

This is a provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Lead

(Chemicals and contaminants)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

The FSCJ conducted risk assessment of lead (hereinafter refer to as Pb), as a Self-Tasking assessment, as a risk assessment related to revision of the standards for apparatus/container and packaging (ACP), and as a risk assessment related to revision of the standards for beverages.

Pb is a substance widely distributed in the environment, and Pb of natural origin and Pb of anthropogenic origin are mixed in human life circumstance. Consequently, humans are supposed to be exposed in the daily life to Pb through a wide variety of mediums including meals (exposure not only through food but also drinking water and ACP), atmosphere, soil, house dust, and others. However, findings on the contribution ratio of each media for the exposure in Japan are inconsistent. Neither a trend that particular food group has a large contribution ratio is found. Estimated daily intake of Pb from meals as a result from surveys by market basket method was more than 100 µg/day in 1978, decreasing sharply by 1982, and keeps decreasing constantly afterward. Both recent surveys by the market basket method and by the duplicate portion method reported the estimated daily intake of Pb of about 2-9 µg/day.

Blood Pb level seems to reflect the actual human situation of Pb exposure through various mediums, including meals. Moreover, blood Pb level has been used widely as the exposure index in epidemiological studies on the effects of chronic exposure to Pb.

To presume the actual situation of exposure of Japanese people to Pb, this working group analyzed the distribution of blood Pb levels among children (12 years old, surveyed for 2015-2018) and among adults (pregnant women, surveyed for 2011-2014), where the children were the target of analysis by Tatsuta *et al.* (2020) among a target of investigations of the Tohoku cohort, and the adults were the target of the Japan Environment and Children's Study. As a result, median and 95 percentile of blood

Pb level in children of 12 years old were calculated as 0.66 $\mu\text{g}/\text{dL}$ and 1.04 $\mu\text{g}/\text{dL}$, respectively. Median and 95 percentile of blood Pb level in pregnant women were 0.61 $\mu\text{g}/\text{dL}$ and 1.11 $\mu\text{g}/\text{dL}$, respectively. It should be noted that the children's data on blood Pb level do not necessarily reflect the situation of children as a whole in Japan, since the data are from limited age group and local areas, and that there is uncertainty in presuming the situation of blood Pb level of all adults in Japan based on the level in pregnant women only, since pregnant women may have blood Pb levels lower than non-pregnant women and age difference and gender difference in blood Pb level have been observed by survey research abroad.

Accurate understanding of blood Pb level of all Japanese is difficult due to the lack of survey research with the representative sample where gender difference, age group, and area were considered, as described above. Nonetheless, the FSCJ concluded that average blood level of Pb of current Japan is about 1 $\mu\text{g}/\text{dL}$ or less based on the data available at present and considering the above-mentioned uncertainty. In addition, blood Pb level of Japan decreased in comparison to that in 1990s, and the level was judged to be at a low standard throughout the world.

Although many model equations have been postulated for conversion of blood Pb level into Pb intake, there are various issues with it and findings to indicate relationship between blood Pb level and Pb intake are insufficient. Because of this fact, the FSCJ concluded that it is difficult to convert blood Pb level into a tolerable daily intake of Pb.

For continuously grasping Japan's reality of Pb exposure from different mediums, including meals, it should be necessary also in Japan to keep a close watch on trend of blood Pb level with representative samples through implementing human biomonitoring on a substantial scale like that which has been conducted over the world.

The FSCJ investigated blood Pb level without adverse effects using data from epidemiological studies, since many results from epidemiological studies on the effects of Pb exposure have been reported. As a consequence of comprehensive evaluation of the findings from previous epidemiological studies, it was suggested that blood Pb level even at the level of 1-2 $\mu\text{g}/\text{dL}$ potentially affects children's neuro-behavioral development or adult renal function. However, results from different epidemiological studies are inconsistent, and depend on the effects. Confounding cannot be excluded completely; it is difficult to evaluate the effect of Pb exposure only, since evidence is insufficient for presuming a causal relationship between Pb exposure and the observed effect. Moreover, clinical significance and public health significance of the observed effects are obscure. Hence, the FSCJ concluded that it is difficult at present to estimate blood Pb level without adverse effects using the data from epidemiological studies.

On the basis of the above findings, the FSCJ estimated the average blood Pb level in current Japan as about 1 µg/dL or less which is close to the level suggested by epidemiological studies to have some effects, 1-2 µg/dL. Therefore, continuous efforts to implement measures to reduce Pb exposure are required.

Note that this assessment was conducted based on the currently available scientific findings. To conduct risk assessment more precisely, it is desirable to accumulate scientific findings such as findings on Japan's Pb exposure from various mediums and of blood Pb level, and scientific findings on the effects of exposure to low level Pb in Japanese people.

In addition, as continuous measures to reduce Pb exposure are required, a close watch on the trend of blood Pb level by human biomonitoring is necessary for verification of the efficiency.