PTMI were smaller than 95% for some age-sex groups.

Although the mean exposures were within PTMI for the majority of the population, 2.5% of all subjects and 6.5% of subjects aged 13 years or less had exposures greater than the PTMI. Note that dairy products contributed significantly to total dioxin exposures for the younger age groups. Measures could be taken to reduce dioxin exposures in these age groups by advising them to drink low fat milk instead of whole milk.

This study may have underestimated the dietary exposures to dioxins, because concentrations of dioxins from only six food groups (including fish, other seafood, meat, eggs, dairy product, and oil) were measured and used to estimate intake dioxins from food ingestion. The total diet study by Llobet et al. (2003) has reported a significant contribution of dietary dioxins exposures from cereals, vegetables, and fruits. Moreover, only PCDDs and PCDFs were measured in the air, soil and tap water samples, this study was not able to take into account the exposures to coplanar PCBs from these sources and, therefore, underestimated the total exposures to dioxins.

This study was limited by either using the 1993-1996 food intake data or the dietary recall data from a local survey to represent the food consumption patterns of the general population in Taiwan. Diet is the main source of dioxins exposures for the general population. Although the exposure estimates based on both data were similar, further confirmation of dietary exposures to dioxins with newer diet intake data from national survey is needed.

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Self evaluation of the study

This study has followed the proposal and finished the following work: (1) extensively literature review of risk assessment methodology for TCDD and related compounds; (2) literature review for health effects of TCDD and related compounds; (3) collection of intake rate (including inhalation, ingestion of food and water, and ingestion and dermal contact with soil) for study population or from other published reports; (4) assessment of exposures to dioxins for different population groups in Taiwan; (5) risk estimations for different population groups in Taiwan; and (6) a written report.