Emergency Report on Radioactive Nuclides in Foods

2011 March

Food Safety Commission of Japan

(Original is written in Japanese. English translation is made by FSCJ Secretariat)

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29 March 2011	The 375th Food Safety Commission Meeting (Notification to the Minister of Health, Labour and Welfare on the same day)

<Food Safety Commission Members>

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<372nd Meeting of Food Safety Commission: List of Special Advisors>

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<373rd Meeting of Food Safety Commission: List of Special Advisors>

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1. History of Request

(1) Background

In response to the accident at the Fukushima I Nuclear Power Plant 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 on March 17, 2011 as provisional regulation values to avoid sanitation hazards of food and beverage, thus aiming at public health protection, and instructed local governments to prevent human consumptions of foods exceeding the said values according to Article 6, Item 2 of the Food Sanitation Act.

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 and should consider necessary administrative measures based on the assessment results.

According to survey data of the MHLW acquired after notification of the provisional regulation values, as of March 26, 2011, radioactivity in excess the provisional regulation values was detected in 23 of 128 samples of raw milk (detected value: radioactive iodine 310~5,300 Bq/kg, radioactive cesium 420 Bq/kg), 76 of 356 samples of vegetables (detected value: radioactive iodine 2,080~54,100 Bq/kg, radioactive cesium 510~82,000 Bq/kg), 0 of 7 samples of meat and eggs, and 0 of 7 samples of sea products. As regards the vegetables, radiation in excess the provisional regulation values was detected not only in those grown in the feild, but also in some cases of greenhouse products.

(2) Content of Assessment Request

According to Article 6, Item 2 of the Food Sanitation Act (Act No. 233 of 1947), the Minister of Health, Labour and Welfare requests for an assessment of the effect of food on health in determining index values for radioactive substances as toxic or harmful substances which are contained in or adhere to food, or are suspected to be contained in or adhere to food.

2. Introduction

Upon the request from the Minister of Health, Labour and Welfare, and considering urgent social situation in which radioactive materials emitted because of the current accident at the nuclear power plant in Fukushima was detected in agricultural products, while the affected range was expanding thus exerting enormous possible effect on people’s lives, FSCJ made an extraordinary decision to invite many experts with knowledge in the related areas as special advisors to the Commission meeting, to focus on this discussion in priority to other issues, and to compile a report urgently.

As compiling this emergency report, FSCJ, based on the idea that the protection of the health of Japanese citizens is a top priority, collected information provided by International Commission on Radiological Protection (ICRP), as well as World Health Organization (WHO) and other sources, and analyzed the those scientific data as thoroughly as possible.

In 1954, ICRP suggested that every effort should be made to reduce exposures to all types of ionizing radiation to the lowest possible level, and then in 1997 recommended that the level should be kept as low as reasonably achievable, after considering social and economic factors.

FSCJ, too, believes that radioactive materials in food should be reduced as low as possible, and that particular attention should be paid to pregnant, parturient or potentially pregnant women as well as infants and small children.

It should be noted that this report was compiled in a very short time using currently available data, as an emergency response, which is different from usual circumstances. In addition, there is no sufficient information at the moment about types and quantities of radioactive nuclides discharged actually from the failed nuclear plant, or about radioactive contamination situation, so many issues remain to be considered; thus FSCJ decided to continue consideration aiming at further assessment of the effect of food on health regarding radioactive materials.

3. Outline of Object Nuclides

The provisional regulation values by MHLW apply to radioactive iodine, radioactive cesium, uranium, plutonium and α-nuclides of transuranium elements.

In case of an accident at nuclear facility, gaseous krypton, xenon and other noble gases as well as volatile radioactive iodine are considered as radioactive nuclides likely to be discharged abnormally and widely in environment surrounding the nuclear reactor facility (*Nuclear Safety Commission of Japan, August 2010*). In case of the accident at Chernobyl Nuclear Power Plant, the main radionuclides were iodine-131 after 60 days, and cesium-134, -137 after 1 year (*FDA, 1998*).

This time, radioactive iodine (iodine-131) and radioactive cesium (cesium-134, -137) were detected in agricultural products with radiation in excess of the provisional regulation values.

There may be undetected radioactive nuclides other than the mentioned two types; besides, materials submitted by MHLW do not include data about what nuclides, and in what quantities, were discharged into the environment as the result of this accident at the nuclear power plant; thus monitoring data and other information will be required to judge about types and quantities of nuclides that may be detected in food.

However, proceeding from experience of past accidents at nuclear power plants and other facilities, radioactive iodine (iodine-131) and radioactive cesium (cesium-134, -137) are considered to be examined urgently in this case; therefore, first of all, those radionuclides are examined and reported urgently.

(1) Iodine

(a) Outline

The stable iodine existing in the nature is iodine-127. Iodine is necessary for thyroid hormone synthesis. Orally ingested iodine is easily absorbed from digestive tract; as it gets into blood, 30% accumulates in thyroid, 20% is excreted immediately, and the rest is excreted in a short time. Dissipation of iodine from thyroid depends on age, the biological half-life being 11 days for infants, 23 days for 5-year-olds, and 80 days for adults.

(b) Element name, atomic symbol etc. (*The Merck Index, 2006; NRC, 1977*)

IUPAC: iodine

CAS No.: 7553-56-2

Atomic symbol: I

Atomic weight: 126.9 (as iodine)

Abundance ratio in nature: iodine-127 100%

(c) Physicochemical properties (*The Merck Index, 2006; Iwanami Dictionary of Physics and Chemistry, 1998*)

Melting point (°C): 113.6

Boiling point (°C): 185.2

Density (g/cm^3): 4.93 (solid: 25°C), 3.96 (liquid: 120°C)

Vapor pressure (mm): 0.3 (25°C), 26.8 (90°C)

Water solubility (mol/L): 0.0013 (25°C) Soluble in organic solvents

(2) Radioactive Iodine (Iodine-131)

(a) Origin and Use

Iodine-127 is main iodine, but iodine is known to have numerous radioisotopes. Iodine-131 with isotopic mass of 130.9 is considered one of the most important isotopes in terms of environmental contamination and radiation dose to humans (*IPCS, 1983*).

Iodine-131 is used as a tracer in medical treatment (*Iwanami Dictionary of Physics and Chemistry, 1998*).

(b) Radioactive Decay and Disposition in Human Body (*Argonne National Laboratory 2005a; Iwanami Dictionary of Physics and Chemistry, 1998*)

Iodine-131 is produced by nuclear fission, being a radionuclide with β^- decay in physical half-life of 8 days. The maximum energy of β-rays is 0.61 MeV. In a nuclear reactor, iodine with high specific activity can be produced efficiently, which also pertains to uranium nuclear fission.

(3) Cesium

(a) Outline

Cesium exists in the nature as cesium-133. Cesium is an alkali metal with metabolism similar to potassium, and has no affinity to particular organs.

(b) Element name, atomic symbol etc. *(The Merck Index, 2006)*

IUPAC: cesium

CAS No.: 7440-46-2

Atomic symbol: Cs

Atomic weight: 132.9

Abundance ratio in nature: cesium-133 100%

(c) Physicochemical properties *(The Merck Index, 2006)*

Melting point (°C): 28.5

Boiling point (°C): 705

Density (g/cm^3): 1.90 (20°C)

(4) **Radioactive Cesium (Cesium-134, -137)**

(a) Origin and Use

There are 11 main known radioisotopes of cesium. Isotopic masses of cesium-134 and cesium-137 are 133.9 and 136.9, respectively. Cesium-134 and cesium-137 have a long half-life *(Argonne National Laboratory, 2005b)*. Cesium-137 is one of the main components of nuclear fission products; due to low price and availability in quantities, it is used widely in industry and medicine as a γ-ray source *(Iwanami Dictionary of Physics and Chemistry, 1998).*

(b) Radioactive Decay and Biological Half-life *(Argonne National Laboratory, 2005b; The Merck Index, 2006)*

Cesium-137 is one of artificial radioactive nuclides of cesium. It is a β^- emitter with physical half-life of 30 years that decays into barium-137m (‘m’ stands for metastable excited state) with physical half-life of 2.55 minutes. Barium-137m emits γ-rays of 0.662 MeV and turns into stable barium-137.

When cesium-137 gets into human body, its excretion half-life is 9 days for children under 1 year of age, 38 days for children under 9 years of age, 70 days for people under 30 years of age, and 90 days for people under 50 years of age. Cesium-134 is a β^- emitter with half-life of 2.1 years.

4. Effects on Human Body

In terms of information available at this point, there are very limited data on effects exerted on human body by low-dose radiation below 100 mSv; no data was found regarding quantitative toxicity to human of particular substances. The only information related to toxicity was that pertaining to radiation doses.

(1) Early and Late Reactions in Tissues and Organs *(ICRP Publication 103 (A69))*

Threshold doses for some tissue and organ reactions in the more radiosensitive tissues in the body are shown in Table 1. These have been deduced from various radiotherapeutic experiences and accidental exposure incidents. In general, fractionated doses or protracted doses at low dose rate are less damaging than are acute doses.

Table 1. Estimates of the thresholds for tissue effect in the adult human testes, ovaries, lens and bone marrow *(from ICRP, Publication 41, 1984)*

Tissue and effect		Threshold dose		
		Total dose received in a single brief exposure (Gy)	Total dose received in highly fractionated or protracted exposures (Gy)	Annual dose rate if received yearly in highly fractionated or protracted exposures for many years (Gy y^{-1})
Testes	Temporary sterility	0.15	—[1)]	0.4
	Permanent sterility	3.5 ~ 6.0	—	2.0
Ovaries	Sterility	2.5 ~ 6.0	6.0	> 0.2
Lens	Detectable opacities	0.5 ~ 2.0	5	> 0.1
	Visual impairment (Cataract)	5.0[2)]	> 8	> 0.15
Bone marrow	Depression of hematopoiesis	0.5	—	> 0.4

1) Not applicable. Since the threshold is dependent on dose rate rather than on total dose.

2) Given as 2-10 Sv for acute dose threshold.

(2) Effects in the Embryo and Fetus

(a) *ICRP Publication 103 (A81~A84, 2007)*

The risks of tissue injury and developmental changes (including malformations) in the irradiated embryo and fetus have been reviewed recently in *Publication 90 (ICRP, 2003)*. In the main, this review reinforced the judgements on in-utero risks given in *Publication 60 (ICRP, 1991)* although, on some issues, new data allow for clarification of views. On the basis of *Publication 90*, the following conclusions can be summarized on the in-utero risks of tissue injury and malformation at doses up to a few tens of mGy low LET. (Note: LET stands for Linear Energy Transfer, a measure of radiation energy).

The new data from animal studies confirm embryonic sensitivity to the lethal effects of irradiation in the pre-implantation period of embryonic developments. At doses of a few tens of mGy such lethal effects will be very infrequent, and the data reviewed provide no reason to believe that there will be significant risks to health expressed after birth.

In the respect of the induction of malformations, the animal data strengthen the view that there are gestation age-dependent patterns of in-utero radiosensitivity with maximum sensitivity being expressed during the period of major organogenesis. On the basis of these animal data it is judged that there is a dose threshold, for practical purposes, risks of malformation after low-dose in-utero exposure may be discounted. *Publication 90 (ICRP, 2003)* reviews the experimental data on neurodevelopment following in-utero irradiation for which dose thresholds generally apply; it also considers human epidemiological data as summarized below.

The review of human A-bomb data on the induction of severe mental retardation after irradiation in the most sensitive prenatal period (8-15 weeks post conception) now more clearly supports a dose threshold of at least 300 mGy for this effect and therefore the absence of risk at low doses. The associated data on IQ losses estimated at around 25 points per Gy are more difficult to interpret and their significance is unclear. Although a non-threshold dose response cannot be excluded, even in the absence of a true dose threshold, any effects on IQ following in-utero doses of a few tens of mGy would be of no practical significance for the vast majority of individuals. This judgement accords with that developed in *Publication 60 (ICRP, 1991)*.

(b) ***Second Interim Report on Introduction of 2007 Recommendations (Pub. 103)*** **of** ***International Commission on Radiological Protection (ICRP) into Domestic Systems*** **(p. 25) by Radiation Council at Ministry of Education, Culture, Sports, Science and Technology (MEXT)**

As regards effects of radioactive exposure on embryos and fetuses, the report offers the opinion that a threshold dose of 100~200 mGy or higher exists; if the fetal dose exceeds this level, there is a possibility of posing damage on fetus, while its severity and scope vary with the dose and pregnancy stage. According to Annex A (A82) to *the 2007 Recommendations*, animal research on lethal effects at the pre-implantation period of embryonic developments shows that the lethal effects are very infrequent at the dose of a few tens of mGy, and that there is no reason to think that there will be significant health risk after birth.

(3) Nonstochastic Effects *(ICRP Publication 40 (Appendix A: A1~A7))*

Nonstochastic effects can appear in any organ or tissue that has been irradiated to a sufficiently high dose, the biological response and threshold depending on the organ or tissue. Comprehensive reviews of this subject have been given by UNSCEAR and the Commission *(ICRP Publication 41, 1984b)*. The data in this appendix of *ICRP Publication 40 (1984a)* are relevant to emergency planning and are based on the ICRP report. The main objective is to identify the levels of dose below which nonstochastic effects are unlikely to occur in an irradiated population. The organs and tissues which may exhibit nonstochastic effects following and accidental release of radionuclides are primarily bone marrow, lung, thyroid and skin. Radiation damage to the bone marrow may be the most important for accidental releases from nuclear power plants, given the composition of nuclides liable to be released.

Uniform irradiation of the bone marrow by acute exposure in the early phase of the whole, or a substantial part, of the body to penetrating radiation at a sufficiently high rate can lead to death within a few weeks. The value for the median lethal dose within 60 days ($LD_{50/60}$) is thought to be in the range 2.5 to 5 Gy; below about 1.5 Gy there is little possibility of early death. The protraction of exposure will also reduce the probability of early death from bone marrow cell depletion, but may not be important in practice since action may well have been taken to terminate such exposures at an early stage. Consequently, early deaths should not occur if whole body doses do not exceed about 1 Gy in the early phase.

Exposure of the lung can be due to external radiation or to internal contamination following inhalation from a cloud. External exposure would be acute, but following inhalation the rate of dose accumulation to the lung will vary depending upon the isotopic composition of the accidental release. The occurrence of death appears to be very dependent upon the pattern of dose accumulation. Generally, the threshold for mortality is about 15 Gy of low LET radiation to the whole lung and the median lethal dose lies between 20 and 30 Gy. Consequently, early deaths from radiation pneumonitis should not occur if lung doses do not exceed 10 Gy following acute inhalation of radioactive material.

Following high doses to the lung, non-fatal damage may occur, particularly less severe lung pneumonitis with subsequent fibrosis, which leaves permanent impairment of health. Again, for low LET radiation, protraction of a given dose reduces the degree of lung pneumonitis. In contrast, high LET radiation does not appear to exhibit any reduction in incidence per unit dose as dose rates decrease. The occurrence of morbidity seems to have a threshold above 5 Gy of acute external exposure to low LET radiation and a median at about 10 Gy. For protracted irradiation the median may be about 30 Gy (low LET) accumulated in a period of weeks. The period of time over which doses are delivered by those nuclides which emit high LET radiation may be several years. Consequently, no lung morbidity should be expected for absorbed doses to the lung below 5 Gy.

Following a whole body dose somewhat in excess of 0.5 Gy received over a period of no more than 1-2 days, vomiting could occur. It is unlikely to recur or be the source of permanent injury although it might cause dehydration and electrolyte imbalance, but the numbers of people involved could exceed those who experience other early effects, including early death and lung pneumonitis.

Dose-response relationships have been established from human data. Vomiting would not be expected for whole body doses less than 0.5 Gy.

Total ablation of the thyroid would occur following a dose of about 300 Gy delivered over a period of 2 weeks. The occurrence of non-fatal thyroid disorders such as hypothyroidism appears to be initiated by acute irradiation of the thyroid in excess of 10 Gy; myxedema is initiated at significantly higher doses. Consequently, nonstochastic effects should not occur for thyroid doses below 10 Gy.

Skin may be irradiated either directly from the plume or from deposits of radioactive material on skin and clothes. The threshold for transitory erythema, the earliest observable skin effect, appears to be between 6 and 8 Gy (low LET) delivered in a short time. Significantly higher doses are needed to produce more severe effects. The threshold for damage to hair follicles is lower than that for erythema, as doses in the range 3 to 5 Gy (low LET) may cause temporary epilation. Protraction of exposure will result in higher thresholds, up to 30 Gy for erythema and 50-60 Gy for epilation. Consequently, effects on the skin would not be expected for doses less than 3 Gy.

The aforesaid can be summarized as shown in Table 2.

Table 2. Dose levels in organs and tissues below which nonstochastic effects will be avoided

Organ/Tissue	Nonstochastic effects	Dose (Gy)
Whole body	Vomiting	0.5
Bone marrow	Death	1.0
Skin	Transitory erythema, Temporary epilation	3
Lung	Pneumonitis	5
Lung	Death	10
Thyroid	Non-fatal disorders,myxedema and ablation	10

(4) Stochastic Effects *(ICRP Publication 40 (Paragraph 27, Appendix A: A8))*

The likely incidence of stochastic effects in an irradiated population can be estimated by the use of risk factors, given that estimates of the dose equivalents in organs and tissues have been made. In *ICRP Publication 26 (1971)* the statement is made:

"In many instances, however, risk estimates depend on data derived from irradiation involving higher doses delivered at high dose rates. In these cases, it is likely that the frequency of effects per unit dose will be lower following exposure to low doses or to doses delivered at low dose rates, and it may be appropriate, therefore, to reduce these estimates by a factor to allow for the probable difference in risk. The risk factors discussed later have therefore been chosen as far as possible to apply in practice for the purposes of radiation protection."

Consequently, in principle, the coefficients used for estimating the stochastic risks following accidental irradiation should be increased by the same factor. However, in accident situations, the uncertainties in estimating doses will generally greater than those in the risk coefficients and, moreover, the major part of the collective dose is likely to be received at low levels of individual dose. It is therefore, sufficient to interpret the risks of fatal cancer in emergency planning in terms of the risk factors recommended in *ICRP Publication 26 (1971)*.

In *ICRP Publication 26 (1971)*, it is stated that the risk factors have been chosen as far as possible to apply in practice for the purposes of radiation protection. These risk factors, which are averages over both sexes and all ages, are shown in Table. 3. These factors represent the incidence of fatal cancer following irradiation of a range of body organs and tissues, together with the risk of hereditary defects in the first two generations following exposure at levels of dose in the range relevant for protection.

Table 3.ICRP Risk Factors for fatal cancers and hereditary defects

Tissue	Risk Factors (Sv^{-1})
Gonads	40×10^{-4} [1)]
Breast	25×10^{-4}
Red Bone Marrow	20×10^{-4}
Lung	20×10^{-4}
Thyroid	5×10^{-4}
Bone	5×10^{-4}
All remaining unspecified tissues	50×10^{-4}

1) Herediatry defects in first two generations

(5) Risks of Leukemia and Childhood Cancer (*Second Interim Report on Introduction of 2007 Recommendations (Pub. 103)* of *International Commission on Radiological Protection (ICRP) into Domestic Systems* (p. 25) by Radiation Council at Ministry of Education, Culture, Sports, Science and Technology (MEXT))

It is assumed that throughout the pregnancy period, the embryo/fetus is exposed to the risk of latent carcinogenic effect to the same degree as infant. According to Paragraph (38) of the *ICRP Publication 84 (2000)*, relative risk of spontaneous cancer incidence at the fetal dose about 10 mGy is about 1.4 or lower. Since spontaneous incidence of childhood cancer is as low as 0.2~0.3%, incidence of childhood cancer after in-utero exposure is as small as about 0.3~0.4% on the individual level.

(6) Risk of Fatal Cancer (*World Health Organization: Derived Intervention Levels For Radionuclides In Food, 1988*)

The risk figure for fatal cancers suggested by *ICRP (1987)* is about 2×10^{-2} Sv^{-1} averaged over age and sex. An average individual exposed to 5 mSv as a result of ingestion of radioactively contaminated foodstuffs in the first year after a radiation accident therefore has a notional lifetime risk of 1 in 10 000 (10^{-4}). This level of risk is some three orders of magnitude greater than the average individual risk of fatal cancer resulting from routine operations of nuclear power establishments. It may be compared with the level of risk from another widespread environmental hazard – radon in houses. In this case no international agency or individual country has proposed a level of dose at which remedial measures should be taken against the *existing situation* that is as low as 5 mSv per year. A WHO expert group recommended that simple remedial actions to reduce concentrations of radon should be considered if the annual effective dose equivalent is more than 8 mSv, and that at doses of 32 mSv per year remedial actions should be taken without long delay *(WHO, 1988)*.

5. Background of Provisional Regulation Values

A brief background on the provisional regulation values based on literature and other publicly-available information is described below.

(1) Background of establishment of Emergency Planning and Preparedness for Nuclear Power Facilities *(Japanese Journal of Health Physics, Vol. 35, No. 4, pp. 449-466 (2000))*

Guidelines by the Nuclear Safety Commission for nuclear accident prevention, *Emergency Planning and Preparedness for Nuclear Power Facilities* (old title: *Off-site Emergency Planning and Preparedness for Nuclear Power Plants*) were formulated in June 1980 and then revised repeatedly; from the very beginning, restriction of food and beverage intake was set up with regard to effects of radioactive iodine on thyroid.

These indices are given in terms of concentration of radioactive iodine (iodine-131) in drinking water, leaf vegetables and milk; the values were calculated as derived concentration for infants considering combined contamination of the three food products, based on the thyroid dose equivalent of 15 mSv.

In the Chernobyl accident of 1986, food and beverage were contaminated by radioactive cesium, strontium and other nuclides which have long half-life, and it became obviously necessary to establish restriction of food and beverage intake with respect to those nuclides. In addition, necessity was recognized to introduce indices for plutonium and other α-emitting nuclides of transuranium elements, thus aiming at more efficient disaster prevention measures at reprocessing facilities.

On the other hand, *ICRP Publication 63 (1992)* recommended averted effective dose of 10 mSv in a year for any single foodstuff as an intervention level that is almost always justified. At the same time, optimized level range was assumed above 1/10 of this justified level. Specific range of optimal values were set to 1,000~10,000 Bq/kg for β/γ-emitters, and 10~100 Bq/kg for α-emitters. In response, International Atomic Energy Agency (IAEA) published indications on restriction of food and beverage intake in *Safety Series No. 109* adjusted to international trade guidelines by FAO/WHO; these indications were then adopted in *Safety Series No. 115 International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (IAEA, 1996)*.

In such circumstances, in November 1998 the Special Committee on Disaster Prevention Measures Around Nuclear Power Plants and Other Facilities of Nuclear Safety Commission revised index values for food and beverage intake restriction, based on results reported by Environmental Working Group (to be explained later). In that revision, previous index values for radioactive iodine were redefined, and new index values were set for radioactive cesium and strontium as well as for plutonium and α-nuclides of transuranium elements.

In addition, index value for food and beverage intake restriction was set for uranium in 2005, thus aiming at more efficient disaster prevention measures at nuclear fuel facilities based on experience of Tokai JCO criticality accident in September 1999.

The revisions were based on the following approach.

(a) These index values pertain not to concentration criteria to judge about health impacts of radioactive substances in food and beverage, but to intervention levels in emergency situations (index of protection measures); in other words, these index values are indicative criteria for introduction of food and beverage intake restriction as a protection measure.

(b) The index values are based on the approach of ICRP, IAEA and other international organizations toward setting index of protection measures, while taking into account eating habits and other circumstances in Japan. Effective dose of 5 mSv/year (50 mSv/year in case of thyroid equivalent dose for radioactive iodine) was used as the basis for judgment on whether introduction of protection measures should be taken or not when an avertable dose (the dose prevented by application of protection measures) will be higher than the dose.

(2) Outline of the Report of Environmental Working Group, Special Commission on Disaster Prevention Measures Around Nuclear Power Plants and Other Facilities, Nuclear Safety Commission (March 6, 1998)

According to 1998 report by the Environmental Working Group, Special Committee on Disaster Prevention Measures Around Nuclear Power Plants and Other Facilities, Nuclear Safety Commission, the following considerations underlay adoption of the effective dose of 5 mSv/year (50 mSv/year in case of thyroid equivalent dose from radioactive iodine) as the basis for judgment on whether introduction of protection measures should be taken or not when an avertable dose will be higher than the dose.

As regards the criteria of taking measures for public radiation protection (intervention dose levels), the notion of upper and lower limits was proposed in *ICRP Publication 40 (1984a)*. The upper limit was defined as the dose level at which countermeasures are required in any case, and the lower level was defined as the dose level, below which countermeasures are not justified. A level for actual countermeasures after an accident was to be set between these two values depending on the situation.

Intervention levels for food and beverage intake restriction were recommended as shown below.

Table 4. Intervention levels for food and beverage intake restriction

	Projected Dose Equivalent in the first year (mSv)	
	Whole-body dose or effective dose	Individual organs preferentially irradiated
Upper dose level	50	500
Lower dose level	5	50

Besides, as regards the optimal activity concentration range of 1,000~10,000 Bq/kg set for β/γ-emitters in *ICRP Publication 63 (1992)*, the lower limit 1,000 Bq/kg corresponds to 5.5 mSv per year, assuming that the total annual food intake is 550 kg (world average, drinking water excluded) which suggested by WHO, and that effective dose per unit intake (1 Bq) is 10^{-8} Sv/Bq (approximate value of the dose conversion factor used for β- or γ-nuclides in case of oral ingestion). Nearly the same value of 5.5 mSv is also obtained for the optimal range of 10~100 Bq/kg for α-emitters, assuming that effective dose per unit intake (1 Bq) is 10^{-6} Sv/Bq (approximate value of the dose conversion factor used for plutonium-139 and actinides in case of oral ingestion). With this in mind, the index for food and beverage intake restriction was calculated using the annual dose of 5 mSv (effective dose) as intervention level.

In addition, *ICRP Publication 63 (1992)* recommended restriction on food and beverage in order to reduce thyroid equivalent dose received by oral ingestion of radioactive iodine. The lower limit of 50 mSv was set for intervention in *ICRP Publication 40 (1984a)*; as regards exposure pathway for inhalation of radioactive iodine, ICRP Recommendations *(Publication 63 (77), 1992)* assumed that prophylaxis by iodine preparation should be justified if 0.5 Sv could be averted, while optimized level would be higher than 1/10 of that; thus, thyroid equivalent dose of 50 mSv per year for radioactive iodine was used as the basis for derivation of index values.

(a) These index values pertain not to concentration criteria to judge about health impacts of radioactive materials in food and beverage, but to intervention levels in emergency situations (index of protection measures); in other words, these index values are indicative criteria for introduction of food and beverage intake restriction as a protection measure.

(b) The index values were based on the approach of ICRP and other international organizations toward setting index of protection measures, while taking into account eating habits and other circumstances in Japan. Effective dose of 5 mSv/year (50 mSv/year in case of thyroid equivalent dose for radioactive iodine) was used as the basis for judgment on whether introduction of protection measures should be taken or not when an avertable dose will be higher than the dose.

(c) In the existing guidelines, radioactive iodine is selected as the main nuclide in terms of food and beverage intake restriction; effects on thyroid are considered for three food categories, namely, milk, drinking water and leaf vegetables.

In this revision, in addition to (i) radioactive iodine, index for intake restriction was considered for (ii) radioactive cesium (based on experience of the accident at Chernobyl Nuclear Power Plant in ex-USSR) and (iii) α-nuclides (with regard to reprocessing facilities).

As regards selection of nuclides for consideration, it would be impractical to calculate derived intervention levels for all radionuclides that might be discharged in case of a nuclear accident. Thus, it was decided to establish index values for selected nuclides that are likely to be discharged in quantities in case of an accident at a nuclear power plant or other facility, while being important in terms of transfer to food products and effects on human health.

(3) About the Index for Food and Beverage Intake Restriction

The following basis for calculation of index for food and beverage intake restriction is shown in appendix to *Emergency Planning and Preparedness for Nuclear Power Facilities*.

(a) Radioactive iodine

According to *ICRP Publication 63 (1992)* and other international trends, index values were established for three food categories, namely, drinking water, milk and dairy products, and vegetables (except for root vegetables and potatoes), based on the thyroid equivalent dose of 50 mSv/year. Cereals, meat and other food products other than the above three categories were excluded because the radioactive iodine has a short half-life and is not likely to significantly accumulate in foods and migrate into human body.

When calculating index values for restriction of intake for the three food categories, 2/3 of 50 mSv/year was taken as basis considering intake of other food products; thus obtained value was divided equally among the three categories. Then index values (radiation per unit intake) corresponding to thyroid (equivalent) dose were calculated for each category with regard to food intake in Japan.

(b) Radioactive cesium

Since necessity for introduction of index for food and beverage intake restriction was confirmed also for radioactive cesium and strontium, respective index values were derived for all food products divided into five categories, namely, (1) drinking water, (2) milk and diary products, (3) vegetables, (4) cereals, (5) meat, eggs, fish and others.

When calculating the index values, combined dose of radioactive cesium and strontium should be used because release of cesium into environment is accompanied by strontium-89 and strontium-90 (assuming that activity ratio of cesium-137 to strontium-90 is 0.1); however, considering promptness of radioactivity analysis, combined radiation value of cesium-134 and cesium-137 was used in calculation.

Specifically, the effective dose of 5 mSv/year was divided equally among the five food categories, and index values for restriction of intake for cesium-134 and cesium-137 were calculated for each category with regard to food intake in Japan as well as contributions of radioactive cesium and strontium.

(c) Uranium

Aiming at more efficient disaster prevention measures for nuclear fuel facilities, index values for uranium were calculated on the basis of effective dose of 5 mSv/year for five food categories, namely, (1) drinking water, (2) milk and diary products, (3) vegetables, (4) cereals, (5) meat, eggs, fish and others based on the policy that those values should be set by taking into account eating habits and other circumstances in Japan.

The index values were obtained assuming that 5%-enriched uranium-235 included in all foods corresponds to 5 mSv/year and taking into account food intake in Japan.

(d) Plutonium and α-nuclides of transuranium elements

Aiming at more efficient disaster prevention measures for reprocessing facilities, index values for α-nuclides (americium, plutonium, etc.) indicated in *IAEA International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (IAEA, 1996)* were calculated on the basis of effective dose of 5 mSv/year for five food categories, namely, (1) drinking water, (2) milk and diary products, (3) vegetables, (4) cereals, (5) meat, eggs, fish and others base on the policy that those values should be set by taking into account eating habits and other circumstances in Japan.

Since multiple α-nuclides may coexist and be released together, index values were not calculated for individual nuclides; instead, the index values for each food category were obtained assuming that α-nuclides included in all foods corresponds to 5 mSv/year and taking into account food intake in Japan.

6. Evaluation of International Organizations

There are no systematic risk assessment results by international and other organizations for radioactive iodine (iodine-131) and radioactive cesium (cesium-134, -137).

There are some investigations on intervention for public protection in case of radiation emergency; these investigations, however, pertain not to concentration criteria to judge about health impacts of radioactive substances in food and beverage, but to discuss indicative criteria for introduction of food and beverage intake restriction as intervention levels in emergency situations.

(1) ICRP

In 1984 ICRP proposed the notion of upper and lower limit for measures to be taken in case of an accident *(ICRP Publication 40, 1984a).* The upper limit is defined as the dose level at which countermeasures are required in any case, and the lower level is defined as the dose level, below which countermeasures are not justified. As regards intervention levels for food and beverage intake restriction, the upper and lower levels were set to 50 mSv and 5 mSv, respectively, as expected dose equivalent for the first year after an accident.

However, this formulation was revised in 1992; in *ICRP Publication 63 (1992),* recommended avertable effective dose of 10 mSv in a year for any single foodstuff as an intervention level that is almost always justified; however, only intervention at projected dose level much higher than 10 mSv per year may be justified in case that alternative food products are not easily available, or that local communities may be severely confused. As regards optimized intervention levels for specific food products, the range of 1,000~10,000 Bq/kg was assumed for radionuclides with a low dose per unit intake (e.g., most β-emitters and γ-emitters), and 10~100 Bq/kg for radionuclides with a high dose per unit intake (e.g., α-emitters).

In addition, *ICRP Publication 63 (1992)* mentions about relation to indication values of Codex Alimentarius Commission (CAC), stating that “it would be illogical to set up local restrictions on food products acceptable in international trade, and these CAC indication values are rather non-intervention levels than intervention levels.”

(2) WHO

Based on *ICRP Publication 40 (1984a),* in 1988 WHO admitted effective dose of 5 mSv as the intervention level for regulations on food distribution. While being intended for locations close to accident sites, this value is considered applicable to remote regions as well.

Besides, when the intervention level of 5 mSv is set as effective dose, in terms of iodine this level corresponds to the thyroid equivalent dose of 167 mSv assuming that thyroid is only irradiated; this is considered too high, and thyroid equivalent dose of 50 mSv is applied to iodine.

After the accident at Chernobyl Nuclear Power Plant, average levels of radioactive materials proved much lower than those predicted from measurement of the total stock of radioactive materials in the region. This is explained by a complex food-web structure; many people got food from a wide area, and only a part of the consumed food products was contaminated at the local level of radiation contamination. If the intervention level of 5 mSv is applied, then individual average doses may be much lower than 5 mSv.

Besides, WHO points out the following issues of health risk must be considered.

According to ICRP, severe amentia occurs at the risk of 0.4 Sv^{-1} when fetuses are exposed during the period of 8~15 weeks after conception *(ICRP Publication 49, 1986)*; assuming that exposure at certain level lasts for one year or longer, the dose of 5 mSv may cause severe amentia of children exposed at the fetal stage in the proportion of 3×10^{-4}. However, ICRP assumes that a significant threshold dose may exist for such exposure effects *(ICRP, 1987)*, and that if this threshold dose exists, its value is very much higher than several hundred mSv; hence no need for additional precautions. Prior to confirmation of such threshold dose, if any, domestic authorities should treat amentia in terms of a critical group of fetuses at the stage of 8~15 weeks after conception and consider it as a possible stochastic effect.

(3) IAEA

In 1994 IAEA presented intervention criteria in a nuclear or radiation emergency *(IAEA Safety Series No.109)*, while some countries believe that 100 mSv is more realistic as the amount of exposure that requires temporary evacuation. With ICRP, 500 mSv (5,000 mSv as skin dose) is considered as justified dose for evacuation.

As regards food standards for international trade in case of a radiation accident, 1,000 Bq/kg is set for radioactive cesium (cesium-134, 137); in case of radioactive iodine (iodine-131), 1,000 Bq/kg is set for general food, and 100 Bq/kg for milk, infant food and drinking water.

In case of a radiation accident, 30 mSv/month is set as the criterion for temporary relocation, and 10 mSv/month for return. However, if the level does not decrease for 1-2 years, permanent relocation should be considered, which also pertains to life-long exposure exceeding 1 Sv.

When applying such interventions, one should consider exposure to radiation from all pathways other than food and beverage intake.

Besides, 1996 International Basic Safety Standards (International Safety Basic Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources) offer compliance with Codex criteria for food recall except for scarcity of food and other special cases *(IAEA Safety Series No. 115)*.

(4) CODEX

Codex General Standard for Contaminants and Toxins in Food and Feed *(CODEX/STAN 193-1995)* gives the Guideline Levels which apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency. These guideline levels are set for infant foods and foods other than infant foods so that exposure from food does not exceed 1 mSv/year which in *ICRP Publication 82*

(1999) considered as the exposure level no special measures are assumed necessary

Annual exposure level was estimated in consideration of food consumption amount for infants and adults, radionuclide- and age-dependent ingestion dose coefficients and the import/production factors when people eat imported foods contaminated with radionuclides at the present Guideline Levels. As the result, the dose for both adults and infants is supposed to be kept within 1 mSv/year.

7. Emergency Report

Investigation and deliberation on this issue were done urgently based on available literature and other sources. Materials provided by the Ministry of Health, Labour and Welfare were not sufficient to conduct an assessment of the effects of food on health; however, in view of gravity of the case, investigation was carried out using other materials that could be obtained, and the report was compiled urgently.

Thus, investigation was based on materials currently available, and the emergency report was compiled; however, considering the time limitations and a big number of remaining tasks, deliberation will be continued.

Proceeding from experience of past accidents at nuclear power plants and other incidents, radioactive iodine (iodine-131) and radioactive cesium (cesium-134, -137) were considered to be examined urgently in this case; therefore, first of all, those radionuclides were examined.

(1) **Radioactive Iodine (Iodine-131)**

As regards iodine-131, in 1988 WHO showed that if intervention level of 5 mSv is set as effective dose equivalent, a thyroid dose of 167 mSv is implied assuming that thyroid is only exposed; given the incidence of nonfatal cancer after thyroid irradiation and the potential of iodine-131 for irradiation to thyroid alone, this dose is considered too high. Therefore thyroid equivalent dose of 50 mSv is applied as restriction value.

After WHO expressed the above opinion, ICRP revised the intervention levels for food that were set to 5~50 mSv; in that document the new value of 10 mSv was indicated, while no mention was made of the above opinion by WHO.

Regarding radioactive iodine (iodine-131), FSCJ has not yet been able to find any evidence to deny the above opinion by WHO. Similarly, no evidence has been found to challenge adequacy of regulations based on the thyroid equivalent dose of 50 mSv (corresponds to effective dose of 2 mSv [Note]) from the standpoint of health effects. Therefore, the thyroid equivalent dose of 50 mSv per year was concluded, at the present situation, to be sufficiently safe for prevention of radiation exposure from food.

Note: Calculated by applying tissue weighting factor of 0.04 for thyroid according to *ICRP Publication 103 (2007)*.

(2) **Radioactive Cesium (Cesium-134, -137)**

The documents examined this time did not provide sufficient information on safety of low-dose radiation; hence an assessment of the effect of food on health is needed in future with respect to radioactive cesium (cesium-134, -137) after collecting and organizing information.

The following information was acquired from documents published by ICRP and other organizations.

- Many large populations have lived for years in areas of the world experiencing typically elevated doses of up to around 10mSv per annum *(ICRP Publication 82(76), 1990).*

- The natural sources of radiation exposure is 1 to 13mSv (an average annual exposure to natural radiation sources 2.4mSv) and sizable population groups receive 10-20mSv *(UNSCEAR, 2008)*.

- Studies on human populations living in areas with elevated natural background radiation in China and India do not indicate that radiation at such levels increase the risk of cancer *(UNSCEAR, 2010)*.

- ICRP indicates, the new animal studies confirm embryonic sensitivity to the lethal effects of irradiation in the pre-implantation period of embryonic developments. At doses of a few tens of mGy such lethal effects will be very infrequent, and the data reviewed provide no reason to believe that there will be significant risks to health expressed after birth *(ICRP Publication 103, 2007).*

- A recent analysis of many of the epidemiological studies conducted on prenatal X-ray and childhood cancer are consistent with a relative risk 1.4 or lower than this following a fetal dose of about 10 mGy. Even if the relative risk were as high as 1.4, the individual probability of childhood cancer after in utero irradiation would be very low (about 0.3-0.4%) since the background incidence of childhood cancer is so low (about 0.2-0.3%) *(ICRP Publication 84 (38), 1999).*

- ICRP also indicates, in the absorbed dose range up to around 100 mGy no tissues are judged to express clinically relevant functional impairment. This judgment applies to both single acute does and to situations where these low doses are experienced in a protracted form as repeated annual exposures *(ICRP Publication 103 (60), 2007)*.

- ICPR endorses the view that, although there are recognized exceptions, in the low-dose range, below about 100mSv, it is scientifically plausible to assume that the incidence of cancer or heritable effects will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues (*ICRP Publication 103 (64), 2007).*

- In 1992, ICRP indicated the basic principles for planning intervention also apply to control of food and water, and recommended that for any single foodstuff, an intervention level that is almost always justified is an averted effective dose of 10mSv in a year. *(ICRP Publication 63, 1992)*

The following comments were made by special advisors.

- No particular adverse health effects are expected at radiation doses up to 10~20 mSv.
- The intervention level of ICRP (10 mSv) may be applied.
- Assuming the intervention dose of 10 mSv, long-term exposure effects are not expected on parturient or potentially pregnant women as well as nursing infants and small children.

Radioactive nuclides are considered to have genotoxic carcinogenicity; this paper, however, did not include detailed consideration of carcinogenic risks at low doses. Many reports indicate that hardly any carcinogenic effects occur at the low-dose area below 100 mSv, while some reports mention some effects. Besides, there is no clear evidence of health impacts at low-dose radiation other than cancer.

ICRP Publication 63 (1992) says that "For any single foodstuff, an intervention level that is almost always justified is an avertable effective dose of 10 mSv in a year." ICRP is an international organization in the field of radiological protection, and its recommendations are considered as evidenced to certain degree, thus being a reference for risk management measures in emergency situations. Such evidences, however, could not be confirmed from the available materials.

On the other hand, considering that there are areas where exposure of about 10 mSv is recognized under the natural environment of human habitat, given the above comments of some special advisors in particular pointing out that the exposure to 10 to 20 mSv would not cause a particular adverse health effect, there is no evidence to challenge adequacy of emergency risk management based on the effective dose of 10 mSv per year proposed by *ICRP Publication 63*. Thus, at least for radioactive cesium, the annual effective dose of 5 mSv was considered as highly conservative in terms of preventing radiation exposure caused by food and securing human health.

(3) **Conclusions in Common for Radioactive Iodine and Radioactive Cesium**

This report does not discuss adequacy of the provisional regulation values that had been already adopted by MHLW but rather emphasizes the need for appropriate future discussion on the risk management side.

It goes without saying that exposure to radiation should be reduced as low as possible. There are data suggesting that the dose threshold of about 100 mGy exists for pregnant women with respect to deformity induction; however, all parties concerned should make efforts toward ultimate reduction of exposure, including that of pregnant women.

As stated above, this emergency report was compiled urgently in the peculiar and critical social situation of the recent accident at the nuclear power plant accompanied by discharge of radioactive substances into environment. It should be clearly heeded that this emergency report is not appropriate as a basis for risk management measures under normal circumstances.

All parties concerned are needed to lay out appropriate risk communication so as to prevent confusing emergency response with non-emergency response.

Risk communication and other measures should be also applied appropriately to health effects and other risks arising from restriction of intake. In this context, related domestic academic societies and ICRP are expressing their opinions from respective professional viewpoints.

8. Future Tasks

This is an urgenly compiled report, and the assessment must be continued through consultations on its scope.

Radioactive substances are considered to be genotoxic carcinogenic; a detailed study on carcinogenesis, fetal effects and other issues are essentially necessary. A number of issues remain to be investigated such as detailed examination of carcinogenic risks. As regards uranium, plutonium and α-nuclides of transuranium elements, which MHLW's request for their assessment was issued, this report did not discuss them; hence, there are needs for assessment with regard to the exposure situation, detailed assessment of genotoxic carcinogens including also radioactive iodine and cesium, investigation of disposition of every nuclide in human body, etc.

Although there was no direct request for an assessment of radioactive strontium; however, considering internal exposure, further investigation seems necessary after enough consideration on the exposure situation and other conditions.

(Reference 1)

On March 24, 2011, the Japan Society of Obstetrics and Gynecology (JSOG) posted *Guideline for Pregnant and Breast-feeding Women Concerned with Tap Water*, and expressed the following opinion on the health effects for mothers and fetuses in case of drinking tap water containing radioactive substances at about 200 Bq/kg for a certain period of time.

(1) If a pregnant woman drinks a liter of water with radioactive contamination of 200 Bq/kg (the same radioactivity level as was detected on March 23, 2011, at the Kanamachi Purification Plant, Tokyo) every day for the entire period of pregnancy from the first day of the last menstrual period through delivery (280 days), she would receive a total radiation exposure equivalent to about 1.2 mSv.

(2) As regards safety limit of radiation exposure for fetuses, some experts set it to 100 mSv based on *ICRP Publication 84 (2000)* and other sources; however, JSOG sets the limit at 50 mSv as recommended by the American Congress of Obstetricians and Gynecologists. The fetus is supposed to be exposed to lower levels than the mother, while some research reports indicate that fetal malformation does not increase under exposure of 100~500 mSv; thus, *ICRP Publication 84 (2000)* suggests that fetal exposure below 100 mSv should not be the reason for termination of pregnancy.

(3) Content of radioactive iodine in breast milk is estimated to be about 1/4 of the mother's intake, though no definite conclusion has been made yet.

(4) Therefore, at the present moment, it is assumed that if a pregnant or breast-feeding woman drinks tap water containing radioactive substances of about 200 Bq/kg every day, there is no

health impact on the mother and fetus, and that continuous breast feeding causes no damage to infant’s health.

In addition, on March 25, 2011, Japan Epidemiological Association issued a statement called *On Health Effects of Radiation Exposure Caused by Fukushima Nuclear Disaster*, in which the Executive Board expressed the following opinion (while assuming that the statement may be revised according to situation).

(1) There is no concern of acute radiation impacts caused by exposure as long as the current situation (comparatively low concentration of radionuclides in water, vegetables, raw milk and other products) does not change considerably. Besides, the possibility of carcinogenesis and other diseases in the long run is negligibly low as compared, for example, to inter-individual variations in lifestyle-related health risk.
(2) As indicated by data of epidemiological study of Hiroshima and Nagasaki atomic bomb survivors, a single exposure of 1,000 mSv increases total cancer risk for adults by about 1.6 times. This difference is equal to that between non-smokers and smokers, while the impact of exposure assumed at the present moment would be much lower.
(3) In case of radioactive iodine, the half-life is 8 days, and the amount of exposure decreases day by day. When radioactive iodine gets into thyroid and surrounding tissues, it may cause thyroid cancer and other effects. Normally, the risk of thyroid cancer grows with exposure dose in case of external exposure higher than 100~200 mSv; however, thyroid cancer is relatively ‘low-grade’ cancer, the probability of death being much lower than with other cancers. According to 2008 report by the UN Scientific Committee says, understanding of effects of iodine-131 exposure was improved by recent studies but there is no sufficient information regarding quantitative relationship between iodine-131 exposure and thyroid cancer risk.
(4) Epidemiological studies conducted so far, both in Japan and abroad, have not submit clear evidence that risks of cancer and other diseases increase due to exposure to low-dose radiation.

The Japan Pediatric Society, Japan Society of Perinatal and Neonatal Medicine, and Japan Society for Premature and Newborn Medicine expressed their common opinions in *Intake of Tap Water with Radioactive Iodine Concentrations Exceeding the Provisional Value of 100 Bq/kg for Nursing Infants according to Food Sanitation Act* issued on March 24, 2011. Particularly, they express that the possibility of health impacts, even for nursing infants, is extremely low in case of short-time intake. On the other hand, nursing infants need higher fluid intake than adults; therefore, deficient fluid intake, even for a short time, leads to serious health disorders, and immediate countermeasures were recommended.

On March 21, 2011, ICRP came out with recommendations for Japan.

Specifically, application of optimization and reference levels was suggested to ensure sufficient protection against exposure from ionizing radiation in emergency exposure situation, and in existing exposure situation. For the purpose of protection of the public in emergency exposure situation, the Commission recommended domestic authorities to set reference levels so that the avertable dose stays in the range of 20~100 mSv at the highest *(ICRP Publication 103, 2007)*. After regaining control over the radiation sources, reference levels should be set in the range of 1~20 mSv per year, with the long-term target being 1 mSv per year *(ICRP, 2009)*.

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