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Challenges in Evaluating Risks from Lead Exposure

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Multiple health authorities have programs to restrict exposure to lead (Pb) in different media to permissible levels. The scientific basis of these approaches was evaluated across several agencies to understand important similarities and differences among them. Agencies and programs were chosen to be a representative, rather than complete, description of the different approaches. The agency approaches evaluated were the US FDA Interim Reference Level (IRL) for Pb in food (Flannery, 2022), the US EPA approach for evaluating Pb in soil at Superfund sites (US EPA 1998, 2016), the US EPA model for evaluating Pb in surface dust in residences (US EPA, 2019), and the CA Office of Environmental Health Hazard Assessment (CA OEHHA) identification of the Maximum Allowable Dose level (MADL) for Pb for under Proposition 65 (CA OEHHA, 1989). The following factors were considered in the evaluation: populations of interest; critical endpoints; risk targets (*e.g.*, blood lead levels [BLLs]); exposure methodology; and description of uncertainty and variability. All agency approaches, except for the CA OEHHA MADL, consider young children as the population of interest, based on associations between BLLs and certain neurodevelopmental endpoints in this population. Because CDC concluded that no threshold can be determined for these associations, the agency identified the 97.5th percentile distribution of BLLs (the blood lead reference value [BLRV]) in young children as a guidance tool for identifying children with elevated BLLs. Therefore, the BLRV is not a health-based value *per se*. The US EPA dust Pb approach and the US FDA IRL use the 2012 BLRV of 5 µg/dL and the 2021 BLRV of 3.5 µg/dL, respectively. In contrast, the US EPA Superfund program uses the pre-2012 CDC health-based level of concern of 10 µg/dL. In addition to a target BLL, the US EPA approach for Pb in surface dust (US EPA, 2019) considers decrements in IQ based on predicted BLLs under different exposure scenarios, explicitly incorporating potential health effects in the analysis. The extent to which agencies consider other populations and endpoints varies. The US FDA analyzed other health endpoints in pregnant women and children to confirm that the IRL for Pb in food is broadly protective. In contrast to the three other programs, the target population for the CA OEHHA MADL for Pb, a notification limit, is the adult male or female of reproductive age. Compliance with the MADL under intermittent exposure conditions can be determined by blood Pb modeling. Other agency approaches also incorporate blood Pb modeling to develop a specific limit, although the details of the approaches differ. While there are similarities across programs, there are also important differences. For example, the CA OEHHA MADL focuses on the average consumer, typically interpreted as a median exposure, whereas the Superfund approach focuses on a high-end exposure, specifically the 95th-percentile BLL. Other differences include choice of risk targets, approaches to estimate BLLs, complexity of the analyses (in particular the characterization of uncertainty and variability), the ability to incorporate site-specific information (*e.g.*, the Superfund program allows incorporation of soil Pb bioavailability), and the ability to compare predicted BLLs with measured BLLs. Our findings highlight challenges in lead risk assessment and management approaches across media, and both across and within agencies.