National Dioxins Program

Proposed Risk Assessment Methodology

Discussion paper

Australian Government
Department of the Environment and Heritage

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PREFACE

The Commonwealth Government has provided funding of $5 million over four years for the National Dioxins Program. The Program will collect data, assess the impact of dioxins and then determine appropriate measures to reduce and where feasible, eliminate dioxins and dioxin-like substances.

This paper outlines the proposed methodology and the consultation process that will be used for the risk assessment. The outcome of this risk assessment will be used to guide and inform the development of appropriate measures to reduce or eliminate dioxins in Australia. The paper was prepared by the Department of the Environment and Heritage, and the Office of Chemical Safety, part of the Department of Health and Ageing.

The Department of the Environment and Heritage is seeking comments on the methodology and consultation process proposed for the risk assessment. These comments will be taken into consideration before the risk assessment begins later in 2003.

Submissions are invited from interested parties including individuals, non-government organisations, industries, professional bodies and government agencies.

Submissions on this paper may be made to:

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Submissions must be received by **5 September 2003** and can be made in hard copy or electronically.

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ABBREVIATIONS

ADD	Average daily doses
AFFA	Department of Agriculture, Fisheries and Forestry - Australia
AMD	Average monthly doses
APVMA	Australian Pesticides and Veterinary Medicines Authority[1]
DEH	Department of the Environment and Heritage
DFAT	Department of Foreign Affairs and Trade
DoHA	Department of Health and Ageing
DVA	Department of Veterans' Affairs
EC-SCF	European Commission Scientific Committee on Food
EPHC	Environment Protection and Heritage Council
FSANZ	Food Standards Australia and New Zealand
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint Expert Committee on Food Additives
LADD	Lifetime average daily doses
NDCG	National Dioxins Consultative Group
NDP	National Dioxins Program
NDPT	National Dioxins Project Team
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No Observed Adverse Effects Level
NOEL	No Observed Effects Level
NPI	National Pollutant Inventory
OCS	Office Chemical Safety
OECD	Organisation for Economic Co-Operation and Development
PCBs	Polychlorinated biphenyls
PCDDs	Polychlorinated dibenzodioxins
PCDFs	Polychlorinated dibenzofurans
PNEC	Predicted no effect concentration
PTMI	Provisional tolerable monthly intake
TCDD	2,3,7,8-Tetrachlorodibenzo-p-dioxin, the most toxic dioxin
TEF	Toxic Equivalency Factors
TEQ	Toxic Equivalents
TGA	Therapeutic Goods Administration
TMI	Tolerable monthly intake
US EPA	United States Environment Protection Agency
WHO	World Health Organization

[1] Formerly the National Registration Authority of Agricultural and Veterinary Chemicals

GLOSSARY

Words in the glossary appear in the text in italics.

Adverse response	The change in morphology, physiology, growth, development or life span of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. Some adaptive changes are not generally considered to be adverse e.g. some changes in enzyme levels.
Average daily doses	See life time average daily doses (LADD)
Ah receptor	Aryl hydrocarbon (Ah) receptor is a cell protein that initiates many of the effects of dioxin-like chemicals. Its primary function in the body is uncertain, and it is structurally related to many other important cell proteins involved for instance in rhythmic functions (clock proteins) and organ development.[2]
Biomarker	Any measurement reflecting an interaction between a biological system and an environmental agent, which may be chemical, physical or biological. Often used to describe measurements used in biological monitoring.
Congener	One of a number of closely related chemicals derived from the same parent compound.
Dioxins	The group of persistent chlorinated chemical compounds, polychlorinated dibenzodioxins (PCDDs), which share certain similar chemical structures, properties and biological characteristics, including toxicity. For the purpose of the National Dioxins Program the term "dioxins" is used in the broader sense and is also taken to include the closely related polychlorinated dibenzofurans (PCDFs or furans) and co-planar polychlorinated biphenyls (PCBs). There are several hundred of these compounds, or congeners, of which 29 are considered by the WHO to have significant toxicity – see Appendix 3.
Dose	A term referring generically to the amount of chemical to which an organism is exposed by any of several routes. Specifying the routes within the environmental context and especially the point of measurement is made possible via subcategories of dose (e.g. potential dose, applied dose, absorbed dose, internal dose, and delivered dose). Dose is normally expressed as a mass per unit body weight per unit time and is frequently expressed in units of mg/kg/day.
Dose additivity	Where a combination of two or more biologically active or toxic chemicals has an effect that is the sum of their individual effects.
Dose-response assessment	Estimation of the relationship between dose, or level of exposure to the substance, and the incidence and severity of an effect, where appropriate.

[2] From *Synopsis on dioxins and PCBs*, KTL (National Public Health Institute, Finland), Division of Environmental Health, Kuopio, Finland, http://www.ktl.fi/dioxin/

Ecotoxicology	A multidisciplinary field of study that was developed to deal with the interactions, transformation, fate and effects of natural and synthetic chemicals in the biosphere. The field involves the interaction of concepts arising from disciplines such as toxicology, biology, physiology, ecology, genetics, microbiology, biochemistry, immunobiology, molecular biology, analytical, organic and environmental chemistry, soil, water and air sciences, engineering and economics.
Endpoint	An observable or measurable biological event used as an indicator of the effect of a chemical on a biological system (cell, organ, organism etc).
Exposure	A measure of the environment leading to a dose. Exposure is quantified as the concentration of the agent in the medium in contact, integrated over the duration of the contact.
Exposure assessment	Estimation of the concentration/dose to which human populations or environmental compartments (e.g. aquatic environment, terrestrial environment, atmosphere) are or may be exposed.
Exposure route	The way a chemical enters an organism after contact e.g. by ingestion, inhalation, or dermal absorption.
Hazard identification	Indication of the adverse effect(s), which a chemical has an inherent capacity to cause.
Lifetime average daily doses (LADDs)	Dose that is averaged over a specified time period taking into account the frequency, duration, and intensity of exposure during that time period. ADDs are usually expressed in units of mg/kg/day.
Lipids	One of the principal classes of macromolecules in our body, the others are proteins and carbohydrates. Lipids include fats and oils (triglycerides), fatty acids, waxes, steroids, phospholipids, glycolipids and lipoproteins.
No observed adverse effects level (NOAEL)	This is a simple estimate of the highest dose in which the incidence of a toxic effect or change in target organ weight, histopathology etc., was not significantly different from the untreated group (from a statistical and biological assessment). It is based on toxic effects of functional importance or pathological significance rather than adaptive responses, and is defined as the highest observed dose or concentration of a substance at which there is no detectable adverse alteration of morphology, functional capacity, growth, development or life span of the target. The NOAEL will depend on the sensitivity of the methods used, the sizes of the exposed groups and the differences between estimated exposures or doses. The NOAEL is an observed value that does not take into account the nature or steepness of the dose.
Occupational assessment	An assessment of the risks associated with the work place.
Picogram	pg = 10^{-12} gram (0.000 000 000 001 g)
Predicted no effect concentration (PNEC)	The exposure concentration at which no adverse impacts will occur. This term is generally used with respect to organisms in the aquatic environment.

Risk assessment	The process of estimating the potential impact of a chemical, physical, microbiological or psychosocial hazard on a specified human population or ecological system under a specific set of conditions and for a certain timeframe.
Risk characterisation	The estimation of the incidence and severity of the effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a chemical.
Toxic Equivalency Factors (TEFs)	See Toxic Equivalent TEQ.
Toxic Equivalent (TEQ)	Since dioxins occur as complex mixtures of congeners in most environmental media (air, water, soil), the concept of toxic equivalents (TEQs) has been developed. This concept allows the toxicity of a complex mixture to be estimated and expressed as a single number. Available animal-based toxicological data have been used to generate a set of weighting factors, each of which expresses the toxicity of a specific congener in terms of its equivalent mass of TCDD (2,3,7,8-Tetrachlorodibenzo-p-dioxin). Multiplication of the mass of the congener by its weighting factor (or toxic equivalency factor, TEF) yields the corresponding TCDD mass (or TEQ). The total toxicity of any mixture is then simply the sum of the individual congener TEQs.

BACKGROUND

Dioxins[3] are a group of toxic persistent organic chemicals that remain in the environment for a long time. These compounds can accumulate in the body fat of animals and humans and have a tendency to remain unchanged for prolonged intervals, giving rise to concern for adverse effects in humans.

The Department of the Environment and Heritage published the first Australian inventory of dioxin emissions to air in 1998 (*Sources of Dioxins and Furans in Australia: Air Emissions*). As there were few Australian data on dioxins, the preparation of that inventory relied heavily on overseas data, using release estimation methodology. The limited monitoring data available indicated that environmental concentrations were generally low, but that there was insufficient information to assess the impact of dioxins in Australia.

At its meeting in December 2000, the Australian and New Zealand Environment and Conservation Council (ANZECC[4]) requested the development of a discussion paper on dioxins for use in consultation with stakeholders. In April 2001, public meetings were held in several cities across Australia to seek public input into the development of a possible national dioxins program. Following on from these consultations, a proposal for a national dioxins program was tabled at the meeting of ANZECC in June 2001. At this meeting, Council noted that the Commonwealth would fund a National Dioxins Program (NDP) with $5 million over four years and that this program would generate data over the following two years which could be used to determine whether a specific regulatory approach would be required to manage dioxins.

The NDP has arisen from domestic concerns about dioxins and will proceed independently of the Stockholm Convention on Persistent Organic Pollutants. However, should Australia ratify the Convention, the program will contribute to its implementation.

A schematic overview of the NDP is provided in Appendix 1.

The Program is being implemented in three phases:

- information gathering about the current levels of dioxins in Australia. Surveys of dioxin levels in the environment and people throughout Australia will provide information, which will be used to prepare a new inventory of dioxins in Australia. Studies under this part of the program began in July 2002 and are scheduled for completion in late 2003. Further details are provided in Appendix 2.
- risk assessment using the information gathered as a basis to assess the potential risks of dioxins to the environment. An assessment will also be made of the potential risks for human health from exposure to dioxins either directly from the environment or from dioxin contaminated food. The methodology for the risk assessment is outlined in the next section of this paper.
- development of measures to reduce, and where feasible, to eliminate the release of dioxins in Australia.

The program will be completed in 2005.

[3] Definitions of words in italics are provided in the Glossary.

[4] ANZECC has been replaced by the Environment Protection and Heritage Council.

RISK ASSESSMENT – PROPOSED METHODOLOGY AND CONSULTATION PROCESS

A *risk assessment* will determine the risk of adverse effects to human health and the environment that could be caused by dioxins in the Australian environment. The risk assessment will use the data gathered in the surveys, together with other available data and information on the fate and effects of dioxins in Australia and overseas.

2.1 Why undertake a risk assessment

Risk assessment is a science based process of estimating the potential impact of chemicals or other stressors such as physical, microbiological or psychosocial hazards on a specified human population or ecological system under a specific set of conditions and for a certain timeframe. The purpose of any risk assessment is to identify and characterise those potential hazards, and to determine the likelihood of their occurrence at the known levels of exposure.

The core function of the risk assessment will be to integrate current knowledge about the hazards of dioxins with new knowledge about dioxin exposure levels in Australia. The risk assessment for the NDP is a necessary and useful step in developing measures to reduce, or where feasible, eliminate the generation of dioxins and their presence in the environment. A risk assessment provides one source of guidance to governments in considering practical and feasible measures to address dioxins. Dioxin risk assessments undertaken by other countries will be drawn on for the Australian assessment.

The steps of risk assessment involve *hazard characterisation or assessment* (*hazard identification*, *dose-response assessment*), *exposure assessment* and *risk characterisation* – see Figure 2. Generally speaking, the first step in human health risk assessment, is to use results from toxicity testing in animal models and human epidemiological data to identify the hazards associated with stressors and to establish safe levels of exposure if they exist; this is the hazard characterisation step. Monitoring data can establish the level of exposure of the population; this is the exposure assessment step. This allows a determination of the level of risk to individuals in the population; this is the risk characterisation step. The goal is to establish controls such that exposure to a particular stressor will not lead to an unacceptable level of risk in relation to human health; this is the risk management step which is the focus of a later stage of the NDP.

Further information on human health risk assessments can be obtained from the Department of Health and Ageing and the EnHealth Council publication, "Environmental health risk assessment - guidelines for assessing human health risks from environmental hazards" http://www.health.gov.au/pubhlth/publicat/document/metadata/env_hra.htm.

Environmental risk assessment evaluates the likelihood that chemicals or other stressors will exert adverse impacts on non-human organisms in the environment. Unlike human health risk assessment, which seeks to characterise risks to individuals, the aim of environmental risk assessment is to characterise risks to populations or ecosystems.

Detailed information on developments in the science of environmental risk assessment can be obtained from the website of the United States Environmental Protection Agency's National Center for Environmental Assessment: http://cfpub.epa.gov/ncea/

2.2 Who will conduct the risk assessment

The overall coordination of the risk assessment, as well as the conduct of the environmental risk assessment component, will be undertaken by the Department of the Environment and Heritage (DEH). Within the Australian regulatory environment for the management of chemicals, DEH undertakes the environmental risk assessments for agricultural, veterinary and industrial chemicals for the respective chemical regulators, the APVMA and NICNAS.

The public health component of the risk assessment will be coordinated by the Office for Chemical Safety within the Therapeutic Goods Administration (TGA) of the Department of Health and Ageing (DoHA). The OCS carries out the public health risk assessment of agricultural and veterinary chemicals, industrial chemicals and therapeutic medicines for the APVMA and NICNAS.

The risk assessment with regard to exposure from food will be conducted by Food Standards Australia New Zealand (FSANZ), a Commonwealth statutory authority responsible for developing, varying and reviewing standards for food available in Australia and New Zealand. It operates under the *Food Standards Australia New Zealand Act 1991*. Its role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. The TGA will also conduct the risk assessment with regard to exposure from sources other than food and provide an integrated risk assessment with regard to exposure from all sources.

If during the exposure analysis, occupational health is shown to be of concern, an occupational health risk assessment will be conducted. If exposure occurs in industrial settings, NICNAS staff of the Office of Chemical Safety will undertake the risk assessment. Occupational exposure that occur in agricultural settings will be assessed by the National Occupational Health and Safety Commission which conducts risk assessment of agricultural and veterinary chemicals for the APVMA. These will be included in the overall report of the risk assessment.

2.3 How will consultation be conducted during the risk assessment

To assist in providing advice to the Commonwealth on all phases of the NDP, two consultative bodies have been formed:

- the **National Dioxins Project Team** (NDPT) brings together representatives of Commonwealth, State and Territory agencies with an interest in dioxins; and
- the **National Dioxins Consultative Group** (NDCG) includes representatives of community organisations, scientific research and industry organisations with an interest in dioxins. An independent expert and government officials also participate.

In addition to consulting through these bodies, opportunities are being provided to seek broader community views under the risk assessment (see Figure 1). Initially, public comments are being invited on the proposed risk assessment methodology as outlined in this paper. The Commonwealth will consult with the NDCG and NDPT throughout the planning, analysis and risk characterisation stages of the risk assessment.

The draft risk assessment report will also be peer reviewed by two or three Australian and overseas experts in the field of dioxins. Their comments will be considered by DEH, TGA and the NDPT and NDCG before the draft report is released for public comment, along with the findings of the information gathering studies, in mid 2004. The aim of this latter public consultation is to seek the views of stakeholders on the science of the risk assessment.

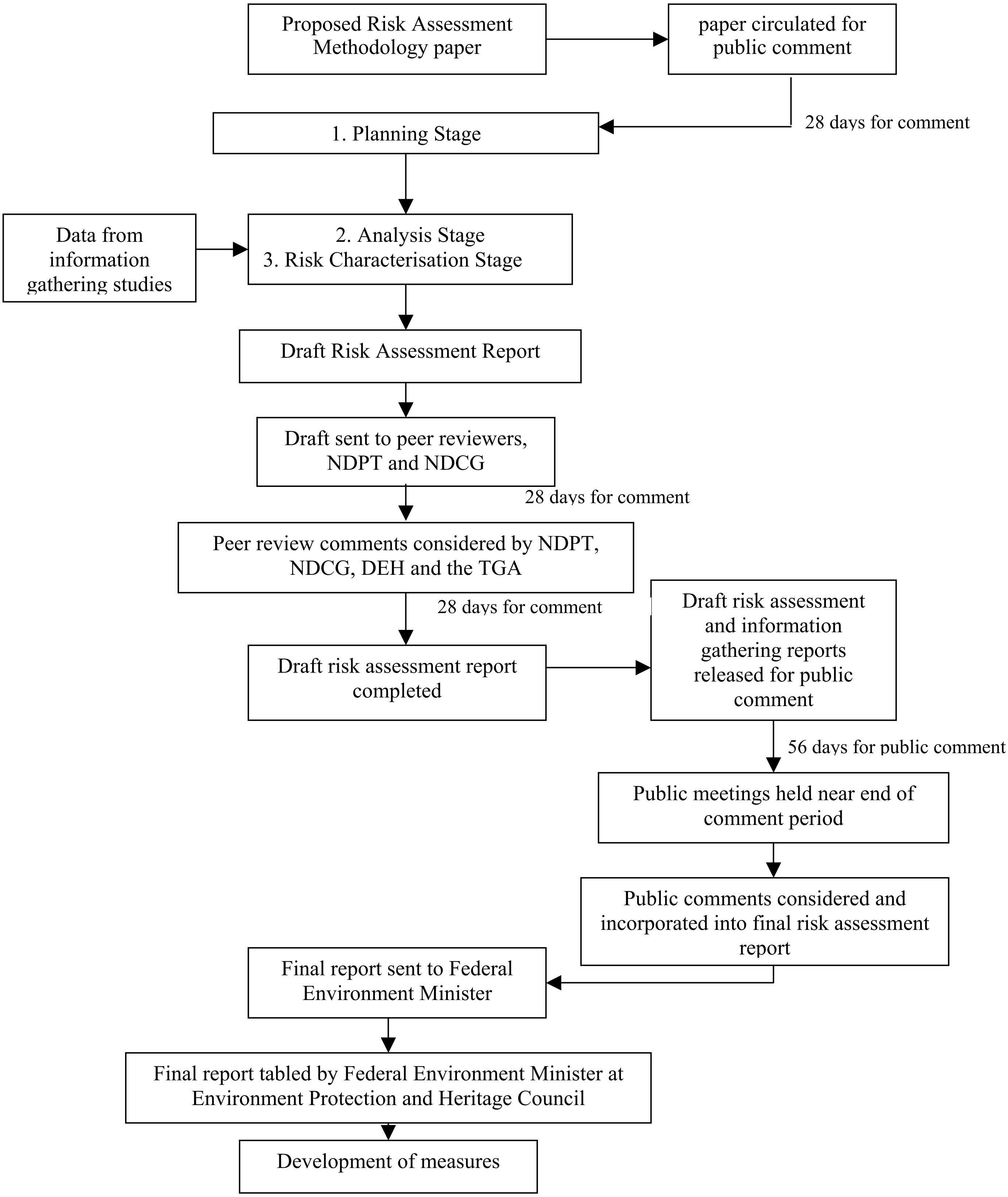
The risk assessment and reports on the information gathering studies will be made available through the NDP website, State environment protection agencies, libraries and environment centres, as well as to individuals and organisations requesting copies. Officers from DEH, the TGA and representatives from the NDPT and NDCG will also present the risk assessment and information gathering studies reports at a series of public meetings across Australia after the reports have been released.

All comments received through the public consultation will be presented to the Federal Minister for the Environment and Heritage, together with details of the person making the comment and whether and how the comment has been taken into account in the risk assessment. This document will be released publicly.

A further public consultation process will be undertaken during the development of measures in light of the outcomes of the risk assessment.

The consultation process for the risk assessment is summarised in Figure 1.

Figure 1: Risk assessment consultation process



2.4 What risk assessment methodology will be used?

For the assessment process, detailed information will be required on human and environmental exposure to dioxins. A significant contribution to this process will be the information gathering studies. Details of these studies are at Appendix 1. This information will comprise the bulk of the exposure and monitoring data required for the risk assessments. The hazard or effects assessment for both the public health and environment risk assessments will be sourced primarily from international reviews and other existing technical reports on dioxins and their toxicology.

2.4.1 Planning

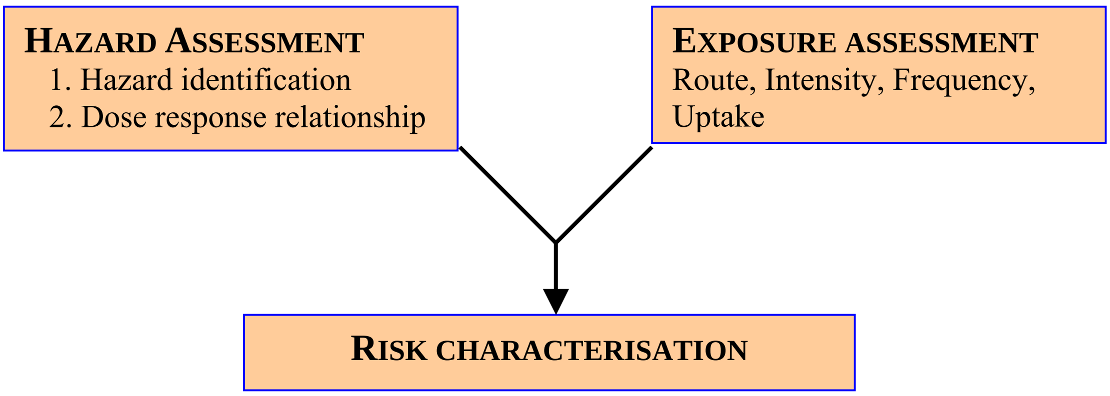
The planning stage will involve consultation between key stakeholders (NDPT and NDCG) and the risk assessment teams from DEH and the TGA. The task is to select assessment endpoints, review conceptual models and make adjustments to the overarching analysis plan for the risk assessment. This stage will clearly formulate the analytical problem and its complexities, indicate how data and analyses will be used to estimate risks and delineate the decision paths that will eventually lead to the risk management stage.

A key product of this process will be agreement on the assessment endpoints for environment and human health that will adequately reflect the management objectives of the NDP. Clearly defined assessment endpoints will provide direction and boundaries for the risk assessment and can minimise confusion and reduce uncertainty. Assessment endpoints will be distinguished from management goals by their neutrality and specificity.

2.4.2 The risk assessment paradigm

The objective of the risk assessment is to determine or predict the risk of *adverse responses* to dioxins under anticipated exposure conditions. It is conventionally broken down into the component parts of hazard assessment (*hazard identification*, *dose-response assessment*), exposure assessment, and risk characterisation. The interrelationship of these steps is shown in Figure 2.

Figure 2: The risk assessment model



2.4.3 Definition of terms

Hazard identification: indication of the adverse effect(s) which a chemical has an inherent capacity to cause.

Dose-response relationship: estimation of the relationship between dose, or level of exposure to the substance, and the incidence and severity of an effect where appropriate.

Doses are often presented as dose rates, or the amount of a chemical (applied or internal) per unit body weight and/or time. Since intake and uptake can vary, dose rate is not necessarily constant. An average dose rate over a period of time is a useful concept for many risk assessments. These are often in the form of *average daily doses* (*ADDs*) or *average monthly doses* (*AMDs*) expressed, for example, in mg/kg body weight/day or month.

Depending on the purpose of an exposure assessment, the numerical output may be an estimate of the rate, duration and frequency of contact exposure or dose. For effects such as cancer, where the biological response is usually described in terms of lifetime probabilities, even though exposure does not occur over the entire lifetime, doses are often presented as *lifetime average daily doses* (*LADDs*).

Exposure assessment: estimation of the concentration or dose to which human populations or environmental compartments (e.g. aquatic environment, terrestrial environment, atmosphere) are or may be exposed. The objective is to determine the nature and extent of contact with chemical substances experienced under different circumstances.

A human exposure assessment includes consideration of the intensity, frequency and duration of contact, the route of exposure (e.g. dermal, oral or respiratory), the rate (chemical intake or uptake rates), the resulting amount that actually crosses from the environmental medium to the site of absorption/uptake (a dose), and the amount absorbed (internal dose).

Risk characterisation: drawing upon the hazard and exposure assessments develops an estimation of the incidence and severity of the effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a chemical.

2.5 Human health risk assessment

The aim of the human health risk assessment will be to determine whether dioxins are likely to cause adverse health effects in the general population; it is not intended to address occupational exposure. If the extent of exposure to dioxins can be determined and reduced, the risk (or likelihood of harm) can be minimised.

2.5.1 Hazard assessment

Several comprehensive hazard assessments of dioxins have recently been performed by international scientific organisations including the World Health Organization (WHO), the International Agency for Research on Cancer, the US Environmental Protection Agency, the Joint Expert Committee on Food Additives (JECFA) and the European Commission Scientific Committee on Food (EC-SCF). These assessments were based on an extensive array of studies in laboratory animals of the adverse effects of dioxins, as well as studies of humans who had been exposed to high levels of dioxins accidentally or occupationally.

These hazard assessments can be utilised without the need to undertake a separate hazard assessment within Australia. Based on hazard assessments of dioxins that have been prepared by the WHO, JECFA and the EC-SCF, the TGA has recommended that the National Health and Medical Research Council adopt a human tolerable intake standard of 70 *picogram* dioxin TEQ/kg body weight/month, from all sources combined. It is important to note that this Tolerable Monthly Intake (TMI) is not a "safe" level of dioxin intake. The JECFA report stated that:

> "the Provisional Tolerable Monthly Intake (PTMI) is not a limit of toxicity and does not represent a boundary between safe intake and intake associated with a significant increase in body burden or risk. Long-term intakes slightly above the PTMI would not necessarily result in adverse health effects but would erode the safety factor built into calculations of the PTMI. It is not possible given our current knowledge to define the magnitude and duration of excess intake that would be associated with adverse health effects."

The epidemiological data which forms an important part of the international hazard assessments is based on dioxin exposures in a "real world" environment i.e. where humans are exposed to dioxins in conjunction with many other chemicals and where any synergistic effects will be evidenced in the reported health effects. Nevertheless, possible synergistic reactions between dioxins and other environmental chemicals will be further investigated as the methodology for the risk assessment is developed.

2.5.2 Exposure assessment

The exposure assessment will utilise data from the information gathering studies, which will include measuring the concentration of dioxins in food and the environment. The assessment will also include data from the surveys of dioxin levels in human breast milk and blood serum, which will provide information on the human body-burden of dioxins and on the exposure of infants. An outline of the data to be collected as part of the exposure assessment is shown in Table 1. The table lists the principal sources and routes of exposure of dioxins and the population subset for which dose estimates will be prepared. Figure 3 shows the possible routes by which people may be exposed to dioxins.

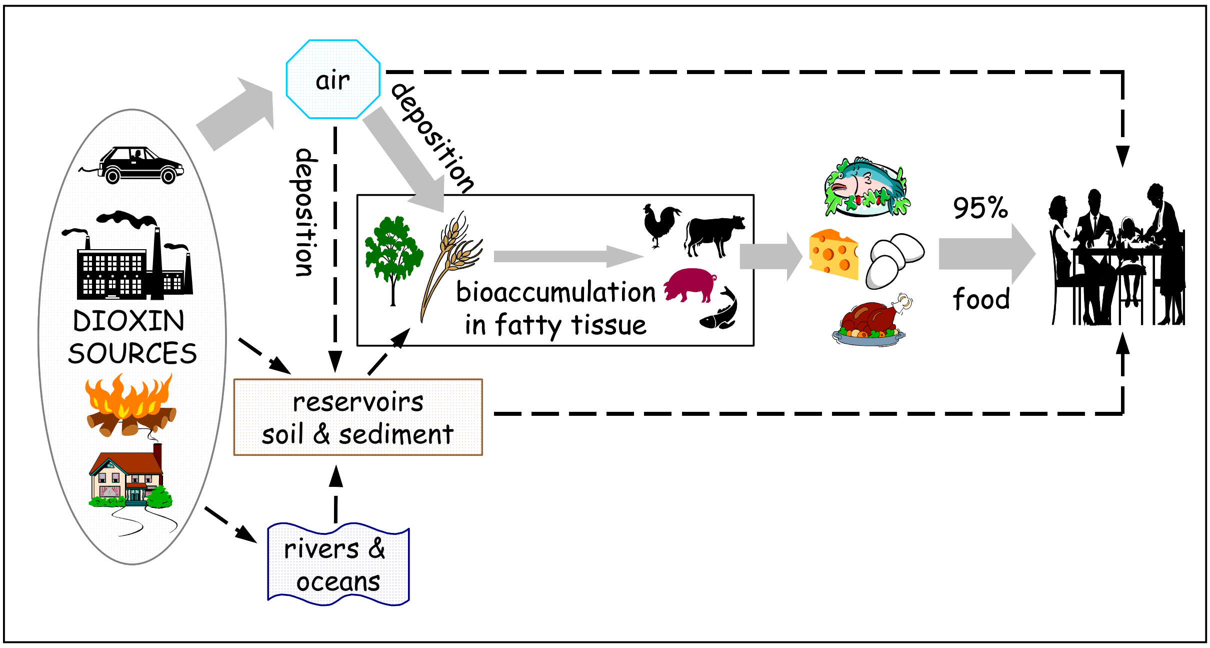
Table 1: Exposure and Human Body Burden

Source of exposure to dioxins	**Route of exposure**	**Groups examined**
Diet: estimated daily intake from food (National Residue Survey and FSANZ Total Diet Survey)	Ingestion	Adults Children Infants
Air: estimated daily intake from levels measured by the environmental levels study	Inhalation	Adults Children Infants
Soil: estimated daily intake from levels measured by the environmental levels study	Ingestion Dermal contact	Adults Children Infants
Breast milk: estimated daily intake derived from levels measured in breast milk study	Ingestion	Infants

Body Burden		
Breast milk: estimated daily intake derived from levels measured in breast milk study	Ingestion	Infants
Blood serum: estimated daily intake derived from levels measured in the blood serum study		Adults Children Infants

Noting that overseas exposure assessments have consistently shown that 95% of human exposure to dioxins arises through dietary intake, emphasis will be placed on the results of the food survey that is being undertaken by Food Standards Australia New Zealand and the assessment of dioxins in agricultural commodities under the National Residue Survey. Dietary exposure to dioxins will be determined by measuring the concentration of dioxins in different foods and then estimating the amount of these foods that are consumed by Australians. Since the amount and type of food consumed varies with age, separate estimates of dietary intake will be prepared for infants, children and adults.

Figure 3: Possible exposure pathways for human exposure to dioxins



The dose of dioxins potentially absorbed into the human body from the air and soil will be derived from the levels detected in these media, using standard exposure factors that estimate the amounts of air inhaled and soil contacted or ingested by infants, children and adults. Estimates will be corrected for the extent of absorption from the gastro-intestinal tract, lungs or skin. If the surveys indicate there is significant regional variation in the concentration of dioxins in the air or soil, a range of estimates of intake will be prepared to encompass these areas of higher or lower exposure. As dioxins are insoluble in water, exposure to humans via this media is minimal but will be considered in the overall risk assessment.

In this way, it will be possible to estimate the cumulative dose of dioxins from all the identified sources that is absorbed by Australians. The exposure assessment is also likely to clarify the pattern of human exposure in Australia, and may identify particular sectors of the population whose exposure to dioxins is increased because of their age, gender, dietary habits or place of residence. Such information may prove valuable for setting priorities in the risk management phase of the NDP, in which national management measures will be developed to reduce and where feasible, eliminate dioxins in Australia.

The risk assessment will incorporate recognition of the need for conservatism in the values used in exposure calculations, especially “exposure case” calculations. This is distinguished from an “exposure scenario” which is a collection of facts, assumptions and inferences about how exposure occurs. For example, an exposure scenario might be urban, rural, industrial or domestic, each with an appropriate selection of possible exposure factors. An “exposure case” defines the level of conservatism to be used by selecting appropriate methods and numerical variables. The choices to be made include central tendency, worst case, maximum exposed individual, reasonable maximum exposure, upper bound etc. The exposure assessment will include transparent selection of the variables chosen and present ranges of possible exposure within each exposure scenario.

2.5.3 Risk characterisation

Risk characterisation is where the hazards are matched to predicted exposures to derive estimates of risk. In general terms, regulators aim is to carry out quantitative risk characterisation, wherever possible, by identifying or extrapolating from the toxicity data, to give concentrations at which no effects are expected and comparing this level with the estimated exposure level. Where quantification is not possible, a judgement on likelihood of risk has to be made on a qualitative basis.

The TGA, together with FSANZ, will integrate the human hazard assessment and exposure assessment to determine whether the current intake of dioxins is likely to cause adverse effects on the health of Australians, including population subgroups. In the first instance, the estimated intake of dioxins will be compared with the Australian tolerable monthly intake (TMI) value of 70 pg dioxin TEQ/kg body weight/month.

Confirmatory data will be obtained from studies measuring dioxin levels in pooled serum and breast-milk samples. This work will provide an estimate of the current Australian body burden of dioxins for comparison to that seen in other countries.

Completion of the risk characterisation stage will enable conclusions to be drawn regarding the occurrence of dioxin exposure and the associated risks. Part of this discussion will be the conduct of a sensitivity analysis detailing the particular assumptions and input variables which most affect the outcomes of the risk assessment, as well as discussion of the significance of the identified relationships. The conclusions of the human risk assessment should provide clear information to risk managers and enable informed decision making.

2.6 Environmental risk assessment

Environmental risk assessment of chemicals evaluates the likelihood of adverse impacts on non-human organisms in the environment. It follows the same framework as human health risk assessment, namely hazard assessment, exposure assessment and risk characterisation. Unlike human health risk assessment, which seeks to characterise risks to individuals, the aim of environmental risk assessment is to characterise risks to populations or ecosystems.

Environmental and human health risk assessments differ in other ways. Environmental risk assessment entails consideration of a broad range of organisms, not just humans, and it can be difficult to decide which are most important to study or to protect. Ecosystem processes tend to be less well understood than human biology, and ecological data are often limited, having regard to the ethical sensitivity of performing tests on fauna. Evaluation and management of ecological risks can be more complicated and time consuming.

The risk assessment process precedes and informs the development of risk management options. The overall objective of the environmental risk assessment and management is to minimise harm to native populations of fauna and flora and ecosystems from exposure to dioxins in Australia. Alternatively, the objective can be expressed as prevention of toxic levels of environmental contamination by dioxins.

In order to meet the above management objective, it is proposed that assessment endpoints for the environmental risk assessment be survival, growth and reproduction, particularly for susceptible organisms like fish and predatory birds. The risks of mortality or impaired growth or reproduction will need to remain sufficiently low that impacts on native fauna and flora are unlikely. In other words, environmental contamination by dioxins needs to be prevented or, if already present, reduced below levels that threaten survival or impair growth or reproduction of native populations that are likely to be impacted upon.

2.6.1 Hazard identification

Dioxins have never been produced commercially but are produced unintentionally as unwanted by-products from a variety of chemical and, in particular, combustion processes. Consequently, they are mostly emitted to the atmosphere. Polychlorinated biphenyls, some of which have dioxin-like properties, and which are, therefore, covered by the NDP are no longer produced commercially but may remain in older electrical equipment. Their residues remain in the environment.

Dioxins are characterised by low solubility in water but higher solubility in *lipids*, high affinity for soils, suspended solids and sediments, and extended environmental persistence. These properties ensure that dioxins, although mostly released to the atmosphere, become associated with and persist in soils and sediments. Some congeners have extremely high chronic environmental toxicity and a strong tendency to bioaccumulate in fatty tissue.

Environmental contamination by dioxins is widespread, but no criteria have been established for protecting ecosystems from their adverse effects.

The main route of exposure to dioxins for aquatic and terrestrial organisms is dietary intake. Residues in soils and sediments are taken up by sediment or soil feeding organisms, which are in turn consumed by organisms higher in the food chain. Thus, environmental risks are largely dependent on the concentrations in soils and sediments. These concentrations tend to reflect historical emissions, because of the environmental persistence of dioxins.

2.6.2 Dose response assessment

In contrast to the human health situation, comprehensive reviews of the toxicity of dioxins to non-human (and particularly non-mammalian) organisms are not available. The Australian dose response assessment will, therefore, be largely based on international literature and reports of toxicity testing with dioxins.

A wide variety of toxicity tests have been conducted for environmental risk assessments, involving acute or chronic exposure of aquatic or terrestrial organisms. The usual endpoints in these tests are survival, growth or reproduction. Testing is conducted with a restricted range of test organisms. It is assumed that protecting the test species will also protect other species in the environment.

Dioxins are understood to exert their greatest toxicity to early-life stages, particularly the sac-fry of fish. The Australian assessment will focus on dose-response relationships obtained from toxicity tests of dioxins in aquatic and terrestrial organisms. Particular attention will be given to tests conducted with early life stages under the chronic exposure conditions believed to be characteristic of the situation prevailing in natural environments.

2.6.3 Hazard assessment

The hazard assessment of chemicals aims to determine the exposure concentration at which no adverse impacts will occur: in environmental risk assessment this concentration is commonly known as the *predicted no effect concentration* (PNEC). This is usually determined in the normal or immediate exposure medium e.g. concentrations in water in the case of aquatic life.

In general, levels of aquatic contamination by a chemical reflect the amounts used over a short period prior to measurement. However, dioxins are different because of their lengthy environmental persistence, strong sorption to soils and sediments, and high bioaccumulation. Dioxins accumulate in aquatic and terrestrial organisms through dietary intake, which depends ultimately on the concentrations in soils and sediments.

2.6.4 Exposure assessment

The level of exposure to a contaminant depends on the volumes released and the fate of those releases. Detailed descriptions of the environmental fate of dioxins are available in overseas assessment reports from authorities such as the US EPA. The Australian assessment of environmental fate will draw upon those reports bearing in mind the unique characteristics of the Australian environment. The results from the information gathering studies will provide guidance on the Australian environmental levels. Current dioxin emissions are dominated by releases to air from combustion sources. However, because of their persistence, the main sources of environmental exposure to dioxins are the reservoirs that have accumulated in soils and sediments.

2.6.5 Risk characterisation

Risk characterisation combines the results from the exposure and hazard assessments to determine the risk or likelihood of adverse effects at particular levels of exposure. The PNEC is compared with the exposure concentration (estimated or measured) in order to determine whether impacts are likely. The risk characterisation will evaluate the likelihood of adverse impacts on non-human populations exposed to dioxins currently in the environment.

The risk characterisation will also determine threshold exposure concentrations at which adverse effects may be expected in sensitive organisms. The threshold concentrations will be determined for soils and sediments as these reservoirs are the fundamental source of longer-term exposure to dioxins.

The risk characterisation will also aim to determine trends whether declining or increasing, or static. Where significant risks are demonstrated, risk reduction measures will be proposed.

2.7 Risk management

The development of risk management options is a separate process from risk assessment. Risk management options will be considered and a process of public consultation undertaken in later 2004.

2.8 The risk assessment report

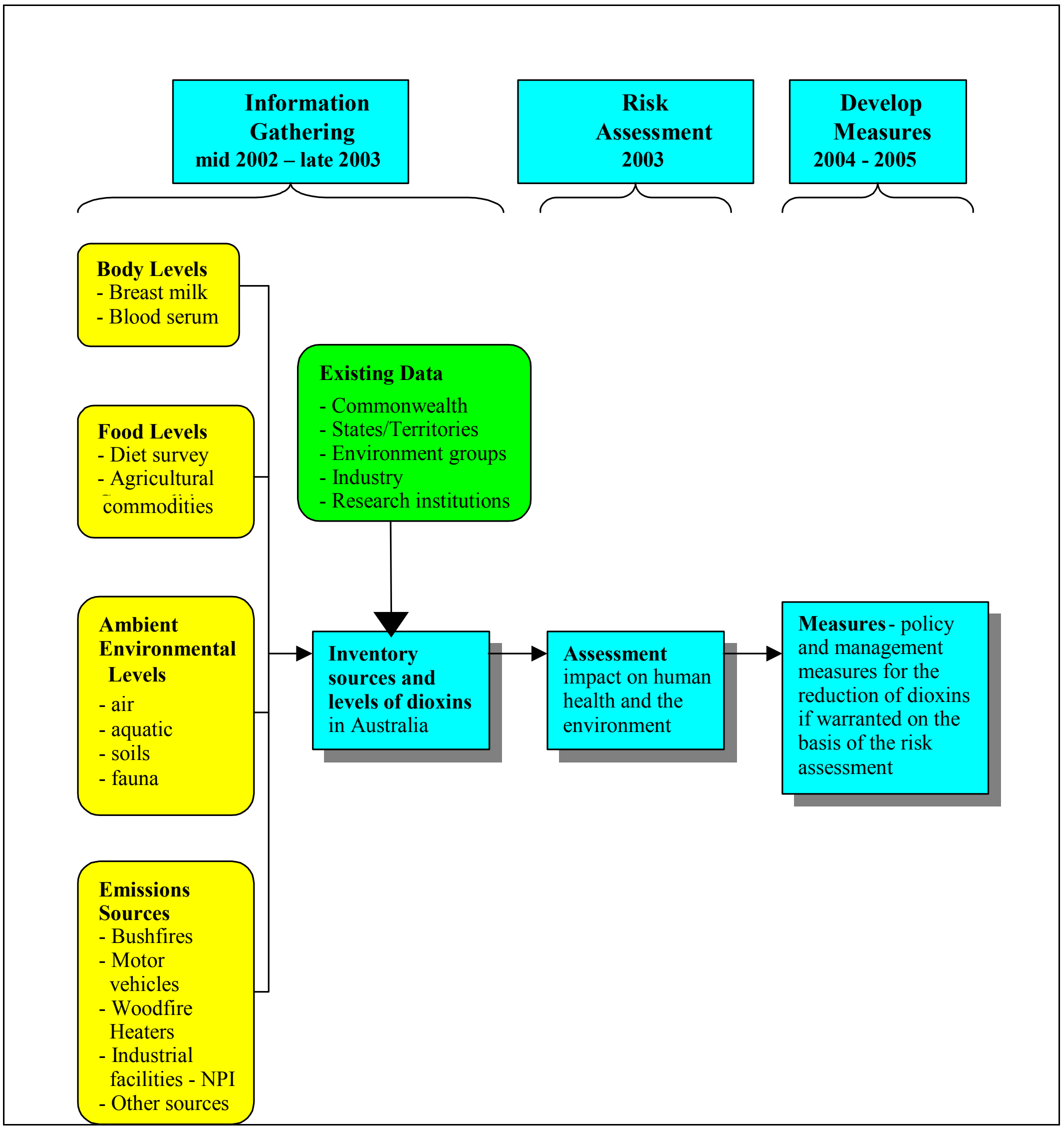
The format of the risk assessment report outlined below will include a summary of the public health and environmental safety risks and a list of recommendations. To protect human health and the environment, these recommendations may include, where practical, risk mitigation measures to be adopted.

Format for the Dioxins Risk Assessment Report

1. Introduction and background, where details such as the scope, purpose and description of the assessment are discussed.
2. The identity and physical and chemical properties of the chemical, including methods of detection and analysis.
3. An inventory of known occurrences of dioxins in Australia. This will include an examination of the data from the information gathering studies to identify likely sources.
4. Environmental exposure and fate assessment. This will consider likely quantities of release of dioxins in Australia, and how they may move through the environment from known sources and any additional sources identified from the monitoring data. With the use of monitoring data and modelling, expected concentrations in the environment will be derived. These concentrations may be considered for air, soil, water, sediments and biota. International reports may be used in this part of the assessment. This could be on a local, regional or wider basis depending on the distribution of dioxins within Australia.
5. Environmental effects and risk. This component will consider any known effects on terrestrial and aquatic species and will rely on international reports and literature. This is followed by an assessment of environmental risk through a comparison of expected environmental concentrations to effects on organisms.
6. Assessment of the health effects (hazard) of the chemical. This will examine the toxicokinetics and metabolism effects in animals and in *in vitro* test systems, as well as human health effects. International reports will be used in this part of the assessment and this section will include an assessment of toxicological results available in the open literature.
7. Public health risk assessment will integrate public exposure with the results of the health hazard assessment to determined level of risk to the general public and/or sections of the public. It is expected that aggregate human exposure through food and the general environment will be calculated using both monitoring data and modelling predictions as appropriate.
8. If necessary, an occupational assessment will be conducted which will include an exposure assessment and any available monitoring data to give a measure of risk to workers in terms of a margin of exposure estimated for each of the various occupational scenarios.
9. A brief summary of the report, highlighting key areas that have influenced the overall report and the recommendations made.
10. Recommendations.

APPENDICES

Appendix 1: Overview of the National Dioxins Program



Appendix 2: Information gathering studies

Dioxins are predominantly generated as unintended by-products of combustion processes and mostly discharged into the air. Therefore, air represents the primary route of deposition of dioxins to the environment. It has been estimated that 96% of dioxins present in the environment have arisen from air emissions. They can be deposited on plant, soil and water surfaces. Dioxins can then enter the food chain when animals eat contaminated leaves. In aquatic environments, filter-feeding animals can absorb dioxins when they filter sediments or particulate matter floating in the water. The dioxins are then absorbed into the animal fat. Dioxins increase in concentration as they migrate up the food chain. The consumption of animal products with high fat content, such as meat and dairy goods, can increase human exposure to dioxins.

Given these factors, the main priorities for the NDP is to carry out studies to determine the levels of dioxins in humans and the environment and to assess the relative importance of sources of dioxin emissions. Results of studies on dioxins by other Commonwealth programs or agencies will also improve the knowledge on dioxin levels in Australia.

The information gathering studies will run from mid 2002 through to late 2003 and aim to:

1. determine the levels of dioxins in the environment and the Australian population;
2. standardise sampling, analyses and reporting of dioxins data nationally; and
3. compare Australian and international concentrations of dioxins.

Up to $2.5 million has been allocated for information gathering studies with much of the work being carried out through contracts let by the Commonwealth to well respected scientific organisations.

Limitations of the studies

Because dioxins are toxic at very low levels, their presence in substances is measured in parts per trillion. Therefore, analysis requires highly sensitive equipment and is time consuming and costly - the costs for the analysis alone may be up to $2,000 per sample. This is in addition to any costs associated with collection of the samples. Accordingly, the number of samples that will be analysed for the studies are low. Nevertheless, the results will still provide a valuable picture of the indicative levels of dioxins in Australia. Follow-up studies may be considered based on scientific advice and where resources allow. The numbers of samples being analysed for each study are as follows:

Breast milk	18	
Blood serum	110	
Foods	165	
Agricultural commodities	240	
Environmental levels		
- air	96	
- soils	110	
- aquatic environment	73	sediments, 36 fauna
- fauna	61	
Bushfires	24	

Human body burden

Dioxins accumulate in body fat and the average concentration increases progressively with age. The measurement of dioxins in humans is an important indicator of dioxin exposure and is extremely useful in determining trends. Trend analysis is an important tool in determining the effectiveness of measures taken to reduce dioxins. To determine the levels of dioxins in the Australian population, two studies will be undertaken by assessing the levels of dioxins in human breast milk and in blood serum.

Breast milk

Together with blood serum data, the study may use the amount of dioxins found in breast milk samples to assess the level of dioxins in the body. Dioxins accumulate in the food chain, particularly in fat containing foods and when humans consume foods, the dioxins in the food remain in the body's fat stores. Since breast milk is a rich source of fat, analysis of the levels of dioxins in breast milk is valuable for estimating the total amount of dioxins in humans.

In this study, breast milk samples will be taken from 200 first time mothers from metropolitan and rural areas in Australia and pooled to form 18 samples for analysis.

Blood serum

The blood serum study will analyse 100 pooled blood samples collected from up to 10,000 male and female donors in four metropolitan and one rural area across Australia in five age groups; <15, 15-30, 30-45, 45-60 and >60 years.

The study will exclude participants who may have been exposed to dioxin levels above those of the general population due to specific occupation or life-styles.

Food levels

International studies have concluded that around 95% of human exposure to dioxins (and other chlorinated chemical compounds) is through food, particularly those foods containing animal fats such as meat and dairy products. Dietary exposure to dioxins can be estimated by determining the concentrations of dioxins in foods likely to contain dioxins and then multiplying these results by the amounts of these foods consumed. This involves sampling of representative foods from the marketplace and analysing these for dioxins content.

Diet Survey

Food Standards Australia New Zealand (funded by DoHA) will analyse the levels of dioxins in approximately 165 samples of foods obtained from retail outlets during 2000 in all State and Territory capitals. The samples are generally those foods that are consumed in significant amounts in the Australian diet and have been prepared to a 'table-ready' state (e.g. cooked) and, thus, best represent the amounts of dioxins that would be consumed.

Agricultural commodities

The National Residue Survey (administered by AFFA) is analysing dioxins levels in approximately 240 samples of agricultural commodities such as meat and dairy products collected across Australia. The number of samples for each type of product is based on the proportion of the total production of that commodity. The findings will be reported as national data and will not identify individual properties from whence the products came.

Ambient environmental levels

Studies will be carried out to determine the ambient level of dioxins in a range of environmental media including air, aquatic environments, soils and fauna. These studies will take samples from three broad areas: metropolitan, agricultural and remote areas such as national parks and other Crown lands. Where possible, samples of soils, aquatic environment and fauna will be taken near the sites of the air sampling locations as well as from other areas.

Air

The objective of this study is to characterise dioxin levels in ambient air in Australia. This will be achieved by sampling air once a month, or every two months, over a twelve month period at ten locations in metropolitan, agricultural and remote areas as shown in Table 1. These measurements will characterise seasonally dependent factors including bushfire smoke and residential wood-heater smoke in areas where these sources impact strongly on air quality:

Table 1 – Location of air sampling sites

Location	Type of environment
Kwinana, Perth, Western Australia	industrial
Duncraig, Perth, Western Australia	metropolitan
Darwin, Northern Territory	metropolitan
Mutdapilly, south-east Queensland	agricultural
Eagle Farm, south-east Queensland	industrial (sampling once every two months)
Westmead, Sydney, New South Wales	metropolitan
Booroolite, lower north-east Victoria	agricultural
Alphington, Melbourne, Victoria	metropolitan
Netley, Adelaide, South Australia	metropolitan (sampling once every two months)
Cape Grim, Tasmania	remote

Soils

The objective of this study is to characterise dioxin levels in Australian soils. Around 110 samples will be collected in a range of climates and landforms across Australia and where possible in areas close to the air sampling sites. Several samples will be collected from each area and combined to form one aggregate sample for the analysis. To obtain an understanding of the historic deposition of dioxins in soils, additional samples will be taken from archived soil samples, or soil cores, for which stratified layers can be attributed to age, representing five periods including before the manufacturing of organochlorines (i.e. prior to 1940s) and the 1950-1960s, 1970s, 1980s and 1990s in two regions.

Aquatic environment

Overseas studies have found that detecting the presence of dioxins in water is unlikely, as dioxins are insoluble in water. It is, therefore, more cost effective to concentrate on sampling from sediments and biota where the dioxins are more likely to accumulate.

This study will involve the analysis of dioxins in a range of representative fauna and sediment samples obtained from freshwater, estuarine and marine environments. The fauna (total of 36 samples) will include common species of fish and sedentary species that are known to accumulate toxic substances, e.g. oysters and mussels. Where possible the sediment samples (total of 73) will be collected in the same area as the fauna. Areas that are subject to dredging or similar periodic disturbance will be avoided.

Fauna

The objective of this study is to characterise the levels of dioxins in range of terrestrial fauna. The species to be covered by the study will include a variety of mammals, birds (including birds of prey), and lizards representing a range of trophic levels from low level herbivores to high level predators and carnivores. These data will allow the quantification of any apparent bioaccumulation throughout the food chain. Where possible the samples (total of 61) will be taken from animals that have been killed accidentally by motor vehicles and from the same areas where the soil and air sampling will be undertaken.

Emissions sources

The 1998 inventory identified a range of sources of dioxins emissions to air of which six may contribute up to 95% of the total amount - bushfires (both wild fires and prescribed burning), residential wood combustion, coal combustion, sinter production and industrial wood combustion. However, as these estimates were based largely on overseas studies, the following studies will attempt to provide more accurate data.

Bushfire emissions

On the basis of overseas data, the 1998 inventory estimated that bushfires may contribute up to 75% of the total dioxins to air in Australia. The objective of this study is to characterise dioxin emissions from bushfires in Australia. This will be achieved by sampling smoke from either wildfires or prescribed burns, and in laboratory controlled fires. A variety of vegetation categories will be examined including native forests and woodlands, pine plantations and agricultural crop residues.

Motor vehicle emissions

Overseas studies show that motor vehicles may contribute less than 3% of the total dioxins emissions in a country. Nevertheless, a study will be undertaken to determine the probable contribution to the dioxin emissions from this source. The study will involve examining studies of motor vehicle emissions in other countries and comparing these with the Australian motor vehicle fleet. Factors such as the composition of the Australian fleet, types of fuels used and their additives, emission control standards and driving patterns, including distances travelled, will be taken into consideration when extrapolating the overseas data to Australia. If necessary a further study may be commissioned to undertake air sampling of traffic in a high volume inner city tunnel to confirm the findings of the initial study.

Wood heater emissions

Under the "Living Cities - Air Toxics Program", the Department of the Environment and Heritage has funded a study to determine the emissions of toxic air pollutants, including dioxins, from domestic wood heaters.

Industrial emissions

Many Australian industrial facilities monitor emissions of substances as part of regulatory requirements or as a commitment to ensuring their processes are operating efficiently and with minimal environmental effects.

Data on estimations of dioxin emissions from industrial and other sources will be provided as part of the reporting requirements under the National Pollutant Inventory (NPI). Estimations of dioxins emissions were reported for the first time in the fourth reporting year of the NPI i.e. 1 July 2001-30 June 2002. Data for this period was publicly made available in January 2003. NPI dioxins emissions data are estimations and not actual monitoring data, therefore, care will be needed in interpreting them.

Appendix 3: Dioxin, furan and PCB congeners to be analysed under the NDP

Under the information gathering studies , samples will be analysed for the following polychlorinated dibenzodioxins, dibenzofuran and PCB congeners:

Congeners		WHO-TEF[5]
Dioxins		
2,3,7,8-TetraCDD		1
1,2,3,7,8-PentaCDD		1
1,2,3,4,7,8-HexaCDD		0.1
1,2,3,6,7,8-HexaCDD		0.1
1,2,3,7,8,9-HexaCDD		0.1
1,2,3,4,6,7,8-HeptaCDD		0.01
OctaCDD		0.0001
Furans		
2,3,7,8-TetraCDF		0.1
1,2,3,7,8-PentaCDF		0.05
2,3,4,7,8-PentaCDF		0.5
1,2,3,4,7,8-HexaCDF		0.1
1,2,3,6,7,8-HexaCDF		0.1
1,2,3,7,8,9-HexaCDF		0.1
2,3,4,6,7,8-HexaCDF		0.1
1,2,3,4,6,7,8-HeptaCDF		0.01
1,2,3,4,7,8,9-HeptaCDF		0.01
OctaCDF		0.0001
CDD – chlorinated dibenzo-*p*-dioxin		
CDF – chlorinated dibenzofuran		
	IUPAC No.	
Non-ortho PCBs		
3,3',4,4' – tetrachlorobiphenyl	PCB#77	0.0001
3,4,4',5 – tetrachlorobiphenyl	PCB#81	0.0001
3,3',4,4',5 – pentachlorobiphenyl	PCB#126	0.1
3,3',4,4',5,5' – hexachlorobiphenyl	PCB#169	0.01
Mono-ortho PCBs		
2,3,3',4,4' – pentachlorobiphenyl	PCB#105	0.0001
2,3,4,4',5 – pentachlorobiphenyl	PCB#114	0.0005
2,3',4,4',5 – pentachlorobiphenyl	PCB#118	0.0001
2',3,4,4',5 – pentachlorobiphenyl	PCB#123	0.0001
2,3,3',4,4',5 – hexachlorobiphenyl	PCB#156	0.0005
2,3,3',4,4',5' – hexachlorobiphenyl	PCB#157	0.0005
2,3',4,4',5,5' – hexachlorobiphenyl	PCB#167	0.00001
2,3,3',4,4',5,5' – heptachlorobiphenyl	PCB#189	0.0001

[5] TEF = Toxic Equivalent Factor (1 = the highest level of toxicity of this chemical)

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