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SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

Opinion on

LEAD – DANISH NOTIFICATION 98/595/DK

Opinion expressed at the 15th CSTEE plenary meeting

Brussels, 5th of May 2000

CONTENT

1. QUESTIONS and SUMMARY of the CSTEE OPINION

1.1. <u>Question B1.</u> Is the situation with regard to the effects and the level of contamination, exposure and risk, as present by Denmark, supported by the scientific information made available by the Danish authorities?

- The Danish Authorities have provided a substantial amount of information to the CSTEE concerning the human health effects and environmental impacts of lead. Much of the information is general in nature and is not directly related to Denmark.

- With respect to the human health risks it is claimed that lead exposure in children in Denmark from dust and food ingestion is close to or exceeds the WHO PTWI (Permitted Tolerable Weekly Intake) value for acceptable exposure. Exposure data in relation to the present, dust soil and food contamination is not provided. However, the information available to the CSTEE indicates that this claim is probably not correct, at least for the great majority of children in Denmark.

- In relation to their environmental concerns, the Danish Authorities have predicted a very small, but steady, increase in soil contamination by lead. No monitoring data for the past few years is provided to support this estimate. The sources of the on-going soil contamination are not identified.

- In the proposal for a derogation by the Danish Authority no attention is given to any adverse impact which could occur in humans or to the environment from the introduction of substitutes for lead.

1.2. <u>Question B2</u>. According to the scientific information made available by the Danish authorities, what is the importance of the contribution to lead exposure from different sources (e.g.: natural presence, production, products, waste, other)?

The current lead exposure situation in Denmark comprises three components:

- historic uses of lead,
- lead from processes and products in current use,
- “imported” lead, which includes lead shot, and airborne lead from nearby countries that have not yet banned lead in petrol.

- In common with the situation in other countries, the available data indicate that for the majority of public, the main sources of exposure derive from historic uses, in particular from dust and land contaminated by the use of lead such as in paints and petrol.

- In specific areas, use of lead piping for distributing drinking water remains also an important exposure source.

- The limited available evidence indicates that the additional body burden of lead from products in current use is probably small.

- The CSTEE notes that the general exposure to lead of the Danish population is lower than in the majority of Member States.

- In Denmark, the main exposure to lead of the general population, including children, is via food (agricultural production in areas of historic soil contamination and lead in imported food) and to a much lesser extent via air or soil contact.

- Danish data indicates that lead levels in food are generally declining and the average dietary intake of lead is considerably lower than the WHO PTWI value of 25 microg/kg body weight (for both children and adults) which has recently been confirmed by JECFA.

- The CSTEE notes that in Member States, including Denmark, there has been a constant decrease in the blood lead levels of children since the late 70s and a new steady state level has not yet been reached. This decrease is mostly due to the progressive elimination of lead from gasoline.

- The CSTEE notes that except in highly polluted areas, blood lead levels usually do not appear to correlate well with soil contamination.

- Very limited data have been provided by the Danish Authorities to support the case that the burden of lead on the general environment is increasing. Data provided on levels in sewage sludge do not support the case.

1.3. Question B 3. **Without prejudice to established policies and procedures for treating notifications of technical rules, does the Committee have any other information available which it deems relevant in the Danish context and how does that affect its evaluation of the situation in Denmark?**

- The CSTEE has identified a number of publications and reports which are not cited by the Danish Authorities, in particular information on the lead levels in air, food, soil and water and blood lead levels in children in other Member States.

- The CSTEE notes that there are epidemiological data on health effects of lead in children indicating, that even below a blood lead level of 100microg/l, adverse effects might occur. Since 1995 several studies on health effects in children have been published which tend to support this conclusion. The validity of these findings has to be carefully evaluated. In this context, it is intended that the CSTEE will review in the near future the appropriateness of the existing WHO PTWI value.

- The CSTEE recognises that there are studies reporting blood lead levels exceeding 100 microg/l in sub-populations of children in most of the European countries. This is usually due to specific exposure from contaminated drinking water, food or industrial areas. In this context, it is warranted to take specific measures to steeply improve the situation.

- The CSTEE recommends that Member States carry out an investigation of total exposure and uptake of lead in young children. Further research should be carried out to determine if safe blood levels of lead can be defined, particularly in very young children.

- With regard to the environment, the increase in soil contamination with lead in Denmark is anticipated to be, at worst, very slow. No evidence is presented indicative that any additional adverse environmental impacts beyond those currently observed will occur within many decade(s). No allowance has been made in the Danish calculations for changes in lead bioavailability with time. Careful monitoring should be encouraged to check as to whether the anticipated increase in Denmark will occur and a risk estimate should be conducted.

1.4. Question B4. Is the situation in Denmark essentially different from the situation in other EU Member States?

- The general situation relating to lead exposure of humans and the environment in Denmark is not different in nature from that in other Member States. Indeed the evidence available to the CSTEE indicates that lead exposure among the public is lower in Denmark than in the majority of Member States.

- The CSTEE considers that, for the Danish situation, it is more appropriate to tackle any areas where levels of lead exposure are significantly above average by identifying the major sources of this exposure and taking appropriate measures for their reduction. It notes that in some instances the lead sources are imported into Denmark.

- The CSTEE does not consider that the Danish Authorities have provided sound scientific evidence to demonstrate that the introduction of a general ban on the use of lead products would result in a significant additional reduction in the body burdens of lead of the general population.

2. SUMMARY BACKGROUND TO THE POSITION OF THE DANISH AUTHORITIES

2.1. General Objective

For heavy metals in general, and lead in particular, to reduce the anthropogenic load on persons and on the environment as far as possible.

2.2. Major Sources of Lead Identified

The Danish Authorities state that there are contributions from many anthropogenic sources to the current environmental contamination by lead. The Danish Authorities are not concerned about the risks due to naturally occurring lead.

Human

Children are considered to be particularly at risk. Lead exposure in children in Denmark is anticipated by the Danish Authorities to be close to or to exceed WHO recommended PTWI values for acceptable exposure. Their principal source of exposure to lead is considered by the Danish Authorities to be lead contaminated soil and dust ingestion, plus foodstuffs.

Environment

Background concentrations found in soil are between 10 and 40 mg/kg dry weight (mean 16 mg/kg) in rural areas in Denmark but in Copenhagen they range between 120 and 470 mg/kg. In drinking water the background concentration is between 5 to 10 microg/l, and in air 150 ng/m^3 in non-polluted areas. Aquatic pollution is assessed as being low and, in general, is considered to be a low concern.

Sources of environmental contamination cited by the Danish Authorities include: lead in waste going to landfill sites, materials of waste origin used for construction work, use of lead shots and fishing line sinkers.

2.3. Main effects of concern identified

Human

The WHO PTWI value was reviewed several times by JECFA since 1986. In 1995, it has been set at 25 microg/kg body weight for both children and adults. It is intended that the CSTEE will review in the near future the appropriateness of the existing WHO PTWI value. The Danish Authorities view children as particularly at risk due to:

- greater exposure potential (high hand to mouth activity),
- greater food consumption (on a wt per kg body weight basis),
- better lead absorption than is the case for adults,
- higher sensitivity to lead (in particular : slowed nerve conduction velocity, impaired neurobehavioral function, encephalopathy, and anaemia).

Environment

The Danish Authorities have calculated that there will be a slow increase in the concentration of lead in agricultural soil and other types of soil. It is assumed that this will cause lead levels in foodstuffs to rise progressively.

The Danish Authorities have identified that lead contamination inhibits options for waste management, both recovery (e.g.: use of incinerator ash/slag) and disposal (e.g.: sewage sludge to land), thereby limiting the goal of sustainability.

2.4. Risk assessment for human health.

The risk assessment provided by the Danish Authorities relates to lead in the environment generally and does not consider individual sources of lead. Critical effects identified with associated blood levels for various groups of the population are:

workers:

decreased in nerve conduction velocity (300 microg/l),

neurobehavioral effects (400-600 microg/l)

children:

decrease in nerve conduction velocity (200-300 microg/l),

cognitive development and intellectual performance (250-300 microg/l) with indication of effects at 100-200 microg/l,

hearing loss (60 –180 microg/l),

jaundice (350 microg/l).

new-born:

inhibition of aminolaevulinic acid dehydratase (30-300 microg/l).

adults:

inhibition of aminolaevulinic acid dehydratase (30-340 microg/l)

blood pressure (70 microg/l)

renal function (100 microg/l)

sperm count (400-500 microg/l).

Since 1995 several studies on health effects in children have been published which tend to support that even below a blood lead level of 100 microg/l, adverse effects might occur. The validity of these findings has to be carefully evaluated.

2.5. Environmental Risk Assessment

No in-depth environmental risk assessment has been conducted by the Danish Authorities. The statements made in 98/595/DK are not data based, referring to general effects of an increase in lead in the environment.

The toxicity data cited by the Danish Authorities are in accordance with a recent evaluation made in the Netherlands by the National Institute of Public Health and the Environment. These can be summarised as follows: aquatic freshwater chronic NOECs range from 10 to 2100 microg/l. Marine NOECs. range from 9 to 1000 microg/l. Predicted No-Effect Concentrations (PNEC-values) of 12 and 6.5 microg/l (dissolved), for fresh- and marine water respectively. The natural background concentration in surface water was calculated at 0.15 microg/l (dissolved). For soil-organisms NOECs range from 40 to 1500 mg/kg. NOECs for bacterial processes in soil range from 15 to 7700 mg/kg. PNECs of 64 and 55 mg/kg, respectively, were obtained for soil organisms and soil processes.

3. CSTEE RESPONSES

3.1. Human health

Human Health Hazard Characterisation

Among the various recent reports on the human health effects of lead, the IPCS 1995/96 one is of particular importance. Rather little of the data cited in the Summary of the Risk Assessment for Human Health by the Danish Authorities post-date the IPCS review.

The following assessment considers both these papers and others obtained by the CSTEE. Young children have been identified as a very sensitive group of the population. The critical effect of lead is the impairment of cognitive and behavioural development of the central nervous system (CNS). Encephalopathy was first observed in children with blood lead levels of 800 microg/l or higher (Goyer and Rhyne 1973). In 1974 during a NIEHS Symposium neuro-physiological impairment in children with blood lead levels below 400 microg/l was reported (NIEHS 1974). At levels of greater than 300 microg/l De La Burde and Choate (1972) found impairment of motor function, concept formation, and altered behavioural profiles in pre-school children. CNS impairment continued in these children when they reached 7 to 8 years old (De La Burde and Choate 1975). Children with previous high lead exposure (blood lead levels >800 microg/l) and encephalopathy showed significant neurobehavioral deficits and a lower score for cognitive function, whereas children with lower blood lead levels did not differ from the controls (Rummo et al.1979). These and other studies have been reviewed by Grant and Davis (1989), the EPA (1989), and WHO (1995) which concluded that CNS effects may occur in infants and young children at blood lead levels as low as 100-150 microg/l.

A meta-analysis on 12 cross-sectional studies supported the hypothesis that lead impairs children's IQ (Needleman and Gatsonis 1990).

The European Multicentre Study combined eight individual cross-sectional studies from 8 European countries, and, using a common protocol, investigated 1869 six to seven year old children covering a range of blood lead levels from less than 50 to about 600 microg/l (Winneke et al 1990). The association between blood lead levels and IQ, as well as psychometric intelligence, were of borderline significance. However, a significant linear relationship between blood lead levels on the one hand and visual-motor integration and serial choice reaction performance on the other hand has been observed. The relevance of these findings in clinical terms to neuro-pediatric disorders is still tentative so that the conclusions from the epidemiological studies need careful evaluation.

The results of the various prospective studies have been reviewed recently by Winneke and Krämer (1997). The strength of the more recent seven studies is that an agreement was reached on the main features of the protocol. However, only four studies reported associations between prenatal lead exposure and reduced Mental Development Index (MDI) or PDI-scores of the Baylea test, following an investigation of up to 6 or 12 months, in the studies of Dietrich et al (1987) and Ernhardt et al (1987), up to two years in the work of Bellinger et al (1987), or to 4 years of age in the study of Wasserman et al (1994). However, these associations were no longer detectable at school age (Bellinger et al 1991, Dietrich et al 1993). In the other studies, after confounder factors were allowed for, no significant association between prenatal lead exposure and MDI/PDI changes were detectable (Moore et al 1989, Cooney et al 1989, Wigg et al 1988).

Whereas the Boston (Bellinger et al 1987, 1991) and the Port Pirie studies (Wigg et al 1988) showed an association between blood lead levels measured at different postnatal ages and the General Cognitive Index at pre-school age assessment, other studies have not. At school age an association between blood lead levels and lower IQ was found in the Boston cohort, the Cincinnati sample (Dietrich et al 1993), and the Port Pirie cohort (Wigg et al 1988, Baghurst et al 1992).

In a more recent study by Osman et al (1999a) hearing effects in 4 to 14 years old children in Katowice, Poland have been investigated. The audiometric results indicate that auditory function in children was impaired at a blood lead level even below 100 microg/l. In addition, in these children there was also an association between blood lead levels ranging between 20 and 280 microg/l and signs of renal dysfunction (Osman et al 1999b).

These studies confirm that children represent a particularly at risk group of the population. Cognitive and sensory motor deficits have been shown in children to be associated with blood lead levels as low as 100 -150 microg/l. An average IQ decrement between 1 to 3 points with increasing blood lead levels from 100 to 200 microg/l corresponds to 20% or less of the standard deviation of a typical IQ distribution (Winneke and Krämer 1997). These and more recent data indicate, that even below 100 microg/l effects might occur and that no clear threshold for effects has been identified.

Only in the case of substantial lead exposures (Bentur and Koren, 1991) have adverse health effects been reported in pregnant women (miscarriage) and their foetuses (death, malformation and neurologic disorders. This is attributed to i) increased blood lead level in the mother due to lead mobilisation from storage in bone during pregnancy and, ii) lead transfer through the placenta and foetal uptake. Women with a blood level close to 500 microg /l have been reported to have a greater risk of miscarriage (Winder, 1993), whereas in a study on 304 women living next to a smelter and with a mean blood lead level of 155 microg/l, no difference on miscarriage was found with a control group of 355 women (Murphy et al 1990).

Human exposure

The public is exposed to lead in ambient air, dust, soils, drinking water, and food. Human exposure above baseline levels in many countries is not uncommon. Elevated lead exposures are usually associated with : living in a urban environment with high traffic density, and/or near point emission sources (e.g. : smelters), or in homes containing lead-based paint and/or having water distribution systems containing lead. A particular risk for young children is through the habit of eating non-food sources (pica).

Lead in air

The principal source of lead exposure is typically anthropogenic emissions to the atmosphere. Once emitted, lead particles remain in the atmosphere for about 10 days during which there is a progressive transfer to soil, surface waters or sediment by wet or dry deposition. Lead is non-volatile and therefore extremely persistent in soil.

In the mid 80's, when leaded gasoline was almost universally used, it was responsible for up to 90% of all anthropogenic emissions. Denmark banned leaded petrol in 1994. As a consequence, total lead emissions from leaded petrol decreased from 900 t in 1977 to almost 0 in 1995. It should be noted that this decision to eliminate lead from petrol and place restrictions on lead manufacturing have probably not had sufficient time to result in a new steady state for environmental lead concentration in Denmark. Assuming that the current emission levels remain stable, it can be estimated that this will take at least another decade.

The European directive 82/884 has set the ambient air limit value at 2 microg/m^3 with a guidance (quality) standard value at 0.5 microg/m^3. In Denmark, the Industrial Air Pollution Control Guidelines stipulate emission limits and the emission concentration contribution for a number of pollutants including lead. For lead compounds, measured as Pb, the value is 0.4 microg/m^3.

Lead in soil

In soils, apart from atmospheric deposition, the most usual sources of contamination are lead containing solid wastes (domestic, ammunition, paint emission). Lead is non-volatile and therefore extremely persistent in soil. The fate of lead in soils is dependent upon specific or exchange adsorption at mineral interfaces. Most lead is retained in soil as it is strongly adsorbed to organic matter, and only a limited fraction can be transported into surface water or groundwater. This occurs principally if the soil is acidic. In soils with pH > 5 and with at least 5% organic matter, lead is retained in the upper 5 cm of undisturbed soil. In Denmark, these conditions may be reached in some important groundwater areas. Generally, the background lead content of soil typically ranges between 10 and 30 mg/kg. Next to roadways, in the upper soil layer, lead can be found at levels as high as 2,000 mg/kg but with a rapid decrease within less than 25 m away from the traffic flow. Close to a smelter, concentrations above 60,000 mg/kg have been reported and, in gardens adjacent to houses with exterior lead-based paints, levels>10,000 mg/kg have been found. As indicated in the Danish document, high concentrations of lead may also be detected immediately around buildings, such as churches, with lead roofs.

The benefits of the decreased atmospheric deposition that has followed replacement of lead in petrol still have to be fully materialised. In the foreseeable future, the Danish Authorities indicate that there will still be a minor increase in the mass balance for soil, largely caused by the atmospheric deposition. This increase is estimated to be in the order of 0.1 %/year over the background of lead in agricultural soil. In the current situation for forest, lead shots and airborne deposition represent the main input of lead. For agricultural lands sewage sludge is the main source. These values are in the same range as those that were recently estimated for Dutch agricultural soils (19 g/ha/year), resulting in a concentration increase of 0.005 to 0.03 mg/kg per year depending on the type of agricultural land.

In Sweden, a human health based limit for lead in soil of 30 mg/kg has been recommended where bioavailability of the soil lead has been demonstrated. The basis for this is that an intake of 0.2 g soil a day by young children, who represent the most sensitive population, should not contribute more than a 10% increase of the blood lead concentration.

In France, the mean concentration of lead in soil is at about 15 mg/kg dry weight with large differences depending on the geologic background and on different contamination pattern. Similarly to the Netherlands, the “alert” value is set at 530 mg/kg.

Lead in water

The speciation of lead in water, which is of paramount importance for its bioavailability and hazard potential, depends primarily on the pH, temperature and the presence of humic materials. Thus, if the drinking water is acidic it will be more corrosive with the consequence of greater leaching lead from water pipes. Equilibrium calculations show that at pH> 5.4, the total solubility of lead is about 30 microg/l in hardwater but can reach up to 500 microg/l in soft water. Sulphate ions react with lead and limit its concentration in solution through the formation of lead sulphate. Carbonates which act the same way, are themselves dependent upon the CO_2 concentrations, partial pressure, pH and temperature. Therefore through reaction with various anions, lead can easily precipitate out of the water column.

In sea water (north Atlantic), the approximate concentration is 14 microg/l. Throughout Europe, sediments may contain high levels with approximately 20 mg/kg in river sediments and 100 mg/kg in coastal ones. The higher the pH the stronger the adsorption of lead on sediments. Desorption may occur depending on changes in pH, salinity, or organic matter conditions.

In drinking water, concentrations ranging from 10 to 30 microg/l are frequent in Europe. Concentrations above 500 microg/l can be found in areas where there is corrosive water together with lead pipes in the water distribution system. In Denmark levels of lead are generally low in water bodies and in drinking water. A mean value close to 4 microg/l has been reported, but ″hot spots“ occur and levels as high as 900 microg/l have been reported.

In Europe, as recommended by EU directive 98/83/EC, the limit of 10 microg/l should be achieved in 2013 at the latest.

Bioconcentration and incorporation in the food chain

Lead is present on plant surfaces as a result of atmospheric deposition. Biological uptake from the soil or leaves may occur as indicated by the presence of lead in internal tissues. In aquatic organisms, more lead is found in benthic organisms and algae than in upper trophic level predators. A difference in the concentration potential between organic and inorganic forms of lead has been reported between various organisms (Madock, 1980). High bioconcentration factors for inorganic lead have been determined in oysters (6,600), in freshwater (92,000) and seawater (700) algaes (Amiard-Triquet, 1980). Lead is not biomagnified in terrestrial and aquatic food chains (Eisler, 1988). Biomagnification seems limited to the phytoplancton or to filtering organisms such as mussels or oysters.

Other sources of lead

In foods, lead may originate from atmospheric dust deposition on fruits, vegetables grains and contamination via environmental origin of meat, seafood or fishes. The use of lead-soldered cans or lead containing kitchen devices (earthenware vessels) used for storage and cooking, and the presence of lead chromates in pigments used to print plastic food wrappers are other important sources. Lead may also leach from lead crystal vessels. Pica is the main source of non-food consumption in young children. Of particular concern is the ingestion of highly contaminated paint dust. Concentrations as high as 28% (Scharman, 1996) have been reported in chips from lead based painted surfaces.

During the last few years several case reports of high lead exposure from previously unidentified sources have been published. Among these are: candles having lead metal wick cores (van Alphen 1999), a toy necklace with lead containing cubes which the child frequently put in his mouth (Jones et al 1999), ceramics containing lead beyond the regulatory limits (Sheets 1999), a nipple shield made of a lead-containing metal which was being used by a breast-feeding woman (Kokori et al 1999), and a severe case of anaemia after ingestion of several traditional medicines from India (Spriewald et al 1999).

Physiologic conditions such as ageing or pregnancy are known to induce a mobilisation of bone complexed lead. It has also been suggested that drinking coffee may mobilise lead stored in tissues and bones.

Actions already taken in Denmark have resulted in average daily intake levels of lead in foods below those of the majority of Member States.

Based on recent health effect studies, whether the present lead WHO-PTWI provides full health protection for vulnerable groups may be questionable. The CSTEE proposes to review this in a subsequent opinion.

3.2. Risk assessment

Following the restriction on lead-gasoline, pulmonary and cutaneous absorption are now minor routes for uptake, ingestion being the principal source of concern in the great majority of non occupational situations. With respect to soil ingestion, the amount of lead absorbed will depend not only on the levels of lead present, but also on the type of soil. For example, in Sweden it has been shown that while very high concentrations of lead in mining areas have no significant effect on blood lead levels in children, this is not the case for lead contaminated soils from some other areas. Based on the assumption of exposure to a soil from which lead has a reasonable bioavailability it has been calculated (Wixson and Davies, 1994) that in order to protect 99% of the population from exceeding a lead blood level of 100 microg/l, the corresponding highest acceptable lead concentration in soils would be 300 ppm. To achieve 95% protection of the population from exceeding a lead blood level of 200 microg/l, a soil concentration of 3750 ppm would be acceptable.

Standards for lead intake have been set by a number of expert bodies.

- A Tolerable Daily Intake (TDI) of 3.5 microg/kg bodyweight has been set by the FAO-WHO Joint Committee taking into consideration that a daily intake of lead, of up to 4 microg/kg bodyweight, will not result in a significantly increased blood lead level above the historical background. In 1986 and again in 1992, WHO has proposed a permitted tolerable weekly intake of 25 microg/kg body weight for both adults and children. This value was confirmed by JECFA. in 1995.
- The USFDA has determined « no risk » and intervention levels of lead in blood. TDIs have been established based on the no-risk level for various population groups. The relationships between TDIs (microg/person/day) and the corresponding lead blood levels (microg/l) are set out below.

Population	**No-risk Lead blood level**	**TDI**
Children (1 year old)	100	60
Children (7 year old)	100	150
Pregnant women	100	250
Adult	300	750

Recent blood lead level measurements in children (74,000) in the Netherlands indicate that for approximately 3.3% of children between 1 and 12 years the 100 microg/l value is exceeded. For the majority (63,000 children), levels are between 100 and 150 microg/l. For 11,000 children blood lead levels are between 150 and 250 microg/l. Children in the highest exposure groups tended to live in the centre of the major cities where drinking water containing lead and heavy traffic were important sources of exposure. The principal source of lead exposure in young children is claimed by the Danish Authorities to be soil, dust, and food. However, no data are provided on the relative importance of each of the three sources.

The level of lead in most foodstuffs is declining progressively in Denmark and elsewhere. In the Danish food survey, between 1988 and 1992 it has been calculated that the average intake of lead from food, by children 1-3 years of age, corresponds to 19 -22% of PTWI, while the 95%ile corresponds to 26 to 34% of the PTWI. In adults the mean intake from food was calculated to be 42 microg/kg/day in the period 1983-1987; it decreased to 27 microg in the years 1988-1992. In the recent published survey from 1993-1997, the intake was decreased to 18 microg (Kemiske forureninger). As a consequence, there has been an increase in the “relative” importance of lead intake from drinking water plus other drinks (juices) followed by vegetables and corn products.

In France the population with the highest intake (5% of all consumers in 1999) and 2.5% of children may ingest up to twice the PTWI. In adults, wine is the major source of ingested lead contamination, followed by vegetables, fruit and fishes. In children in France most of the ingested lead is assessed as coming from vegetables, fruits and fruit juices.

An important consideration in assessing the risk to children is the likely bioavailability of lead from soil and dust. The relative contribution from polluted soil, as potential source of lead exposure, in Denmark is not known. Estimates vary greatly on this. As mentioned above, lead contaminated soil may affect children’s blood lead levels, in particular when the source of the soil lead is automobile exhaust or lead based paint. For children living in inner-city areas lead particles from the traffic flow may fall directly to the soil and be ingested by the children (Mielke et al. 1989). In such circumstances, lead in dust and lead blood levels may be closely related (Lanphear et al. 1998 b).

The relationship of lead in soil to lead in blood have been investigated in several studies (Lanphear et al., 1998a, Mielke et al., 1997 and 1998, Jin et al., 1997). Increasing lead concentration from background to 400-microg/gram soil is estimated to produce an increase of 11.6 % in the percentage of children estimated to have a blood lead level exceeding 100 microg/l (Lanphear et al., 1998a).

As with Denmark, in Sweden lead in petrol has been banned for a number of years. A recent Swedish study has shown that food is now the main source of lead exposure even in young children living in areas with high soil lead concentrations, i.e. downtown Stockholm (<10-330 mg/kg in soil) and mining areas (20-5,000 mg/kg). It was concluded that lead in soil and dust contributed little to the total intake. There were no significant differences in blood lead levels between the differently contaminated areas (average 28 microg/l in an urban area and 19 microg/l in the mining area) and control areas with much lower concentrations of lead in soil (average blood level concentrations 27 microg/l in an urban area and 21 microg/l in a rural non-mining area). In the urban area, there was a peak in blood lead levels at around two years of age, probably due to the mouthing behaviour of the children. The hand-to-mouth contact generally peaks at that age. There was also an association between blood lead concentrations and indoor dust lead concentrations, not seen in the mining area. This indicates that the soil lead originating from automobile exhaust has a higher bioavailability than soil lead of mining origin. (Berglund et al in press).

From the latest intake estimate in Denmark, in adults, the daily mean intake is 7% of the PTWI with the ninety percentile being 10% and the ninety-five percentile being 11% of the PTWI. The "worst case" could be 22-33% of the PTWI if it is assumed that the children eat 2-3 times more per kg body weight than adults. The majority would have an intake well below the PTWI, however possible hot spots have to be taken into consideration.

The report on lead exposure of children from the Danish Institute of Epidemiology of 1978 describes blood lead levels in children from various areas in Denmark. The highest levels were found in children living near major traffic routes and whose fathers have been working in secondary lead smelters (90-290 microg/l). Those living in non contaminated areas without intense traffic, had levels between 60 and 170 microg/l. (Bach, 1978). This agrees with Swedish data of 1978 as reported by Skerfving et al 1999.

The concentrations of lead in the blood of Swedish children have steadily decreased in the past 15 years (Skerfving et al, 1999). It is not clear if the concentrations have now reached a new steady state level. A similar situation would be expected for children in Denmark.

3.3 Environment

Whether lead is a significant environmental problem in practice has not been identified by the Danish EPA in the 1998 report.

Soil

Soil concentrations for different types of soil in Denmark indicated concentrations in urban areas ranging from 30-500 mg/kg dry weight but in polluted areas concentrations up to 12,000 mg/kg can be found. Median values in agricultural soils are typically in the range of the background concentrations. The conclusion that it is likely that there may be harmful effects associated with the most highly contaminated soils in Denmark can be endorsed in light of the PNEC for soil (based on effects on the most sensitive organisms) which probably lies around of 50-60 mg/kg. It must be noted however, that these high soil concentrations are likely to have been caused by emissions some time ago rather than current deposition levels.

A second argument brought forward refers to the potential accumulation in soil due to atmospheric deposition and a number of intentional and unintentional diffuse emissions. It is estimated that in the current situation an increase in the soil lead content of approx. 0.1 % occurs per year. This implies that it will take at least 1000 years in order to double the current soil concentration.

It is very difficult to estimate the long-term fate of the lead fraction in the soil. Part of it will be tightly bound as a result of the strong binding potential of lead but part of it may also become bioavailable, especially if there are changing land-use conditions.

Water

The document from the Danish authorities states that the major problem with lead in the aquatic environment appears to be lead poisoning of water birds due to the use of lead shot and possibly also lead sinkers for fishing lines. Concentrations in the freshwater and marine environment have decreased over the last decades and current levels do not indicate a heavy burden of lead for the aquatic environment.

The problem of lead poisoning due to the ingestion of lead shot has been generally acknowledged and has been the reason for a ban on the use of lead shot in several countries including Denmark.

Due to the fact that this ban is not EU-wide, imported lead shots are still used in countries regardless of the national ban. For the Netherlands it is estimated that still 20% of the shot are lead shot and this figure appears to be increasing. It is understood that a substantial import of lead shot also occurs in Denmark.

The Danish Authorities state that ”it cannot be denied that lead will impair animal and plant life where environmental exposure is highest”. Except in specific situations such as local dissolution of lead shots, this statement can neither be endorsed nor rejected in regard to the situation for water since no specific data are given in the Danish report to substantiate this statement.

Based on a comparison of the surface water concentrations of lead in Denmark and the critical levels given above, it can be concluded that the present concentrations do not indicate a risk, although higher point source concentrations might do so.

Waste effluents

<u>Landfilling</u>

The Danish Authorities state that the current and future amounts of lead in landfills will ultimately leach into soil and groundwater and represent a potential burden for the aquatic environment. Greater inputs of lead contaminated waste to landfill are likely to have occurred in the past than is currently the case.

Whether or not leaching from landfills will result in a very long-term risk for the environment cannot be judged on current knowledge. A potential exists for volatilisation of organic lead and should be taken into consideration. Given the strong binding properties of lead to organic matrices in the landfill, it can be assumed that emissions will be largely localised; however, widespread leaching into the aquatic environment does not seem likely. If leaching occurs, it is likely to be very slow and to continue for a very long time period.

Sewage sludge

The Danish Authorities have estimated that a dilution of at least 50–500-fold of agricultural waste products occurs, when applied to agricultural soil, assuming that the waste is applied in accordance with the current regulations. A twelve year study in which 12 tonnes of sludge dw/ha were applied every fourth year indicated an increase in soil lead content of 11% (as compared to a 50% increase in copper; p.21 in the Danish report). Analysis of lead in a limited number of agricultural sludge samples indicated that in no case was the Danish limit value exceeded (p. 94 of the Danish report).

Investigations of lead and other metals uptake in radishes, carrots and onions grown on soil treated with sludge indicated rather poor uptake of lead (with higher uptakes of cadmium and nickel). However, lead may be relatively concentrated in the skin of root crops such as potatoes (p. 118 in the Danish report). There was no concentration of lead in fruit and leaves, in contrast to cadmium and nickel (Danish EPA, 1997).

The concentrations of lead in municipal wastewater tend to be low. The main source of lead appears to be domestic wastewater: 45% to 83% of the lead measured at three municipal wastewater treatment plants (Ministry of Environment and Energy, Denmark, 1997).

In the treatment plants there is a very effective segregation of lead (90-95%); thus only a small amount is found in the outlets of such plants. Nonetheless, approximately 10-20% of human sewage sludge do not fulfil the Danish Limit value of 120 mg/kg dw (80%-ile 90mg/kg dw 90%-ile 180 mg/kg dw) for application to agricultural land. The principal sources of lead responsible for this has not been identified (Ministry of Environment and Energy, Denmark, 1996).

Waste incineration

Incineration of lead contaminated waste will result principally in lead contaminated bottom ash and slag. This may impair their use as building materials. The lead contaminated slag and bottom ash may, as a consequence, be required to be landfilled. This creates the potential for slow leaching. The importance of this for the environment has not been evaluated properly. Although impacts are likely to be rather small, they can influence attainment of sustainability goals. The CSTEE point out that the question of sustainability with regard to fly ashes must be tackled.

3.4 Conclusions

- In general, environmental exposure to lead of both the public and of environmental species has been decreasing in the EU Member States, including Denmark.
- The principal cause of this decrease is the ban on the use of lead in petrol.
- The reduction in airborne lead and, to a much lesser extent, in food (for which lead contamination is partially dependent upon atmospheric lead) is considered to be a primary reason for the general lowering in lead blood levels in children and adults in Member States.

- A further reduction in both food and blood levels might be anticipated because the full impacts of the lead in petrol ban has yet to be realised.

- For the public this means that inhalation is no longer the principal route of lead exposure, rather it is the ingestion of contaminated foods and drinks and, in the case of young children, also dirt and soil, especially in heavily contaminated areas.

- Lead-contaminated soil has been recognised as potential source of lead exposure, but the relative contribution from polluted soil in Denmark is not known. The relationship of lead in soil to lead in blood have been investigated in several studies outside Denmark. Increasing lead concentration from background to 400-microg/gram soil is estimated to produce an increase of about 12 % in the percentage of children estimated to have a blood lead level exceeding 100 microg/l.

- Levels of lead in food have declined in Denmark over the past decade, with levels in milk remaining rather stable. The average intake of lead from food, in Danish children of 1-3 years of age, during the period 1988-92 corresponded to 19 – 22 % of the WHO PTWI, while the 95th percentile corresponds to 26 – 34 % of the PTWI. A worst case calculation of the intake of lead in children, based on lead intake from 1993-1997, showed that it did not exceed 33 % of the PTWI. These data do not support the Danish argument that lead exposure in children from dust and food ingestion is close to or exceeds, the PTWI value.

- Remedial measures in Denmark should be targeted on specific sources of high lead exposure, e.g.: lead piping/solder in contact with drinking water. An important contributor to a further reduction in lead exposure in Denmark would be a general ban of lead in petrol in all others European countries.

- There is inadequate scientific data to demonstrate conclusively what is a safe blood level for lead. Young children are considered particularly at risk. In young children subtle effects have been reported below 100microg/l blood. The CSTEE will review this further in a subsequent opinion.

- With regard to impacts of lead on environmental species, the available data is much less substantial. There are a number of local areas with high lead levels for historic reasons. The Danish Authorities have predicted a very slow increase in lead levels in soil. Even if the calculation is correct, this is not expected to cause a significant change in impacts on environmental species for many hundreds of years. It is also very unclear whether this lead would have a significant bioavailability. Environmental monitoring of lead is encouraged in order to identify whether changes in lead levels will occur in practice and, if so, appropriate remedial actions should then be identified and implemented.

- Very local increases may arise for specific reasons, for example the continuing use of lead shots imported into the country, although its production is banned in Denmark. This raises the issue of whether or not lead shot should be banned throughout Europe.

- A further issue is the lead contamination of some batches of human sewage and agricultural waste, thereby preventing its application to agricultural land. This is an important consideration with respect to a sustainable waste disposal policy. Research should be conducted to identify the principal sources of this lead contamination.

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