

# THE APPLICATION OF HEALTH RISK ASSESSMENT TO SETTING NATIONAL ENVIRONMENTAL REGULATORY STANDARDS OF DIOXIN

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## Introduction

Over the last two decades Vietnam has undergone rapid economic development. This has resulted in environmental pollution from toxic chemicals, including dioxin from industrial, agriculture activities and waste incineration. Vietnamese soils also have high dioxin levels as a consequence of extensive use of herbicides during US war. From 1961 to 1971, Vietnam was subjected to the widespread spraying of the chemical defoliants Agent Orange<sup>1</sup>, containing the most toxic dioxin congener 2,3,7,8 TCDD<sup>1</sup>. Dioxin residues have decreased over time; however, 40 years after the war, high concentrations of dioxin still remain in South Vietnam soils<sup>2-5</sup>. A recent study on health risk posed by the dioxin has indicated significant risk value to citizens living the vicinity of Da Nang airbase<sup>9</sup>. Nevertheless, it has been found high concentration in human tissues and medical investigations has pointed the abnormal disease pattern, birth defect and reproductive problem of the habitants living there<sup>2-6</sup>. This has demonstrated an association between public health and soil contaminated with dioxin.

To manage the contaminated sites and mitigate the human health risk, the government has undertaken a number of solutions, such as dioxin remediation, restricting access to the area, the provision of health care and a sanitation system. To successfully implement these solutions, the Vietnamese needs to establish National Regulatory Standards (NRS) for dioxin in soils. This article provides an overview of the Vietnam process used to set soil standards for dioxin. To ensure there is a scientific basis to the standard, the Human Health Risk Assessment (HHRA) was studied and applied to set the regulatory standard. The result shows that HHRA can provide a good tool for delivering the environmental standards; however, the realizable process needs elements beyond risk assessment.

Vietnam experience in applying HHRA to regulate soil standards and manage the contaminated sites can provide direction for related policy so that the lessons learned can be helpful to the regional and global partners. In our knowledge, this is the first study on the approach and recent practice of setting dioxin standards in environment based on risk assessment in Vietnam.

## Method and Materials

The soil standard values are generic quality standards adopted by many countries to regulate and otherwise manage contaminated land. Measure concentration (mg/kg soil dry weight) exceeding the soil standard will result in recommended or enforced. The implications of exceeding the soil guidelines vary according to the regulatory framework of the particular national or regional jurisdiction.

The risk-based human-health standards have used in developed countries for many years<sup>10-15</sup>. In general, setting risk based standards involves multi-steps process consisting of defining the problem, choosing a target or scenario, assessing the risk, and then decision making. The process often also takes into account economic constraints and policy directives. Figure 1 present the studied (and recent applied) process for deriving dioxin standard in Vietnam. In practice, the conceptual approach method employed for different project phases were developed through intensive discussion between stakeholders (e.g. general public, government authority, and environmental experts). Additional goals of the project were creation of smoother administrative process and a consideration of the linkage of science with sustainable land management.

Acceptable risk level are derived for threshold contaminants (usually non-carcinogens) and non – threshold contaminants (usually carcinogens). Acceptable risk level for non-threshold contaminants are define as an incremental probability of less than one in a million (1/1,000,000) of a deleterious occurrence (usually contracting cancer). Acceptable risk level for threshold contaminants is defines as a Hazard Quotient less than or equal to one the ratio of the protection of human health are typically based on generic assumptions about exposure incorporated into standard equations. The standard exposure equation for a particular “i” is as follows:

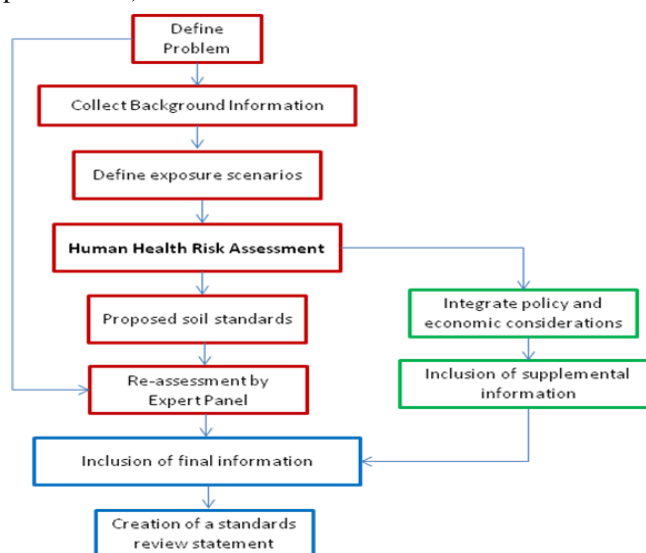
$$\text{Intake}_i = \text{soil concentration} \times \text{contact rate}_i \times \text{exposure time} \text{ [equation 1]}$$

The intake is usually normalized to an intake rate per unit of body weight (BW, in kilogram) and unit of time (day) by dividing by body weight and an averaging time. In addition, the exposure time is typically represented as exposure frequency in days per year multiplied by exposure duration in years, resulting in:

$$\text{Intake rate}_i = \frac{\text{soil concentration} \times \text{contact rate}_i \times \text{exposure frequency} \times \text{exposure duration}}{\text{body weight} \times \text{averaging time}} \quad [\text{Equation 2}]$$

The intake rate is then compared with some acceptable intake rate for the substance (the reference health standard) and, for some substances, the particular pathway – with a human health risk indicated for exposure to that particular soil concentration and pathway if the intake rate exceeds the acceptable intake rate. The acceptable intake is either the tolerable daily intake (TDI) for threshold compounds, or the dose that yields a specified increased cancer risk (the risk-specific dose).

Figure 1. Process structure for dioxin regulatory standard setting based on HHRA in Vietnam



A more usual approach is to back-calculate the guideline value combined over the relevant pathways. This is achieved by equating the sum of the hazard quotients (HQ) for each pathway with 1 (unity). The hazard quotient for a particular pathway is simply the ratio of the intake rate over the allowable intake.

$$\frac{\text{intake rate}_1}{\text{acceptable intake}_1} + \frac{\text{intake rate}_2}{\text{acceptable intake}_2} + \frac{\text{intake rate}_3}{\text{acceptable intake}_3} + \dots = \text{HQ}_1 + \text{HQ}_2 + \text{HQ}_3 + \dots = 1 \quad [\text{Equation 3}]$$

The soil standard value is then calculated for each exposure pathway, and then redefining the soil concentration (assumed to be the same for each pathway) as the desired generic guideline value. After rearranging to bring the soil guideline value to the left hand side, the equation becomes:

$$\text{Soil standard value} = \frac{1}{\left( \frac{1}{\text{soil conc. value}_1} + \frac{1}{\text{soil conc. value}_2} + \frac{1}{\text{soil conc. value}_3} + \dots \right)} \quad [\text{Equation 4}]$$

Key components of the generic human health guidelines include standard human exposure scenarios relevant to a variety of land uses (e.g., agricultural, residential, commercial, parkland) and exposure through a variety of pathways (e.g., inhalation, ingestion, and skin absorption). The soil standard values for dioxin are then calculated to ensure that some pre-determined allowable daily intake of this contaminant is not exceeded<sup>1,3</sup>.

For this study, available dioxin concentration data collected by Vietnamese and international scientists between the 1980s and the present was used. Samples were collected from southern Vietnam locations where herbicides were sprayed, applied and/or stored during the war and also from the industrial zones, agricultural and urban areas throughout Vietnam.

## Results and discussion

*Define problems:* Since the 1980s there have been the investigations by Vietnamese and foreign researchers to identify dioxin concentrations in soil throughout the country<sup>2-8</sup>. Their data is given in Table 1.

**Table 1:** Concentration of dioxin (ng TEQ/kg PCDD) in soils at many location of country

	Location	Sampling time	Concentration, ng TEQ/kg
1	Gio Linh, Cam Lo, Quang Tri	2003	1.2 -20
2	A So, Thua Thien - Hue	1999	123

3	A Luoi, Thua Thien - Hue	1999	13 - 879
4	Tay Ninh	1993-98	14
5	Rung Sac, Ho Chi Minh city	1986 - 1990	16 (1986); 4 (1990)
6	Ma Da, Dong Nai	2000	10.2-122
7	Phan Rang airport	2004	24
8	Tan Uyen, Binh Duong	1998 - 2009	15 (1998) ; 0.99 – 11.5 (2009)
9	Bu Gia Map, Binh Phuoc	2008 - 2009	6.2 - 243
10	Da Nang (cultivated sites near airport)	2005	24,7 - 269
11	Da Nang (residential sites near airport)	2006	5,34 - 36,1
12	Phu Giao, Binh Duong	2009	1.2 – 26.9
13	Nha Trang airport	2009	63
14	Pleyku airport	2009	22
15	Can Tho airport	2009	57
16	Bien Hoa airport	2008 - 2010	262.000 (2008); 61.800 (2010)
17	Da Nang airport	2006 - 2010	365.000 (2006) – 163.000 (2010)
18	Phu Cat airport	2008	238.000

Locations that were sprayed with herbicides during the war exhibited comparable dioxin concentration between areas; concentrations reported soon after the war years were significantly higher than those recorded in recent years. The highest concentration levels have been found in three airbases where herbicides were stored in large quantities during Operation Ranch Hand: Da Nang, Bien Hoa and Phu Cat. These locations are referred to as the key “dioxin hotspots” in Vietnam, although other hotspots may also exist. A recent assessment has indicated that the health risks for residents living near the Da Nang dioxin hotspot are significant<sup>8</sup>. There are also some dumping sites with high concentration of dioxin in big cities<sup>7</sup>. Therefore, the problem is defined as – “the need to mitigate the risk to people and control the contaminated sites”.

Development of the National Regulatory Standard for dioxin in soil is therefore important for the Government of Vietnam. According to the current dioxin standard, the government or local authorities can recommend mitigation solutions (interim and long-term) such as: restricting access to the site, soil containment, water management, remediation and rehabilitation of contaminated soil, among others.

*Selection of exposure scenarios:*

Dioxins are a family of 75 similar related compounds commonly referred to as polychlorinated-dibenzo Dioxins (PCDD) congeners and of 135 similar related compounds as polychlorinated-dibenzo Furan (PCDF) congeners. This family is divided into eight groups of chemicals based on the number of chlorine atoms in the compound. Dioxins have varying harmful effects. Of the dioxins, 2,3,7,8-TCDD is the most toxic of the PCDDs to mammals and has received the most attention.

With the problem definition mentioned above, the scenarios are setting limits for farmers, residents and workers in agricultural, residential and industrial land, respectively. Health risk assessment in contaminated-site practice is based on the assumption that individuals are exposed to contaminated soil while going about their normal activities (Table 2). Route of exposure called exposure pathways and include soil ingestion, dermal absorption, and consumption of vegetables grown in contaminated soil. In rural/countryside of Vietnam, about 80% -90% of houses keep poultry and have a vegetable garden for their own use. Ingestion of contaminated soil and consumption of home-grown produce are typically the most significant exposure pathways for dioxin to reach people in rural residential areas.

**Table 2:** Exposure scenarios to dioxin from soil with different land uses in Vietnam

	Land uses	Scenario
1	Agricultural	work by hands, direct & high rate contact
2	Residential	80%-90% home grown produce intake (e.g. vegetable, domestic animals,)
2.1	Countryside, rural	
2.2	Urban, cities	limited soil contact, few home garden
3	Park/playground	Bio-diverse, plant, trees
4	Commer./Industrial	Pavement/no pavement, out/indoor worker

**Table 3:** Acceptable intake of dioxin based on risk in rural residential land (with assuming dioxin as a threshold carcinogen)

	Exposure pathways	Dioxin TEQ pg/kg body weight
1	Soil ingestion	127.5
2	Dermal absorption	11.18
3	Produce ingestion	3.2
4	Inhalation	0.02

Vietnam has a tropical monsoon climate with four distinct seasons: spring, summer, autumn and winter. This climate affects crops and types of cultivated plants in the dry seasons and rainy season. In agricultural areas, the

Vietnamese farmer typical works by hand, with minimal use of machine; consequently, farmers have a high contact rate/exposure frequency with soil. Soil standards derived using the farmer exposure scenario will protect the health of farmer at any farm property, both exposure via consumption of home grown livestock and produce, as well as through direct contact with contaminated soil. Soil within industrial or commercial lands are generally paved or covered in buildings. Workers in factories or commercial buildings will have little, if any, direct exposure to soil, but may have exposure to dust particle inhalation.

Applying the method recommended by New Zealand (2011)<sup>13</sup>, the acceptable intake of dioxin was estimated for rural residential scenario using four exposure pathways, as shown in Table 3.

#### *Decision making for dioxin soil standard guideline*

Background information was assessed within the context of the management target and a human health risk assessment was carried out using methods recommended by USEPA (2002)<sup>9</sup>.

Once the draft standard was determined, the expert panel re-assessment included refining input parameter values and making the final decision associated with deriving the dioxin soil standards. Panel members consisted of are scientific experts, environmental managers, a lawyer and other representative officials working in related government ministries and sectors. During the re-assessment process, the members evaluated additional information, necessary factors, reassessed with altered conditions and carefully selected. Therefore, more decision choices could present themselves after reassessment. The economic constraints and policy directives are taken into account along with the multiple choices for a feasible standard setting. At a final step, a standard review statement was drafted and was provided as the basis for public comment and discussions.

**Table 4.** Comparison of allowed concentration limits of dioxin in soil of various countries (ng/kg TEQ)<sup>10-15</sup>

Land uses	VN	Germany	Japan	USA	NZealand	England	Finland	Taiwan
Agriculture	40	40		27-50	10	80		1000
Residential countryside	120				110	350	500	1000
urban, cities	300	1000	1000		190-410			1000
park side	600				1100			1000
Industrial side	1200	100000		950-1000	1200	1000		1000

When comparing the allowed concentration limits of dioxin of Vietnam with those of other countries, the result shows mostly equal levels and some lower levels in Vietnam (Table 4). It indicated that the Government of Vietnam had been made a great effort to control dioxin contaminated soils steps by step in whole the country, especially in herbicides sprayed areas consequences of the war.

#### **Conclusion**

The risk based standard setting process is expected to offer scientific sound information regarding the regulatory standards as well as a vehicle for better communications with public and stakeholders. However, several challenges remain for the regulators. For instance, the process of defining an assessment target could be creating diverse opinions. While the protocol for risk assessment is in place, the parameters used for the assessment could also raise questions regarding the representative of local situation and other uncertainties. Thus, a comprehensive investigation with extensive background information should be undertaken as part of the process. Through this study result, it should recognize that a risk-based approach is a useful instrument for setting regulatory standards. In addition to scientific evidence, economic and political constraints need to be considered in the decision making process for establishing soil dioxin standards in Vietnam.

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