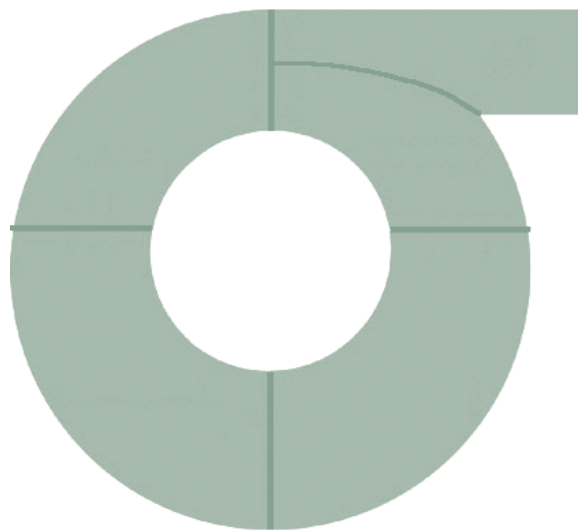


SETTING THE GREEN LEAD STANDARD

GREEN
LEAD
WORKSHOP
APRIL 28TH TO APRIL 30TH 2004
L O N D O N



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INTRODUCTION

Lead can enter the environment through many routes, and in the development of a “Green Lead Environmental Performance Standard” for an industrial facility (mine, smelter, recycler, manufacturer, etc.), the multiple exposure pathways of lead to both humans and other biota must be considered (Figure 1). Compared to many other metals, lead is poorly mobile in the environment, and in general it will be retained in soils or sediments due to the ability of these media to bind the lead (by adsorption and precipitation reactions). Thus unlike cadmium, plant uptake of lead is not an important exposure pathway, nor is lead leaching from soils to groundwater a high risk compared to elements such as arsenic or cadmium.

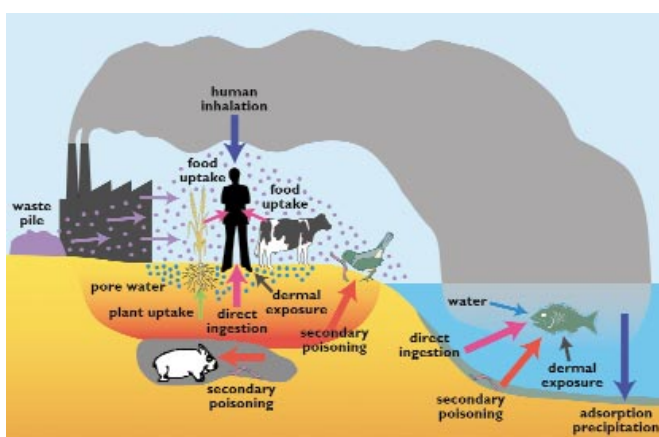


Figure 1. Exposure pathways for lead relating to humans and terrestrial and aquatic environments.

GUIDING PRINCIPLES FOR STANDARD DEVELOPMENT

Environmental performance standards to which Green Lead certification procedures can be indexed have yet to be developed. The development of such standards would pose logistic and scientific challenges if meaningful performance criteria are to be developed that are amenable to implementation by industry sectors operating in a diverse range of cultural, socioeconomic, regulatory, and geographic settings. The following issues merit consideration in the development of such standards.

- 1) Standards should promote primary prevention of lead exposure: Standard development has typically operated in accordance with principals of secondary, as opposed to primary, exposure risk reduction. This is to say, monitoring is conducted to determine levels of exposure in the environment, in the workplace, or in the general population and determinations made if resulting exposures are excessive. Excessive exposures in turn serve as the trigger for appropriate risk reduction activity. Appropriately structured Green Lead performance standards should seek to effect primary prevention of lead exposure – measures to restrict or otherwise modulate industrial emissions would be implemented to prevent exposures prior to the need for intervention measures, analogous to hazard analysis critical control point (HACCP) procedures.
- 2) Standards should encompass the full range of industrial activity that may result in environmental releases: All too often standards focus upon the end product of environmental releases (e.g., loading of environmental compartments and/or resulting human exposures). Goals of primary prevention are best served by performance standards that provide guidance on the full range of industrial processes and environmental control measures that might result in exposures to lead. Although it is commonly accepted that health and environmental protection can be afforded by setting maximum exposure limits for

"receptor organisms", an effective standard should also provide guidance regarding technical performance criteria associated with releases from industrial facilities that may result in environmental and/or human exposures. Proactive measures that govern emissions from a given industrial process or facility are central to primary prevention. Thus, stack or fugitive emissions limits should be concordant with the environmental exposure limits being sought. Furthermore, "end-of-pipe" emission control solutions should be recognized as only one component in this process - technology and process decisions associated with specific industrial processes have qualitative and quantitative impacts upon the measures that must be implemented to ensure compliance. Put another way, the adequacy of end-of-pipe control strategies to achieve environmental compliance goals is facilitated if consideration is given to process design so as to minimize reliance upon pollution control systems. Technology selection can minimize the generation of emissions that must be controlled and can be extremely important within contexts (e.g. in developing countries) wherein access to, or maintenance of, sophisticated emission control technologies is difficult to ensure.

3) Standards should be holistic and attentive to the full industrial lifecycle: Development of a "Green Lead Performance Standard" implies focus upon lead emissions and the potential adverse impacts that might result from such emissions. However, although high priority might be set upon limiting lead emissions, a holistic perspective should be maintained upon industry environmental performance parameters. As a function of different industry sectors and production processes, consideration of other metrics of environmental performance must be maintained. For example, the choice of technology for the production and/or use of lead could be influenced by considerations of green house gas emissions, emissions of other toxic substances, and the qualitative and quantitative characteristics of components of air, solid and liquid waste streams that must be managed.

4) Standards should be flexible: Although a focus upon limitations in lead emissions is implicit for a Green Lead program, national jurisdictions may place an emphasis upon other process considerations that will impact choices of technology and/or emission limitation goals. For example, national specifications for the generation and disposal of solid and/or liquid waste (independent of lead-related issues) may impact upon technology selection and other environmental performance goals. Flexibility is also necessitated by the highly variable relationships that can exist between environmental lead emissions and the subsequent exposures that might occur under different geographic and climatic conditions. Emission limits that might be adequately protective under one set of conditions may be inadequate under other conditions or time frames.

5) The process of standard development must be transparent and open to external review: The establishment of Green Lead performance standards should be conducted via a transparent process open to external scrutiny and review. Ideally standards would also be attentive to the deliberations and activities of other organizations that have been concerned with lead-related issues. For example, performance standards applicable to industry sectors in developing countries would ideally be cognizant of deliberations conducted under the auspices of the Basel Convention to define environmentally sound management practices at lead recycling facilities. Similarly, standards for limits upon human and environmental exposures should be compatible with the deliberations of international scientific and regulatory bodies such as the International Program for Chemical Safety, the World Health Organization, and the Joint Expert Committee on Food Additives. Standard development should also recognize national and/or regional efforts to evaluate and refine regulatory strategies that minimize potential lead exposures.

Given the preceding, the development of a Green Lead standard could take advantage of opportunities presented by other voluntary efforts such as those of the European industry to conduct a Voluntary Lead Risk Assessment (VLRA). Efforts to develop a VLRA are proceeding in accordance with official EU guidelines for the conduct of risk assessments that establish dose-effect relationships and exposures that might occur in workplace, to the consumers of lead-containing products, and exposures that might result to humans and/or environment as a consequence of point source and diffuse emissions. This integrated VLRA analysis is being conducted via a process employing expert external peer review as well as oversight from a national government authority. The final product of the VLRA effort will be an assessment that is then put forward for official review and adoption by EU Member States. A Green Lead standard that embraces the principles of the VLRA, while at the same time seeking to expand it to have international applicability, could be a logical starting point that seeks to accommodate aforementioned logistic and practical challenges.

LIMITATIONS UPON HUMAN EXPOSURE

Limits that are established for human exposure would necessarily seek to protect "at risk populations" as defined through either opportunities for exposure or by unique susceptibility to the toxic effects of lead. Specific attention would thus be paid to exposures that might occur in the occupational setting and to at-risk groups in the general population. The development of appropriate standards would proceed through a step-wise analysis of dose-effect relationships for each population of concern followed by the promulgation of protective measures that should be pursued to ensure adverse health impacts do not result. Occupational exposure standards would focus upon evaluation of the health-effects literature pertinent to the exposure of healthy adult individuals and place strongest reliance upon

existing occupational health and industrial hygiene literature. Point source emissions, and diffuse sources for lead in the environment, would impact upon the general population where effects upon young children and/or pregnant women would likely be of greatest concern and would require establishment of a separate set of dose-effect relationships. In both instances the dose-effect relationships that serve as the basis of standard development will be fluid and subject to refinement as a function of new scientific developments. The identification of the at-risk populations would be followed by a process in which occupational and environmental release standards compatible with primary prevention principles would be developed.

Standards so developed would attempt to predict the exposure pathways of greatest concern and the fashion in which lead production and use would influence exposure routes. Appropriate standard development would entail consideration of both the direct impacts of active emission sources and, when appropriate, the time frames over which cumulative environmental loading may result in the development of excess exposure risk. By way of example, emissions to air can be predicted to produce defined impacts upon human exposure, with exposure risk varying as a function of current emission intensity. However, emissions to soil and dust can produce a cumulative loading of environmental compartments to which children may be exposed at a future date. Initial environmental loading may be limited and secondary in importance to active (air) emissions. However, over time lead accumulation within soils and dust will assume greater importance and become a predominant source of exposure. Standard development must thus consider both the intensity of environmental emissions and the probable period over which emissions will occur.

LIMITATIONS FOR ENVIRONMENTAL EXPOSURE

From a 'zero harm' concept to a 'predicted no effect concentration'

The Green Lead standard for the environment aims for lead exposure that is associated with 'zero harm'. The 'zero harm' concept can only exist if the dose-response curve of lead follows a threshold model (Figure 1a) in which case the 'zero harm' exposure occurs at doses below a measurable threshold. It is still unknown if lead toxicity follows this model or not. The experimental dose-response curves measured to date (Figure 1b) usually suggest that this is the case and the threshold is typically derived as the NOAEL, i.e. the highest dose that does not significantly affect an organism. That statistical criterion is a pragmatic choice, thereby realizing that the threshold becomes larger as the experimental variability within the curve increases. Conversely, this also means that the threshold might become small if experimental error converges to zero and that 'zero harm' is only observed at 'zero

exposure'. The question if this occurs might be an academic issue because zero experimental error is not achievable. Practically, surrogates for 'zero measurable harm' have been derived using conventions, one of which is the definition of a 'Predicted No Effect Concentrations' (PNECs) as used in the VLRA.

The PNEC levels for environmental compartments (soil, water, air and sediment) are calculated from laboratory based NOAEL values and a whole set of conventions apply for treatment of these data (species sensitivity distributions of NOAELs, safety factors, selection of test organisms, reliability criteria etc.). In the end, the PNEC's are aimed to protect an acceptable percentage (usually 95 or 99%) of the organisms living in the ecosystem and multiple comparisons of PNEC values with effects in 'model ecosystem' (artificial streams, field trials,...) have corroborated the set of conventions used. As noted above, the convention of using 95 or 99 percentile no-effect concentrations in ecological risk assessments means that "zero harm" cannot be guaranteed.

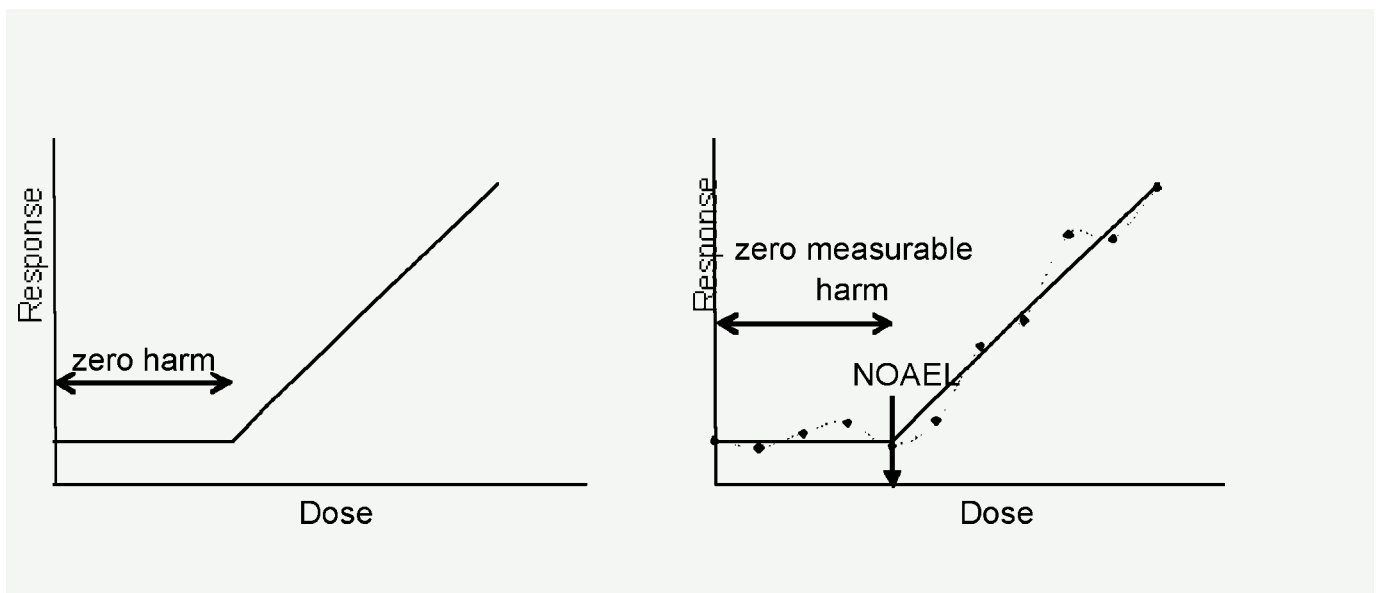


Figure 2 The dose response curve for environmental exposure. (a) a threshold model and (b) an experimental curve (points) with threshold model (lines) fitted. NOAEL = no observed adverse effect level.

The environmental assessment traditionally focuses on the biota closely associated with the compartment, e.g. higher plants in soil, invertebrates in sediments or algae in water and the laboratory tests use model exposure systems, e.g. pot trials, bottle tests etc. The protection of higher organism which are mainly exposed to lead via the food-web (e.g. birds, mammals) is more complicated than with the former biota because of the multiple exposure routes. It appears that this so-called secondary poisoning is critical for lead. These organisms dwell in several locations and the definition of 'zero harm' for a point emission cannot be derived without additional assumptions (e.g. fraction of food samples near point source, etc.).

The PNECs of lead derived in the VLRA will be presented at the workshop but, as discussed in the introduction, these standards should also be open for external review and should be contrasted with other deliberations.

The persistency of lead in soils and sediments complicates the 'zero harm' concept

The PNECs as surrogates for the lead exposure with 'zero harm' might be converted to emissions using exposure modeling, finally yielding acceptable emissions for a Green Lead protocol. In this way, straightforward calculations can be made of acceptable lead emissions to surface water taking into account typical dilution factors and residence times. For soils and sediments, this situation is more complex. Lead is strongly retained in soils and sediments and estimated "elimination half-lives" often exceed 103 years. This means that lead concentrations continuously increase in such compartments and that acceptable emissions cannot be defined without reference to a probable time-frame over which such emissions take place, because soil thresholds for adverse effects often occur at concentrations less than steady state values (Figure 3). For mines, smelters or industrial facilities, a finite life is probably not unreasonable given the operational life of most mines, and the continual upgrading of smelting and industrial facilities as technology improves and economics dictate process changes.

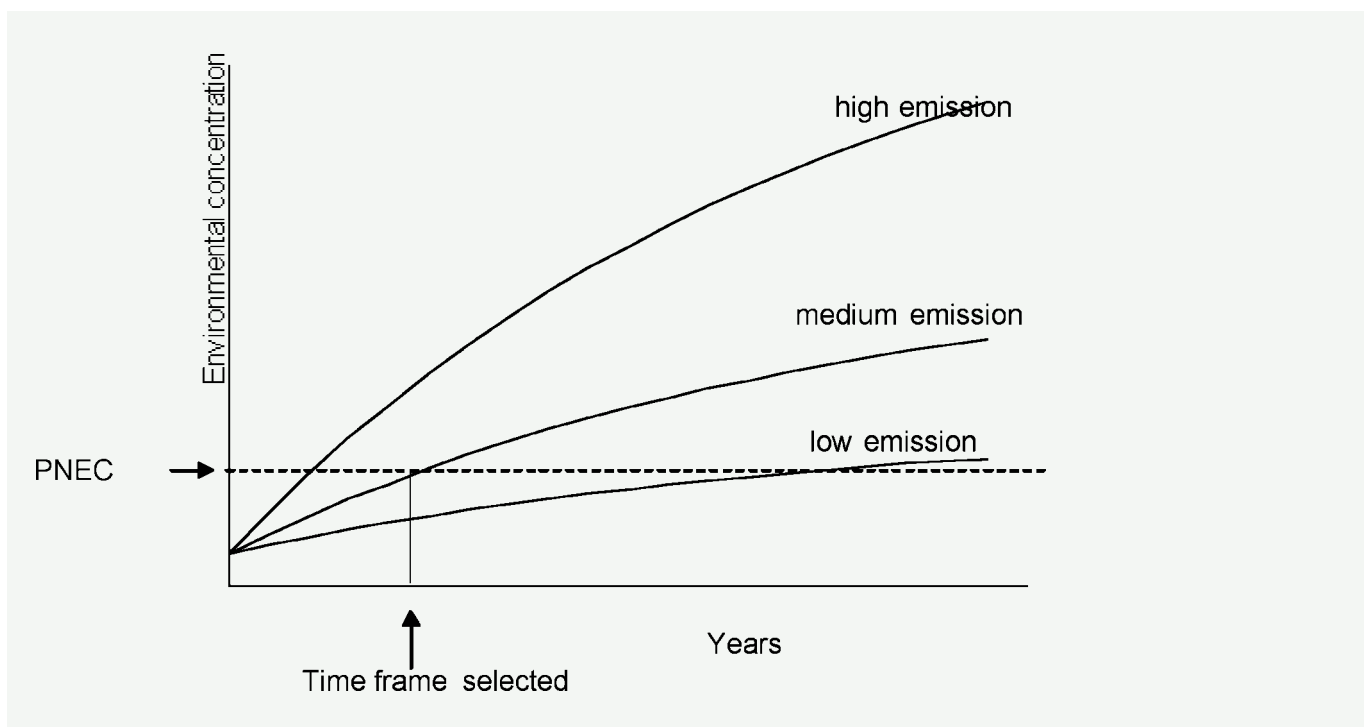


Figure 3. Environmental concentrations of lead continuously rise in soil and sediments due to its immobile nature. These concentrations may exceed the PNEC even at low emissions if the time frame considered is very long, therefore acceptable emissions (i.e. "Green Lead Standards") cannot be defined without reference to a selected time-frame e.g. 50, 100 or 200 years.