

# **The Complex Risk Governance Issues Posed by Radionuclides in Food After the Fukushima Disaster**

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## **Introduction**

The Great East Japan Earthquake, the tsunami, and the subsequent accident at the Fukushima Daiichi nuclear power plant led to an unprecedented major disaster. Food safety concerns raised by radioactive substances are a major issue in Japan as a consequence.

The issue of radionuclides in food represents a complex risk issue that is in urgent need of governance considerations. In contrast to routine kinds of risk, the risk posed by radionuclides cannot be considered in terms of “food safety” alone. Radiation exposure must be considered in terms of aspects both internal (food intake and inhalation) and external (skin absorption from sources such as air, water, and land). Moreover, “safety considerations” are not enough in taking risk management measures because the standards for radionuclides in food can affect other socio-economic factors, such as

food availability, compensation for affected farmers, international food trade, and the life of the affected area.

The objective of this paper is to show the complexity of the issue and to analyze the processes focusing on the setting of limits for radionuclides in foods in order to identify governance issues. It presents the preliminary findings from this analysis and the implications for future governance of complex risk issues.

## **1. Radionuclides in Food as a Complex Governance Issue**

### **1.1 Risk, risk trade-off, and the governance of complex risk.**

#### ***(1) Risk Society and increasing complexity.***

As Ulrich Beck has put it, modern society can be characterized as a risk society (Beck, 1986). The traditional view of risk, that of “simple risk,” treats the nature and the effects of risk as well known. This view leads to the idea that measures to control that risk are automatically taken in a linear way. However, the emergence of new issues, such as climate change, the global financial crisis, and the worldwide concern for pandemics, have made it clear that risk has increasingly become complex, systemic, and diverse (OECD, 2003; OECD, 2011; IRGC, 2005). The risk of radionuclides posed in the aftermath of the Great Eastern Japan Earthquake is no exception.

There is thus a need for a new kind of risk governance that sees the nature of risk as complex, uncertain, and ambiguous (van Asselt et al., 2011; Renn et al., 2011). It is important that decision makers take a balanced approach by capturing all aspects of risk, including potential risks. In their famous book *Risk vs. Risk*, Graham and Wiener introduced the concept of a “risk trade-off,” according to which certain kinds of risk

management, intended to reduce a particular risk, can sometimes increase other types of risk (although it is also possible to reduce a particular risk and at the same time reduce other types of risk, leading to a win-win situation) (Graham & Wiener, 1997). For the better management of complex risk, it is essential to have a portfolio of full risk mapping.<sup>1</sup>

***(2) The concept of governance and the importance of institutional architecture.***

The perspective of “governance” is crucial in grasping the relationship between risks and their management. Governance is defined as “the process and institutions, both formal and informal, that guide and restrain the collective activities of a group” (Keohane & Nye, 2000, p. 12). Institutional architecture is the key factor in successful governance. As risk is contextualized through the institutional environment, recent literature emphasizes the importance of the relationship between risk and institution, risk and regulation, and how the risk governance is structured (IRGC, 2005; OECD, 2011). The path-dependent nature of decision making and institutional stickiness strongly influence the framing and choices made within an institution. As such, a historical event is usually needed to open the “policy window” for radical change (Kingdon, 2011). In order to avoid being captured by the risk governance deficits that hinder fair and efficient governance (IRGC, 2009), analysis of the institutions in an organization, its procedures, and the surrounding political environment become major subjects for research (Hutter & Power, 2005, Hutter 2006).

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<sup>1</sup> Matsuo, “Report of the Lecture by Jonathan B. Wiener ‘Risk, Precaution, and Tradeoffs in a Complex World,’” held at the University of Tokyo, July 11, 2011, in GrasPP News Letter.

## **1.2 Radionuclides in food as a complex risk issue.**

The risk of radionuclides in food that this paper is going to address is also considered to be a complex issue. Three aspects of the risk trade-off issues as they occurred in relation to the disaster in Japan are described below.

First, there were health-risk trade-off issues. When the radioactive materials were detected in tap water, pregnant women refrained from taking water for fear that ingesting radionuclides in water might have an adverse effect on their baby. This posed the potential health risk of dehydration. In addition, it is said that the patients in affected areas were reluctant to take medical radiation for fear of increasing their cumulative radiation exposure. The consequence of this was the possibility of other health risks.

Second, there were potential trade-off issues related to food safety risk and other socio-economic risks. It is of course imperative to have measures in place that ensure food safety, but measures that are too tough can give rise to other trade-off issues with non-safety risks. For example, the safety limit of radionuclides in food can affect the availability of food, the survey monitoring cost for detection, compensation for the affected farmers, the socio-economic life of local agriculture, and the mid- to long-term recovery of the community and international trade etc.

Third, there were risk trade-off issues with other sources of food risk. Since public attention was strongly directed towards radionuclides in foods, huge efforts were put into the management of this risk, but this attention might have diverted resources that may have been needed for other potentially high risks related to food.

### **1.3 Food safety governance and radiation hazard prevention—No governance structure existed for the unexpected disaster of radionuclides in foods.**

Food safety governance underwent a major reconstruction in 2003 in response to the BSE crisis. The now well-known concept of risk analysis, composed of three elements of risk assessment (scientific advice), risk management (consider risk assessment with other factors relevant to health and weighing policy alternatives), and risk communication, was for the first time introduced into food safety administration in Japan.<sup>2</sup> The Food Safety Commission of Japan (FSCJ), a risk assessment body, was established, based on the Food Safety Basic Law.<sup>3</sup> With the creation of the FSCJ, the element of risk assessment was institutionally separated from the risk management body, the Ministry of Health, Labor, and Welfare (MHLW), and the Ministry of Agriculture, Forestry, and Fishery (MAFF). The regular procedure for food safety control is initiated by a risk manager (MHLW) asking a risk assessor (FSCJ, expert committee) for a risk/safety assessment, and the MHLW takes risk management measures after having consulted with the Council of the MHLW, based on the FSCJ's scientific advice.

For radionuclides, a different governance structure existed. The Radiation Council is a council established in the Ministry of Education, Culture, Sports, Science, and Technology (MEXT), under the Act on Technical Standards for the Prevention of Radiation Hazard, with the mandate to give advice on the technical standards for radiological prevention to ensure their consistency.<sup>4</sup> This Council has long been

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<sup>2</sup> Although there were similar mechanisms for assessment and control, the difference between the functions of risk assessment and management were not recognized until then.

<sup>3</sup> Tentative translation in English, [http://www.fsc.go.jp/sonota/fsb\\_law160330.pdf](http://www.fsc.go.jp/sonota/fsb_law160330.pdf).

<sup>4</sup> MEXT hp, "About the Radiation Council" (in Japanese), [http://www.mext.go.jp/b\\_menu/shingi/housha/gaiyou/1283235.htm](http://www.mext.go.jp/b_menu/shingi/housha/gaiyou/1283235.htm) (accessed 22/11/2012).

working on the introduction of the recommendations made by International Commission on Radiological Protection (ICRP). The ICRP is an international organization that makes recommendations regarding radiological protection.

Neither the MHLW nor the Radiation Council of the MEXT has ever considered the limits for radionuclides in food within its own country.<sup>5</sup> The only reference that existed was the Indices for Food and Beverage Intake Restriction, which was considered by the Nuclear Safety Commission of Japan (NSCJ) in response to the Chernobyl nuclear accident.

Consequently, the establishment of the new safety limits for radionuclides in food was considered under this existing framework. It followed existing procedure: a request for risk assessment from the MHLW to the FSCJ, submission of the FSCJ's assessment, the MHLW's Pharmaceutical Affairs and Food Sanitation (PAFS) Council (the Subcommittee and Section meeting) 's consultation, followed by the consultation of the Radiation Council of the MEXT, before a decision was made by the MHLW.

## **2. The Process of the Provisional and New Standards of Radionuclides in Food**

### **2.1 The provisional regulation values of radionuclides in food.**

On March 15, the MHLW and the MAFF initiated consideration of the measures concerning possible contamination of food by the spread of radionuclides, as a high level of radioactivity had been detected from the surrounding area of the Fukushima power plants. This was a very difficult task because there was a very limited amount of

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<sup>5</sup> After the Chernobyl nuclear accident, MHLW did set the provisional limit (total of C134 and C137 = 370 Bq/kg) for foodstuffs, but this was intended for imported foods mainly targeted at the foodstuffs affected by Chernobyl.

information on the levels of actual radiation exposure and its effect on health. At the same time, there was enormous concern that if too stringent a limit were introduced, people would suffer from reduced supply on the market and increased food price. The only reference for such circumstances was the Indices for Food and Beverage Intake Restriction by the NSCJ (as described in 1.3). Based on Article 26 of the Act on Special Measures Concerning Nuclear Emergency Preparedness, as an emergency measure, restrictions were considered on food and drink and the distribution of food, based on these indices. This level was the reference level for whether to consider such restrictions and was not a safety limit. The MHLW considered that the limits on food should be dealt with under this Act by the Nuclear Emergency Response Headquarters (NERHQ) in the first instance (ICANPS, 2012). However, the scope of this Act was limited to the region in a state of emergency (in this case, the Fukushima Prefecture only). Questions arose concerning whether controlling the contamination of food based solely on this Act would be effective, as food moved across the boundary of the affected and non-affected areas. However, to apply this limit nationwide, a different law, such as the Food Sanitation Law, should be used. On the March 15, the minister of the MAFF requested a standard for radionuclides in food at the meeting at the NERHQ.<sup>6</sup> According to Otsuka, the former vice minister of the MHLW, there existed different perspectives amongst the MHLW, the MAFF, and affected local governments at that time (Otsuka, 2012, p. 56-57), although all shared the same major objective of public health safety assurance. Simply speaking, the MAFF wanted to have in place the regulatory safety limit for radionuclides to avoid consumer confusion and the ungrounded rumors that

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<sup>6</sup> NERHQ hp, “Summary of the Minutes of the 8th NERHQ Meeting,” [http://www.kantei.go.jp/jp/singi/genshiryoku/pdf/gensai\\_gaiyo\\_08.pdf](http://www.kantei.go.jp/jp/singi/genshiryoku/pdf/gensai_gaiyo_08.pdf) (accessed 22/11/2012).

can have a negative impact on products in the affected area. It considered that the regulatory limits can show what is and is “not safe” and hence send the message that the foods on the market were considered to be “safe”. On the other hand, the MHLW's major concern was the feasibility of monitoring. It felt that it was not meaningful to set in place such standard unless the regulatory limit could be effectively monitored and detected (it was soon discovered that the infrastructure for monitoring was inadequate, as will be seen in 2.2). The affected local governments were most concerned about the impact of the restriction on distribution of agricultural products and were less willing to accept the immediate introduction of the limit.

In the end, on March 17, the MHLW adopted the NSCJ's Indices for Food and Beverage Intake Restriction and set in place the provisional regulation values on the basis of Article 6, Item 2 of the Food Sanitation Act (Act No. 233 of 1947; the Act)<sup>7</sup> (Table 1).

Table 1. Provisional Regulation Values for Radionuclides in Foods<sup>8</sup>

Provisional Regulation Values (from March 17th)		
Radioactive iodine	Drinking water/Milk + dairy products  *provide guidance so that materials exceeding 100 Bq/kg are not used in milk supplied for use in powdered infant formula or direct drinking	300 Bq/kg
	Vegetables (Except root vegetables and tubers),	2,000

<sup>7</sup> Press release, “Handling of food contaminated by radioactivity (Relating to the accident at the Fukushima Nuclear Power Plant),” <http://www.mhlw.go.jp/english/topics/foodsafety/dl/food-110317.pdf> (accessed 22/11/2012).

<sup>8</sup> FSCJ hp, “Graphical Explanation of “Emergency Report on Radioactive Nuclides in Foods,” [http://www.fsc.go.jp/english/emerg/graphical\\_explanation\\_radiofoods.pdf](http://www.fsc.go.jp/english/emerg/graphical_explanation_radiofoods.pdf). MHLW hp, “Reference,” <http://www.mhlw.go.jp/english/topics/foodsafety/dl/110318-1.pdf> (accessed 22/11/2012).



	Fishery products (from April 5th)	Bq/kg
Radioactive cesium	Drinking water/Milk + dairy products	200 Bq/kg
	Vegetables/Grains/Meat, egg, fish, etc.	500 Bq/kg
Uranium	Infant foods/ Drinking water/Milk + dairy products	20 Bq/kg
	Drinking water/Milk + dairy products	100 Bq/kg
Alpha-emitting nuclides of plutonium and transuranic elements	Infant foods/ Drinking water/Milk + dairy products	1 Bq/kg
	Drinking water/Milk + dairy products	10 Bq/kg

As this measure was taken in an emergency without the assessment of the risk assessment body, the FSCJ, the MHLW asked the FSCJ for an assessment (based on Article 24, Item 3 of the Food Safety Basic Act). In response, on March 29, the FSCJ submitted an “Emergency report.” The chairperson of the FSCJ remarked of the report that the provisional regulation is “in line with such a bit too stringent safety criteria” and therefore, it is “effective enough to ensure the safety” of foodstuffs in Japan.<sup>9</sup> The FSCJ's emergency report concluded that “there is no evidence to challenge adequacy of emergency risk management based on the effective dose of 10 mSv per year as proposed by ICRP pub 63,” and thus, “at least for radioactive cesium, the annual effective dose of 5 mSv was considered as highly conservative” and “radioactive

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<sup>9</sup> FSCJ hp, “To All Concerned in Overseas (2011 April 8) - Message from chairperson of FSCJ - On the occasion of completing an emergency report on radioactive nuclides in foods.”

iodine's thyroid equivalent dose of 50 mSv (corresponding to effective dose of 2 mSv) per year is concluded as sufficiently safe.”<sup>10</sup>

The FSCJ announced that as this report was carried out in an emergency situation within short time period, it has decided to continue with further assessments of the health effect of the radionuclide in foods.

## **2.2 The restriction of the distribution of contaminated food.**

On March 22, the Director-General of the Nuclear Emergency Response Headquarters (NERHQ) issued for the first time an instruction to the governors of four prefectures (Fukushima, Ibaraki, Tochigi, and Gunma) to restrict the distribution of foods contaminated with radionuclides. It ordered an end to the distribution of spinach and kakina harvested in Fukushima, Ibaraki, Tochigi, and Gunma Prefectures and fresh raw milk produced in Fukushima Prefecture. This measure was based on Article 20.3 of the Act on Special Measures Concerning Nuclear Emergency Preparedness (Act No. 156, 1999).<sup>11</sup>

Soon, the tap water in Fukushima was found to be exceeding the provisional limit. On March 23, when tap water in Tokyo exceeded the provisional limit for infants (100 Bq), concern over the contamination of radionuclides led to a nationwide panic. Bottled water disappeared off the shelves. The contamination of tap water soon stopped, but the concern remained.

The decision of whether to impose restrictions was a difficult one. As the

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<sup>10</sup> FSCJ (2011), “Emergency Report on Radionuclides in Foods,” [http://www.fsc.go.jp/english/emerg/emergency\\_report\\_radioactive\\_nuclides.pdf](http://www.fsc.go.jp/english/emerg/emergency_report_radioactive_nuclides.pdf) (accessed 22/11/2012).

<sup>11</sup> Press Release Issuance of Instruction to restrict distribution of foods concerned, in relation to the accident at Fukushima Nuclear Power Plant: <http://www.mhlw.go.jp/english/topics/2011eq/dl/food-110321.pdf>.

provisional limits were calculated on the basis of accumulation per year from a single release from the nuclear power plant, taking into account the physical half-life, in theory, a single incident of an excess means a possible excess over the limits, in particular in the case of radioactive iodine, whose half-life is very short. In general, however, a single incident of an excess does not immediately lead to adverse health effects, unless total accumulated exposure for that year exceeds the permissible level. Hence, there was a discussion whether the restrictions should be imposed on the basis of just one case or whether it was necessary to repeat the sampling test several times and see what happens.

In addition, under the Act, monitoring and testing were to be conducted by local governments, but a serious problem was that they did not have the infrastructure or the capacity (for example, at the time when the incident occurred, Fukushima Prefecture owned four germanium semiconductor detectors, but two of them were in the evacuation zone, and the remaining two were used for environmental monitoring, so there were none that could be used for food testing) (NIIC, 2012, p.92 ICANPS, 2012, p.311). In addition, some local governments were unwilling to conduct testing for the fear of damaging local producers' businesses when limits were found to have been breached (Otsuka, 2012). This led to variation in the testing plan, depending on the prefecture (NIIC, 2012, p. 92)

On April 4, the NERHQ issued "The concepts of inspection planning and establishing and cancelling items and areas to which restriction of distribution and/or consumption of foods concerned applies." On the same day, iodine was found in fishery products, and on April 5, the provisional regulation values of radioactive iodine in fishery products were added, upon the Nuclear Safety Commission's advice.<sup>12</sup> After

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<sup>12</sup> <http://www.mhlw.go.jp/english/topics/2011eq/dl/food-110405.pdf>

that, there were cases of excess radiation found in other vegetables, mushrooms, tea leaves, beef cattle fed with radiation-contaminated rice-straw and rice.

## **2.3 The establishment of new standard limits for radionuclides in food.**

### ***(1) The FSC's Risk Assessment Report.***

After the submission of the “emergency report,” the FSCJ continued its efforts to conduct risk assessment of the effect of radioactive nuclides in food on health. It established a working group, which met nine times from April 21 to July 26, 2011. The fact that they received more than 3,000 public comments when they made the draft report open to public shows the significance of public attention. On October 27, the FSCJ published the Risk Assessment Report on Radioactive Nuclides in Foods. When releasing the report, the chairperson of the FSCJ remarked<sup>13</sup> that the FSCJ had concluded that “more than around 100 mSv of the extra cumulative effective dose: cumulative effective doses of radiation during lifetime, could increase health risk<sup>15</sup> ... [a]nd health effects from the extra cumulative exposure below 100 mSv are difficult to verify based on the current available knowledge”. It also recommended that the sensitivity of children be taken into consideration.<sup>16</sup>

### ***(2) Consultation on new limits at the PAFS Council of the MHLW***

On the October 28, the MHLW minister made an announcement concerning her basic idea for the revision of the new safety limit, stating that the current provisional

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<sup>13</sup> FSCJ hp " To All Concerned in Overseas - Remarks from the chairperson of Food Safety Commission of Japan (FSCJ) - About the assessment of the effect of food on health of radioactive nuclides in foods"

[http://www.fsc.go.jp/english/emerg/remarks\\_fsc\\_chair.pdf](http://www.fsc.go.jp/english/emerg/remarks_fsc_chair.pdf)

<sup>15</sup> This amount does not include radiation from the natural environment and medical exposure.

<sup>16</sup> During childhood, susceptibility to radiation, increasing the possibility of developing thyroid cancer and leukemia, may be higher than in adulthood.

regulation that allows for 5 mSv/year can in general be expected not to cause adverse health effects, but to ensure further safety and public assurance, the MHLW would consult with the PAFS Council with the aim of reducing the level to 1 mSv/year.<sup>17</sup>

In response, the matter was discussed at the Subcommittee and Section meetings of the PAFS Council. The new limits followed 1 mSv/year, which was an intervention exemption level stated in the Guideline levels of the Codex Alimentarius Commission (CODEX STAN 193-1995).<sup>18, 19, 20</sup> For the drinking water limit, it referred to the WHO's guidance level of 10 Bq/kg, which corresponds to 0.1 mSv/year as the effective dose. It subtracted this 0.1 mSv/year from 1 mSv and determined the effective dose for “general foods” as 0.9 mSv/year. It then calculated the limit value for cesium based on the intake and conversion coefficient in each age category and determined the limit for general foods across all ages as 100 Bq/kg.

The cesium level of Japanese limits differs from that of the Codex, as shown in the tables below (Table 2 and Table 3). The reasons for this are as follows: (1) whereas the Codex guideline level was based on the assumption that 10% of foodstuffs were imported from the contaminated area, Japan assumed that 50% of the marketed foods were contaminated<sup>21</sup> (this was derived from its self-sufficiency rate of 40%); (2) Japan

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<sup>17</sup> The minutes of the section meeting of PAFS Council (of 31/10/2011). Of course, it was explained that this announcement would not constrain the discussions or the conclusion of the PAFS Council. It was asked to consider if this basic idea was acceptable.

<sup>18</sup> The 121st minute of the Radiation Council of MEXT, MHLW hp, “New limit on Radionuclides in Food” (in Japanese), [http://www.mhlw.go.jp/shinsai\\_jouhou/dl/leaflet\\_120329.pdf](http://www.mhlw.go.jp/shinsai_jouhou/dl/leaflet_120329.pdf) (accessed 22/11/2012).

<sup>19</sup> This level of 1 mSv/year is based on the intervention exemption level as recommended by ICRP's Publication 82 (1999).

<sup>20</sup> The new limit was not directly considered on the basis of the risk assessment report of food safety commission, but it was felt that the newly established limit was not contradictory to the FSC finding.

<sup>21</sup> This assumption was later criticized by the Radiation Council of MEXT as an overestimate and unrealistic. Daily Yomiuri Online hp, “Ministry sets stricter cesium

took into account the contribution of other radioactive substances (strontium, plutonium) in developing the limit for cesium; and (3) Japan took age category into consideration.

Table 2. New limits for radionuclides in foods

Category	Limit Bq/kg
Drinking water	10
Milk	50
General Foods	100
Infant Foods	50

Table 3. Codex guideline levels for radioactive cesium

Category	Limit Bq/kg
Infant foods	1000
Other foods	1000

### ***(3) Consultation of the Radiation Council of the MEXT.***

After the PAFS Council's consultation, the Radiation Council of the MEXT considered this new limit from the technical perspective of radiological protection. It met six times, from December 27, 2011, to February 22, 2012. The discussion between experts from the Radiation Council and officials from the MHLW revealed the inherently different paradigms used for food risk management and radiation protection.

The Radiation Council reported that while it did not object to the decision to reduce the current 5 mSv/year to 1 mSv/year, it concluded that it did not consider that this

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limits for food" (February 18, 2012), <http://www.yomiuri.co.jp/dy/national/T120217006336.htm> (accessed 26/11/2012).

reduction would likely lead to higher radiological protection. It made two points in this respect. The first concerned the difference in the paradigm between food risk management and radiation hazard prevention (to be discussed more in detail in 3.2). The Radiation Council pointed out that in radiological protection, a feasible reference level is used in the first place and then reduced on a phased basis to fix a regulatory limit, whereas in food regulation the limit was regarded as a legal regulatory limit from the outset. The approach of radiological protection also stresses the importance of the concept of “optimization,” which takes into consideration the economic and social factors needed to sustain the affected local activities and recovery and focuses on the importance of stakeholder involvement. Second, the Council pointed out that a “special safety consideration” (implicitly meaning “too tough”) was made for milk and infants by setting the limit at 50 Bq/kg. The calculation of limit values shown to the Radiation Council by the MHLW stated that the lowest among the age categories was the 13–18 category's 120 Bq/kg (thus taking the side of safety and setting the limit at 100 Bq/kg for all general foods), whereas for those under the age of one year it was 460 Bq/kg. The Council pointed out that the new limit for general food was already considered to be safe for under-one-year-olds even without additional special reduction to 50 Bq/kg<sup>22</sup>. They also stressed that it would be imperative to have a monitoring system to ensure effective detection of foods exceeding the limits for small amounts and to avoid the reduction in the number sampled and the possibility for overlooking the contaminated foods (because it generally takes more time to test for small levels of radionuclide, thus leading to a decrease in the sampling number for each germanium semiconductor).

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<sup>22</sup> It is said that the MHLW minister was deeply concerned about the protection of children. Daily Yomiuri Online hp, “Ministry sets stricter cesium limits for food” (February 18, 2012), <http://www.yomiuri.co.jp/dy/national/T120217006336.htm> (accessed 26/11/2012).

On, February 24, 2012, the PAFS Council of MHLW approved the new limit. The new limit came into force from the April 1, 2012.

#### **2.4 Current instructions and restrictions and estimated exposure.**

The instructions for inspection and restrictions were revised on June 27, 2011, and on March 12, 2012. The MHLW is monitoring and collecting the data of testing outcomes of radionuclides in food. When food exceeding the limits is found, all the products in the same lot of samples are recalled and disposed of. The restrictions in the distribution of foods are imposed by the NERHQ on the affected prefectures/smaller region units taking into consideration the spread of contamination based on the Act on Special Measures Concerning Nuclear Emergency Preparedness. It will lift the restriction after all the samples on at least three locations in the restricted area are found to be negative in a one-month period.

According to the MHLW, the estimated radioactive cesium from food purchased in Fukushima Prefecture is considered to be less than 0.02 mSv/person/year, which is far below the current new limit of 1 mSv/year.<sup>23</sup>

### **3. The Challenges Identified in the Control of Food Safety Risk and the Governance Structure of Radionuclides**

The following section will discuss the preliminary findings from the above process.

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<sup>23</sup> MHLW hp, reference for the 22/12/2011 meeting of the PAFS Council of MHLW “Estimate of daily intake of radionuclides in food” (in Japanese). The estimation of radioactive cesium in foods purchased in Tokyo was 0.0026 mSv/man/year. <http://www.mhlw.go.jp/stf/shingi/2r9852000001yw1j-att/2r9852000001ywe9.pdf>.



### **3.1 How safe is safe enough? Decision making in conditions of uncertainty.**

Uncertainty is inevitable in the risk assessment and management of radionuclides. There is general consensus, based on the epidemiological research data of Hiroshima and Nagasaki atomic bomb survivors, that the incidence rates or mortality rates of solid cancers caused by radiation exposure increase with exposure doses linearly and around 150 mSv in the extra effective dose could increase health risks. However, many reports indicate that hardly any carcinogenic effects found at the low-dose area below 100 mSv, although some reports mention some effects (FSC emergency report). As a result, as mentioned above, the FSC's risk assessment concluded that it is difficult to assume any health effects of a lifetime cumulative exposure dose below 100 mSv.

This inherent uncertainty in low-dose exposure has spawned divergent and contentious views among the experts. There is a general agreement that an ALARA (as low as reasonably achievable) approach should be adhered to, and based on that, a linear non-threshold (LNT) model was developed, but there is still diversity in how experts approach safety and their control measures for risk. Some consider that the fact that the effects below 100 mSv are "unknown" does not mean that the risk is negligible and that we should not be relaxed about exposure at such levels. Others regarded "100 mSv" as a virtual threshold and consider that no health effects would be found in exposure below 100 mSv.

The scientific uncertainty also created public confusion with regard to risk communication because it was repeatedly explained by the government right after the accident that, concerning the health effect of radionuclides, they did not "pose (an) immediate adverse health effect." It was later explained in the report of Investigation Committee on the Accident at the Fukushima Nuclear Power Stations, ICANPS

(ICANPS, 2012) that the meaning of this statement was that the effect of accumulated radiation was unknown but did not have acute adverse health effects although, since these were radionuclides, it cannot be said that they had no effect at all if accumulated.

Because risk is characterized by probability and severity (a function of the probability of an adverse health effect and the severity of that effect), there is no specific line that can be drawn between safe and unsafe. With regard to radionuclides in foods, as with other non-threshold risks, the pursuit of zero risk is impossible. Selection and utilization of various scientific assumptions must be conducted to cope with uncertainty in risk assessment. Then, the risk manager or the decision maker is assigned with the difficult task of choosing an appropriate level of protection that is acceptable to society from the range or the band of risk. So, “how safe is safe enough?” becomes the usual question that risk regulation faces. Safety is not self-evident. It is something that must be discussed and agreed upon by the actors involved in the society (Kishimoto, 2011, Kai 2011).

There were mixed views for reducing the limit at this time. The MHLW and the FSCJ considered that the provisional regulation values set right after the accident were adequate to ensure safety based on the current scientific knowledge, but, “in pursuit of further safety and assurance of foods”<sup>24</sup> and “to achieve further food safety and consumer confidence,”<sup>25</sup> the MHLW took the decision to reduce the maximum permissible dose from 5 mSv/year to 1 mSv/year.

What does “further food safety” mean? Some believed the MHLW should not have reduced the values if it was going to pursue a policy based on science, because it already considered 5 mSv/year to be scientifically safe and had no need to tighten the

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<sup>24</sup> MHLW, Notice No. 0315 Article 1 of the Department of Food Safety.

<sup>25</sup> MHLW, “New Standard Limits for Radionuclides in Foods.”

limit so soon. Others felt that if the limit was going to be stricter than what was already regarded as “safe,” then evidence to justify further reduction had to be shown.

Acknowledging that the risk should be as low as possible, they believed it should also consider other socio-economic factors, such as affected local producers and the implications for recovery. There were still others who felt that it was important that Japan have in place a level that is consistent with international standards (in this case, the Codex standard of 1 mSv/year). Moreover, this 1 mSv/year is the level that the ICRP recommends for public exposure under normal conditions. The number of 1 mSv/year by the two international organizations may have had a symbolic effect to reassure the public.

### **3.2 The governance of food safety and radionuclides.**

#### ***(1) The interface between science and politics, risk assessment, and management.***

The purpose of the establishment of the FSCJ was to secure the independence of objective, neutral, and unbiased scientific advice. In the practice of risk assessment, however, the separation of science and interpretation, science and its context is not as easy as it might seem. In the practice of risk assessment, choices and scientific value judgments on scientific assumptions are made to fill in the gap that could impact the outcome (FAO/WHO, 1997). The Codex procedural manual stresses the importance of the “functional separation” of risk assessment and risk management to ensure scientific integrity, but at the same time it emphasizes that risk analysis is an iterative process. It stresses the importance of “interaction” between them is essential for practical application (CAC, 2011, p. 106). How far a risk assessment body should go into interpretation or employing various scientific assumptions that serve regulatory

decisions is an issue that must be seriously addressed in the governance of risk. Some consider that just reviewing and compiling the existing literature and saying that the effects below 100 mSv are unknown is not enough (Kanno, 2011). Others believe risk assessors should not go so far that they might stray into the realm of risk management. This kind of confusion might have been solved if a Risk Assessment Policy (RAP) had been explicitly conducted. RAP is defined as the “Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained” (CAC, 2011, p. 112). Just as the routine request for consultation starts with just one paper, the request for consultation for the new limit this time simply stated its aim as being “[t]o set values for radionuclides based on Article 6, Item 2 of the Food Sanitation Act.” It was unclear what forms of assessment, approach, situations, and factors were appropriate for the risk assessment. If an RAP had been properly institutionalized, then there might have been less confusion and more effectiveness in terms of risk control and risk communication.

***(2) Different management paradigms—radiological protection and food risk control.***

As described in section 2.3 (3), different management paradigms were revealed in the discussions at the Radiation Council after the consultation of the PAFS Council of the MHLW.

For a long time, the Radiation Council of the MEXT has<sup>26</sup> been working to introduce the recommendations of the ICRP into Japanese nuclear safety administration

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<sup>26</sup> This Council was disbanded with the establishment of the Nuclear Regulation Authority (NRA) and its secretariat in 2012 September, and the role assigned to the Council has been taken over by the NRA.

and thus was familiar with the ideas developed in the field of radiation protection. The ICRP has three principles: “justification” (any decision that alters the radiation exposure situation should do more good than harm), “optimization” (exposure should be kept as low as reasonably achievable, taking into account economic and societal factors), and “dose limit” (the total dose from regulated sources in planned exposure situations other than medical exposure should not exceed the appropriate limits specified by the Commission). It has introduced a situation-based approach for radiological protection: “emergency exposure situations” (unexpected situations requiring urgent attention), “existing exposure situations” (exposure situations that already exist when a decision on control has to be taken), and “planned exposure situations” (situations involving the planned introduction and operation of sources).

The Radiation Council considered following this phase-based idea. They believed, if the current situation is recognized as “existing exposure situation” (no longer an emergency exposure situation but there is still contamination around, so it needs to be under control), a continuous approach allowing flexibility in taking measures in response to changing situations was required. Consequently, the Council felt that the control limit should be a reference and not a regulatory limit. It considered that the limit should be flexible enough to respond to the risk posed and that measures must be always balanced with the benefits of introducing such measures, such as forced evacuation and restrictions on food. It also emphasized the stakeholder views of the affected area.

On the other hand, under the Food Sanitation Law, food risk control employs a different paradigm. As food moves across the boundary between the affected and non-affected areas, it is considered reasonable to adopt a national-level approach.

Instead of a phased approach, a strict limit is imposed and enforced. Under this law, the regulatory limit is treated as a mandatory obligation and food that exceeds the limit, even by a small amount and considered to pose no immediate adverse health effect or as having no risk, is not allowed on the market. This approach does not allow for any flexibility as a matter of law, however, it is more predictable and stable than the flexible approach.

Both paradigms have their merits and disadvantages, and how we should approach this issue with regard to radionuclides in food must be considered from the perspective of governance.

### ***(3) The need for meta-governance.***

In the management of risk posed by radionuclides, it is stressed that identification of all major exposure sources, including external exposure (from cloudshine and ground shine) and internal exposure (from ingestion of foodstuffs and inhalation) is important (WHO 2012). However, many reports point out that this was not considered. For example, according to the report of the National Diet of Japan Fukushima Nuclear Accident, Independent Investigation Commission (NIIC (2012)), the administrative structure of radiological protection was divided among at least seven organizations.<sup>27</sup>

This will lead to a fragmented governance structure and a governance deficit (Although the fragmentation does not always lead to governance deficit as it can ensure

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<sup>27</sup> According to the NIIC report, these seven organizations are as follows: (1) Nuclear Safety Commission (Cabinet Office): basic reports to prevent hazards that result from the use of nuclear power; (2) MEXT: oversees the Act on Prevention of Radiation Disease Due to Radioactive Isotope, etc.; (3) Radiation Council: reports on radiation technology standards; (4) Nuclear and Industrial Safety Agency (METI): oversees the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material, and Reactors; (5) MHLW: oversees the Food Sanitation Act and considers limits for radionuclides in food; (6) FSCJ: risk assessment of radionuclides in food; (7) MHLW: Industrial Safety and Health Act.

the cross-check by different agencies). It is imperative to consider this dilemma from the meta-governance perspective.

#### **4. Conclusion: No Single “Right” Answer for the Management of Risk—Society Needs to Decide**

In this paper, the measures taken to control the risk of radionuclides in food in response to the unprecedented disaster caused by the Great East Japan Earthquake was analyzed, and the preliminary findings from this analysis were discussed.

The paper revealed that radionuclide risk is a very complex issue that involves consideration of risk trade-off issues not limited to health risks but also including other socio-economic risks. The risk management of such complex risks, with uncertainty surrounding scientific issues and the information of exposure coming within a limited time frame, was a very difficult task. In response to this unprecedented disaster, the measures were taken, basically, using the existing framework, but as a consequence, 1) it was reaffirmed that there is an inherent science and politics (or risk assessment and management) interface issue, 2) it was revealed that there is a difference in management approaches between food risk control and radiological protection, and 3) it was shown that there is a need for a meta-governance perspective.

Two implications can be inferred from these preliminary findings. First, there were divergent views as to what is considered to be “right,” and there is no self-evident “right” answer for that. The different paradigms for radiological protection and food risk control in the handling of radionuclides in food tell us that there can be different approach. What is “right” in legal terms is not necessarily right in terms of risk or economic terms. Societal discussion about how to approach this matter must take place

to explore what society considers to be “right.” At the same time, it would be worthwhile to explore whether there is common ground for reconciling these distinct management approaches.

Second, a reconsideration from the perspective of governance must take place. The paper showed that there is a different governance structure in the control of radionuclides. To avoid being bogged down in a governance deficit, it is essential to capture all aspects of risk to identify what risks are covered from legal and management perspectives and to identify if there are any risks being overlooked. This must be discussed at the newly created Nuclear Regulation Authority.

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