Compilation of EU Dioxin Exposure and Health Data

Summary Report

Report produced for

European Commission DG Environment

UK Department of the Environment Transport and the Regions (DETR)

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Dr Deborah Buckley-Golder
AEA Technology plc
Culham
Abingdon
Oxfordshire OX14 3ED
Telephone +44 (0)1235 463571
Facsimile +44 (0)1235 463005

	Name	Signature	Date
Author	D Buckley-Golder		
Reviewed by	K King		
Approved by	K Brown		

Project Team:

AEA Technology, England
Deborah Buckley-Golder (Project Manager)
Peter Coleman
Mark Davies
Katie King
Anne Petersen
John Watterson
Mike Woodfield

University of Bayreuth, Germany
Heidelore Fiedler

Karolinska Institute, Sweden
Annika Hanberg

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Executive Summary

INTRODUCTION

There is considerable public, scientific and regulatory concern over the possible adverse health effects of chronic exposure to trace levels of persistent organic pollutants. The class of compounds made up of the polychlorinated dibenzo-*p*-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF), often collectively known as dioxins, has received widespread attention and attracted a great deal of research, following the accidental release of the most toxic of these (2,3,7,8 TCDD) at Seveso in 1976.

Dioxins, and dioxin-like compounds which may have similar effects, are found in all environmental compartments, are persistent and, being fat soluble, tend to accumulate in higher animals, including humans. Their resistance to degradation and semi-volatility means that they may be transported over long distances and give rise to trans-national exchanges of pollutants. In addition, dioxins released into the environment many years ago continue to contribute to contemporary exposure.

Over the past two decades the European Commission (EC) has implemented wide ranging legislation aimed at directly or indirectly reducing or controlling the release of dioxins into the environment, with the objective of reducing human exposure and protecting human health. However, the recent WHO re-evaluation of the toxicology of dioxins, which recommended a Tolarable Daily Intake (TDI) of 1-4 pg TEQ[1]/kg body weight (including dioxin-like PCBs), has suggested that additional measures might be required, at the Community level, to further reduce human exposure to an acceptable level, within an appropriate timescale. Such action can only be formulated on the basis of a detailed knowledge and understanding of the effectiveness of existing legislation, any continuing risk to human health and ecosystems, and an appreciation of the additional control measures already being implemented by individual Member States.

This study provides such information and recommendations which will assist in the formulation of future policy to reduce exposure to dioxins, in order to further protect the population and ecosystems of the European Union (EU). In seeking to establish the current situation within the EU the scope of this work has been broad; encompassing current concentrations of dioxin in the environment, longevity and environmental transport, current levels of human exposure, concentrations of dioxin in the human body and observed trends, an analysis of acceptable levels of exposure for humans and the ecosystem. In addition, in considering future policy options, it has been necessary to establish what legislation and guidelines are already in place within Member States, which go beyond the requirements of existing EC Directives.

In view of the broad scope of the work it has been necessary to consider only PCDD/PCDFs and not to include PCBs, although conclusions relating to PCDD/PCDFs have been interpreted in the broader context of other dioxin-like compounds. It was not within the scope of this study to consider sources of dioxins, which have been the subject of a number of other recent studies.

In addition to achieving its main objective, of providing a strategic assessment of the EU situation regarding dioxins, additional benefits for the European Commission have also resulted from this project; namely:

- the co-ordination of input from an extensive group of experts and technical policy advisers across the Member States of the EU;
- the assembly of possibly the largest body of information and data yet achieved on the EU situation regarding dioxins;
- the creation of a directory of current Member State legislation and guidelines for the reduction and control of dioxin releases and human exposure;
- the compilation of a catalogue of current research and development requirements relating to dioxins.

ANALYSIS

The most important route for human exposure to dioxins is food consumption, contributing 95-98% of total exposure. Data suggest that, over the past two decades, the average dietary exposure to dioxins within EU Member States has decreased by between 9% and 12% per year, as a result of changing patterns of food consumption and decreasing concentrations of dioxin in foodstuffs. Concentrations of dioxin in human tissue and body fluids are an indicator of the exposure history of the individual or group of individuals concerned and, over the period 1988 to 1993, the average dioxin concentration in human breast milk in EU Member States decreased by around 8% per year. The limited amount of data available on dioxin concentrations in human blood suggests a decrease of around 12% per year over a similar period. It is, therefore, clear that the actions taken to reduce human exposure to dioxins, whether by limiting and controlling the release of dioxins into the environment, restricting their movement through the foodchain, or establishing permissible concentrations in foodstuffs, have led to a reduction in the rate at which dioxins accumulate in the body of the ‘average’ citizen of the European Union.

However, background exposure to dioxins in the general population of the EU is still at a level where subtle health effects may occur. Estimates of average total dietary exposure to dioxins for consumers within the EU are in the range 0.9-3.0 pg I-TEQ/kg body weight/day, assuming an average body weight of 70 kg. The WHO recommended TDI of 1-4 pg TEQ/kg body weight/day includes exposure to dioxin-like PCBs and, on average, dioxins and dioxin-like PCBs contribute equally to total dietary exposure. This indicates that, for many individuals, total exposure will currently exceed even the upper limit of the recommended TDI.

In addition, certain individuals or sectors of the community might be regarded as being ‘at risk’, as a result of their higher than average dietary exposure to dioxins and dioxin-like compounds. These are generally people consuming higher than average amounts of fatty foods, particularly fatty fish and fish products, but also meat and dairy products. It is also important to consider the implications of the concentrations of dioxin in human breast milk for the daily intake of breast-fed infants. Data assembled in the course of this study suggests that the exposure of first-born infants, up to 2 months of age, could be between 27 and 144 times greater than the WHO recommended TDI, without accounting for exposure to dioxin-like PCBs. However, the WHO recommendation is based upon an average lifetime exposure and it has been assumed that the high levels of infant exposure are counter-balanced by lower levels of exposure in later life. This could be so, but consideration must also be given to whether the effects of short periods of very high exposure differ from those of prolonged periods of much lower exposure, particularly

[1] Toxic Equivalent (TEQ); the system used by WHO includes PCDDs, PCDFs and dioxin-like PCBs. The International Toxic Equivalent (I-TEQ) does not include dioxin-like PCBs.

when the former occur during a critical period for infant neurological, physical and intellectual development.

In most countries a broad range of dioxin concentrations has been detected in all environmental media and the Table, below, presents the range of reported typical concentrations and maximum concentrations measured in locations with known contamination. Within the context of this study it was not possible to carry out any statistical analysis of available data, which were generally in the form of aggregated data covering varying numbers of samples, time periods and locations.

Due to the high persistence of dioxins and dioxin-like compounds, concentrations in soils and sediments decrease very slowly, following any reduction in releases to air and water. Concentrations in air, deposition and vegetation are more responsive to emissions reductions and information drawn, primarily, from German and United Kingdom data suggests that the concentrations of dioxin in ambient air and grass samples decreased by around 10% to 20% per year during the 1980s and early 1990s. However, it is currently not possible to make reliable projections of the future rate of decrease of concentrations in the different environmental media, or the resulting average levels of human exposure to dioxins.

Concentrations of PCDD/PCDF measured in EU Member States

Environmental Matrix	**Measured Typical Range**	**Max. Concentration Contaminated Sites**	**Units***
Soil	<1 – 100	100,000	**ng I-TEQ/kg d.m.**
Sediment	<1 – 200	80,000	**ng I-TEQ/kg d.m.**
Air (ambient) **(bulk deposition)**	<1 – 100s <1 – 100s	14,800	**fg I-TEQ/m^3** **pg I-TEQ/m^2 d**
Sewage Sludge	<1 – 200 (average 10 – 40)	1,200	**ng I-TEQ/kg d.m.**
Spruce/Pine Needles (biomonitors)	0.3 – 1.9	100	**ng I-TEQ/kg d.m.**

***** d.m. = dry matter.

In the past, the main focus of national regulatory activity to reduce or control dioxin releases to the environment in EU Member States has been stack emissions from waste incinerators. Indeed, regulation relating to dioxin releases to air has, in the majority of Member States, already gone beyond the requirements of the existing Incineration Directives and the limit value for air emissions (0.1 ng I-TEQ/m^3) proposed in the Waste Incineration Directive (98/0289 SYN) is widely applied to existing and new Municipal Solid Waste Incinerators (MSWI), as well as for the incineration of hazardous waste. However, no Member State has yet gone beyond the requirements of current EC legislation in its regulation of dioxin releases to water. The focus of regulatory activity within Member States is now moving towards industrial processes, as important sources of dioxin releases to both air and water, such as ferrous and non-ferrous metal production processes and other combustion sources. Despite the attention given to the regulation of dioxin releases, there is no consistent approach to monitoring the state of the environment with respect to dioxins within EU Member States.

RECOMMENDATIONS

The work undertaken within this study has been extensive and has led to a wide range of conclusions and recommendations. This Executive Summary focuses on the findings which are of particular relevance to the European Commission; other recommendations, which are equally important but of more general significance, can be found in the Summary Report and the reports on each of the individual Tasks comprising the study. In presenting the recommendations below consideration has been given not only to their importance to the Commission but also to the practicality of their implementation. The focus has been placed on measures aimed at reducing human exposure to dioxins in the short-term and to maintaining exposure at safe levels throughout the medium/long term. It is, therefore, recommended that the Commission:

1. **undertake** a cost/benefit analysis to optimise the control of dioxin releases to the atmosphere and aqueous environment from the main industrial sources, thus extending the actions of individual Member States and harmonising the regulation of emissions across the EU. This would build upon the work undertaken by Landesumweltamt Nordrhein-Westfalen (LUA), on behalf of EC DG XI, to construct an inventory of the sources of dioxin emissions to air, land and water across the EU. Within this context, any future regulation should take due account of emission rates (eg. g/year) as well as concentrations of dioxin in waste streams (eg. ng TEQ/m^3), such that processes with high emission rates but low concentrations might be fairly regulated in comparison to those with low emission rates but high concentrations;

2. **instigate** the development of indicators to monitor the impact of regulatory controls on future levels of human exposure to dioxins and dioxin-like PCBs. These should include concentrations in ambient air and deposition, sediments and human blood (human breast milk is already monitored within the WHO co-ordinated programme). Standardisation of sampling, analytical and reporting procedures will be essential;

3. **instigate** the establishment and implementation of Maximum Tolerable Concentrations (MTCs) of dioxins and dioxin-like PCBs (as identified by WHO) for key foodstuffs across EU Member States. In collaboration with the appropriate Agencies, due account will have to be taken of geographical variations in diet and consideration given to the mechanisms and possible routes to contamination, as well as the procedures required to monitor compliance;

4. **instigate** actions to identify the main contributors to dietary exposure to dioxins and dioxin-like PCBs in Southern Member States; including an improved understanding of the significance of climate, agricultural practices and dietary regimes which differ from those of the Northern Member States. This might draw upon the existing network of research organisations across Europe. Such information is necessary to ensure that any future policies aimed at reducing exposure to these compounds are relevant and applicable throughout the European Union;

5. **encourage** Member States to put in place a system for Public Information, including information on the concentration of dioxins and dioxin-like PCBs in particular foodstuffs, actions already taken to limit these and guidance, where necessary, on recommended levels of consumption for particular foods. This should present a cost-effective route to targeting ‘at risk’ groups within the community, which might include various cultural, religious and ethnic groups, who consume above average quantities of certain foods, and of providing the information necessary for them to reduce their exposure to dioxins;

6. **encourage and support** the development of a better understanding of the importance for breast-fed infants of short periods of high exposure to dioxins and dioxin-like PCBs, including the effects on neurological, immune system, reproductive system, endocrinological and intellectual development. Such work should include measurements of the rates of accumulation of these compounds in the body tissue of breast-fed infants, both for the first-born and subsequent children. Although the wider benefits of breast-feeding are well recognised, such information is required in order to reduce the uncertainties and, in due course, to allow a full cost/benefit analysis to be carried out of the options for reducing exposure to dioxins and dioxin-like PCBs;
7. **encourage** Member States to adopt the WHO recommended TDI of 1-4 pg TEQ/kg/day (including dioxin-like PCBs).

Contents

1 Introduction

There is considerable public, scientific and regulatory concern over the possible adverse health effects of chronic exposure to trace levels of persistent organic pollutants. The class of compounds made up of the polychlorinated dibenzo-*p*-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF), often collectively known as dioxins, has received widespread attention and attracted a great deal of research, following the accidental release of the most toxic of these (2,3,7,8 TCDD) at Seveso in 1976.

Dioxins, and dioxin-like compounds which may have similar effects, are found in all environmental compartments, are persistent and, being fat soluble, tend to accumulate in higher animals, including humans. Their resistance to degradation and semi-volatility means that they may be transported over long distances and give rise to trans-national exchanges of pollutants. In addition, dioxins released into the environment many years ago continue to contribute to contemporary exposure.

Dioxins have never been intentionally manufactured but can be released into the environment from a number of different sources; including chemicals manufacturing, combustion processes, metallurgical processes, paper and pulp processing. Although there are 210 congeners of PCDD/PCDF, only the 17 which have chlorine substitution in at least all of the 2,3,7,8 positions are of concern, owing to their toxicity, stability and persistence in the environment. In order to simplify the handling of data on the individual compounds, a system of toxic equivalency factors (TEFs) is used to derive an equivalent concentration of the most toxic dioxin (2,3,7,8 TCDD). This enables the toxicity of complex mixtures to be expressed as a single number - the toxic equivalent or TEQ (see Appendix 1).

Previous studies have shown that the principal route to exposure of the general human population is through ingestion of food which carries trace levels of dioxins. In view of this, experts have derived acceptable or tolerable daily intakes (TDIs), designed to ensure that the human population is not exposed to levels of dioxin that could give rise to adverse effects.

Due to the complexity of studying the effects of trace doses of a mixture of chemicals, there is considerable scientific debate about the acceptable level of exposure to dioxins. There is uncertainty about the mechanism of action of the compounds, in relation to causing a range of physical effects in humans and animals, and the alternative interpretations of the available data have led to significant differences in the recommended tolerable dose - notably between the United States Environmental Protection Agency (US EPA) and the World Health Organisation (WHO). In 1990, a WHO (Europe) review group recommended that a daily intake of not more than 10 pg 2,3,7,8 TCDD /kg body weight would give an acceptable level of protection for human health. Whereas, the US EPA advocated a daily intake of less than 0.006 pg TCDD/kg body weight.

In 1998, the WHO European Centre for Environment and Health (WHO-ECEH) and the International Programme on Chemical Safety (IPCS) convened a group of international experts, in order to perform a health risk assessment of dioxin-like compounds. This was based on the most up-to-date knowledge and information regarding critical effects (including developmental, reproductive, hormonal, immune system and neurobehavioural effects), dose-response relationships and quantitative risk extrapolation. A TDI of 1-4 pg TEQ/kg body weight (including dioxin-like PCBs) was recommended. The US EPA has yet to complete its own reassessment.

Over the past two decades the European Commission has implemented wide ranging legislation aimed at directly or indirectly reducing or controlling the release of dioxins into the environment, with the objective of reducing human exposure and protecting human health. However, the recent WHO re-evaluation of the toxicology of dioxins has suggested that additional measures might be required, at the Community level, to further reduce human exposure to an acceptable level, within an appropriate timescale. However, such action can only be formulated on the basis of a detailed knowledge and understanding of the effectiveness of existing legislation, any continuing risk to human health and ecosystems, and an appreciation of the additional control measures already being implemented by individual Member States.

It is the objective of this study to provide information and recommendations, which will act as a sound basis for the formulation of future policy to reduce exposure to dioxins, in order to further protect the population and ecosystems of the European Union.

1.1 SCOPE

In seeking to establish the current situation within the EU the scope of this work has been broad; encompassing current concentrations of dioxin in the environment, longevity and environmental transport, current levels of human exposure, concentrations of dioxin in the human body and observed trends, an analysis of acceptable levels of exposure for humans and the ecosystem. In addition, in considering future policy options, it has been necessary to establish what legislation and guidelines are already in place within Member States, which go beyond the requirements of existing EC Directives.

In view of the broad scope of the work it has been necessary to consider only PCDD/PCDFs and not to include PCBs, although conclusions relating to PCDD/PCDFs have been interpreted in the broader context of other dioxin-like compounds.

1.2 METHODOLOGY

Data have been compiled through contacts with Government Departments, Agencies, research organisations and individuals within all the EU Member States, as well as through reference to the published literature. As issues relating to dioxins fall across a range of disciplines this has involved contacts with Ministries of the Environment, Health, Industry, Agriculture, Fisheries and Food and the exercise of data collection has been extensive. No new research has been undertaken as part of this project, rather the aim has been to assemble, compare and critically review the most recent data available from across the EU, in order to determine the current situation.

1.3 STRUCTURE

The study has been divided into nine separate Tasks under the following headings:

1. Member State Legislation and Programmes
2. Environmental Levels
3. Environmental Fate and Transport
4. Human Exposure
5. Human Tissue and Milk Levels
6. Trends
7. Ecotoxicology
8. Human Toxicology
9. Generic Issues

It was not within the scope of this study to consider sources of dioxins, which have been the subject of a number of other recent studies.

The summary report from each of the above Tasks constitutes a component of the Main Report on the study, and describes the findings of the Task, the conclusions and recommendations. Each Task Report is supported by a Technical Annex, providing the detailed information and data underlying the analysis, with appropriate references to the published literature. Each of these reports has been reviewed by selected experts in each of the Member States, to confirm the accuracy and completeness of the factual information reported.

This Summary Report draws together the main findings of the study as a whole, and presents them in a format which is accessible to officials and policy makers within the European Commission and national governments.

Section 2 of this report summarises the main findings and conclusions of each of the Tasks comprising the study and the recommendations are presented in Section 3.

2 Analysis

2.1 MEMBER STATE LEGISLATION AND PROGRAMMES

The European Commission has introduced twelve Directives which, directly or indirectly, reduce or control the release of dioxins into the environment. Member States are legally required to transpose EC Directives into their national legislation within a specified period of time and, therefore, for the purpose of this study, it has been assumed that all Member States have already complied with the requirements of the Directives under consideration. It was not within the scope of the study to check either transposition or compliance.

This study has sought to identify whether Member States have already gone beyond the requirements of the specified EC Directives relating to dioxins in the environment and, if so, in what way and to what extent. It has also sought to identify whether target concentrations have been set for dioxins in ambient air, stack emissions, waste water, soils, sediments and foods, their values and whether they are recommendations or part of national legislation. Information has also been compiled on the national monitoring programmes currently underway within Member States, aimed at assessing the state of the environment with respect to dioxins and/or the effectiveness of measures taken. Any relevant nationally funded research programmes have also been identified.

A country has been deemed to have 'gone beyond' the requirements of an EC Directive if:

- it has set target concentrations for dioxins in a specified environmental medium which exceed the requirements of the Directive; this might be either that a target has been set where none was previously required or a more stringent maximum concentration has been set by the national authorities;
- it has addressed processes or media not regulated by existing EC Directives.

Table 1 presents a summary of the main findings of the study.

In the past, the main focus of national regulatory activity to control dioxin releases to the environment has been stack emissions from waste incinerators. However, in several Member States waste incineration is still an important source of dioxins, and only through implementing the requirements of the proposed Waste Incineration Directive will the importance of the sector be reduced. Indeed, regulation relating to dioxin releases to the air has, in the majority of Member States, already gone beyond the existing Incineration Directives, and the limit value for air emissions proposed in the Draft Waste Incineration Directive (0.1 ng I-TEQ/m^3) is widely applied. However, no Member State has yet gone beyond the requirements of current EC legislation in its regulation of dioxin releases to water.

Within Member States attention is now moving towards industrial processes, as important sources of dioxin releases to both air and water, and the levels of dioxin contamination in dairy foods, as a major route to human exposure (although there are currently no guidelines relating to fish, which is also an important source of exposure in certain countries). In both of these areas there is evidence that countries are moving ahead of EC regulation and implementing national guidelines and/or legislation. Nine Member States have recommended a maximum TDI of dioxin, five of which are more stringent than the previous WHO guideline of 10 pg 2,3,7,8-TCDD/kg body weight (UK includes PCBs in the TDI), with the remaining four equal to the guideline.

Five countries have established guidelines concerning dioxin concentrations in soils, but no ambient air quality standards have been set, or standards for deposition.

Five Member States have introduced legislation completely prohibiting the production, marketing and use of PCP, thus going beyond the requirements of the EC Directive.

There is no general approach or consistent pattern across the EU to monitoring the 'state of the environment' with respect to dioxins. The largest *number* of both monitoring and research programmes focus on human exposure, including work on dioxin concentrations in foods as well as concentrations in human tissue, blood etc as indicators of exposure, although the balance of *resources* employed might be quite different. Most activity, with respect to regulation, monitoring and research, is focused in the Northern European States.

2.2 ENVIRONMENTAL LEVELS

During this study extensive amounts of quantitative data on dioxin concentrations in the various environmental media and other matrices have been collected from EU Member States. These matrices include soils, sediments, air, vegetation, wildlife, sewage sludge, residues and consumer goods. Early results date back to the 1970s and many countries, such as Austria, Finland, Germany, the Netherlands, Sweden and the United Kingdom, have carried out monitoring activities or research programmes, to either update their existing databases or to gain further insight into sources, fate and transport of dioxins in the environment. For Ireland, Luxembourg, and Greece there is only limited information available from a few or single studies. For Italy, there is little information available, and for Belgium and Spain data which are available relate to only one part of the country, namely Flanders and Catalunya, respectively. Portugal is in the process of initiating dioxin-related programmes, France is intensifying its efforts to obtain more data, especially in the neighbourhood of incinerators and other combustion units, and Denmark is proposing to carry out an overall re-evaluation of dioxin in the country to update and enlarge the database.

It has not been possible to carry out any statistical analysis of available data, as countries or individual reports provided aggregated data covering varying numbers of samples, time periods and locations. From an analysis of the data it was, in most cases, impossible to distinguish significant differences in background concentrations of dioxin in rural and urban locations. In several locations, seasonal trends have been observed, with lower air concentrations of dioxin in summer and higher concentrations in winter. The cause for these differences is not fully understood: some authors indicate additional combustion sources, whereas others relate the differences to meteorological conditions with poor mixing in the colder season.

Most data are available for dioxin concentrations in soils and, to a lesser extent, sediments and air. Biomonitors, such as vegetation or cows' milk, have been successfully applied to identify or monitor ambient air concentrations in the neighbourhood of potential point sources, although a linear correlation between dioxin concentrations in vegetation and air samples cannot be established. Due to public concern regarding dioxins and furans, many studies have been aimed at identifying potential 'hotspots' of contamination. As a result, such locations have been more intensively sampled and analysed than background or baseline locations.

In most countries a broad range of dioxin concentrations has been detected in all media. Table 2, below, presents the range of reported typical concentrations and maximum concentrations measured in locations with known contamination.

It is clear from this study that there are many data on environmental concentrations of dioxin, which cover many environmental compartments and other matrices, such as consumer goods and residues. However, the information is not easily accessible and is very scattered, especially in countries with a long dioxin history. In such cases, the relevant governmental agencies do not necessarily own the data or maintain a comprehensive database containing the results generated in the country. This fact is due to the widespread interest in issues relating to dioxins and shared responsibilities within each country.

Table 2: Concentrations of PCDD/PCDF measured in EU Member States

Environmental Matrix	Measured Typical Range	Max. Concentration Contaminated Sites	Units
Soil	<1 – 100	100,000	**ng I-TEQ/kg d.m.**
Sediment	<1 – 200	80,000	**ng I-TEQ/kg d.m.**
Air (ambient) **(bulk deposition)**	<1 – 100s <1 – 100s	14,800	**fg I-TEQ/m^3** **pg I-TEQ/m^2 d**
Sewage Sludge	<1 – 200 (average 10 – 40)	1,200	**ng I-TEQ/kg d.m.**
Spruce/Pine Needles (biomonitors)	0.3 – 1.9	100	**ng I-TEQ/kg d.m.**

2.3 ENVIRONMENTAL FATE AND TRANSPORT

The previous Task identified the environmental media in which dioxins have been detected and the measured concentrations which can be regarded as typical of background or contaminated locations. However, it is an essential component in the development of policy to control and reduce human exposure to dioxins, that a thorough understanding is developed of how these compounds behave in the environment and the pathways which lead to human exposure.

A critical evaluation has, therefore, been made of the current state of knowledge and understanding. The average exposure of the EU population to PCDDs, PCDFs and PCBs, at around 1-6 pg I-TEQ/kg body weight/day, is already below the 1990 WHO recommended TDI and is gradually declining (see Section 2.4: Human Exposure). An examination has, therefore, been made of the feasibility of developing models to predict how exposure might change in the future, and whether it is likely to continue declining at a rate sufficient to bring it below the new recommended TDI, within an acceptable timescale.

Once released into the environment, dioxins follow a range of familiar routes. In the atmosphere they exist in both the gaseous phase and bound to particles, depending upon the environmental conditions, and are deposited on soil, vegetation and water bodies by wet and dry deposition or in mist. Dioxins have been measured in areas with no local sources and it can, thus, be deduced that they are available for long-range transport over a scale of 1000s of kilometres.

Soil run-off can transfer dioxins from land to water and, in water bodies, dioxins rapidly adsorb to organic matter and subsequently settle out in sediments. Once associated with soils and sediments dioxins degrade slowly and may persist for many years. They may be released by both natural and anthropogenic processes over extended timescales, with soils and sediments representing the greatest environmental reservoirs of dioxin. Landfill sites are also thought to be important reservoirs, since some contain incinerator ash and chemical wastes containing relatively high concentrations of dioxin in comparison to other media.

The major routes to human exposure are those relating to foodstuffs. Hence, in Northern Europe, research interest has focused on the air-grass-cow exposure pathway, although consumption of seafood is also important. Other pathways representative of Southern European climates, agricultural practices and dietary regimes have not been studied to the same extent. (See Section 2.4 for dietary exposure).

Dioxin fate and transport has often been modelled, to predict movement between environmental compartments (e.g. air to land) or from one part of an environmental compartment to another (e.g. water to sediment), often with the aim of predicting the media that are likely to accumulate the highest concentrations and the concentration in those media.

Human exposure from specific sources (e.g. waste incinerators) has also been modelled, and has involved using multi-media models of varying complexity. However, some of the dioxin transport and fate models use parameters which are often scarce, or show a wide range of possible values. Predictions that are based on such imprecise data will also be inherently imprecise.

It has been concluded that it is, currently, not possible to make reliable projections of future average levels of human exposure to dioxins, as vital information is lacking in a number of important areas. These include the mechanisms and rates of key environmental transfer and degradation processes; the role played by reservoir sources in determining future levels of exposure; the pathways to exposure of citizens in Southern European Member States and validation of the output of existing environmental models against measured data.

2.4 HUMAN EXPOSURE

The most important route for human exposure to dioxins is food consumption, contributing 95-98% of total exposure, with products of fish and animal origin making the greatest contribution. Data on concentrations of dioxins in foodstuffs are available for most EU Member States, with the most comprehensive data sets being available for Finland, Germany, the Netherlands, Spain, Sweden and the United Kingdom. Although some data are available on concentrations in foods from areas of contamination in other countries, no data on background concentrations in foods have been identified for Austria, France, Greece, Luxembourg or Portugal.

The range of measured concentrations in the various food types from background locations or retail sources across the EU is shown in Table 3, below. The fish data, in particular, have a very wide range because of the differences in fat content and ages of the fish analysed. In Sweden much emphasis has been put on marine fish, because of the high measured concentrations of dioxin and their importance in the Swedish diet. These fish are, therefore, over represented in the figures shown and removing the Swedish data from the set reduces the range from 2-214 pg I-TEQ/g fat to 2-50 pg I-TEQ/g fat.

Table 3: Measured background concentrations of PCDD/PCDFs in foodstuffs across the EU (pg I-TEQ/g fat)

	Milk	Milk products	Meat and products	Poultry	Fish	Eggs	Fats and oils	Bread and cereals *	Fruit and vegetables *
Min.	0.2	0.5	0.1	0.7	2.4	1.2	0.2	0.1	0.01
Max.	2.6	3.8	16.7	2.2	214.3	4.6	2.6	2.4	0.2

* pg I-TEQ/g fresh weight

Data on total dietary exposure are available for eight Member States, with none available for Austria, Belgium, Greece, Ireland, Italy, Luxembourg and Portugal.

Estimates of average total dietary exposure to PCDD/PCDFs for consumers has been found to vary from 69 pg I-TEQ/day in the Netherlands to 210 pg I-TEQ/day in Spain, equal to 0.93-3.0 pg I-TEQ/kg body weight/day respectively, assuming an average body weight of 70 kg. The WHO recommended TDI of 1-4 pg TEQ/kg bw/day includes exposure to dioxin-like PCBs. PCDD/PCDFs and dioxin-like PCBs each contribute roughly 50% of total dietary exposure measured as TEQ, indicating that, for many individuals, total exposure will exceed the recommended TDI.

Variations in exposure within countries have been considered in three dimensions, where data are available: by age; through time; and for specific population sub-groups or ‘at risk’ groups. In general, total exposure increases with age in childhood. However, when normalised by body weight specific exposure is found to decrease with childhood age due to increasing bodyweight.

Exposure has decreased over time in all countries where data are available. In the United Kingdom exposure has fallen by 71% between 1982 and 1992 (equivalent to 12% per year), and in Germany it has fallen by 45% between 1989 and 1995 (9% per year).

‘At risk’ individuals have been defined as those people consuming higher than average amounts of fatty foods, particularly fatty fish and fish products, but also meats and dairy products. Such high level consumers (95 or 97.5 percentile) have been exposed to around 3.1 pg I-TEQ/kg bw/day in the Netherlands and 1.7-2.6 pg I-TEQ/kg bw/day in the United Kingdom. Once again, when PCBs are also taken into account, the exposure of such individuals is likely to exceed the WHO recommended TDI, of 1-4 pg TEQ/kg bw/day.

2.5 HUMAN TISSUE AND MILK LEVELS

Dioxins are ubiquitous in the environment and the entire population of the EU has, to some extent, been exposed to dioxins primarily through the ingestion of contaminated foodstuffs, although accidental and occupational exposure can also occur. Dioxins accumulate in the body and the average concentration increases progressively with age. Concentrations have been measured in human breast milk, blood and body tissue, and are an indicator of the exposure history of the individual or group of individuals concerned. It is recognised that dioxin concentrations can be influenced by a number of factors; some are directly associated with the various possible routes to exposure; such as the location, occupation, living conditions and dietary habits of the individual; others include the number of breast-fed children and length of the nursing period; the age, sex and body weight of the subject concerned. However, within the scope of this study, it has proved impossible to identify comparable sets of data on which to base a quantitative assessment of the impact of most of these factors. The only influencing factor which could be analyse in any detail was location; whether the subjects concerned lived in a rural, urban or industrial environment within each Member State.

Data on the concentrations of dioxin in human breast milk, blood and body tissue, measured within EU Member States have been assembled, compared and critically reviewed. However, the only substantial source of comparable data relating to the majority of Member States is the WHO co-ordinated study of dioxin concentrations in human breast milk which, by definition, relates only to young women. There is very little comparable data relating to concentrations in the blood and tissue of children, teenagers, men or older women.

Over the five-year period from 1988 to 1993 the average dioxin concentration in breast milk in EU Member States decreased by around 35% (8.3% per year), with a slightly higher decrease in rural areas and slightly lower in industrial areas. Measurements taken in Germany over the eight year period from 1988 to 1996 showed that the average concentration of dioxins in the blood of adult males decreased by around 64% (12% per year). The annual rate of accumulation of dioxins in the body had, therefore, decreased and was estimated to be around 0.3 pg I-TEQ/g fat per year due, primarily, to the continuous ingestion of contaminated foodstuffs.

Although the only comparable data relating to the concentration of dioxins in the population of EU Member States is for nursing mothers, it is safe to assume that, for the population as a whole, the rate of accumulation of dioxins in the body has declined over the past two decades. It is, therefore, clear that the actions taken to reduce human exposure to dioxins, whether by limiting and controlling the release of dioxins into the environment, restricting the movement of dioxins through the foodchain or establishing permissible concentrations in foodstuffs, have led to a reduction in the rate at which dioxins accumulate in the body of the ‘average’ citizen of the European Union.

However, it is also appropriate to consider here the implications of the concentrations of dioxin in human breast milk for the daily intake of breast-fed infants. Data assembled in the course of this study suggests that, in 1993, the dioxin intake of first-born infants, up to 2 months of age, might be around 106 pg I-TEQ/kg/day in rural areas of the EU and 144 pg I-TEQ/kg/day in industrial areas. This would suggest that the exposure of such infants could be a factor of between 27 and 144 times greater than revised WHO recommended TDI, without accounting for dioxin-like PCBs. However, the WHO recommendation is based upon an average lifetime exposure and it might be assumed that the high levels of infant exposure are counter-balanced by lower levels of exposure in later life. This could be so, but consideration must also be given to whether the effects of short periods of very high exposure differ from those of prolonged periods of much lower exposure, particularly when the former occur during a critical period for infant neurological, physical and intellectual development.

2.6 TRENDS

During the course of this project a number of individual studies have been identified which have specifically investigated trends in dioxin concentrations in the environment, wildlife, foodstuff, human milk and blood. These have mostly addressed time trends, rather than spatial variations or congener patterns.

Although the information is sometimes somewhat contradictory, it can be concluded that the anthropogenic input of dioxins into the environment started around 1940. Earlier samples only contained very low concentrations of dioxin, which might have originated in minor sources such as forest fires, domestic heating and smaller industrial activities. Since 1940 marked increases in concentration have been observed which, generally, peaked between the late 1950s and 1970s and started to decline in more recent years, as a result of measures taken to reduce dioxin emissions. It was found that the congener profiles also changed with time: whereas the older congener profile is indicative of the production and use of chlorinated phenols, the more recent profile is indicative of combustion sources.

Congener-specific dioxin analysis (very often using high resolution mass spectrometers) has only been used routinely for around 10 years and, thus, long time series of data are not available. The extension of a number of current monitoring and research programmes, for at least a decade, in order to establish an adequate database of trends in dioxin concentrations in the environment, would greatly assist the implementation of a number of international agreements. These would include the 5th Action Plan of the EU, which states that dioxin emissions should be reduced by 90% between 1985 and 2005; the UN-ECE Long-Range Transport and Assessment Programme, which also sets target dates for the minimisation of dioxin emissions; and the future POPs Convention, which will aim to reduce dioxins in the environment.

Trend analysis is, clearly, a helpful tool in investigating the input and occurrence of dioxins in the environment and human food-chain. It helps to determine the effectiveness of measures taken by governments and agencies to reduce the release of dioxins into the environment. The data have shown clearly that there is a need for long-term follow-up of such data gathering, as between-year variation can be significant and, thus, long time periods are required in order to establish trends. As there is still dynamic in many matrices and locations, it can be assumed that the dioxin concentrations in the Member States of the EU have not yet levelled of and, thus, there is a need to continue the analyses that have established the present trends.

2.7 ECOTOXICOLOGY

Hitherto, political and research activity relating to dioxins has been directed at assessing and reducing levels of human exposure, although this family of chemicals is also known to have effects on other animals. These effects are of importance because affected animal populations may have commercial or conservation value, or be important pathways to human exposure. A review has been carried out of the ecotoxicological effects of dioxins and an examination made of attempts to set Environmental Quality Standards for these pollutants.

A wide range of toxicological effects has been observed in wildlife exposed to dioxins. They range from chronic to acute and include reduction in reproductive success, growth defects, suppression of the immune system and formation and development of cancers. However, outside the laboratory, it has often not been possible to demonstrate a clear cause/effect relationship between the observed effects and exposure to dioxins. A range of sensitivities to dioxin toxicity has been noted in different animal groups, and early life stages of most species studied (eggs, embryos, larval stages) tend to be more sensitive than adults. This is because the chemicals act on a number of systems important to growth and development, such as Vitamin A and sex hormone metabolism. However, a number of studies have shown that the total toxic quotient of dioxins and dioxin-like compounds, in field samples of birds and mammals, can largely be accounted for by PCBs rather than PCDD/PCDFs.

The conventional approach to setting Environmental Quality Standards (EQSs) involves relating pollutant levels in water to observable effects in target species. This approach has been used for dioxins in several countries. However, it is now not generally considered applicable to dioxins, because of their very low solubility in water and high affinity for adsorption to organic matter. Animals and plants will, generally, be exposed to dioxins via close association with particulate organic matter, and not through uptake of dissolved dioxins in water. A number of methods for establishing EQSs have been developed, the best of which is the Tissue Residue Based method. This method allows calculation of a sediment contamination threshold, above which adverse effects would be expected in the receptor species to be protected. Published environmental quality guidelines vary considerably, depending upon the assessment method used and the environmental compartment being protected.

Within the EU the Netherlands and United Kingdom have been developing the concept of environmental quality guidelines for sediments. However, these have not yet been widely applied because they represent a departure from established EQS frameworks. Some authorities have indicated that there is also a reluctance to set firm guidelines, since this would require expensive sampling/monitoring programmes to check compliance, when there are already many other compounds of similar or greater concern.

There are conflicting views as to whether environmental quality guidelines set to protect natural ecosystems need to be more or less stringent than those set to protect the human population. The values identified by this study do not consistently support either view.

2.8 HUMAN TOXICOLOGY

At present, exposure to dioxins in the general population of the EU is at a level where subtle health effects might occur and it is, therefore, of utmost importance that the assessment of health risk is improved. Over recent years a vast number of research reports has been published on the toxicity of dioxins and, in particular, the most toxic dioxin, TCDD. This study has reviewed the toxicological effects of dioxins, recent assessments of health risk and exercises to set Tolerable Daily Intakes (TDIs) for dioxin-like compounds.

Toxicology can be defined as the study of the harmful effects of chemicals upon biological systems. Besides epidemiological studies in humans, knowledge on human toxicology is mostly based upon extrapolation from studies in experimental animals (i.e. mammals). Work on the molecular and cellular effects of dioxins to date suggests that the way in which the various congeners act is broadly the same. This is important, because it allows assumptions to be made of the effects for many dioxins which have not been tested toxicologically.

Dioxin-like compounds elicit a broad spectrum of responses in **experimental animals**. Among these effects are:

- liver damage (hepatoxicity);
- suppression of the immune system (immunotoxicity);
- formation and development of cancers (carcinogenesis);
- abnormalities in foetal development (teratogenicity);
- developmental and reproductive toxicity;
- skin defects (dermal toxicity);
- diverse effects on hormones and growth factors;
- and induction of metabolising enzyme activities (which increases the risk of metabolising precursor chemicals to produce others which are more biologically active).

Cancer was for long considered as the critical effect, i.e. the most sensitive effect, of dioxin exposure. However, in recent years, the foetus and newborn offspring of several species have been shown to be particularly sensitive to TCDD, resulting in effects on reproduction, immune function and behaviour.

In humans effects associated with exposure to dioxins are mainly observed in accidental and occupational exposure situations. A number of cancer locations, as well as total cancer, have been associated with exposure to dioxins (mostly TCDD). In addition, an increased prevalence of diabetes and increased mortality due to diabetes and cardiovascular diseases has been reported. In children exposed to dioxins and/or PCBs in the womb, effects on neurodevelopment and neurobehaviour (object learning) and effects on thyroid hormone status have been observed at exposures at or near background levels. At higher exposures, children exposed transplacentally to PCBs and PCDFs show skin defects, developmental delays, low birth-weight, behaviour disorders, decrease in penile length at puberty, reduced height among girls at puberty and hearing loss. It is not totally clear to what extent dioxin-like compounds are responsible for these effects, when considering the complex chemical mixtures to which human individuals are exposed. However, it has been recognised that subtle effects might already be occurring in the general population in developed countries, at current background levels of exposure to dioxins and dioxin-like compounds.

The risk assessments of dioxins reviewed as part of this study used different approaches and established different TDIs. The risk assessment of US EPA (1985) was unique in that it assumed a linear dose-response relationship for dioxin-induced cancer, which is usually only assumed for carcinogens which damage the genetic material (DNA). The one in a million cancer risk was calculated for an exposure of 0.006 pg TCDD/kg body weight per day (corresponding to a TDI). This level lies about three orders of magnitude below the currently estimated background exposure of TEQs.

All other risk assessments used the uncertainty, or safety factor approach. Depending on the choices of critical effect and uncertainty factors, the recommended TDIs were in the range of 1-10 pg TEQ per kg body weight. These assessments supported the use of the TEF-scheme in risk assessment and risk management of PCDDs, PCDFs and, more recently, PCBs.

The WHO risk assessment performed in 1998 is the most recent risk assessment. It is of high quality, due to the broad range of highly qualified international experts participating. In the WHO risk assessment all available new data on developmental effects of dioxins were evaluated. In addition, dose extrapolation from animals to humans was performed on a body burden basis, which is more toxicologically relevant than using external dose. The WHO risk assessment was based on the most recent knowledge regarding critical effects, dose-response relationships and quantitative risk extrapolation. The assessment recommended a TDI of 1-4 pg TEQ/kg body weight which, in contrast to the earlier assessments, included dioxin-like PCBs.

2.9 GENERIC ISSUES

A very brief assessment has been made of a range of issues which are of general relevance to a number of Tasks within the study. These relate, primarily, to data generation, reporting and interpretation. Assessing the concentrations of dioxin in the various environmental media and other matrices across the EU Member States, and any observed trends, has proved to be particularly difficult because of wide variations in the sampling strategies employed by the different monitoring/research groups involved. In addition, the reporting of analytical data often provides inadequate or insufficient information for comparisons to be made between different data sets.

It is clear that the value to the broader research community, as well as to policy makers, of the data generated could be greatly enhanced if a number of straightforward procedures were followed. These could be encapsulated in formalised standards for sample collection, analysis and reporting, comparable with the European CEN standard for the analysis of hazardous waste emissions.

The general lack of information on dioxin concentrations in the Southern European Member States means that is not currently possible to analyse geographical trends. However, when new monitoring and research programmes are set up in these countries, it will be essential that the procedures adopted are consistent, and the data comparable, with existing programmes in other Member States.

3 Recommendations

The recommendations resulting from each of the individual Tasks comprising this study are presented in full below and, in view of the very broad scope of this work, a wide range of issues has been addressed. There is, inevitably, some overlap between the various Tasks, which serves to strengthen the basis on which these recommendations are made. In the Executive Summary to this report the recommendations are presented in a summarised form, which focuses on measures aimed at reducing human exposure to dioxins in the short term and to maintaining exposure at safe levels throughout the medium to long term.

TASK 1 – MEMBER STATE LEGISLATION AND PROGRAMMES

In order to further reduce and/or control the exposure of the population to dioxins the following measures should be implemented at the Community level:

- Recommendations should be made of appropriate limit concentrations for dioxin releases to the atmosphere and aqueous environment from the main industrial sources, thus extending the actions of individual Member States by regulating emissions across the EU. This would build upon the work undertaken by Landesumweltamt Nordrhein-Westfalen (LUA), on behalf of EC DG XI, to construct an inventory of the sources of dioxin emissions to air, land and water across the EU.
- Future regulation should take due account of emission rates (eg. g/year) as well as concentrations of dioxin in waste streams (eg. ng TEQ/m^3), such that processes with high emission rates but low concentrations might be fairly regulated in comparison to those with low emission rates but high concentrations.
- The production, marketing and use of PCP should be phased out in all Member States.
- Recommendations should be made of maximum concentrations of dioxin in milk, dairy products, fish and fish products, thus regulating a major route to human exposure for all Member States.
- Ambient air quality and deposition monitoring programmes for dioxins should be set up, in order to measure the effectiveness of regulation and control strategies.
- Methods should be established for implementing guidelines for dioxin concentrations in soils classified according to land use; whether agricultural, residential or recreational etc, and appropriate procedures for land remediation.
- A co-ordinated and consistent approach to monitoring the state of the environment with respect to dioxins should be implemented across the EU, together with an integrated approach to research, thus ensuring value for money and appropriate coverage of the key issues. This could build upon the existing regional fora, such

as the Oslo and Paris Commission (OSPARCOM) and the UN-ECE European Monitoring and Evaluation Programme (EMEP).

TASK2 – ENVIRONMENTAL LEVELS

- For monitoring purposes, cows' milk has proved to be an appropriate monitor for air quality and human exposure. A substantial database of dioxin concentrations in EU Member States is available and guideline concentrations for human consumption. Thus, it is recommended that the use of cows' milk for monitoring purposes should be further applied and extended within the European Community.
- It is clear from this study that there are many data on environmental concentrations of dioxin, which cover many environmental compartments and other matrices, including consumer goods and residues. However, the information is not easily accessible and is very scattered, especially in countries with a long dioxin history. In such cases, the relevant government agencies do not necessarily own the data or maintain a comprehensive database containing the results generated in the country. This fact is due to the widespread interest in issues relating to dioxins and shared responsibilities within each country. It is recommended that, for compliance with future European Commission Directives, all relevant data from public and private organisations should be reported to the local or federal authorities and, thus, be accessible to governments and the general public.

TASK 3 – ENVIRONMENTAL FATE AND TRANSPORT

It has been concluded that it is currently not possible to make reliable projections of future average levels of human exposure to dioxins. Hence, five recommendations are made of work which should be undertaken in order to make this a feasible prospect for the future:

- A programme of work is required to improve the understanding and quantification of the fundamental transfer processes by which dioxins move between the different environmental media, particularly within the aquatic and terrestrial environments, and the degradation processes occurring within these media.
- The contribution to human exposure from reservoir sources, especially landfills, requires examination, and in particular work to assess the behaviour and degradation processes of dioxins in these environments. Without this knowledge it will be impossible to predict the effect of regulatory controls on the future levels of human exposure.
- Policies aimed at further reducing human exposure to dioxins will have to be relevant and applicable across the EU. Most research work undertaken so far has been focused on the Northern Member States, although circumstances in Southern Member States might be very different. Further research is required to identify the important environmental pathways of dioxins in climates, agricultural systems and dietary regimes representative of Southern Europe.
- Measurement programmes across the Member States should be co-ordinated, in order to provide the data necessary for the validation of the key environmental

models and to extend their current range of application. Some additional, targeted measurements may also be required.

- A dynamic (non-equilibrium) integrated model system should be developed, that would cover the majority of routes to human exposure. The components for this model system may well already be available, although they may require validation, and the output should be probabilistic, in order to take account of the many uncertainties in the available input data and to avoid unrealistically extreme views of possible future levels of exposure.

TASK 4 – HUMAN EXPOSURE

The following recommendations are provided with the objective of improving the information available for establishing levels of exposure to dioxins across the EU and reducing this exposure to be within the new WHO recommended TDI:

- It is clear that many citizens of EU Member States may have a daily intake of dioxins and dioxin-like PCBs in excess of the WHO recommended TDI. As dioxins and dioxin-like PCBs can contribute equally to total TEQ intake, future policy measures should be focused equally on reducing human exposure to both groups of pollutants, in order to protect the health of the European population.

- In view of the importance of PCBs in the total TEQ exposure, it is recommended that a more detailed study of concentrations of PCBs in foodstuffs and total exposure to these compounds across Europe is undertaken.

- Maximum Tolerable Concentrations of dioxins and dioxin-like PCBs should be established for key foodstuffs across Europe, with a view to setting limit or guideline values to be met by the food producers.

- Information on the risks associated with exposure to dioxins and dioxin-like PCBs should be made available to the public, via a suitable public awareness campaign. This could include information on particular foodstuffs, the actions already taken to limit the concentrations of dioxins and dioxin-like PCBs in these and guidance, where necessary, on levels of consumption of particular foods.

- Further analysis is required of the major contributors to dietary exposure in Member States, especially for the Southern European countries. In particular, confirmation is needed of the recent analysis of Spanish breads, cereals, fruit and vegetables that found higher than expected concentrations of dioxins.

- ’At risk’ individuals can be defined as those consuming higher than average amounts of fatty foods, particularly fatty fish and fish products but also meats and dairy products all of which can contain high concentrations of dioxins and dioxin-like PCBs. More information is required on the dietary habits of the various cultural, religious and ethnic groups across the EU before specific.

TASK 5 – HUMAN TISSUE AND MILK LEVELS

There are three main recommendations from this study:

- An EU-wide programme should be established for the routine monitoring of dioxin concentrations in the blood of males and females across all age groups, following similar procedures to the WHO co-ordinated assessment of human breast milk, in order to assess and monitor any changes in the age-related increase in dioxin concentrations as a result of the measures implemented to reduce exposure.
- Measurements are required of the actual rates of accumulation of dioxin in the body tissue of breast-fed infants, both for the first born and subsequent children.
- Whilst recognising the wider benefits of breast-feeding infants, a better understanding is required of the importance of short periods of high exposure to dioxins on the neurological, immune system, reproductive system, endocrinological and intellectual development of such infants.

TASK 6 – TRENDS

As this Task draws on information collected within other components of the study, many of the key recommendations have been made elsewhere. However, a number of more general observations and recommendations are made below:

- As congener-specific dioxin analysis (very often using high resolution mass spectrometers) has only been used routinely for around 10 years, long time series of data are, clearly, not available. Thus, a number of current monitoring and research programmes should be extended for at least a decade, in order to establish adequate series of data to demonstrate trends in dioxin concentrations in the environment. A database of trends in dioxin concentrations in European Union Member States would greatly assist the implementation of a number of important international agreements.
- In general, governmental agencies, research institutions and private laboratories have generated data on dioxin concentrations for specific locations or matrices. Assuming that these samples have been analysed using methods which are comparable with the high standard in dioxin analysis available today, these institutions should be encouraged to continue their programmes on a similar basis.
- A number of Tasks within this study have highlighted the fact that there remain considerable data gaps for a number of countries and, in particular, the Southern EU Member States. New monitoring and research programmes should be set up in these countries in such a way that the procedures are consistent, and the data comparable, with existing programmes in other Member States. Such information would help to establish whether geographical patterns of dioxin concentration exist in the various regions of the EU.
- New Member States of the European Union should be encouraged and assisted in establishing monitoring and research programmes to generate data which is consistent and comparable with that from the existing Member States. If necessary, this should involve support in achieving the highest standards of dioxin analysis.

TASK 7 – ECOTOXICOLOGY

The following actions are recommended for a balanced approach to establishing adequate environmental quality standards for dioxins for application across the EU:

- Member States should be encouraged to identify habitats or areas most likely to be at risk of damage from dioxin contamination.

- Cost/benefit analyses should be carried out to assess the justification for setting, and regulating, environmental quality standards for dioxins.

- Assuming there is a justifiable case (on the basis of cost/benefit) for setting environmental quality standards, effort should be committed to reducing the uncertainty associated with the methods of deriving standards by carefully targeted research into:

  - identification of species the protection of which will ensure the protection of "at risk" habitats or sites;
  - derivation of appropriate bioaccumulation factors, lower effect levels and other input data for the standard-setting methodology for the target receptor species;
  - the effects of chronic or periodic exposure to dioxins.

TASK 8 – HUMAN TOXICOLOGY

The following priority actions are recommended in order to reduce the health risk from exposure to dioxin-like compounds across the EU.

Member States should be encouraged to:

- apply the WHO recommended TDI of 1-4 pg WHO-TEQ/kg/day;
- include both dioxins and dioxin-like PCBs in the TDI for dioxin-like compounds;
- reduce as far as possible the discharge of dioxins to the environment;
- identify highly exposed groups most likely to be at risk of damage from dioxin contamination;
- investigate the need for establishing dietary recommendations for certain foodstuffs.

Effort should be committed to reducing the uncertainty associated with the health risk assessment by carefully targeted research into:

- dose-response relationships, including no adverse effect levels for the developmental effects in animals;
- a more reliable and complete mechanistic understanding and support for the applicability of the TEF concept to the critical effects, i.e. developmental effects of PCDD, PCDF and PCB exposure;
- epidemiological follow-up on reproductive, neurobehavioural, immune system effects, as well as cancer in children exposed to dioxin-like compounds in the womb. These studies should include exposure analysis in order to describe the dose-response relationships of the effects.

TASK 9 – GENERIC ISSUES

Many environmental monitoring and research programmes relating to dioxins are undertaken each year within the EU. The value of the data generated to the broader research community, as well as to policy makers, could be greatly enhanced if a number of straightforward procedures were followed during data generation, analysis and reporting. These are summarised in the following recommendations**:**

- Further work is required on the inter-calibration of dioxin laboratories in order to ensure consistent results across Europe.
- Guidelines/standards are required for environmental sampling, data generation and reporting, which are comparable to the CEN standard for analysis, and which would greatly improve the comparability of results.
- An improved understanding is required of the significance of climate, agricultural practices and dietary regimes to dioxin exposure in Southern Member States of the EU, which differ from those of the Northern Member States. Such information is necessary to ensure that any future policies aimed at reducing exposure to dioxins are relevant and applicable throughout the European Union.
- Governmental agencies, research institutions and private laboratories should be encouraged to make data relating to dioxin concentrations in environmental media and other matrices more widely available, in order to facilitate a more informed debate on the strategic options for reducing human exposure.

Appendix 1

Toxic Equivalency Factors (TEFs)

Many regulatory agencies have developed so-called Toxic Equivalency Factors (TEF) for risk assessment of complex mixtures of PCDD/PCDF (Kutz *et al.* 1990). The TEFs are based on acute toxicity values from *in vivo* and *in vitro* studies. This approach is based on the evidence that there is a common, receptor-mediated mechanism of action for these compounds. However, the TEF approach has its limitations due to a number of simplifications. Although the scientific basis cannot be considered as solid, the TEF approach has been developed as an administrative tool and allows the conversion of quantitative analytical data for individual PCDD/PCDF congeners into a single Toxic Equivalent (TEQ). TEFs particularly aid the expression of cumulative toxicities of complex PCDD/PCDF mixtures as one single TEQ value. It should be noted that, as interim values, TEFs are based on the present state of knowledge and should be revised as new data become available.

Today's most commonly applied TEFs were established by a NATO/CCMS Working Group on Dioxins and Related Compounds as International Toxicity Equivalency Factors (I-TEF) (NATO/CCMS 1988, Kutz et al. 1990). Throughout this study these I-TEFs are used, if not specified otherwise.

The Nordic countries (Scandinavia) developed their own scheme, called the N-TEFs. The N-TEFs are identical to the I-TEFs with one exception, the TEF for the 1,2,3,7,8-Cl_5DF. Whereas in the I-TEF scheme, this congener is given a TEF of 0.05, the Scandinavian countries assigned it a value of 0.01.

In 1997, a WHO/IPCS working group re-evaluated the I-TEFs and established a new scheme. The two schemes are found in the Tables below. The WHO re-evaluation chose also to include *non-ortho* and *mono-ortho*–substituted polychlorinated biphenyls (PCB) into the TEF scheme for dioxin-like toxicity (van Leeuwen and Younes 1998).

No TEFs have been assigned for the non-2,3,7,8-substituted congeners.

References:

Kutz F.W., D.G. Barnes, E.W. Bretthauer, D.P. Bottimore, H. Greim (1990): The International Toxicity Equivalency Factor (I-TEF) Method for Estimating Risks Associated with Exposures to Complex Mixtures of Dioxins and Related Compounds. Toxicol. Environ. Chem. **26**, 99-110.

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van Leeuwen F.X.R. and M. Younes (1998): WHO Revises the Tolerable Daily Intake (TDI) for Dioxins. Organohalogen Compd. **38**, 295-298

Table 1: International Toxic Equivalency Factors (I-TEFs) for PCDD/PCDF (Kutz *et al.* 1980)

Congener	I-TEF
2,3,7,8-Cl_4DD	1
1,2,3,7,8-Cl_5DD	0.5
1,2,3,4,7,8-Cl_6DD	0.1
1,2,3,7,8,9-Cl_6DD	0.1
1,2,3,6,7,8-Cl_6DD	0.1
1,2,3,4,6,7,8-Cl_7DD	0.01
Cl_8DD	0.001
2,3,7,8-Cl_4DF	0.1
1,2,3,7,8-Cl_5DF	0.05
2,3,4,7,8-Cl_5DF	0.5
1,2,3,4,7,8-Cl_6DF	0.1
1,2,3,7,8,9-Cl_6DF	0.1
1,2,3,6,7,8-Cl_6DF	0.1
2,3,4,6,7,8-Cl_6DF	0.1
1,2,3,4,6,7,8-Cl_7DF	0.01
1,2,3,4,7,8,9-Cl_7DF	0.01
Cl_8DF	0.001

Table 2: WHO Toxic Equivalency Factors (WHO-TEFs) for PCDD/PCDF (van Leeuwen and Younes 1998)

Congener	Humans/Mammals	Fish	Birds
2,3,7,8-Cl_4DD	1	1	1
1,2,3,7,8-Cl_5DD	1	1	1
1,2,3,4,7,8-Cl_6DD	0.1	0.5	0.05
1,2,3,7,8,9-Cl_6DD	0.1	0.01	0.01
1,2,3,6,7,8-Cl_6DD	0.1	0.01	0.1
1,2,3,4,6,7,8-Cl_7DD	0.01	0.001	<0.001
Cl_8DD	0.0001	-	-
2,3,7,8-Cl_4DF	0.1	0.05	1
1,2,3,7,8-Cl_5DF	0.05	0.05	0.1
2,3,4,7,8-Cl_5DF	0.5	0.5	1
1,2,3,4,7,8-Cl_6DF	0.1	0.1	0.1
1,2,3,7,8,9-Cl_6DF	0.1	0.1	0.1
1,2,3,6,7,8-Cl_6DF	0.1	0.1	0.1
2,3,4,6,7,8-Cl_6DF	0.1	0.1	0.1
1,2,3,4,6,7,8-Cl_7DF	0.01	0.01	0.01
1,2,3,4,7,8,9-Cl_7DF	0.01	0.01	0.01
Cl_8DF	0.0001	0.0001	0.0001

Table 1 Legislation and Guidelines (Part 1)

Sector	Applicable Directive	Directive Limits	Country	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Luxembourg	Netherlands	Portugal	Spain	Sweden	UK
Existing Municipal Waste Incineration Plants (ng I-TEQ/m^3)*																		
Air emissions	89/429/EEC	None set		**0.1**	**0.1**	0.1	**1.0**	0.1	**0.1**	C	0.1	**0.1**	**0.1**	**0.1**	C	0.1	0.1	1.0
New Municipal Waste Incineration Plants (ng I-TEQ/m^3)*																		
Air emissions	89/369/EEC	None set		**0.1**	**0.1**	0.1	**1.0**	**0.1**	**0.1**	C	0.1	**0.1**	**0.1**	**0.1**	0.1	0.1	0.1	1.0
Incineration of hazardous waste (ng I-TEQ/m^3)*																		
Air emissions	94/67/EC	0.1		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Releases to water	94/67/EC	None set		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Air Pollution from Industrial Processes (ng I-TEQ/m^3)$																		
Metal production and processing (1)	N/A	N/A		**0.1**	**0.5**			1.0	0.1				0.1					1.0
Sintering plant for iron ore production	N/A	N/A		**0.4**	**0.5**				0.1				0.1	0.4				
Combustion plant emission (2)	N/A	N/A		**0.1**	**0.1**				**0.1**				0.1					0.1
Papermaking processes	N/A	N/A						1.0	0.1				0.1					1.0
Coke manufacture	N/A	N/A							0.1				0.1					0.1
Cement and lime manufacture	N/A	N/A						0.1	0.1				0.1					0.1
Water and Aquatic Environment																		
Protection of ground water	80/68/EEC	Organohalogens prohibited		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Discharge into aquatic environment	76/464/EEC	Content of PCP; organohalogens prohibited		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Animal Nutrition (pg I-TEQ/g)																		
Citrus pulp pellets as feedstuffs	98/60/EC	500		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Marketing and Use of Chemicals																		
PCBs	85/467/EEC	P		C	C	C	C	C	**P**	C	C	C	C	C	C	C	C	C
PCP	91/173/EEC	0.1%		**P**	C	**P**	C	C	**P**	C	C	C	C	**P**	C	C	**P**	C

Key:

Figures in **bold** are legislative limits, others are guidelines

N/A = None applicable

* Measured at 11% O_2, 0°C, 101.3 kPa

$ Measured at 16% O_2, dry gases, 0°C, 101.3 kPa

C = Assume compliance with Directive ____________________ (1) Includes iron and steel plant
P = Prohibited production, marketing and use________________ (2) Includes boilers and/or crematoria

Table 1 Legislation and Guidelines (Part 2)

Sector	Applicable Directive	Directive Limits	Country	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Luxembourg	Netherlands	Portugal	Spain	Sweden	UK
Major Accident Hazards																		
The Seveso Directive	82/501/EEC	1 kg of 2,3,7,8-TCDD		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Sewage Sludge (ng I-TEQ/kg d.m.)																		
Application	N/A	N/A		**100**					**100**					190				
Compost use	N/A	N/A		**100**														
Soils and Terrestrial Environ. (ng I-TEQ/kg d.m.)																		
Soil: residential	N/A	N/A					500		1000					1000			10	
Soil: agricultural	N/A	N/A					500		40					1000			10	
Soil: dairy farming	N/A	N/A												10			10	
Children playground	N/A	N/A							100								10	
Industrial areas	N/A	N/A							10000								250	
Fertiliser/soil additives	N/A	N/A		**50**					17					63			10	
Food (pg I-TEQ/g fat)																		
Milk and dairy products with > 2% fat	N/A	N/A			**5**													
Milk and dairy products with ≤2% fat	N/A	N/A			**100**[+]													
Milk and dairy products	N/A	N/A						5	5 ; 3					**6**				16.6
Human Exposure (pg I-TEQ/kg bw.day)																		
Daily intake TDI	N/A	N/A		10		5[#]	5[#]	1	10			10		10			5[*]	10[*]

<u>Key:</u>

Figures in **bold** are legislative limits, others are guidelines

N/A = None applicable

C = Assume compliance with Directive

+ pg I-TEQ/g food

pg N-TEQ/kg b.w.day

***** Includes PCBs