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INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT PROCEDURE - SUPPORTING DOCUMENTATION

Tetraethyl lead

Note from the Secretariat

1. Annexed to this note is the documentation provided by the European Community in support of their notification of final regulatory action on tetraethyl lead.

* UNEP/FAO/PIC/ICRC.4/1

List of Documentation Annexed to UNEP/FAO/PIC/ICRC4/15/Add.2

Supporting documentation on tetraethyl lead and tetramethyl lead from the European Community:

- Environmental Health CriteriaNo.3: Lead. IPCS/WHO, 1977, www.inchem.org.
  This document can be found at the web address as indicated here.

- OCDE/GD(93)67 Risk Reduction Monograph No1: Lead – background and national experience with reducing risk, OECD, 1993 (www.oecd.org).
  The Executive Summary of the Monograph is annexed to documents UNEP/FAO/PIC/ICRC4/15/add.2 and UNEP/FAO/PIC/ICRC4/16/add.2.
  The full document (275 + page) can be obtained at the Secretariat on request at the meeting.

- Notification of final regulatory action to ban tetraethyllead and tetramethyllead – studies in Germany.

- International Chemical Safety Cards (ICSCs) peer review 1993, 1995, www.inchem.org.
  This document can be found at the web address as indicated here.

- Poison Information Monograph (PIM 302): Organic Lead, www.inchem.org.
  This document can be found at the web address as indicated here.

GENERAL DISTRIBUTION

OCDE/GD(93)67

RISK REDUCTION MONOGRAPH NO. 1

LEAD
BACKGROUND AND NATIONAL EXPERIENCE WITH REDUCING RISK

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1993

RISK REDUCTION MONOGRAPHS

Risk Reduction Monograph No. 1: LEAD - Background and National Experience with Reducing Risk is the first in a planned series of OECD documents on risk reduction activities for specific chemicals or groups of chemicals. These Monographs will normally include sections on: the commercial life cycle, including releases from the major point sources and categories of diffuse sources; the environmental life cycle, including qualitative and quantitative health and environmental exposure determinations and estimations; linkages between sources and targets; risk reduction and control measures and their cost/effectiveness; and conclusions that can be drawn regarding the effectiveness of risk reduction measures, the identification of major exposures that need to be addressed in order to contribute to the reduction of risk, and critical information gaps.

The Risk Reduction Monographs are part of the OECD Environment Monograph Series. This series is designed to make available to a wide readership selected technical reports on the risk reduction of chemicals prepared under the OECD Chemicals Programme. The Environment Policy Committee recommended that this report be made public under the authority of the Secretary-General, who subsequently agreed. Copies of this Monograph on a limited basis can be forwarded on request.

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FOREWORD

Background

In 1990 the Council of the OECD adopted a Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals (C(90) 163/Final). This Act is aimed at the reduction of risks from chemicals to the environment and/or the health of the general public or workers. It is based on the premise that international co-operation in risk reduction activities can enhance the technical and institutional aspects of risk management in Member countries through burden-sharing and a reduction of duplicative efforts. Furthermore, such activities can lead to a more effective use of the knowledge about risks that is being generated through, for example, national chemicals reviews and assessments, the OECD co-operative investigation of existing chemicals, and the work of the United Nations International Programme on Chemical Safety (IPCS) in developing an international hazard and risk evaluations.

International co-operation in risk reduction can provide a forum for the exchange of views on risk reduction strategies, thus increasing mutual understanding and facilitating the harmonization of programmes being undertaken at the national level. By means of this forum, technical barriers to trade can also be prevented.

The OECD's approach to risk reduction

The risk reduction process normally begins at the national level. However, the international character of the use and marketing of chemicals, and the mobility of certain chemicals in the environment, have given risk reduction activities an international dimension. The new work on risk reduction in OECD is a major step towards greater international co-operation, consistency and, ultimately, harmonization. It is designed to enable Member countries to use a variety of options flexibly as part of a co-ordinated international initiative to reduce risk.

The OECD's approach to risk reduction relies on the sharing and exchange of information on the management of specific chemicals. Readily available information concerning national risk reduction strategies will make comparative analyses possible. Where common interests emerge, the development and implementation of measured and consistent responses to unacceptable health and/or environmental risks can be facilitated.

In this context, risk reduction activities can take into account all stages of a chemical's commercial and environmental life cycle, beginning with the natural resources needed to produce it and extending through the chemical's uses to its eventual disposal. The chemical's health and environmental effects, and those of its possible substitutes, can be considered together with exposure via all routes and media to different populations. In addition, the relative benefits of the different elements of a risk reduction strategy at all stages of a chemical's commercial and environmental life cycles can be weighed.

OECD work on lead risk reduction

OECD Member countries chose lead as one of the five chemicals or groups of chemicals for inclusion in the initial pilot project on co-operative risk reduction. The United States prepared a summary of information on the current "state-of-the-art" with regard to national strategies for lead risk reduction. With Australia, Canada and Germany, it formed an OECD Clearing House which collected further information from Member countries, including the industries involved with the chemical. The Clearing House countries completed this Monograph, and the Member countries of OECD agreed that it should be made public.

EXECUTIVE SUMMARY

The main purposes of this document on lead risk reduction are:

- to provide a summary of information regarding releases of lead to the environment, the ensuing environmental and human exposures, and the way OECD Member countries and countries with observer status perceive the risks associated with exposure to lead;

- to describe the actions those countries and industry have taken, or contemplate taking, to reduce risks associated with exposure to lead; and

- to identify the benefits, in terms of protection of human health and the environment, that could result from taking such actions, to the extent that information is available.

This document reflects information provided from 1990-1992 and should be considered as a "snapshot" of the most recent thinking and activities during this time period. It may assist in evaluating the effectiveness of national risk reduction strategies for lead by identifying common trends in setting criteria, standards or national policies. It may also suggest rationales and possibilities for concerted international actions.

Risk reduction activities for lead are expected to continue to create information and technology conduits between Member countries, and to promote the development and transfer of knowledge regarding the nature and efficacy of responses to deal with unacceptable risks resulting from exposure to lead.

Chapter Summaries

1. Lead Production, Use and Disposal

Lead is a naturally occurring element within the earth's crust. It is believed to have been mined as early as 5000 B.C. Easily shaped and highly valued for its malleability and ductility, lead was used in ancient times in making pottery glazes, art objects, coins and water piping.

Today, lead is produced from the beneficiation of ores and concentrates and/or from recycling in over 50 countries. In 1990, world production of lead metal was 5.659 million tonnes, valued at over $US 4.6 billion, with slightly over 50 per cent derived from recycled materials. In that year, OECD countries accounted for 50 per cent of the world's production of lead in ores and concentrates and about 64 per cent of the world's metal production.

Primary lead from mining is often produced as a by-product or co-product with other metals such as zinc, silver, copper and cadmium. In 1989, 155 mines in 35 countries produced 2.21 million tonnes of lead in concentrate, with co-product (copper, zinc, silver) output valued at over $US 9 billion.

Lead is also among the most recycled non-ferrous metals in the world. Secondary production (from recycled materials) has risen steadily. It surpassed primary output for the first time in 1989. This growth reflects the favourable economic conditions associated with lead recycling and the fact that lead retains its physical and chemical properties when recycled. As lead applications are used worldwide, scrap lead has become a readily renewable resource to which countries without lead mines have access.

Since 1970, the world demand for lead's unique chemical, electrical and physical properties has increased by 25 per cent to a record level of 5.627 million tonnes in 1990. OECD countries accounted for 65 per cent of world demand in 1990, with the Central and Eastern European countries consuming 21 per cent. Asia is now the third largest, and fastest-growing, lead-consuming region, representing 9 per cent of world demand.

Demand for lead within OECD countries increased by 10 per cent between 1970 and 1990. The battery sector recorded the greatest growth and accounted for 63 per cent of demand in 1990. During the same period, health and environmental concerns were largely responsible for the decline in the use of lead in gasoline, soldered food cans, solder and piping for potable water systems, and pigments used in household paints. Most of the decline in other uses, such as cable sheathing, reflects changes in technology and market-driven requirements for lighter, more cost-competitive and more efficient products.

New applications are being developed for lead and lead compounds in microelectronics, superconductors, asphalt, earthquake damping materials and radon gas shielding, and for retrievable storage or permanent disposal of nuclear waste, to name a few. Industry has acknowledged that risk analyses should accompany the introduction of new products, and that recycling and reuse concepts should be developed where appropriate.

Daily prices for lead are based on international market factors, as it is traded worldwide. Regionally, Europe and Japan are the largest importers of lead concentrates and Europe is the major importer of lead bullion and refined lead. Australia, Canada and Peru are principal suppliers of both lead concentrates and lead metal. Mexico is a major exporter of refined lead.

Environmental releases of lead can occur naturally (for example, through crustal weathering, volcanism) or from anthropogenic sources relating to industrial activity, power generation (coal and oil burning), and the use and disposal of consumer products. Industrial wastes (i.e. emissions, effluent and solid waste) are often regulated within OECD countries. Post-consumer wastes containing lead may be regulated, depending on their hazard classification and/or their destination (i.e. recycling, final disposal, international trade).

Lead materials that can be recycled vary from industrial and consumer scrap to remediation and abatement wastes. Post-consumer product scrap constitutes more than 80 per cent of the scrap supply for recycling, with batteries accounting for up to 90 per cent in a given year.

Battery recycling rates are high in many countries, sometimes exceeding 90 per cent. However, it has become apparent that the weakest link in the recycling chain is usually the consumer who retains or discards a used battery rather than returning it for recycling. In a number of countries, governments are working with industry to increase recycling by focusing on the battery life cycle and encouraging consumers to return used batteries.

If lead-containing industrial solid wastes and post-consumer products are not recycled or reused, they are generally sent to landfills for disposal or are incinerated. The composition and volume of wastes destined for final disposal, as well as management methods, vary according to country and region depending on factors such as end use patterns, recycling rates and population density.

Some countries have estimated that batteries and consumer electronic products account for most of the lead in municipal solid waste. Others have identified lead in soldered food cans as the main source of lead in household refuse. It has been observed in some countries that the volume of lead in municipal waste is declining. Studies have also found that health concerns are minimal for properly managed landfills with runoff and leachate controls, and that lead emissions from incinerators can be controlled, with proper technology, to 99 per cent or greater efficiency. While much of the atmospheric emission of lead from incineration can be eliminated, lead captured by emission control devices and the lead remaining in ashes must be disposed of properly, usually in landfills.

2. Environmental Fate, Transport and Occurrence

Human activities remove lead from the earth's crust, where it is relatively immobile, and transfer it to environmental media. The potential for human and ecosystem exposure is thus greatly increased. Industrialization has vastly accelerated the transport of lead into human and environmental exposure pathways. Substantial human and ecosystem exposure to lead can occur in all environmental media.

It has been estimated that the amount of lead emitted per year into the atmosphere from anthropogenic sources has declined to about 30 per cent of the estimated 332 350 metric tonnes in 1983. Sources of atmospheric lead emissions may be considered as belonging to one of two main categories: mobile sources (through the use of leaded fuels in automobiles) and stationary ones (refining, manufacturing and incineration). Air emissions from smelters, processing facilities and solid waste incinerators occur as point source releases from stacks and as fugitive releases from storage, processing or materials handling. Lead concentrations in the air in cities in some OECD countries have ranged from 0.5 $\mu g/m^3$ up to 10 $\mu g/m^3$ in densely travelled inner city areas. However, restrictions on lead levels in gasoline in many countries have resulted in a marked decrease in automotive emissions of lead into the atmosphere. Air concentrations near point sources often still remain high.

Lead accumulates in soils and sediments. As a result of the decline in atmospheric lead emissions, the total annual anthropogenic loading of lead to soils worldwide is considered to have been reduced, from a 1983 estimate of between 479 000 and 1 113 000 metric tonnes per year. Atmospheric deposition of lead is a major source of soil and sediment contamination. The concentration of lead in soils near highways is related to traffic density, local meteorological conditions, vegetation and topography. Lead concentrations decrease with distance from the highway and with depth in the soil column. Lead concentrations associated with stationary sources are dependent on the rate of release from source, dispersion, and deposition rate. Generally, the concentration of lead in soil decreases exponentially downwind of a point source.

House paint containing lead can significantly contribute to household dust or soil concentrations of lead. Shot and fishing weights contribute large quantities of lead to soils and sediments. Lead tends to be immobilized by the organic component in soil and remains bound to the soil. It has been suggested that lead immobilized in soil can be released by decreases in the pH of precipitation. However, there is as yet no evidence to confirm that acid rain is influencing the chemistry and transport of lead in the soil environment.

Lead is a natural, usually very minor constituent of surface and ground waters. As with lead in soils, the total input of lead to aquatic ecosystems worldwide is considered to have declined, from an estimated 97 000-180 000 metric tonnes per year in 1983, as a result of the decrease in atmospheric lead emissions. Input of lead to aquatic ecosystems can occur from sources such as industrial wastes, effluents from mining, smelting, refining and manufacturing processes, dumping of sewage sludge, and atmospheric fall-out. Most of the lead introduced into surface waters is readily absorbed into sediments, where it complexes with organic material. Due to its relative immobility in water, lead tends to accumulate wherever delivered (for example, near point sources).

3. Linkages to Exposure

Inhalation and ingestion (of water, food, paint, soil and/or dust) are the primary routes of human exposure to lead. The relative importance of any single source of exposure is difficult to predict. It will vary with geographic location, climate and local geochemistry. Similarly, the intensity of exposure experienced by an individual can vary as a function of age, sex, occupation, socio-economic status, diet and cultural practices. In addition, the amount of lead taken up into the body is believed to vary depending on the concentration and composition (for example, particle size, chemical form) of the lead inhaled or ingested.

Some countries monitor the levels of lead in environmental media, as well as in blood, as a basis for assessing risks of exposure and the effectiveness of measures to reduce these risks. In countries that monitor trends in lead levels, data indicate that while the demand for lead products (and possibly the amount of lead destined for final disposal) has increased, the average levels of lead in air, food and blood declined to below levels of national concern. However, some countries have identified portions of the population that continue to be exposed to levels that exceed those of national concern. These elevated lead exposures often relate to point source releases, to past use of paints containing lead, or to lead piping and solder in potable water systems.

Reasons for the decline in lead levels vary according to country or region, and are in part influenced by local factors (for example, climate, socio-economic considerations, etc.). Declining lead levels in various environmental media and blood are commonly attributed to the following factors:

- restrictions on, and reductions in, dispersive uses of lead that result in its being readily bioavailable, such as:
    - lead in gasoline,
    - lead in soldered food cans,
    - lead solders and piping in drinking water systems,
    - lead in selected paints, and
    - lead-based pesticides;
- the introduction of regulatory and non-regulatory measures for management of industrial emissions and effluents (for example, from smelters);

- monitoring of water supply systems to reduce the solubility of lead from lead-bearing service lines by controlling the pH; and

- the development and implementation of regulations and technology for safe management of lead-bearing and other wastes destined for final disposal in landfills or incinerators.

4. National Positions on Current Risks from Lead

The Member country statements in this chapter essentially present the rationale for any actions the country has taken to address effects associated with environmental or human health exposures to lead. The risk assessments and risk characterizations that have led countries to take action have a national character. Countries develop positions on the need for risk reduction activities only after they have analysed the hazard and the significance of certain exposures and have factored in local social, economic and political considerations. These positions are usually arrived at after considerable debate on the numerous factors involved, and thus are not consistent across Member countries.

This chapter also contains an internationally agreed assessment of the risks of lead from the International Programme on Chemical Safety (IPCS). The IPCS assessment is taken directly from Chapters 1 and 9 of the recent Task Group-approved update of the Environmental Health Criteria Document on Lead, which will be published in late 1993 or early 1994.

5. Mechanisms for Risk Reduction

During the past few decades, most Member countries have taken steps to reduce unacceptable human and ecosystem risks from exposure to lead. Among the most successful of these measures have been restrictions on the use of lead in certain products with significant exposure potential (for example, interior paint, gasoline). Accompanying these measures have been actions to establish criteria for acceptable levels of lead in environmental media, to limit industrial emissions of lead to the environment, to control occupational exposures, and to identify biologically based indices for determining populations at risk. Despite the success of many of these measures in reducing lead exposure, some Member countries continue to consider possible steps to reduce lead exposure further, especially in light of new evidence of potential health effects at levels previously believed to be safe.

This chapter reviews risk management activities in Member countries. Included are discussions of steps taken in the past to reduce lead exposure, as well as current activities and potential future measures contemplated by certain countries. *Country-specific risk management activities* are summarized in Table 5.1. As shown in the table, the extent of these activities varies substantially among countries.

The lead risk reduction activities of thirteen individual countries (Australia, Canada, Denmark, Finland, France, Germany, Japan, Mexico, New Zealand, Sweden, Switzerland, the United Kingdom and the United States), the Nordic countries and the European Community are described in this chapter, followed by a summary of industry risk reduction activities. *At the end of the chapter is a series of tables that summarize available data on lead risk reduction activities in all*

Member countries and Mexico. Repeated requests for information on lead risk reduction activities were made to all Member countries in 1991 and 1992. Lack of information in this report on a particular country means either that no risk reduction activities have taken place in that Member country, or that the Member country has declined to respond to the requests for information.

The following is a brief summary of the information given in this chapter, apart from that presented in the tables:

Australia: The Australian Government supports the production and uses of lead, consistent with the principles of ecologically sustainable development. Australia restricts the manufacture and use of lead-based household paint with a 0.25 per cent non-volatile content, and the lead content of gasoline is limited to levels ranging from 0.3 g/l to 0.84 g/l, depending on location. Since 1 January 1986, all imported and domestic new cars have been required to operate on unleaded petrol (i.e. less than 0.013 g/l). This policy has resulted in unleaded petrol sales now approaching 50 per cent of total sales. A penetration level of about 80 per cent is forecast for the end of the decade. Australia also limits the emission concentration from stationary point sources to 1.5 $\mu g/m^3$ over a three-month average. The concentration of lead in drinking water should not exceed 0.05 mg/l and the permissible levels for lead in specific foods are between 0.2 and 2.5 mg/kg, depending on the foodstuff. The lead content of ceramic glazes is restricted, as is the lead content of pencils, toys, crayons and artists' paints (to 0.01 per cent). Although there are no recycling regulations governing lead batteries, the industry reports that over 90 per cent of the lead used in batteries is recycled.

Canada: The advertisement, importation and sale of paints containing lead are restricted. Lead is permitted in products (paints) for exterior use only and must be properly labelled. The Canadian paint industry voluntarily stopped using lead in household (interior and exterior) paint in 1991. In 1990 Canada prohibited the use of leaded gasoline (not to exceed 5 mg/l), except for use in critical equipment (not to exceed 26 mg/l). Canada currently allows a maximum of 10 µg/l of lead in drinking water and the plumbing code permits a maximum concentration of 0.2 per cent lead for solder and fluxes in contact with potable water.

Lead concentrations allowed in food vary between 0.08 mg/kg for infant formula and 1.5 mg/kg for tomato products. National standards exist for ambient water quality (0.001 to 0.007 mg/l freshwater aquatic life), soil and air (emissions of particulates from secondary lead smelters from 0.023 to 0.046 g/m^3). Lead is limited to 0.5 per cent in coating materials applied to children's products. Canada recycles an estimated 93 per cent of lead-acid batteries. Lead batteries that are filled with acid are classified as hazardous and, as a result, their transportation and storage are regulated by federal and provincial requirements. Regulation of the handling of lead-bearing scrap is divided between federal and provincial authorities. Canada has undertaken extensive education and labelling programmes designed to increase community awareness of the hazards associated with lead exposure.

Denmark: Danish lead risk reduction activities are aimed at phasing out the use of lead totally. Possible actions are regulation and voluntary agreements. The means could be substitution and, where this is not possible, improved recycling. International action is seen as a necessary means of eliminating lead use.

Finland: The use of white lead and lead sulphate has been prohibited in interior paints since 1929. Lead carbonates and lead sulphates may not be used in paints after 1 January 1993, except in paint intended for restoration and maintenance of works of art and historic buildings. The lead content of gasoline is limited to 0.013 g/l (unleaded) and 0.15 g/l (leaded). Maximum values for emissions from facilities into air and water are set on a case-by-case basis during environmental permitting procedures. The maximum allowable concentration of lead in workplace air is 0.10 mg/m^3 (time-weighted average over eight hours). The maximum allowable lead concentration in the blood of exposed workers is 50 µg/dl. Food safety standard: the maximum lead content in fruits and vegetables is 0.3 mg/kg, in drinks 0.3 mg/kg, and in canned food 1.0 mg/kg. Maximum lead leaching from ceramic ware that will come into contact with foodstuffs has been defined. The maximum lead level for drinking water is 0.05 mg/l.

France: The lead content of gasoline was reduced to 0.15 g/l in 1991, and unleaded (less than 0.013 g/l) gasoline has been granted a tax reduction which makes its retail price lower than that of leaded gas. France has adopted the EC limit of 0.05 mg/l lead content of surface water to be used as a source for potable water. The average annual limit value for ambient air concentration of lead is 2 µg/m^3. Standards exist for limiting lead emissions from industrial and other facilities. Sewage sludge used in land application must not have a lead concentration greater than 800 ppm. France limits the migration of lead from ceramic kitchen utensils into food, allows only external soldering of cans, and adheres to the January 1993 prohibition of lead capsules for overcorking wine bottles imposed by the EC. Import and sale of paint containing white lead compounds is prohibited from 1 February 1993. Battery recycling is accomplished through voluntary agreements designed to facilitate recovery and transport of spent batteries.

Germany: Regarding paint, white lead compounds are banned from sale and lead-based anti-corrosive paint is being phased out. Containers for paint with more than 0.15 per cent lead content must be labelled. The maximum content of leaded gasoline has been restricted to 0.15 g/l since 1976, and unleaded (less than 0.013 g/l) gas has been on the market since 1982. In 1992, the market share of unleaded gas was greater than 80 per cent.

Municipalities responsible for drinking water supply systems have to maintain a lead level of less than 40 µg/l at the mains connection. Lead service lines are no longer used, and old lead systems are gradually being replaced. Copper pipes have to be soldered with lead-free alloys. Many German states have limited the lead concentration in the soil. For example, Northrhine-Westphalia has a limit of 20 mg/kg lead in the sand of children's playgrounds. The maximum tolerable lead concentration in air is limited to 2.0 µg/m^3 (annual mean); the maximum deposition on soil to 0.25 mg/m^2/day. Total metal emissions (including lead) from lead smelters are limited to 5 mg/m^3. For direct discharges to water, limits vary from 0.3 to 2.0 mg/l, according to the type of facility. The use of sewage sludge for agricultural purposes is legally prohibited if its lead content exceeds 900 mg/kg.
In Germany, guide values (*Richtwerte für Schadstoffe in Lebensmitteln*, ZEBS) have been established for most foodstuffs in a range of 0.03-2.0 mg/kg. In addition, a limit value for wine has been introduced through the "wine regulation". For other foodstuffs, guidelines for lead have been established. There is no use of soldered cans for food packaging. Lead capsules for overcorking wine bottles are prohibited from 1993, in accordance with

an EC regulation. The recycling rate for lead-acid batteries is reported to be above 95 per cent. In the workplace, the maximum allowable air lead concentration is 0.10 mg/m^3 (eight-hour time-weighted average). The maximum allowable blood lead concentration for workers is 70 µg/dl for men and for women over 45, and 30 µg/dl for women under 45. Some physiologists and toxicologists recommend that the blood lead levels of adults should not exceed the concentration of 15 µg/dl, and that those of children and of women of childbearing age should not exceed 10 µg/dl.

Japan: Japan does not prohibit the use of lead-based paints but does, through voluntary agreements, limit the extent to which lead-based paint is used (prohibited for toys, households). Lead-based paints are used primarily in construction, automobiles and electronic products. Lead gasoline is not manufactured, imported or used in Japan. The maximum permissible lead concentration in drinking water is 0.1 mg/l. Japan has set emission standards for smelters and other lead processing facilities at 10-30 mg/m^3 depending on the facility. Waste water effluent must have a lead concentration of less than 1 mg/l. The administrative level for lead in the workplace is set at 0.1 mg/m^3.

Mexico: Mexico has an aggressive programme underway to reduce tetraethyl lead concentration in regular gasoline. In 1990, unleaded gasoline (less than 0.01 g/l) was introduced. From 1988 to 1992, an 88 per cent reduction in the lead content of gas took place. For drinking water the government established a lead level of 0.05 mg/l. Mexico has also set standards for lead in foodstuffs, drugs and cosmetics. The maximum permissible level of lead in tomato sauce is 0.36 mg/kg and the maximum permissible level of lead in synthetic organic dyes added to food, beverages, drugs and cosmetics is 10 ppm.

Mexico has eliminated the use of lead solder in welding of tin cans and has established a maximum permissible level of lead in surface paint of 90 mg/kg. Industries have agreed to eliminate the use of lead red oxide and lead-based carbonate from pigments, lacquer, enamel, paint and varnish on toys, pencils, school articles, printing inks, cosmetics, furniture and paints for interiors. Labelling on products containing lead is now required. In addition, a coalition of industry and artisans has agreed with government on maximum solubility levels for kiln-fired glazed pottery. Mexico has established a maximum permissible level of lead in the workplace of 150 µg/m^3. A further reduction to 50 µg/m^3 is being considered.

New Zealand: White lead compounds cannot be manufactured, imported or used in paint, distemper, powder coatings, pigments, or antifoulant. The maximum permissible amount of lead in paint is 5000 mg/kg; however, it is anticipated that this level will be reduced to 2500 mg/kg during 1993. The maximum permissible level of lead in petrol is 0.013 g/l (unleaded) and 0.46 g/l (leaded). A target date for elimination of lead in petrol has been set as January 1996. Material used for writing, drawing, marking or painting that contains more than 100 mg/kg of lead is prohibited. The maximum permissible amount of lead in coating materials for toys is 5000 mg/kg. This level will be reduced to 2500 mg/kg in the Fourth Amendment of the Toxic Substances Regulations 1983. Accessible plastic material on toys is restricted to a maximum permissible amount of 250 mg lead/kg.

New Zealand's drinking water guideline of 0.05 mg/l was established based on the WHO Guidelines for Drinking Water Quality, 1984. There is a proposal to review the standard in 1993 to align with the new WHO Guidelines. The maximum permissible amounts of lead in food range from 0.2 to 10 parts per million, depending on the food product. Limits for lead in sewage sludge intended for application to arable land were established in 1992. The maximum acceptable concentration of lead in dry sewage sludge is 600 mg/kg, the limit value allowable in soil is 300 mg/kg, and the maximum cumulative loading is 125 kg/ha. New Zealand has proposed a national ambient air quality guideline of 1.0 µg/m^3 for an average time of three-month moving average. The workplace exposure standard for lead in air is 0.15 mg/m^3.

Sweden: In 1991, the Swedish Government decided that measures should be carried out in order to phase out the use of lead on a voluntary basis, and in the long run to ensure its cessation. White lead compounds are not used in paints; however, some lead is used in paint as pigments, drying agents and rust-proofing agents. Sweden limits the lead content in gasoline at 0.15 g/l for leaded and 0.013 g/l for unleaded products and recently a ban has been proposed on the manufacture and import of leaded gasoline from 1 July 1994. Water with lead concentrations of less than 0.01 mg/l is deemed suitable for use as drinking water. Air and water standards are set on a case-by-case basis during the facility licensing process. Food tolerance levels have recently been lowered to 0.3-0.5 mg/kg for most canned food, and to between 0.02-0.5 mg/kg for various foodstuffs (higher values for spices, etc.). Ceramic ware, intended for handling food and beverages, is prohibited for sale if more than 3 mg/l lead is leached out during a standardized acetic acid leaching test. Sweden has instituted an aggressive recycling programme for batteries, supported in large part by taxes on batteries. The maximum allowable air lead concentration in the workplace is 0.10 mg/m^3 (total) and 0.05 mg/m^3 (respirable).

Switzerland: The use of lead and its compounds is prohibited in water paints and non-washable distempers used for interior paintwork. The lead content of gasoline is limited to 0.15 g/l (leaded), 0.013 g/l (unleaded), and 0.56 g/l in aircraft petrol. The permissible lead concentration in drinking water is 0.05 mg/l. Switzerland has set a general emission standard for combusters with a mass flow greater than 25 g/hr at 5 mg/m^3. For municipal waste incinerators, the sum of lead and zinc, including compounds emitted into the atmosphere, is not allowed to exceed 1 mg/m^3. The maximum tolerable lead concentration in air (suspended solids) is limited to 1 µg/m^3; the maximum tolerable deposition at 100 µg/m^3 per day. Waste water effluents must have a lead concentration of less than 0.5 mg/l. The quality criteria for surface water flows and impounded river water is set at 0.05 mg/l. The use of sewage sludge and compost is prohibited if their lead content exceeds 500 mg/kg or 120 mg/kg, respectively. The maximum allowable air lead concentration in the workplace is 0.1 mg/m^3 (time-weighted average over eight hours) for lead and lead compounds (except alkyl compounds), and 0.075/m^3 for tetramethyl and tetraethyl lead.

United Kingdom: The United Kingdom has implemented legislation concerning lead paint that prevents the use of lead carbonates and lead sulphates in paint. Under these rules, lead carbonates and sulphates may only be used in paint for certain historic buildings and for art preservation. The maximum allowable concentration of lead in gasoline is 0.15 g/l. Unleaded gasoline has a maximum allowable concentration of 0.013 g/l.

Rules governing the maximum concentration of lead in drinking water are set at 50 µg/l. Recently regulations have been proposed to prohibit the use of certain lead solders in domestic water supply installations. A maximum permissible concentration for lead in soils of 300 mg/kg dry solids after the application of sewage sludge has been established.

The ambient air quality standard for lead is 2.0 µg/m^3 (mean annual concentration). The UK regulates air point sources and other lead works using the best practicable means. Industrial sources must meet an allowable lead concentration of 0.002 g/m^3. Total particulate emissions cannot exceed 0.1 g/m^3. Permissible lead concentrations in waste water effluent vary by industry and plant location. The typical range of permissible concentrations is 1.0-5.0 mg/l.

The UK has established quality and labelling standards for a range of consumer products, such as a general limit for lead in food of 1.0 mg/kg with lower limits for special types of food such as baby food (0.2 mg/kg). As of 1988, ceramic wares have been subject to regulation. Industry was given five years to meet maximum lead concentrations of 0.8 mg/dm^2 for flatware, 4.0 mg/l for small hollow-ware (less than three litres) and 1.5 mg/l for hollow-ware greater than three litres. The UK also restricts the use of lead-based paints in consumer products. Although there are no rules governing the disposal of lead batteries within the UK, there are very high recycling rates (exceeding 90 per cent) for lead-acid batteries used in buildings and automobiles.

The maximum allowable concentration of lead in the workplace is 0.15 mg/m^3 (eight-hour TWA), blood lead concentration of 70 µg/dl for men and 40 µg/dl for women. For the general population, the government advice published in 1982 recommended taking steps to reduce exposure if blood lead level exceed 25 µg/dl.

United States: The United States has restricted or banned the use of several products containing lead where risks from these products are high and where substitutes for lead or lead-based products are available. The Centers for Disease Control (CDC) lowered the childhood blood lead concentration of concern to 10 µg/dl in 1991. Earlier, the EPA had lowered the level of concern to 10µg/dl ("10-15 and possibly lower") in 1986. The Agency for Toxic Substance Disease Registry (ATSDR) identified the same level of concern in the 1988 Report to Congress on childhood lead poisoning.

One of the highest-risk sources of lead poisoning for children in the United States is lead-based paint. The federal government has set a standard for lead in residential paint of 0.06 per cent, which effectively bans lead use in residential paint. In 1992, the Residential Lead-based Paint Hazard Reduction Act of 1992 was enacted (Title X). This law provides the framework for a national approach to reduce hazards from lead-based paint exposure, primarily in housing.

The US restricts the amount of lead allowed per litre of leaded gas to 0.026 grams. Since 1988, all new light-duty vehicles, trucks, motorcycles and heavy-duty gasoline engines must operate on unleaded gas (0.01 g/l). Starting in 1995, a total ban on leaded gasoline and lead gasoline additives will be in place for highway use. A new regulation of 1991 outlines the treatment requirement for drinking water that sets an "action level" of 15 µg/l measured at the home source. A series of remediation steps are prescribed for households exceeding this level. Interim guidelines exist for abatement of lead-based paint in public housing. These guidelines recommend abatement at 1µg/cm^2 paint of 0.5 per cent lead by weight and clearance levels for lead in household dust of 200 µg/ft^2 for floors, 500 µg/ft^2 for window sills and 800 µg/ft^2 for window wells. The interim guidance for residential soil recommends that clean-up should attain soil concentrations of between

500 and 1000 mg/kg.

The US ambient air quality standard for lead is currently 1.5 µg/m^3 (quarterly average). The most stringent standard for surface water quality is a maximum four-day average of 1.3 µg/l with a one-hour maximum average of 34 µg/l. The US has proposed regulations for the use and disposal of sewage sludge containing lead that would allow a maximum concentration of lead in sludge of 300 mg/kg and cumulative pollutant loading for lead in the soil of 300 kg/ha. In the US, certain lead-containing wastes are specifically listed as hazardous. These wastes must be managed by a permitted treatment, storage or disposal facility.

The federal and state governments also regulate the use of lead paints and surface coatings used in toys, children's products and household furniture. The canning industry has undertaken a voluntary phase-out of the use of lead in food cans. The US government also regulates the lead content of ceramic glazes, food, wine and pesticides. A number of states have adopted legislation to limit the levels of lead used in packaging materials. A large recycling effort is ongoing in the US to deal with most lead-acid batteries (it is likely that many small consumer batteries may not be recycled). Recent studies indicate that more than 95 per cent of all such batteries are recycled.

The current Permissible Exposure Limit for air concentrations of lead in the workplace is 50 µg/m^3. Blood level monitoring is triggered by an air lead concentration above 30 µg/m^3. The medical removal blood lead concentration in the workplace, which became effective in 1983, is 50 µg/dl for three consecutive checks and 60 µg/dl for any one check. A worker is permitted to return to that workplace when his blood lead level falls below 40 µg/dl.

Nordic Countries: The Nordic countries have undertaken a number of joint initiatives towards protecting the environment. Denmark, Sweden and Norway have signed the Ministerial Declaration of the Third International Conference on the Protection of the North Sea. This declaration states that the emissions of lead (and other micropollutants) shall within 1995 be reduced by 70 per cent compared to the level in 1985. Denmark, Finland and Sweden have, through the Baltic Marine Environment Commission (HelCom), adopted the goal of reducing lead emissions by 50 per cent within 1995, using 1987 as a reference year.

The Nordic Working Group for the Chemicals Group of the Nordic Council of Ministers has prepared a draft report describing Nordic experiences regarding the technological possibilities for reducing the use of lead. The long-term goal for the Nordic countries is to completely eliminate the intentional use of lead in products and to minimize the amount of lead discharged to the environment. The strategy to reach this goal includes, in preferential order: cleaner technology (substitution and process modifications); effective recollection and recovery systems; and environmentally acceptable waste treatment.

European Community: The European Community has issued directives regulating lead in products, and across different environmental media and environmental sources. It is important to note that a directive is a legislative action addressed to Member States. It may either contain very specific information or be narrative in nature. A directive often sets a deadline for adoption by Member States into their own laws; typically, however, a directive will contain specific information and will set a deadline on the order of three years. If a Member State fails to adopt the directive into law within the specified amount of time, then action may be taken against that Member in the European Courts.

Beginning in 1989, the EC prohibited the use of lead carbonates and lead sulphates in paints intended for all purposes other than preservation work. Also in 1987, the EC limited lead levels in gasoline in a directive which sets the maximum permitted lead compound level of leaded gas at 0.15 g/l and defines unleaded gasoline as that containing less than 0.013 g/l of lead. In 1993, the EC prohibited the use of lead capsules for overcorking wine bottles.

All sources of drinking water should have a maximum allowable lead concentration of 0.05 mg/l. In 1989, standards were established for sewage sludge used in agricultural application. The lead concentration limit for soils with pH levels ranging from 6-7 is 50-300 mg/kg dry matter, while the limit in sewage sludge is 75-1200 mg/kg and the annual limit of sewage sludge applied to agriculture is 15 kg/ha (based on a ten-year average).

The EC has set feed standards to limit the exposure of livestock to lead. As of 1988, the marketing of cosmetic products containing lead was prohibited. No more than 20 mg/kg lead may be contained in colouring matters, and not more than 10 mg/kg lead in antioxidants and emulsifiers used for food. The maximum leaching rate for ceramic articles that can be filled is 4 mg/l and for ceramic cookware 1.5 mg/l.

Beginning in 1988, paints, varnishes, printing inks and similar products that have one per cent weight associated with heavy metals must be classified, packaged and labelled according to EC standards. In 1986, the EC established concentration limits for air of 0.15 mg/m^3 and blood lead of 70 µg/dl, and action levels for air of 40 $\mu g/m^3$ and blood lead of 40 µg/dl.

Industry: The international non-ferrous metals industry has effected a variety of initiatives which can be considered lead "risk reduction" measures. Summaries of these activities are provided in this section. These initiatives generally fall into one of several categories, as follows: 1) changes in processing technology and/or emission controls; 2) implementation of medical surveillance and occupational hygiene programmes for exposed workers; 3) support of research to validate the effectiveness of existing occupational and general population exposure limits and develop new monitoring procedures for ensuring human and environmental health; and 4) implementation of product stewardship programmes to inform downstream users of lead of the precautions which should be exercised so as to protect the health of employees and consumers.

Occupational standards for exposure to lead vary among OECD countries. For example, OECD countries have established maximum occupational exposure limits for lead in blood ranging between 40 and 80 µg/dl. Standards for occupational exposure to airborne lead also vary among OECD countries, with 50, 100 and 150 $\mu g/m^3$ all being specified in national regulations or legislation. Engineering controls backed by personal hygiene and other protective programmes are employed by lead producing and consuming industries to minimize worker exposure. In areas where exposure limits cannot otherwise be met, personal respirators are employed. Correlations between lead in air and lead in blood are generally poor, with good personal hygiene widely regarded as the most significant factor in limiting exposure. This factor also serves to minimize the transport of lead particles into the home. The European Federation of Capsule Manufacturers (EUCAPA) agreed in

June 1990 to stop the production of lead-containing capsules for overcorking wine bottles.

The information presented in this overview was, in large part, collected via a questionnaire administered to the international industry by the International Lead Zinc Research Organization in early 1992. Respondents to the questionnaire included corporations whose lead production capacities comprise a significant proportion of both annual global production and production in OECD Member countries. Responses to this questionnaire were not received from all lead-producing industries. As a result, the information presented must be viewed as a qualitative overview that is likely to be incomplete in some areas. Similarly, risk reduction measures implemented by the industry show evidence of geographic variation that is reflective of regional differences in the perception of relative risk associated with lead exposure. The nature and extent of risk reduction activity by industry in individual countries is thus variable.

6. Summary and Considerations

Almost all OECD countries have introduced regulatory or non-regulatory measures to reduce unreasonable human and ecosystem risks from exposure to lead. The risk assessments and risk characterizations that have led countries to take actions have a national character. Although some countries have taken the same number of measures, no two countries have adopted the same set of risk reduction measures (i.e. initiatives relating to environmental media, industrial or municipal releases, products, occupational exposures, etc.).

Blood lead sampling is one of the methods most widely used to assess human risk from exposure to lead. Approximately 30 per cent of OECD countries have reported blood lead monitoring data for the general population and/or segments of the population at greatest risk. These countries have reduced average blood lead levels for the general population to below 10 µg/dl by introducing either a few measures or a considerable number of initiatives.

Data for those Member countries that monitor lead in various media also indicate that the average concentrations of lead in environmental media have declined to below national levels of concern. However, some countries have identified releases of lead from point sources and/or the long-range transport of lead in air as concerns. Others have indicated that, given the recent progress in reducing lead in air, there are more significant domestic concerns such as lead in imported canned food, lead in drinking water (especially for critical groups such as bottle-fed infants), or lead in dust and chips from deteriorating old household paint.

It is suggested that when considering risk reduction strategies for lead, Member countries not already doing so may wish to undertake environmental and blood lead sampling to identify populations at highest risk and to evaluate the extent of lead exposure in their general population. Countries may also want to draw on experiences described in the document when developing regulatory and non-regulatory measures to reduce unreasonable risks from exposure. These measures may include: regulations and standards (for example, on lead in food packaging, lead in gasoline, smelter emissions) aimed at reducing ongoing releases of lead to air, water, soil, dust and the workplace; implementation of cleaner technology (for example, substitution, process modifications), effective recollection and recovery systems, or environmentally acceptable waste treatment; abatement activities to reduce risks from exposure to historical sources of release (for example, deteriorating paint, piping in potable water systems); and voluntary industry product stewardship programmes such as the industry phaseout in some countries of high-risk applications (for example, lead in soldered food cans or household paints).

In addition, consideration should be given to reviewing progress every few years with lead risk reduction strategies. This could include the collection of Member countries' environmental and blood lead monitoring data, as well as of new information on their regulations, criteria, standards or national policies regarding exposure to lead.

Annex 1

Notifications of final regulatory actions to ban tetraethyllead and tetramethyllead – studies in Germany

There are a number of measured concentrations of lead in various environmental compartments including humans from Germany. They suggest that these concentrations of lead were almost exclusively caused by emission of exhaust fumes from motor vehicles using fuels containing alkyl lead additives. Concentrations in terrestrial compartments and human blood closely followed the marketed volumes of leaded gasoline. According to the Federal Environmental Agency (UBA), atmospheric emission of lead from motor vehicles dropped from 3620 metric tonnes per annum in 1985 to 1120 t/a in 1990 and to 240 t/a in 1995. Example registered emission data on airborne lead (gaseous and particles) from various parts of Hessen (Germany) underline the sharp decline of lead emissions caused by the ban of leaded gasoline (figure 1)

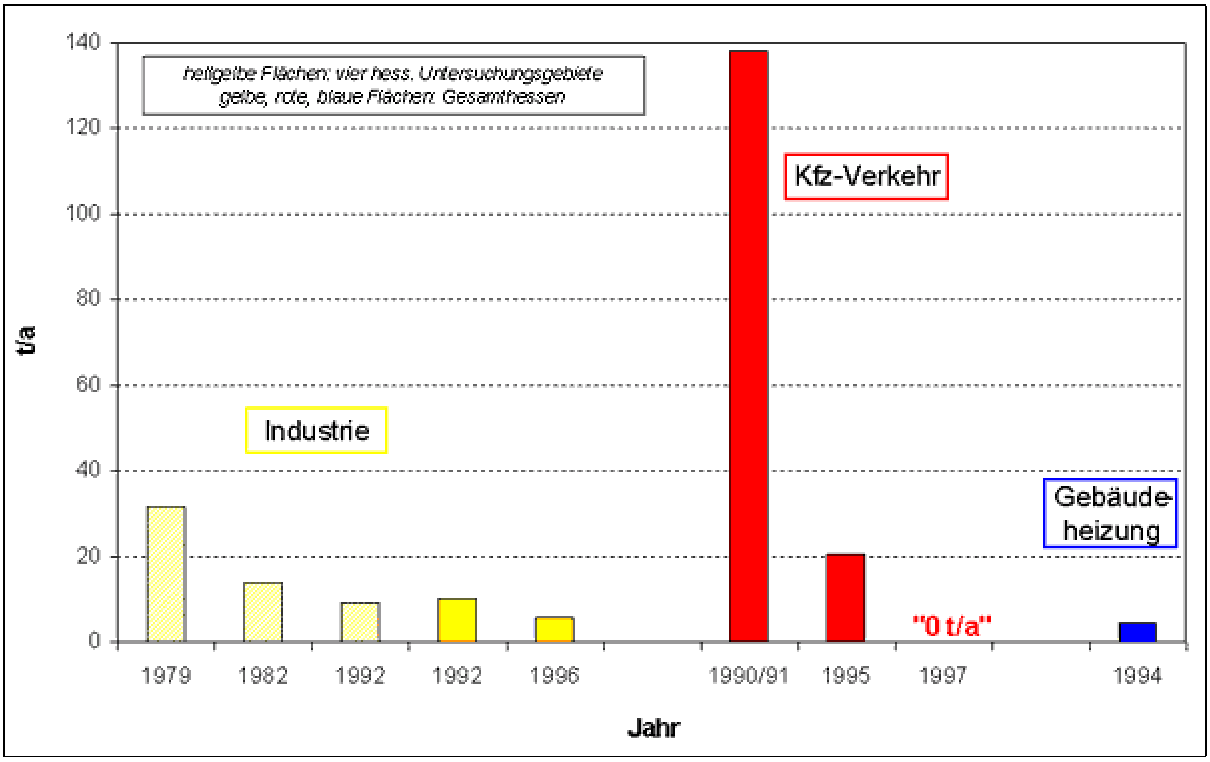

figure 1 Airborne lead from different sources caused by industry (*Industrie*), motor vehicles (*Kfz-Verkehr*) and heating installations of buildings (*Gebäudeheizung*) in Hessen; the light yellow pillars indicate data from four regions of Hessen, the yellow , red and blue pillars refer to the total of Hessen. [source: Hessisches Landesamt für Umwelt und Geologie (HLUG)]

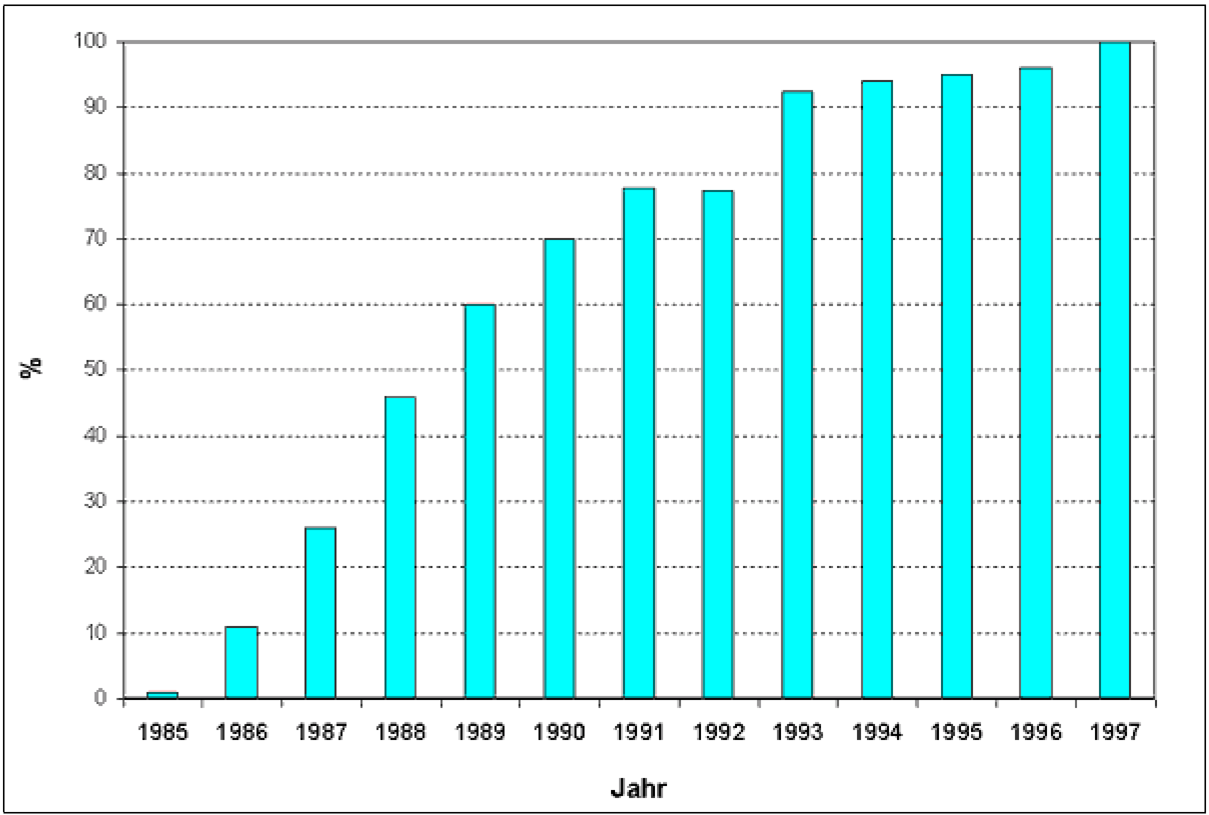

figure 2 Market shares of unleaded gasoline in Germany [source: http://www.umwelt.hessen.de/atlas/luft/ik/qualitaet/pb_staub/pb_staub.htm#eigenschaften]

In parallel with the decline of market shares of leaded gasoline commencing in 1984, a continuous decrease of lead concentration could be observed in human tissue and in terrestrial specimens, e.g. plants (figure 3). The lead content in human blood samples from the German town of Münster revealed a reduction of more than 75 per cent from 1981 to 1998 (> 80 µg/l to 21 µg/l (figure 4).

According to monitoring data from Hessen, lead concentrations of airborne particles dropped from 460 – 580 ng/m3 in 1976 (at some urban heavy traffic sites 750 ng/m^3) to as low as 10 - 30 ng/m3. in 2000. This corresponds to a factor of 20 - 40. Also in remote areas emissions sharply fell by about a factor of 10 (e.g. at Heyerode from 70 ng/m^3 in 1978 to 7 ng/m^3 in 2000).

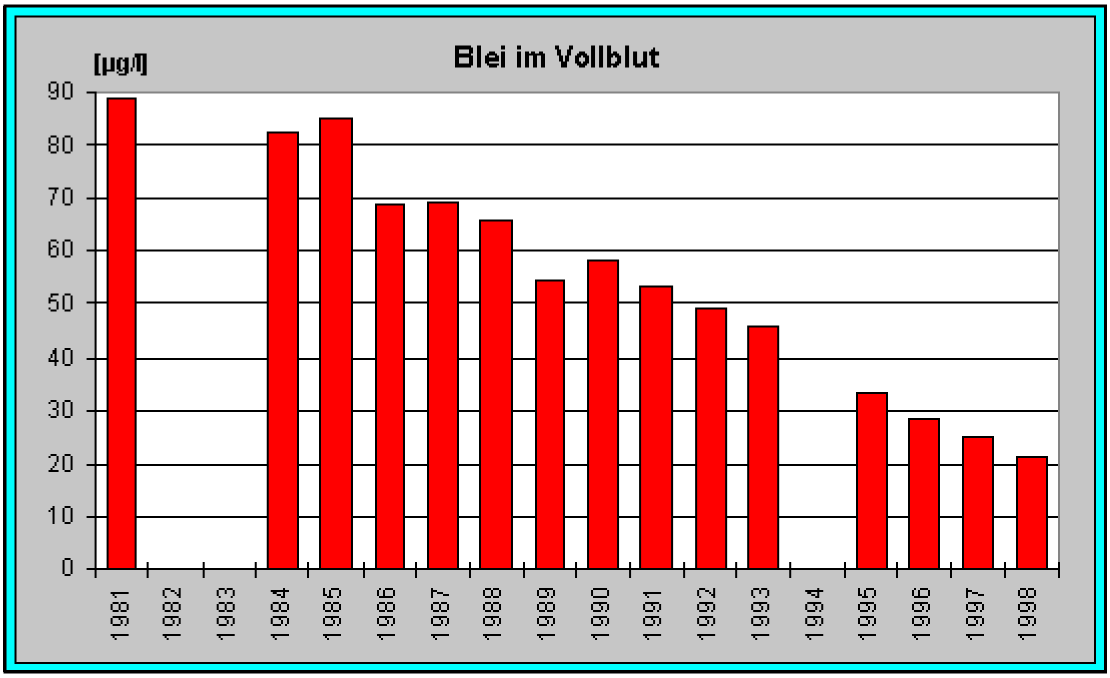

figure 3 reduction of lead content in human blood (*Blei im Vollblut*) in the German region of Münster [source: http://www.umweltbundesamt.de/umweltproben/upb62.htm]

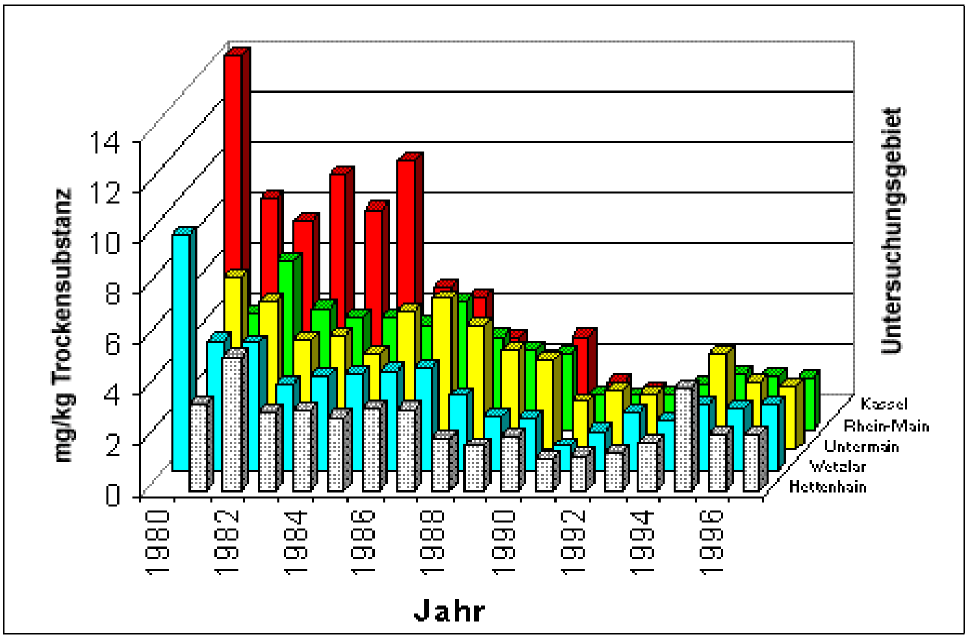

figure 4 reduction of lead in rye grass in mg/kg dry weight (*Trockengewicht*) in several regions of Germany (*Untersuchungsgebiet*), caused by declining sales of leaded gasoline during 1980 – 1996 (*Jahr*) (source: German Federal Environmental Agency)