Safety issues related to polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) in fish and shellfish in relation with current Malaysian laws

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Abstract
Dioxins (PCDDs) and furans (PCDFs) exposure has been linked to birth detects, child growth retardation, reduced levels of male reproductive hormones, altered ratios of male to female births, diabetes and cancer. These show that PCDDs and PCDFs give awful impact to man-kind. This paper will highlight on the concentration of the contaminants in fish and shellfish as well as the estimate intake of the contaminants based on data from other countries. This paper also will identify the relevant regulatory framework presently available in Malaysia that governs the environmental management of PCDDs and PCDFs. In response to aggressive attempts globally to control PCDD/Fs emissions over the last 35 years, human exposures to PCDD/Fs from the environment have declined significantly. The primary source of human exposure to PCDDs and PCDFs is animal foods including fish and shellfish. The sources of these contaminants in the foods are not well understood and are probably varied. Data on the levels of PCDD/Fs measured in various fish samples collected from one country to another varies which correlate with the varied species of fish and shellfish available besides the human industrial activities nearby. As for Malaysia, the information on the level and type of PCDD/Fs present in food especially fish and shellfish is still lacking and need to be made available in order for specific recommendations (kind of species, frequency and size of meals) regarding human consumption to be made. This paper also has noticed that there is no specific legislation in Malaysia that governs the safety and environmental management on PCDDs and PCDFs. However, there are several legislations that regulate the safety and environmental management of PCDDs and PCDFs which include Environmental Quality Act (1974); the Occupational Safety and Health Act (1994); the Customs Act (1967) and the Food Act (1983). The enforcement of these legislations is not the responsibility of a single government agency. Different government departments may enforce the legislation relevant to the operation of that department. Hence, the Environmental Quality Act (1974) is the responsible of the Ministry of Natural Resources and Environment, the Occupational Safety and Health Act (1994) is by the Ministry of Human Resources whilst the Food Act (1983) is by the Ministry of Health and as for the Customs Act (1967) under the supervision and administration of the Ministry of Finance. Finally, this paper concluded that Malaysia has a sufficient regulatory framework in which may adequately control on PCDDs and PCDFs emission in various life cycles. However, there is no legal provision on the control of exposure toward PCDDs and PCDFs especially for human consumption by setting specific maximum residue level for various groups of food.

Key words: Dioxins (PCDDs), furans (PCDFs), fish and shellfish, regulations, safety and environmental management.

Introduction
Polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) are two clusters of chemical compounds that comprise very similar properties and structures 1. They may contain between 1 and 8 chlorine atoms; dioxins contain 75 possible positional isomers and furans contain 135 positional isomers. They are generally very insoluble in water, lipophilic and very persistent. The chemical properties of each of the isomers have not been illuminated; more problematic discussion of their properties which fluctuate with the number of chlorine atoms present. Neither furans nor dioxins are produced commercially, and they comprise no known use 1. They are by-products resulting from the production of other chemicals. PCDFs are the key contaminant of PCBs. Dioxins may be released into the environment through the production of other chlorinated substances and pesticides. Both furans and dioxins are related to a variety of incineration reactions, and the synthesis and use of a variety of chemical products 1.

In sequence to smooth the progress of a comparison combinations, the International Toxicity Equivalency Factors (TEFs) have been assigned to individual PCDDs and PCDFs established on a comparison of toxicity to 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD), the most toxic dioxin congener. For instance, 2,3,7,8-TCDD has been shown to be approximately one-tenth as toxic as 2,3,7,8-TCDD in animal tests, and its toxic equivalent value is 0.1. TEFs are considered as safety and environmental management tools and they do not inevitably correspond to actual toxicity with respect to all endpoints.

The toxicity of PCDDs and PCDFs to human have been well documented which include dermal toxicity (chloracne), immunotoxicity, carcinotoxicity, reproductive toxicity and
possible neurobehavioral (cognitive) effects. Potential public health risks from environmental exposures to chlorinated dioxins and related compounds continue to be the subject of much research, regulation, and debate. Human exposure to PCDDs and PCDFs occurs mainly from foods that contain these chemicals. Among the foods such as meat, dairy products and fish that make up to more than 90% of the intake of PCDDs and PCDFs to diet. Study carried out in Spain to determine the level of chemicals contaminants including PCDDs/PCDFs in 11 groups of foodstuffs concluded that the highest level of both contaminants were mainly detected in fish and seafoods. The toxicological effects of dioxins are thought to arise due to binding of PCDD/Fs to a specific receptor protein within cells known as the aryl hydrocarbon receptor (AhR) that is present in most tissues of animals and humans. In an animal study using adult male C57BL/6 mice, the animals demonstrated sustained AhR activation by TCDD exposure that increases the blood pressure and induces cardiac hypertrophy.

International action has been initiated to protect human health and the environment through measures which will reduce and/or eliminate the emissions and discharges of POPs including PCDDs and PCDFs. Subsequently, the Stockholm Convention on Persistent Organic Pollutants (POPs) was opened for signature on 23rd May 2001 with the objective of to protect the environment and human health from hazardous chemicals including PCDDs and PCDFs. Its function is to be of global relevant and of multimedia coverage. Under the Convention, various parties involved are obligated to take whatever measures to reduce or eliminate releases of the POPs including PCDDs and PCDFs. Based on available data on emissions, environmental and food levels as well as human body burdens of dioxins indicate a several-fold reduction in exposures and body burdens since 1970, suggesting that the global efforts to control dioxin emissions and to reduce exposures are succeeding. In Malaysia, however, a specific statute to ensure the safety of animal foods including fish and shellfish in relation to PCDD/PCDFs exposure to human is still in the formulation process. Therefore, this paper will highlight on the concentrations and the estimated intake of these contaminants through fish and shellfish consumption from other countries in human as the basis for the importance to address on this issue. This paper will also identify the relevant legislations and subsidiary legislations that are presently available in Malaysia that governs the environmental management of PCDDs and PCDFs emission.

Concentrations of PCDD/Fs in Marine Fish and Shellfish

PCDD/PCDFs are chlorinated environmental contaminants with no known commercial applications. They occur as by-products of industrial processes (such as combustion processes including natural combustion) and their presence have been identified in almost all environmental compartments as a result of industrial emissions. The emission of PCDD/PCDFs to air may ultimately result in deposition in the terrestrial environment and in aquatic sediments, followed by uptake into food chain such as ruminants and fish. Both PCDD/PCDFs are resistant to degradation due to their lipophilic characteristics that accumulate in fatty tissues of animals. In Europe, it was reported that fish and fish products contribute to 2-63% of the dietary intake while other animal source such as meat and milk products as well as milk and dairy products contributed to 6-32% and 16-39%, respectively.

It is well known that the quality of seafood products is dependent on the genetic basis, size, reproductive period of fish as well as characteristics of the environment (pH, salinity, temperature of water, composition of phyto- and zooplanton during the year and the presence of other fish species). For wild fish, main exposure to PCDD/Fs is associated with chronic contamination due to leaching of agricultural or industrial chemicals into surface waters. UK Ministry of Agriculture, Fisheries and Food (MAFF) reported that in a survey of marine salmon sampled between 1995 to 1996, the mean concentration of PCDDs, PCDFs and PCBs of 12 samples were 25 pg/g (WHO-TEQ) and 12 pg/g WHO-TEQ. Earlier reports also have detected significant levels of PCDDs, PCDFs and PCBs in fatty tissue of herring from Baltic Sea. However, in a more recent study in Ireland on fish and fishery products available in Irish market, the levels of PCDD/Fs including dl-PCBs were generally below the maximum limits (8.0 pg/g of w/w of WHO-TEQ) laid in Council Regulation 1881/2006. The Council Regulation 1881/2006 also stated that certain fish species from the Baltic region with level of PCDD/Fs that does not comply with the maximum levels set should be excluded from the diet. Similarly, in another study carried out in Spain on 14 species of fish and shellfish, the concentration of PCDD/Fs showed a significant decrease in comparison to earlier findings in 2003. In two Spain studies, when only 3 marine species (sardine, hake and mussel) were analyzed in both surveys, a reduction could be observed among samples collected in 2000 and 2005 where 0.11 vs 0.04 pg WHO-TEQ/g in sardine, 0.66 vs 0.22 pg WHO-TEQ/g in hake, and 0.30 vs 0.14 pg WHO-TEQ/g in mussel. The reduction in level of these contaminants as observed in the few countries discussed, suggest that the aggressive efforts to control PCDD/Fs emission and to reduce exposures over the past few decades are succeeding.

In farmed fish, however, the potential exposure hazards to PCDD/Fs and some other selected coplanar biphenylyl compounds are associated with the use of contaminated fish oil. For the aquaculture industry, diets based on marine fish oils are being favoured as to provide the source of dietary lipid. For example, herring oil is the standard oil fed to farmed salmon in UK. Fish oil, a by-product of the fish meal manufacturing industry may come from many different parts of the world. The oil extracted from fish caught in polluted waters may be contaminated with chlorinated compounds. Various studies carried out in UK during 1995-2000 indicated the presence of elevated organochlorine contamination of farmed fish. In a later study on farmed Scottish salmon samples for PCDDs, PCDFs and selected coplanar PCBs, findings showed that contamination problem is still present and confirms previous reports of relatively high concentration of PCDDs and PCDFs in farmed Scottish salmon.

In this study, all main PCDDs and PCDFs, such as 1,2,3,7,8-PeCDD; 2,3,7,8-TCDD; 2,3,4,7,8-PCDF and 1,2,3,7,8-PCDF including 2,3,7,8-TCDD, which is the most toxic compound, were detected. The highest level was detected in oldest/mature fish (>3 years) at value of 1.09 pg/g lipid-adjusted compared to 0.51 pg/g lipid-adjusted in a-year old fish. These findings therefore suggest further investigation on salmon samples from this area is highly warranted and special attention need to be paid for other farmed fish, especially those that are fed on fish oil.
Differences in the level of PCDD/Fs in wild and farmed fish also exist due to the different practices and habitats of these fish. In an investigation into levels of PCDD/Fs in fishery produce in Ireland in 2006, marked reduction in both PCDD/Fs were observed where PCDD/Fs were 40% lower in wild salmon than its farmed counterparts. Even larger reductions were observed where PCDD/Fs were 40% lower in wild salmon than in Ireland in 2006, marked reduction in both PCDD/Fs were also exist due to the different practices and habitats of these fish. In an investigation into levels of PCDD/Fs in fishery produce in Ireland in 2006, marked reduction in both PCDD/Fs were observed where PCDD/Fs were 40% lower in wild salmon than in Ireland in 2006, marked reduction in both PCDD/Fs were also exist due to the different practices and habitats of these fish.

The EU has established a regulatory framework to limit the levels of PCDD/Fs and other coplanar biphenyls such as PCBs in fishery produce, with levels being on average about 70% lower in wild salmon than in farmed fish. Even larger reductions were observed where PCDD/Fs were 40% lower in wild salmon than in Ireland in 2006, marked reduction in both PCDD/Fs were also exist due to the different practices and habitats of these fish. In an investigation into levels of PCDD/Fs in fishery produce, it was estimated that dioxin intake for the total US population and children of 3-age groups were below 2 pg TEQ/kg BW/day. However, the dioxin intake in the US population was attributed to meat and dairy products. In a more recent survey in Spain, the estimated intake of PCDD/PCDFs for adult male and female was lower at 0.09-0.11 pg TEQ/kg BW/day for both PCDD/Fs through fish and seafood consumption (14 species of fish and shellfish). However, the daily intakes of PCDD/PCDFs, estimated according to the respective average body weight for each age/sex, children (boys and girls), showed higher value of 0.13 pg TEQ/kg BW/day. The average daily intake of adult (70 kg BW) for PCDD/Fs was estimated at 6.02 pg TEQ and among the different age and sex groups studied, adult men followed by adult women and senior men had the highest PCDD/PCDF intake. Based on these data, it is clear that the exposure of PCDD/Fs to human in industrialized countries such US and some European countries were still below the recommended exposure limit. Therefore, on the basis of these results, it can be concluded that there is no need to amend the existing advice on fish consumption. However, the monitoring of the level of these contaminants should be carried out on regular basis in order to ensure the safety consumption of fish, especially oily fish and intake of fish oil supplements. Besides that, regular monitoring of PCDD/PCDF levels also is very important as to protect vulnerable groups of people such as children at 2 to 6 years of age as well as pregnant and lactating women.

Since 1990, the US EPA has been debating on the appropriate exposure limit. However, no risk or exposure limit has been agreed and established by the US FDA. Only in 2001, the Joint FAO/WHO Expert Committee on Food Additives has proposed a tolerable monthly intake of 70 pg TEQ/kg BW as being protective of human health based on developmental effects observed in male rats exposed to 2,3,7,8-TCDD during gestation. The proposed intake is equivalent to 2 pg TEQ/kg BW daily, consistent with recommendations of European Commission’s Scientific Committee of Food and the UK Food Standards Agency on Toxicity.

**Description on Legislations and Subsidiary Legislations Concerning with the Management on PCDDs and PCDFs Emission**

The main sources of the Malaysian regulatory framework on PCDDs and PCDFs consist of both legislations and subsidiary legislations. Legislations refer to laws enacted by a body constituted for this purpose. In Malaysia, Parliament at federal level and various State Legislative Assemblies for their respective states enacted legislations. Laws passed and enacted by Parliament are called Acts but those after the Malayan Union 1946 till independence, 1957 are referred Ordinances and those laws made by State Legislative Assemblies are known Enactment. However, laws passed by Sarawak Legislative Assembly are called Ordinances.

Subsidiary legislations are also known as subordinate legislations or delegated legislations. Subsidiary legislations are rules and regulations enacted by an authority under the powers conferred on it by the parent legislations. In addition, according to the section 2 of the Interpretation Act (1967), provides the definition of the terms subsidiary legislation as any proclamation, rule, regulation, order, notification, by-law or other instrument made under any Ordinance, Enactment, Act or other lawful authority and having legislative effect.

**Environmental Quality Act (1974):** The Environmental Quality Act (1974) is a general Act, which applies to activities affecting the environment. The purpose of the Act is to set up standards and legislative on areas needing an overall control such as waste, air, soil and water.

According to Section 21 it was stated that the Minister of Natural Resources and Environment, after consulting with the Environmental Quality Council, may specify the acceptable conditions for the emission, discharge or deposit of environmental hazardous substances, pollutants or wastes or the emission of noise into any area, segment or element of the environment and may set aside any area, segment or element of environment within which the emission, discharge or deposit is prohibited or restricted whilst Section 51(u) of Environmental Quality Act (1974), conferred the Minister of Natural Resources and Environment, after consulting with the Environmental Quality Council, may make regulations for or with respect to prohibit or regulate the manufacture, storage, transportation, or the application or use, emission, discharge, or deposit into the environment, of any environmentally hazardous substances.

Therefore, with the powers conferred by these two sections above, the Minister after consulting the Environmental Quality Council has made a number of relevant regulations under this Act to protect environment which include protecting environment against hazardous chemicals such as PCDDs and PCDFs.

**Environmental Quality (Dioxin and Furans) Regulations (2004):** These regulations came into force on 1st May 2004 and are the primary set of regulatory controls on emission PCDDs and PCDFs. Regulation 2 of Environmental Quality (PCDDs and PCDFs) Regulations (2004) defined “PCDDs” as polychlorinated dibenzo-penta-dioxin which is tricyclic, aromatic compound formed by two
benzene rings connected with two oxygen atoms and hydrogen atoms, which may be replaced by up to eight chlorine atoms. As for the definition “PCDFs” as polychlorinated dibenzofuran, which is tricyclic, aromatic compound formed by two benzene rings connected with one oxygen atom, one carbon-carbon bond and hydrogen atoms which may be replaced by up to eight chlorine atoms.

These regulations shall only apply to these facilities, i.e. municipal solid wastes incinerator, scheduled wastes incinerator, pulp or paper industry sludge incinerator and sewage sludge incinerator. This provision has been highlighted by Regulation 3 of the Environmental Quality (Dioxin and Furan) Regulations (2004).

These regulations basically regulate the control of emission PCDDs and PCDFs for the above-said facilities, method of computing air emission of PCDDs and PCDFs and method on sampling and analytic for dioxins and furans parameter.

Customs Act (1967): Section 31(1) of the Customs Act (1967) provides that the Minister may by order: 1) prohibit the importation into, or the exportation from Malaysia or any part thereof, either absolutely or conditionally, or from or to any specified country, territory or place outside Malaysia, or the removal from one place to another place in Malaysia of any goods or class of goods; and 2) prohibit the importation into, or the exportation from Malaysia or any part thereof, or the removal from one place to another place in Malaysia of any goods or class of goods, except at specified ports or places.

As the result of the above-said provisions, the Minister has exercised the powers conferred by Section 31 of the Customs Act (1967) created the Customs (Prohibition of Imports) Order (1988) and the Customs (Prohibition of Exports) Order (1988).

The import and export of hazardous waste is monitored and controlled by the Royal Custom and Excise Department under the Ministry of Finance by virtue of the Customs Act (1967), specifically under these two subsidiary legislations, i.e. the Customs (Prohibition of Imports) Order 1988 and the Customs (Prohibition of Exports) Order (1988). Banned and severely restricted chemicals are listed in the Custom Import and Export Orders of 1988.

Description on Legislations and Subsidiary Legislations Concerning with the Management on PCDDs and PCDFs Exposure

Occupational Safety and Health Act (1994): The coverage of the Occupational Safety and Health Act 1994 is to protect the safety, health and welfare of employees at place of work. This Act is to give safety and protection other persons than those at work from risks to safety arising from the work activities, to encourage an occupational surrounding that is tailored to the physiological and psychological needs of the employees and to attain this through a sequence of subsidiary legislations. The Act has authority over all occupational matters except for work in the armed forces and on board of ships.

The Act highlights general responsibilities based on employers and selfemployed designers, manufacturers and suppliers and employees. It is a set of subsidiary legislations for written safety and health policy, safety and health organization and arrangements. There is also a subsidiary legislation on the duty of the employer to establish safety and health organizations and safety and health arrangements which fall down under Section 66 of the Occupational Safety and Health Act (1994).

Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations (2000): Occupational Safety and Health Regulations (2000), which came into force 4th April 2000, put responsibility to the employers’ shoulder to classify the chemicals hazardous to health and assess their risk in the occupational environment, based on Part III of the Occupational Safety and Health Regulations (2000), on regards of permissible exposure limit. Regulation 6 states that an employer shall ensure that the exposure of any person to any chemical hazardous to health listed in Schedule I at no time exceeds the ceiling limit specified in that Schedule. Meanwhile Regulation 7(1) provides that an employer shall ensure that the exposure of any person to any chemical hazardous to health listed in Schedule I in any eight hours shift of a workweek does not exceed the eight-hour-time-weighted average airborne concentration specified for that chemical during the work shift. In addition, Regulation 7(2) indicates that notwithstanding sub-regulation (1), the exposure of any person to any chemical hazardous to health listed in Schedule shall not exceed to the maximum exposure limit for that chemical during the work shift. However, PCDDs and PCDFs are not listed in the Schedule I (List of Permissible Exposure Limits) of the Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations (2000).

Food Act (1983): The coverage of the Food Act (1983) is in regards to chemicals, to limit the amount of certain chemicals in products meant for human consumption by setting specific maximum residue level for various groups of food. Examples are food additives, antibiotic residue and pesticide residue.

Section 34 of the Food Act (1983) has laid down that the Minister of Health may make regulations for better carrying into effect the purposes and provision of this Act and particular without prejudice to generality of the foregoing, for all or any of the food matters. In exercise of the powers conferred by Section 34 of the Food Act (1983) above, the Minister of Health made the Food Regulations (1985) and came into force on 1st October, 1985.

Food Regulations (1985): Basically Regulation 37 to 41 of the Food Regulations stated the coverage of the limitation amount of certain chemicals in products meant for human consumption by setting specific maximum residue level for various groups of food. These provisions cover on the drug residue, pesticide residue, microorganisms, monochloropropane and metal contaminant. However, these provisions do not cover PCDDs and PCDFs.

Conclusions
The availability of the information on the level and type of PCDDs and PCDFs present in food, especially fish, is very important in order for specific recommendations (kind of species, frequency and size of meals) regarding human consumption to be made. Besides that, this information will enable an easy trade of the marine product between countries, as fish is one of the good source of protein and the best source of essential fatty acids. From the above discussion, it is obvious that Malaysia has an adequate regulatory framework that can control PCDDs and...

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