Risk Assessment Report on Radioactive Nuclides in Foods

(Working Group for an assessment of the effect of radioactive nuclides in food on health)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

In response to the accident at the Fukushima Dai-ichi Nuclear Power Station by Tokyo Electric Power Company (TEPCO) and detection of higher-than-normal radiation levels near the plant after the Great East Japan Earthquake that occurred on March 11, 2011, the Ministry of Health, Labour and Welfare (MHLW) adopted Indices for Food and Beverage Intake Restriction posted by the Nuclear Safety Commission of Japan as provisional regulation values. These provisional regulation values were established urgently without an assessment of the effect of food on health; thus, on March 20, 2011 the Minister of Health, Labour and Welfare requested the Food Safety Commission of Japan (FSCJ) to conduct an assessment according to Article 24, Item 3 of the Food Safety Basic Act.

For this risk assessment of the effect of food on health, a wide-ranging publications on radioactive material were analyzed including references cited in reports of radioactive materials by Agency for Toxic Substances and Disease Registry (ATSDR) and United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), documents published by International Commission on Radiological Protection (ICRP) and World Health Organization (WHO). Numbers of publications available on health effect by oral ingestion of radioactive materials were limited. Therefore not only the reports on internal exposure from oral ingestion, but findings related to the toxicity of chemical substances were extensively collected. Radioactive nuclides which were examined are: radioactive iodine, radioactive cesium, uranium, plutonium, α particles of transuranium elements (americium and curium), which the provisional regulation values are defined by the MHLW, and additionally, radioactive strontium. However there were little data on health effect by oral ingestion of examined radionuclides. Tolerable daily intake (TDI) was decided to be established for uranium, whose toxicity as the chemical substance was determined to exceed the toxicity effect from radiation. Apart from uranium, there are still important radioactive nuclides: radioactive iodine, which exerts a profound effect on thyroid thus could lead to thyroid cancer, and radioactive cesium, which was considered to be most critical radioactive nuclide in regard to intake from food according to current detection outcome of radioactive materials in food. However there are not enough knowledge on all the radioactive nuclides except uranium including radioactive iodine and radioactive cesium to establish risk assessment on each radioactive nuclide.

Based on the findings above, focusing on epidemiological data, the effect on health of low dose radiation to human health was investigated, and concluded. Only for uranium, TDI was established.

Epidemiological data have various limitations, however, by fully recognizing those limitations, FSCJ conducted its own investigation based on available publications.
The publications were classified from various viewpoints such as the validity of study design and study subject population, existence or non-existence of statistically significant difference, appropriateness of estimated exposure amount, the influence of the confounding factors, and the presence of uncertainty referred by the author in order to identify its applicability for this assessment.

As a result, following studies covering the detection of effect at low dose radiation to human health and studies reporting no detection of effect at high dose radiation to human health in adults based on a large body of epidemiological data were taken into consideration as authentic research.

(1) A study reporting no identification of increased cancer risk in high background radiation area in India where the cumulative radiation dose is 500 mGy or higher. (Nair et al.2009)
(2) A study covering the excessive relative risk of solid cancer mortalities among atomic bomb survivors in Hiroshima and Nagasaki. A significant linearity was observed for dose-response relationship in the dose range of 0-125 mSv, but no significant relationship was observed in the dose range of 0-100 mSv. (Preston et al. 2003)
(3) A study reporting estimated relative risk of leukemia mortalities among atomic bomb survivors in Hiroshima and Nagasaki. In the case where the estimated relative risk of leukemia mortalities among atomic bomb survivors in Hiroshima and Nagasaki was compared to those in the control group (0 Gy), statistically significant increase was observed in organ-absorbed dose over 0.2 Gy, but no significant difference was observed in dose below 0.2 Gy. (Shimizu et al. 1988)

Based on the above mentioned researches, in regards to the assessment of the effect of food on health, FSCJ concludes that more than around 100 mSv of the extra cumulative effective doses: cumulative effective doses of radiation during lifetime, could increase the risk of effect on health. The amount does not include radiation from natural environment and medical exposure.

During childhood people are considerably more susceptible to radiation than adults, posing a possibility to develop thyroid cancer and leukemia.

Some epidemiological researches indicate the health effects from radiation doses at below 100 mSv, however data reliability of those researches remains uncertain.

There is an undeniable possibility that health effect from low radiation doses has not been validated by epidemiological research considering various factors. Therefore, health effects from the extra cumulative exposure below 100 mSv are difficult to be verified based on the current available knowledge.

For uranium, an administration study in drinking water for 91 days was conducted on groups of 15 male and 15 female weanling Sprague-Dawley rats. LOAEL of uranium was proposed 0.06mg/kg bw/day based on changes in kidney tubule functions were seen in all administered rats. Nuclear vesiculation of the tubular epithelial nuclei were observed in both sexes. In males, proximal tubular dilatation, apical displacement of the proximal tubular epithelial nuclei, and cytoplasmic vacuolation were observed. (Gilman et al. 1998 a) In this study, various examinations were conducted including the histopathological surveys. The calculation of TDI was considered to be applicable based on the LOAEL with safety factor of this study. No further adjustment was considered necessary to add a safety factor based on a sub-chronic study for 91 days, on the ground of nonsevere influence of uranium on kidney from this experiment, and the disposition, rapid excretion of uranium as well as rapid return to its steady state. Considering the rapid excretion of uranium from human kidney, the application of safety factor 300 was determined to be adequate. (species difference: 10, individual difference: 10, extrapolation of LOAEL to NOAEL: 3) Hence regarding uranium, based on 0.06 mg/kg bw/day as LOAEL from the result of toxicity study in rat, FSCJ proposed 0.2μg/kg bw/day as TDI with the safety factor 300.