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Master Thesis (Minor)

Radioactive contaminants in food

- A comparative study on regulatory and guideline limits in selected countries and the Codex -

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Abstract

This study performed a comparative analysis of the organizations related to control on radioactive contaminated food, and on the limits of radionuclide concentrations used for food control in order to find the way to harmonize the existing limits in four countries (Japan, Australia, Canada and the US), one region (the EU) and the Codex.

The existing national limits are not harmonized with the Codex guideline levels (GLs) for radionuclides in food traded internationally following a nuclear accident, but the basic concept of calculation deriving the Codex GLs was shared with the national limits. In other words, the components of the equation deriving the Codex GLs, namely the intervention level, dose coefficient, mass of food and ratio of contaminated food, are included in the equations deriving the national limits. By comparison between national limits and the Codex GLs, it was revealed that grouping of radionuclides and food, the selection of the values for each component of equations, the rounding of calculated values, and the values of limits are not harmonized. It would be difficult to harmonize the national limits completely because the Codex GLs allow national governments to adopt different values for internal use in order to set limits suitable for the situation in each country. However, the efforts for harmonization of the methods deriving national limits can be made to reduce the difference between national limits and the Codex GLs. In particular, the rounding of calculated values should be harmonized, and the intervention level and dose coefficient should be adopted from the latest ICRP and IAEA recommendations. The ratio of contaminated food should be selected carefully because of its large impact on the final calculated values. To facilitate the harmonization of the intervention level used for the calculation, it is recommended that ICRP and IAEA clarify the intervention level for food in emergency exposure situations. In addition, most of the countries shown in the study have their national limits as guidelines, which can give the interpretation of the “unsafe” food written in the national food laws. The limits as guidelines are convenient to avoid the trading conflict because they assure the flexibility in selecting values of limits following the accident based on the situations in each event.

In order to promote the harmonization of limits for radionuclides in food, the organizational framework should also be considered. At international and national level, both of radiation protection organizations and food safety organizations are involved in risk assessment and/or management related to the control of radioactive contaminated

food. It is recommended that national radiation protection bodies and food safety bodies should communicate regularly to clarify the task division on the exposure assessment used for decision making in existing exposure situations and to share their principles provided by key international organizations, namely ICRP, IAEA and Codex. Such communication is expected to promote consistency with key principles in setting and implementing the limits, and to result in harmonization of national limits themselves.

Key words: radioactive contamination of food, limit as regulation or guideline, Codex, ICRP, IAEA

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List of abbreviations

AFFC	Agriculture and Agri-Food Canada
AL	Action Level
ALARA	As Low As Reasonably Achievable
ANRE	Agency for Natural Resources and Energy of Japan
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
BSS	International Basic Safety Standards published by IAEA
CAC	Joint FAO/WHO Codex Alimentarius Commission
CBSA	Canada Border Services Agency
CCCF	Codex Committee on Contaminants in Foods
CCRPB	Consumer and Clinical Radiation Protection Bureau of Health Canada
CEO	Chief Executive Officer of ARPANSA
CFIA	Canadian Food Inspection Agency
CNSC	Canadian Nuclear Safety Commission
DAFF	Department of Agriculture, Fisheries and Forestry of Australia
DG ENER	Directorate-General for Energy of EC
DG SANCO	Directorate-General for Health and Consumers of EC
DIL	Derived Intervention Level
DoHA	Department of Health and Ageing of Australia
EC	European Community
EFSA	European Food Safety Authority
EPA	United States Environmental Protection Agency
EU	European Union
EURATOM	European Atomic Energy Community
eWG	electronic Working Group of CCCF
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration in the United States Department of Health and Human Services
FSANZ	Food Standards Australia New Zealand
FSC	Food Safety Commission of Japan
GALs	General Action Levels
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice

GL	Guideline Level
GSCTFF	General Standard for Contaminants and Toxins in Food and Feeds, the Codex
GSG	General Safety Guides published by IAEA
GSR	General Safety Requirements published by IAEA
HC	Health Canada
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
JNES	Japan Nuclear Energy Safety Organization
MAFF	Ministry of Agriculture, Forestry and Fisheries of Japan
METI	Ministry of Economy, Trade and Industry of Japan
MEXT	Ministry of Education, Culture, Sports, Science and Technology of Japan
MHLW	Ministry of Health, Labour and Welfare of Japan
ML	Maximum Level
MLIT	Ministry of Land, Infrastructure, Transport and Tourism of Japan
MOE	Ministry of Environment of Japan
MPI	Ministry of Primary Industries of New Zealand
MPL	Maximum Permitted Level
MRL	Maximum Residue Limit
NEPC	Nuclear Emergency Preparedness Council of Japan
NERHQ	Nuclear Emergency Response Headquarters of Japan
NISA	Nuclear and Industrial Safety Agency of Japan
NPP	Nuclear Power Plant
NRA	Nuclear Regulation Authority of Japan
NSC	Nuclear Safety Commission of Japan
OECD	Organization for Economic Co-operation and Development
OIL	Operational Intervention Level
PHAC	Public Health Agency of Canada
RA	Risk Assessment
RM	Risk Management
RPB	Radiation Protection Bureau of Health Canada
SPS	Sanitary and Phytosanitary
UN	United Nations
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation

US	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization

List of chemical symbols

^{241}Am	Americium-241
^{14}C	Carbon-14
^{144}Ce	Cerium-144
^{60}Co	Cobalt-60
^{134}Cs, ^{137}Cs	Cesium-134, 137
^{3}H	Tritium
^{129}I, ^{131}I	Iodine-129, 131
^{192}Ir	Iridium-192
^{238}Pu, ^{239}Pu, ^{240}Pu	Plutonium-238, 239, 240
^{103}Ru, ^{106}Ru	Ruthenium-103, 106
^{35}S	Sulphur-35
^{89}Sr, ^{90}Sr	Strontium-89, 90
^{99}Tc	Technetium-99
^{235}U	Uranium-235

1. Introduction

1.1. Problem statement

Nuclear science and its techniques are used for many peaceful purposes including energy production, human health and food safety. In regard to nuclear energy production, the International Atomic Energy Agency (IAEA) reported that 437 nuclear power reactors were in operation in 30 countries, and that 68 reactors were under construction in 14 countries, in 2012.[1] Accidents in radiological facilities and activities might cause harmful effects of ionizing radiation[2] on public health and the environment; therefore, efforts for nuclear safety and security have been continuously made up to the present time.

However, the world experienced the Chernobyl accident in 1986, which is recognized as the most severe accident in the history of the nuclear power industry.[3] A considerable amount of radioactive materials were released into the environment and were spread by the wind into the territories of Belarus, Russia and Ukraine, and to a lesser extent, to the rest of Europe. People in the affected areas were exposed to radionuclides, mainly iodine-131 (I-131), cesium-134 (Cs-134) and cesium-137 (Cs-137). I-131, which, due to its short physical half-life[4] (eight days), was able to be transferred to individuals via air and contaminated milk and leafy vegetables. Cs-134 (physical half-life: 2 years) and Cs-137 (physical half-life: 30 years) caused long-term problems through both internal and external exposure.[5] While the later effects of long-term exposure at low doses is still unrevealed, it is most likely that a large fraction of thyroid cancers diagnosed in the group of those who were children at the time in the affected area and drank milk with

[1] IAEA, 2013a

[2] WHO defines ionizing radiation as "radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionized" (WHO, 2013).

[3] UNSCEAR, 2012

[4] IAEA explains physical half-life as "the time that it takes for half the radionuclides to disintegrate or decay" (IAEA, 2013b).

[5] ICRP defines internal exposure as the exposure which "can occur by inhalation of airborne radionuclides from a cloud, inhalation of re-suspended radionuclides, and by ingestion of contaminated food or water", and external exposure as that which "may occur from radionuclides released from installations and which are present in the air, soil, or water" (ICRP 2007, at p. 309).

high levels of radioactive iodine is attributable to radioiodine intake. Food is considered the main route of internal exposure; therefore, the Chernobyl accident led the legislation for the regulations of radioactive contaminants in food in countries and at international level. These regulations were established within the radiological protection[6] framework at the international level.

The main international organizations related to radiological protection are the United Nations Scientific Committee on the Effect of Atomic Radioactive (UNSCEAR), the International Commission on Radiological Protection (ICRP) and IAEA:

- UNSCEAR was established in 1955 based on Resolution 913 (X) adopted by the General Assembly of the United Nations (UN), which determines that the mandate of UNSCEAR is to assess and report levels of ionizing radiation in the environment and the effects of ionizing radiation on man and environment.

- ICRP is a Registered Charity (a not-for-profit organization) in the UK established in 1928.[7] ICRP provides recommendations on all aspects of radiological protection to regulatory and advisory agencies. The latest recommendations for the system of radiological protection issued in 2007 (ICRP Publication 103) aim primarily to protect human health by controlling exposure to ionizing radiation and consider the three fundamental principles of radiological protection to be *justification*, *optimization* and *application of dose limits*:
    - Justification: Any decision that alters the radiation exposure situation should do more good than harm.
    - Optimization: The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal factors.
    - Application of dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by ICRP.

  ICRP Publication 103 (2007) newly introduced the situation-based approach to

[6] Radiological protection means "the protection of people from the effects of exposure to ionizing radiation, and the means for achieving this" (IAEA, 2007).

[7] ICRP (2013)

characterize possible situations where radiation exposure may occur as planned,[8] emergency, and existing exposure situations. Radiation exposure due to a nuclear accident is considered to be relevant to both the *emergency exposure situation* and *existing exposure situation*:

- Emergency exposure situations: Unexpected situations such as those that may occur during the operation of a planned situation, or from a malicious act, requiring urgent attention.
- Existing exposure situations: Situations that already exist when a decision on control has to be taken, such as those caused by natural background radiation. Situations of exposure due to residual radioactive material that derives from past practices that were not subject to regulatory control, or that remains after an emergency exposure situation.

ICRP recommendations have presented reference levels, representing the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimization of protection should be implemented. For example, ICRP Publication 103 (2007) states that reference levels for the public in emergency exposure situations are typically in the 20 mSv[9] to 100 mSv band of projected dose,[10] and that reference levels for the public in existing exposure situations should be set typically in the 1 mSv to 20 mSv band of projected dose. ICRP considers that the maximum value for the acute or annual reference level is 100 mSv because there is an increased likelihood of deterministic effects and a significant risk of cancer at doses higher than 100 mSv. UNSCEAR reports have been used as references in ICRP recommendations.

- IAEA was created in 1957 based on the Statute of IAEA approved in 1956 by the Conference on the Statute of the IAEA held at the UN Headquarters. Its missions are to serve as the global focal point for nuclear cooperation; to assist its Member States in using nuclear science and technology for various peaceful purposes; to develop

[8] ICRP defines the planned exposure situations as "everyday situations involving the planned operations of sources" (ICRP, 2007).

[9] Sv (Sievert) is the special name for the SI unit of equivalent dose (a measure of the absorbed dose delivered by radiation to a tissue or organ designed to reflect the amount of harm caused) and effective dose (the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body). The unit is joules per kilogram (J kg^{-1}). (ICRP, 2007; IAEA, 2007)

[10] Projected dose means the dose that would be expected to be incurred if no protective measure(s) – were to be taken.

nuclear safety standards and promote the achievement and maintenance of high levels of safety in applications of nuclear energy, as well as the protection of human health and the environment against ionizing radiation; and to verify through its inspection system that States comply with their commitments.[11] In 2011, IAEA published the latest International Basic Safety Standards (BSS)[12] which established requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources by taking account of the UNSCEAR findings and the ICRP recommendations. The 2011 BSS is intended primarily for use by governments and regulatory bodies and provides requirements for radiation protection. With regard to the protection strategy for the public in emergency exposure situations, the 2011 BSS states that a reference level shall be set typically in the range 20–100 mSv in one year, via all exposure pathways. For existing exposure situations, it is written that the reference level shall typically be expressed as an annual effective dose in the range 1–20 mSv and that the specific reference level for exposure via each of the commodities (such as construction material, food, feed and drinking water) shall typically be expressed as an annual effective dose which does not generally exceed a value of about 1 mSv. Additionally, the latest version of General Safety Guides No.2 (GSG-2) issued in 2011[13] provides criteria for use in preparedness and response to nuclear emergency. For example, the GSG-2 2011 presents the values of Operational Intervention Level (OIL)[14] for the restriction of consumption of contaminated food in emergency exposure situations so as to keep annual exposure below 10 mSv. The 2011 GSG-2 also states that the Codex guideline levels established by the Joint FAO/WHO Codex Alimentarius Commission (CAC) and national limits should be used to determine whether the food is suitable for international trade and for long-term consumption after the emergency phase, respectively.

These international organizations provide the basis for the radiological protection policies of countries and international organizations. For radioactive contaminants in

[11] IAEA, 2013c

[12] IAEA, 2011a. The 2011 BSS is the Safety Requirements of IAEA, which must be met to ensure radiological protection. The previous version of BSS was published in 1996.

[13] IAEA, 2011b. The GSG-2 2011 is the Safety Guide of IAEA, which provides recommendations and guidance on how to comply with the Safety Requirements of IAEA.

[14] OIL is “a type of action level that is used immediately and directly to determine the appropriate protective actions on the basis of an environmental measurement” (IAEA, 2007).

food, countries and international organizations (e.g. CAC, IAEA) have developed limits of radionuclides' concentrations in food. National limits intended to be used for control of radioactive contaminated food following a nuclear accident have been established in the presence of publications from UNSCEAR, ICRP, IAEA, and CAC etc.; however, they are not harmonized with the Codex guideline levels. In other words, existing national limits differ from the Codex guideline levels and with each other in the values of limits, in the scope, in the calculations for deriving the limits, in citations of the ICRP and IAEA recommendations, and in the legal status.

On March 2011, twenty-five years after Chernobyl, another nuclear accident happened, this time in Fukushima Daiichi nuclear power plant (NPP), Japan, which was triggered by the Great East Japan Earthquake and the subsequent enormous tsunami. Radionuclides were released into the environment from the Fukushima Daiichi NPP; therefore, protective measures for public health were taken inside and outside Japan, including countermeasures against radioactive contamination of food, such as monitoring, restriction on distribution/intake of contaminated food by the government of Japan, and restrictions on food imports from Japan by governments around the world. This accident became the motivation to review and improve the radiological protection systems and related documents at international level, like the Codex guideline levels for radionuclides in food traded internationally.

The Codex guideline levels, namely the Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency,[15] were adopted by CAC in 1989, and revised in 2006. In 2012, the 6th Codex Committee on Contaminants in Foods (CCCF) agreed to establish an electronic working group (eWG) on the review of the Codex guideline levels. According to the proposed draft revision of guideline levels,[16] the eWG made recommendations to the 7th CCCF that (1) there was no need to change the structure and the values of the current guideline levels and that (2) the guidance on interpretation and implementation of guideline levels needed to be improved by revising the current Fact Sheet of the Codex guideline levels.[17] At the 7th CCCF in April 2013, IAEA informed the Committee that an Inter-agency Working Group, together with relevant international organizations including FAO and WHO,

[15] The Codex guideline levels are included in the General Standard for Contaminants and Toxins in Food and Feeds (GSCTFF, CODEX STAN 193-1995).

[16] CAC, 2013a

[17] FAO, 2011

would carry out work in relation to the control of foodstuffs and drinking water contaminated by radioactive substances. The Inter-agency Working Group will publish a Technical Document in mid-2014 which will provide a full and detailed explanation of various existing national and international standards. Based on the information provided by IAEA and recommendations from the eWG, the 7th CCCF agreed to discontinue work on the revision of the guideline levels.[18]

Unless mankind stops using nuclear power and its techniques, continuous efforts towards nuclear safety and radiological protection are required. With regard to food, it is necessary to prepare for the radioactive contamination of foods due to nuclear accidents in the future. The differences between the Codex and national limits might cause food trade barriers, undesired disturbances in the food supply chain, misinterpretation of limits, distrust over the control of contaminated food, etc. It is necessary to consider how to achieve harmonization by taking into account the experiences following the Fukushima Daiichi NPP accident. Wahidin (2013) carried out a comparative study on radiological protection organizations, limits for radionuclides in food, and countermeasures taken in the EU, the US, Indonesia and the Codex; in a similar vein, the present study will (1) expand the research objects to include other countries (i.e. Japan where the Fukushima Daiichi NPP accident happened, and Australia and Canada which are considered key participants of CCCF), (2) assess the differences between the Codex and countries in organizations, limits and countermeasures, and (3) give recommendations on how to harmonize and improve the existing limits of the Codex and countries by taking into consideration the experiences following the Fukushima Daiichi NPP accident. The present study will perform a comparative analysis of organizations related to the control of radioactive contaminated food, and of limits on radionuclide concentrations used for food control. The analysis will be performed with the use of the radiation protection framework at international level and the Codex guideline levels as the baselines; in addition, the Codex Working Principle for Risk Analysis and the ICRP and IAEA publications will be used as the criteria for comparison.

[18] CAC, 2013b

1.2. Aims of the study

The main objectives of this study are to:

- Explore the organizations related to radiological protection, limits for radionuclides in food applied to emergency/existing exposure situations, and countermeasures taken after the Fukushima Daiichi NPP accident in Japan, Australia and Canada;
- Analyze similarities and differences between organizations and limits regarding radioactive contamination in food in Japan, Australia, Canada and countries studied by Wahidin (2013) (the EU and the US[19]) by taking into consideration the radiation protection framework regarding food control at international level, the Codex Working Principles, the Codex guideline levels, and ICRP/IAEA publications;
- Examine the countermeasures taken after the Fukushima Daiichi NPP accident in Japan, Australia and Canada, to discuss the usability of existing limits;
- Update information about the countries and international organizations studied by Wahidin (2013); and
- Discuss how limits on radionuclides in food should be harmonized successfully.

1.3. Research questions

This minor thesis study will provide answers for the following research questions:

1. Which organizations are related to radioactive protection in Japan, Australia and Canada and how do they coordinate?
2. How are organizations and limits regarding radioactive contamination in food different between countries (Japan, Australia, Canada, the EU and the US) and the Codex?
3. What countermeasures against radioactive contaminated food have been taken by countries (Japan, Australia and Canada) following the Fukushima Daiichi NPP accident in 2011?
4. In what ways can limits for radionuclides in food be harmonized?

[19] Wahidin (2013) studied Indonesia as well as the EU and the US. In this study, Indonesia will not be included in the scope because the author of this study cannot access the original references written in Indonesian.

1.4.Methodology

To understand radiological protection organizations, limits and countermeasures related to radioactive contaminants in food, a legal research method is applied, consisting of a systematic review of legal documents, policy documents and secondary literature. The comparative study by Wahidin (2013) is fully utilized to obtain information about the organizations, limits and countermeasures in the EU and the US and at the international level.

1.5.Report Framework

Chapter 2 introduces the radioactive protection organizations in Japan, Australia and Canada. This Chapter presents answers to Question 1. Chapter 3 describes regulatory frameworks regarding radioactive contamination of food in Japan, Australia and Canada in answer to Question 2. Countermeasures taken following the Fukushima Daiichi NPP accident in Japan, Australia and Canada are explained in Chapter 4, targeting Question 3. Chapter 5 integrates information provided by previous Chapters and analyses similarities and differences between organizations and limits regarding radioactive contamination of food in Japan, Australia, Canada, the EU, the US and the Codex. Chapters 6 and 7 present the discussion and recommendations respectively, to answer Question 4.

2. Organizations related to radiological protection

2.1. Organizations in Japan

The Japanese government is three-tiered: central government, prefectures and the municipalities. The central government is based on a parliamentary cabinet system which is represented in Figure 1.

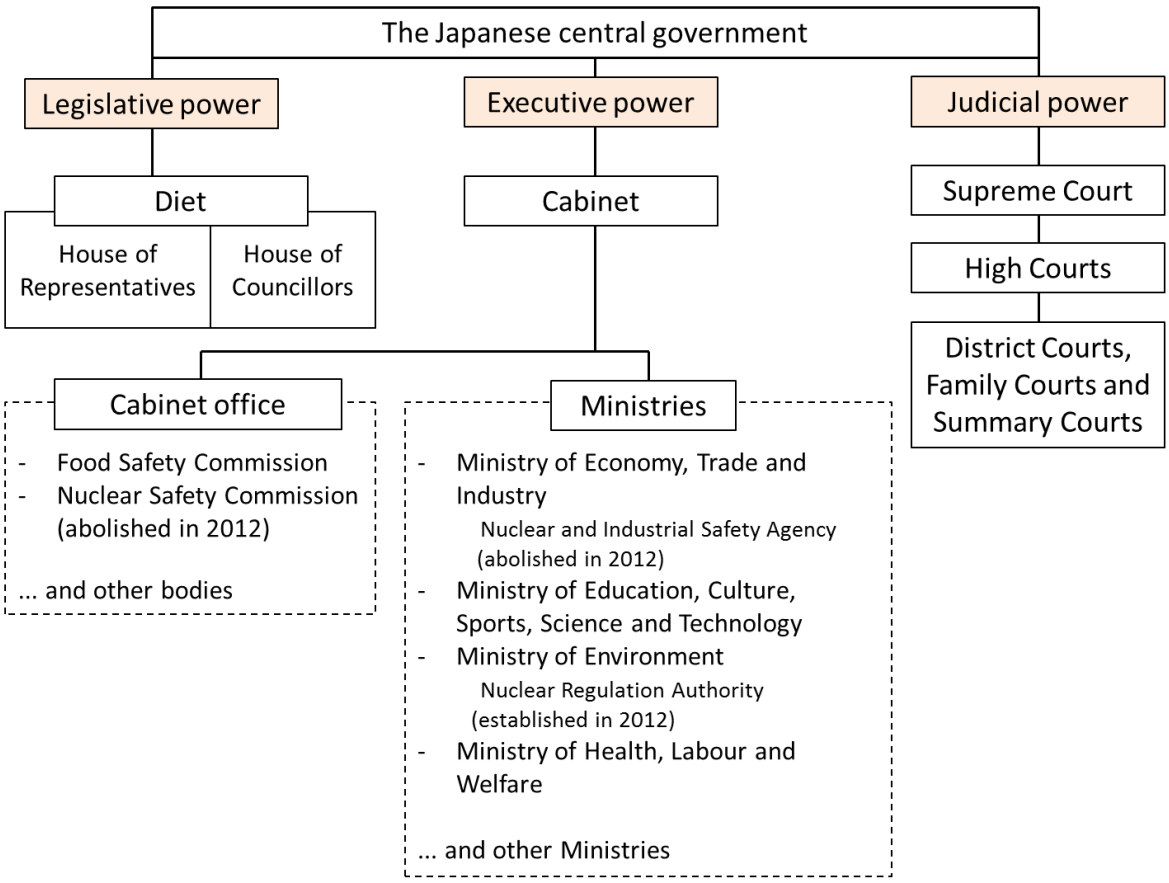

Figure 1: Structure of the Japanese central government (adopted from Consulate-General of Japan in San Francisco (2013) with amendments)

There were three main organizations for radiological protection in Japan, namely the Nuclear and Industrial Safety Agency (NISA) under the Ministry of Economy, Trade and Industry (METI), the Nuclear Safety Commission (NSC) under the Cabinet Office, and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). After the Fukushima Daiichi NPP accident, the Japanese Government transmitted a report to IAEA in June 2011, which mentioned problems of governmental organizations observed

in the emergency.[20] The basic policy on the reform of organizations[21] was decided by the Cabinet on August 2011, and subsequent discussions resulted in the establishment of the Nuclear Regulation Authority (NRA) under the Ministry of Environment in September 2012, which integrated the responsibilities for nuclear safety that had previously been divided between several organizations.

In addition, Japan has a special governmental framework for nuclear emergency response in accordance with the Act on Special Measures Concerning Nuclear Emergency Preparedness (Act No. 156 of December 17, 1999). Under this mechanism, which essentially has not changed after the Fukushima Daiichi NPP accident, the Nuclear Emergency Response Headquarters (NERHQ) shall be established when the Prime Minister has issued a declaration of a nuclear emergency situation.

2.1.1. Before the reform of organizations in 2012

NISA, NSC and MEXT were the main organizations for radiological protection before the reform in 2012, but other governmental bodies, namely the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), and the Ministry of Health, Labour and Welfare (MHLW) were also partially involved in radiological protection.

2.1.1.1. Nuclear and Industrial Safety Agency (NISA)[22]

NISA was established in the reform of the central government in 2001 as a special organization of the Agency for Natural Resources and Energy (ANRE) of METI in order to ensure nuclear and other energy and industrial safety.[23] NISA could make a decision independently or consult its proposals with the Minister of Economics, Trade and Industry without the involvement of ANRE,[24] which aimed to ensure the stable and efficient supply of energy and mineral resources and to promote the appropriate use of them.[25] As for nuclear safety, NISA was responsible for the safety regulations on nuclear power reactors, nuclear fuel cycle activities, and the management of radioactive

[20] NERHQ, Government of Japan (2011), page XII-12

[21] Basic Policy on the Reform of an Organization in charge of Nuclear Safety Regulation (Cabinet Decision, on August 15, 2011).

[22] NISA does not exist now.

[23] Based on the former provisions of the Act for Establishment of METI (Act No. 99 of July 16, 1999).

[24] NERHQ, Government of Japan (2011), page II-4

[25] The Act for Establishment of METI (Act No. 99 of July 16, 1999), Article 16

waste generated from nuclear facilities.[26] Additionally, nuclear emergency preparedness, response and recovery in collaboration with local governments, nuclear operators and the central government were also crucial tasks for NISA.[27]

NISA had a technical and scientific support organization, the Japan Nuclear Energy Safety Organization (JNES), which was established in 2003 as an incorporated administrative agency. JNES conducts inspections and assessments on nuclear facilities and supports nuclear accident preparedness, response and recovery.[28]

2.1.1.2. Ministry of Education, Culture, Sports, Science and Technology (MEXT)

MEXT was established due to the reform of the central government in 2001 as a body aiming to promote education, sports, culture, science and technology and to perform administrative affairs regarding religions.[29] In the reform of 2001, the former Science and Technology Agency, which was responsible for nuclear power and science policies, was integrated into MEXT; therefore, MEXT was from that moment on in charge of safety regulations for nuclear reactors for research purposes and the use of radioisotopes, as well as the necessary safeguards.[30] Additionally, MEXT was responsible for nuclear accident preparedness, response and recovery regarding the research facilities, and radiation monitoring in the scheme of disaster management (refer to Section 3.1.2.1).

2.1.1.3. Nuclear Safety Commission (NSC)[31]

NSC was established in 1978 based on the former provisions of the Atomic Energy Basic Act (Act No. 186 of December 19, 1955).[32] It was the independent body under the Cabinet Office, and aimed to formulate a set of guidelines for safety review by

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[26] NRA, 2013a. This information is based on the former provisions of the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No. 166 of June 10, 1957, Reactor Regulation Act) and the Electricity Business Act (Act No. 170 of July 11, 1964).

[27] Mainly based on the former provisions of the Act on Special Measures Concerning Nuclear Emergency Preparedness and the Reactor regulation Act.

[28] The Act of JNES (Act No. 179 of December 18, 2002), Article 13

[29] The Act for the Establishment of MEXT (Act No. 96 of July 16, 1999), Article 3

[30] Based on the former provisions of the Reactor Regulation Act and the Act for Prevention of Radiation Hazards due to Radioisotopes, etc. (Act No. 167 of June 10, 1962). Safeguards are activities to verify that nuclear materials are not used for nuclear weapon purposes.

[31] NSC does not exist anymore.

[32] NRA, 2013b

regulators (e.g., METI and MEXT), to supervise/audit the activities of regulators, and to make recommendations through the Prime Minister to regulatory bodies if necessary.[33] With regard to a nuclear emergency, NSC established regulatory guides for nuclear accident preparedness and response, such as the Regulatory Guide: Emergency Preparedness for Nuclear Facilities.[34]

2.1.1.4. Other ministries in the central government

The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) took responsibility for the commercial marine reactors and is partially responsible for the transport of radioactive materials.[35] Radiological devices and materials for medical use and the limit of radiation exposure dose for workers are regulated by the Ministry of Health, Labour and Welfare (MHLW)[36].

2.1.1.5. Framework for emergencies

In a nuclear emergency, the relevant bodies shall respond in accordance with the Act on Special Measures Concerning Nuclear Emergency Preparedness. The framework for emergencies (refer to Figure 2 in Section 2.1.2.3), which remains basically unchanged after the Fukushima Daiichi NPP accident, gives the Prime Minister powers to instruct local governments and related bodies (e.g. a nuclear operator) directly for emergency response measures.

The Nuclear Emergency Response Headquarters (NERHQ) shall be established in Tokyo (the capital) when the Prime Minister, who shall be the Director-General of NERHQ, has issued a declaration of a nuclear emergency situation. At the relevant Off-Site Center,[37] the Nuclear Emergency Response Local Headquarters (Local NERHQ) shall also be set up. In order to facilitate the exchange information and cooperation between the central government, local governments and related bodies (e.g. a nuclear operator), the Joint Council for Nuclear Emergency Response should be organized at the Off-Site Center, if necessary. NSC, which was abolished in 2012,

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[33] NERHQ, Government of Japan (2011), page II-4; Fukasawa and Okusaki, 2012.

[34] Published in June 1980, lastly revised in May 2007, and abolished in 2012.

[35] NRA, 2013c, 2013d and 2013e.

[36] Based on Ordinance on Prevention of Ionizing Radiation Hazards Ministry of Labour Ordinance (No. 41 of September 30, 1972).

[37] The Off-site Center is the facility that serves as the center for emergency response measures, and that is located within the area of the prefecture that includes the area where the relevant nuclear site is located.

would give technical advice concerning emergency response measures to the Director-General of NERHQ (i.e. the Prime Minister).

In response to the Fukushima Daiichi NPP accident, organizations in the central government played their role under NERHQ. In view of nuclear emergency measures related to food, for instance, NERHQ directed the restrictions on distribution/intake of contaminated food and the restrictions on rice planting aimed at local governments, while the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) established provisional regulation values for radionuclides in food and implemented food control directed by NERHQ (refer to Chapter 4). The Food Safety Commission (FSC) conducted an assessment (hazard identification and hazard characterization) of radioactive contamination of food to respond to the request from MHLW.[38]

2.1.2. After the reform of organizations in 2012

After the Fukushima Daiichi NPP accident in March 2011, the Japanese Government transmitted a preliminary accident report to IAEA in June 2011, which summarized the evaluation of and the lessons learned from the accident. The report pointed out that (1) it was not clear where the primary responsibility for ensuring the safety of citizens in a nuclear emergency laid within the governmental structure at the time, and that (2) the existing organizations and structures hindered the mobilization of capabilities in responding promptly to such a large-scale nuclear accident.[39] In August 2011, the Cabinet decided on the Basic Policy of the Reform of Organizations in charge of Nuclear Safety Regulation, which stated that NISA should be separated from METI in view of "the separation of nuclear regulation and promotion" and that new agency integrating functions regarding nuclear safety should be created under the Ministry of Environment (MOE).

Taking account of recommendations from the advisory committees,[40] the Government of Japan established the Nuclear Regulation Authority (NRA) under MOE[41] and the

[38] Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company, 2011 and 2012

[39] NERHQ, Government of Japan (2011), page XII-12

[40] The Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company, and the Advisory Committee for Prevention of Nuclear Accidents

[41] The Act for Establishment of NRA (Act No. 47 of June 27, 2012)

Nuclear Emergency Preparedness Council (NEPC) under the Cabinet[42] in September 2012. NRA integrates the functions of NISA, MEXT, NSC and MLIT related to nuclear safety and security (and will absorb JNES in the future), while NEPC aims to promote policy enforcement regarding nuclear emergency preparedness. NISA and NSC were abolished in September 2012. The basic framework for emergency, setting NERHQ at a top, has remained the same up until now.

2.1.2.1. Nuclear Regulation Authority (NRA)

The Act for Establishment of NRA (Act No. 41 of June 27, 2012) was passed in June 2012 and entered into force in September 2012. NRA is founded under MOE as an independent commissioning body aiming to ensure nuclear safety and has the following tasks declared in the Act for Establishment of NRA:[43]

- Ensuring nuclear safety;
- Safety regulations on activities related to nuclear energy materials as well as on nuclear reactors;
- Safety regulations on the use of nuclear fuel materials and nuclear source materials;
- Regulations for safeguards and the peaceful use of nuclear power;
- Radiological protection;
- Radiation monitoring;
- Assessment of nuclear accidents; and
- Making recommendations to relevant governmental organizations, if necessary.

NRA integrates the functions regarding nuclear safety and security which belonged to NISA, MEXT, NSC and MLIT, in addition, will absorb JNES into NRA itself in the future after necessary legal amendments.[44] With regard to nuclear emergency preparedness, NRA established the Nuclear Emergency Preparedness Guide in October 2012 in accordance with the Act on Special Measures Concerning Nuclear Emergency Preparedness.[45]

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[42] By the revision of the Atomic Energy Basic Act (Act No. 186 of December 19, 1955)

[43] Article 4

[44] NRA, 2013f. Some of the tasks regarding the transportation of nuclear materials have remained under the responsibility of MLIT (NRA, 2013e).

[45] Article 6-2 Item 1

2.1.2.2. Nuclear Emergency Preparedness Council (NEPC)

NEPC was created in the Cabinet in September 2012 by the revision of the Atomic Energy Basic Act (Act No. 186 of December 19, 1955). The roles of NEPC are to promote enforcement of (1) policies based on the Nuclear Emergency Preparedness Guide published by NRA and related to nuclear emergency preparedness, and (2) policies requiring long-term collaboration between many stakeholders following a nuclear accident. NEPC consists of, amongst others, the Prime Minister as the chair, the Chairman of NRA, all ministers, etc.

2.1.2.3. Framework for future emergencies

The framework for emergencies has primarily remained as described in Section 2.1.1.5 (note: NSC does not exist now), but the Act on Special Measures Concerning Nuclear Emergency Preparedness was revised in June 2012 to strengthen the function of NERHQ[46] and to clarify that NRA can make a decision without the notification of the Director-General of NERHQ (i.e., the Prime Minister) in order to ensure the safety of nuclear facilities based on technical and professional knowledge.[47]

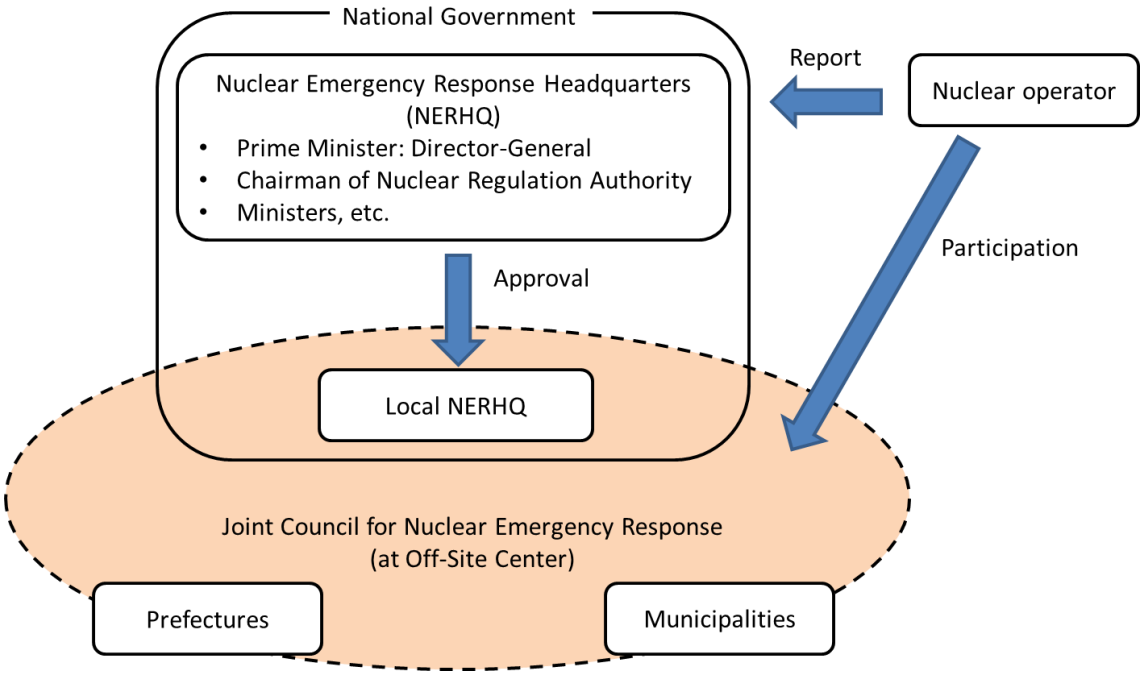

Figure 2: Framework for nuclear emergency in Japan (adapted from NERHQ, Government of Japan (2011), amended)

[46] NRA, 2013f

[47] Article 23 Item 3 of the Act on Special Measures Concerning Nuclear Emergency Preparedness

2.2. Organizations in Australia

The Government of Australia is three-tiered: (1) Commonwealth (or Federal), (2) State and Territory, and (3) Local. The Australian Constitution defines the responsibilities of the Commonwealth government, which include foreign relations, trade and the activities of trading corporations, defense and immigration. Governments of States and Territories are in charge of all matters not assigned to the Commonwealth government.[48] The structure of the Commonwealth government is shown in Figure 3.

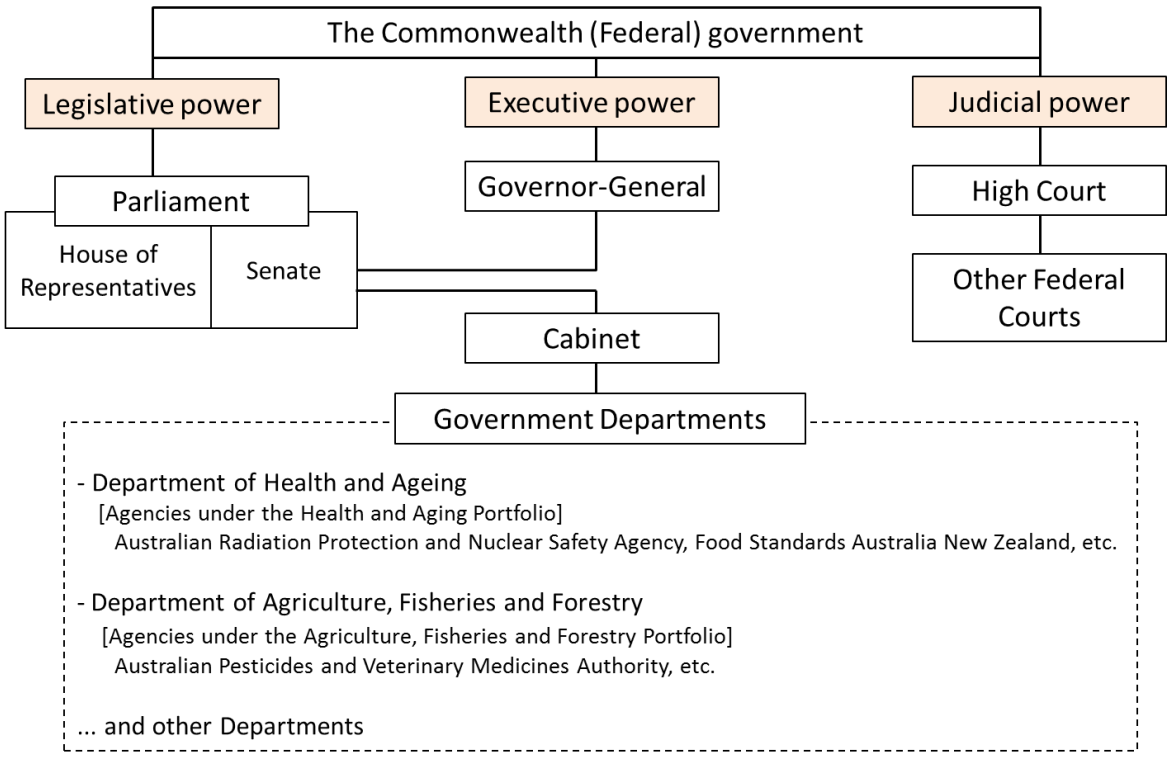

Figure 3: Structure of the Australian Commonwealth government (adapted from Parliament of Australia (2013) with amendments)

The main body for radiation protection in the Commonwealth government is the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), which is an agency in the Health and Ageing Portfolio. With regard to radioactive contamination of foods, the Food Standards Australia New Zealand (FSANZ) as a Health and Ageing Portfolio agency and the Department of Agriculture, Fisheries and Forestry (DAFF) also play their roles.

[48] Department of Foreign Affairs and Trade, 2009

2.2.1. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

ARPANSA is a Commonwealth Government agency established in 1998 by the Australian Radiation Protection and Nuclear Safety Act 1998 (Act No. 133 of 1998, the ARPANS Act). ARPANSA is charged with the responsibility of protecting the health and safety of people and the environment from the harmful effects of radiation.[49] The functions of ARPANSA can be summarized as follows:[50]

- To promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories;
- To regulate the Commonwealth's use of radiation and nuclear technology, by using licensing power to control material/apparatus/facilities, by developing standards, codes of practice, guidelines and other relevant materials, and by appointing inspectors;
- To provide advice on radiation protection, nuclear safety and related issues;
- To undertake research in relation to radiation protection, nuclear safety and medical exposures to radiation;
- To provide services relating to radiation protection, nuclear safety and medical exposure to radiation;
- To accredit persons with technical expertise for the purposes of the ARPANS Act;
- To advise the government and the community on radiation protection and nuclear safety;
- To undertake scientific research and provide services in the field of radiation protection; and
- To represent Australia in international forums that develop new principles and practices in radiation protection and nuclear safety.

The ARPANS Act allowed the Chief Executive Officer (CEO) of ARPANSA to delegate his/her powers to staff[51] and established three bodies that advise the CEO: the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee. The functions of each body are defined in the ARPANS Act as follows:

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[49] ARPANSA, 2004

[50] ARPANSA, 2012, Part 2; the ARPANS Act, Section 15

[51] ARPANSA has six offices/branches. Among them, the Radiation Health Services Branch (including Monitoring and Emergency Response, Environmental & Public Health, Non-ionising Radiation, Occupational Exposure and Personal Radiation Monitoring Service) is most relevant to the radioactive contamination of food.

- *The Radiation Health and Safety Advisory Council*:
  Identifies emerging issues, examines matters of major concern to the community, and advises the CEO on the adoption of recommendations, policies, codes and standards in relation to radiation protection and nuclear safety.
- *The Radiation Health Committee*:
  Advises the CEO and the Council on matters relating to radiation protection, including formulating draft national policies, codes and standards for consideration by the Commonwealth, states and territories.
- *The Nuclear Safety Committee*:
  Advises the CEO and the Council on matters relating to nuclear safety and the safety of controlled facilities, including developing and assessing the effectiveness of standards, codes, practices and procedures.

In any type of disaster and emergency, including a radiation emergency, the State and Territory authorities have an essential responsibility, within their jurisdictions, of emergency management. The Commonwealth government, including ARPANSA, provides support to the States and Territories in developing their capacity for emergency management and provides assistance to States or Territories when requested, under the coordination of the national emergency response by the Attorney-General's Department.[52]

Following the Fukushima Daiichi NPP accident, ARPANSA has been assessing the situation in Japan, analyzing samples of foods imported from Japan which have been mostly the samples obtained via the Imported Food Inspection Scheme (organized by DAFF), and monitoring the atmosphere and ocean in order to properly advise the Commonwealth government and the public on radiation protection and nuclear safety issues.[53] For instance, ARPANSA has provided advice to FSANZ, which can develop assessment policies relating to imported food,[54] specifically in relation to which prefectures (in Japan), foods, and radionuclides should be targeted for testing.[55] In addition, ARPANSA published a technical report in October 2012 which summarizes

[52] Attorney-General's Department, 2009, Chapter 2

[53] ARPANSA, 2011, Part 3; ARPANSA, 2012

[54] The Food Standards Australia New Zealand Act 1991, Section 13

[55] ARPANSA, 2012, Chapter 4

the assessment of the impact of the release of radioactive materials from the Fukushima Daiichi NPP on the Australian people and environment.[56]

2.2.2. Food Standards Australia New Zealand (FSANZ)

FSANZ, which was established by the Food Standards Australia New Zealand Act 1991 (Act No. 118 of 1991, the FSANZ Act), is an independent statutory agency in the Health and Ageing Portfolio. The FSANZ Act determines the functions of the FSANZ as follows:

- To develop and review the Australia New Zealand Food Standards Code (the Code)[57] and codes of practice;
- To promote consistency between standards in Australia and New Zealand with those used internationally, based on the best available scientific evidence;
- (only in Australia) To coordinate the monitoring, surveillance and recall of food, to conduct research and surveys, to develop assessment policies related to imported food and food education initiatives, to facilitate the harmonization of State and Territory laws relating to food, and to provide advice to the Minister of Health and Ageing;
- To provide information about the Australia New Zealand Food Standards Code;
- To participate in international, regional and bilateral negotiations; and
- At the request of New Zealand, to perform functions for New Zealand similar to the functions that FSANZ may perform.

In both Australia and New Zealand, the Code regulates contaminants and natural toxicants in food, novel foods and genetically modified foods, and substances added to foods (e.g. food additives, vitamins, minerals and processing aids). Also, the Code sets food labeling requirements, microbiological limits and food product standards, which are applied in both countries. The Code also has standards for primary production and processing, standards for food hygiene and residue limits for agricultural and veterinary products, but these apply only in Australia.

Currently FSANZ has not developed food regulatory measures (i.e. standards or codes of practice) regarding radioactive materials in foods, but it would be possible for

[56] ARPANSA, 2012. The assessment is based on environmental monitoring and testing of people, wildlife, shipping, aircraft and imported food and vehicles.

[57] Standards in the Code are given legal effect by the Australian Commonwealth, State and Territory and New Zealand government laws.

FSANZ to take action in radiation emergencies within its responsibilities. As countermeasures against the Fukushima Daiichi NPP accident in Japan, FSANZ developed assessment policies related to foods imported from Japan[58] and provided advice to DAFF, Australia.[59] The information available about the actions of FSANZ toward the New Zealand government is limited, but it is said that the Ministry of Primary Industries (MPI) in New Zealand "has been working closely" with FSANZ.[60]

2.2.3. Department of Agriculture, Fisheries and Forestry (DAFF)

DAFF is the Commonwealth department which has the Agriculture, Fisheries and Forestry portfolio. The Administrative Arrangements Order, which lists matters dealt with by each department and legislation administered by each minister administering each department, determines matters dealt with by DAFF as follows:

- Agricultural, pastoral, fishing, food and forest industries;
- Soil and other natural resources;
- Rural adjustment and drought;
- Rural industry inspection and quarantine;
- Primary industry research, including economic research;
- Commodity marketing, including export promotion and agribusiness;
- Commodity-specific international organizations and activities;
- Administration of international commodity agreements;
- Administration of export controls on agriculture, fisheries and forestry industries products; and
- Food security policy and programs.

The legislation set out for DAFF in the Administrative Arrangements Order includes the Imported Food Control Act 1992 (Act No. 221 of 1992), which allows DAFF to run the inspection on imported foods for ensuring their compliance with Australian food standards as detailed in the Code and the requirements of public health and safety. Following the Fukushima Nuclear NPP accident, DAFF conducted testing for radionuclides in foods imported from Japan in accordance with the assessment policies provided by FSANZ.

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[58] DAFF, 2012a

[59] FSANZ, 2011, page 5

[60] Ministry for Primary Industries, NZ, 2012

2.3. Organizations in Canada

Canada has a federal system of parliamentary government. Government responsibilities and functions are shared among Federal, Provincial and Territorial governments.[61] Canada has ten provinces and three territories, and each of them has a parliamentary government like the Federal government. Provincial and Territorial governments are responsible for many crucial activities, including education and municipalities function, and also share responsibilities with the Federal government for health services, immigration, farming, social assistance, transportation and the environment[62]. The structure of the Federal government can be seen in Figure 4.

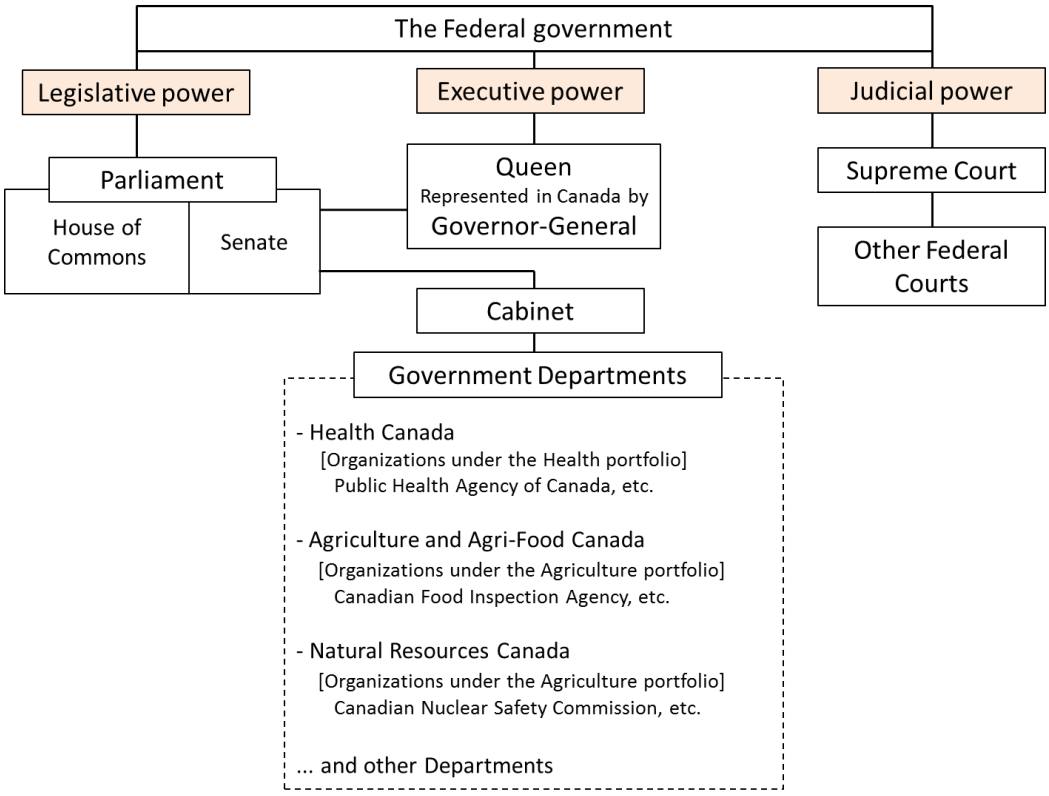

Figure 4: Structure of the Canadian Federal government (adapted from Parliament of Canada (2011) with amendments)

The main bodies for radiation protection in the Federal government are Health Canada (HC) as a department leading the Health portfolio and the Canadian Nuclear Safety Commission (CNSC) as an independent regulator under the Natural Resource portfolio. These bodies work with other federal departments and agencies such as the Canadian

[61] Government of Canada, 2011

[62] Citizenship and Immigration Canada, 2011

Food Inspection Agency (CFIA), Environment Canada, Public Safety Canada, and/or Transport Canada and also the provincial and territorial regulatory bodies with respect to radiation protection. For radioactive contamination of foodstuffs in particular, CFIA plays a vital role.

2.3.1. Health Canada (HC)

HC was founded by the Department of Health Act (S.C. 1996, c. 8).[63] The powers and functions of Health Canada include, but are not limited to, the following:[64]

- Promotion and preservation of the physical, mental and social well-being of the people of Canada;
- Protection of the people of Canada against risks to health and the spreading of diseases;
- Investigation and research into public health, including the monitoring of diseases; and
- Establishment and control of safety standards and safety information requirements for consumer products (e.g. food, drugs, and cosmetics) and of safety information requirements for products intended for use in the workplace (e.g. chemicals, medical devices, and pesticides).[65]

In HC, two Bureaus play the main roles in radiation protection: the Radiation Protection Bureau (RPB) and the Consumer and Clinical Radiation Protection Bureau (CCRPB). RPB is responsible for promoting and protecting Canadians' health with respect to the risks posed by radiation exposure in living, working and recreational environments, by developing guidance,[66] managing occupational radiation dose records, and providing advice to relevant bodies, etc. RPB also operates occupational radiation dosimetry services, and conducts research on occupational radiation exposures. In terms of preparedness for nuclear emergencies, RPB issued the Federal Nuclear Management Plan[67] (4th edition) in 2002 and should follow it in emergencies. CCRPB regulates the

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[63] The Department of Health Act, Section 2

[64] The Department of Health Act, Section 4

[65] Health Canada, 2008a

[66] Guidance to protect Canadians from the effects of nuclear accidents, radioactivity in water and food, Radon in indoor air, and naturally occurring radioactive materials from non-nuclear industries (Health Canada, 2007b).

[67] Health Canada, 2002

X-ray and non-ionizing radiation devices in accordance with the Radiation Emitting Devices Act (R.S.C., 1985, c. R-1).[68]

The Health Products and Food Branch in HC may also contribute to radiation protection related to foods. The Branch establishes the policies, regulations and standards related to the safety and nutritional quality of all food sold in Canada and monitors the activities of the Canadian Food Inspection Agency (CFIA), which is responsible for enforcement and administration of policies, regulations and standards established by HC.[69] There are no federal regulations restricting radioactivity levels in food under non-emergency situations; however, the Canadian Guidelines for the Restriction of Radioactively Contaminated Food and Water Following a Nuclear Emergency, including the action levels for radionuclides in foods and water in a nuclear emergency, were issued by the RPB in 2000. The parts of the Guidelines referring to foods will be implemented under the authority of the Food and Drugs Act (R.S.C., 1985, c. F-27).[70]

Following the Fukushima Daiichi NPP accident in 2011, HC monitored the radiation levels in the atmosphere across Canada[71] and radionuclides in food sold in Canada through its Total Diet Study.[72]

2.3.2. Canadian Nuclear Safety Commission (CNSC)

The Canadian Nuclear Safety Commission (CNSC) was established in 2000 under the Nuclear Safety and Control Act (S.C. 1997, c. 9)[73], as a body in the Natural Resource portfolio.[74] The objectives of CNSC are as follows:[75]

- To regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment, and information in order to (1) prevent unreasonable risk to the environment and to the health and safety of people, (2) prevent unreasonable risk to national security, and

[68] Health Canada, 2007a; Health Canada 2007b

[69] The Canadian Food Inspection Agency Act, Section 11

[70] Health Canada, 2000

[71] Health Canada, 2011a

[72] CFIA, 2011a. The TDS provides estimated levels of exposure to chemicals that Canadians in different age-sex groups accumulate through their food (Health Canada, 2009).

[73] The Nuclear Safety and Control Act, Section 8

[74] CNSC, 2012a

[75] The Nuclear Safety and Control Act, Section 9

(3) achieve conformity with measures of control and international obligations to which Canada has agreed; and

- To disseminate objective scientific, technical, and regulatory information to the public concerning the activities of the Commission and the effects, on the environment and on the health and safety of the public, of the development, production, possession and use of nuclear energy, substances and equipment.

Through the Nuclear Safety Control Act and its related Regulations, CNSC regulates nuclear facilities[76] and activities[77] in Canada by its licensing power[78] and by designating inspectors.[79] In the Radiation Protection Regulations (SOR/2000-203), CNSC requires licensees to implement a radiation protection program for keeping the amount of exposure to ionizing radiation as low as reasonably achievable (ALARA) and lower than the dose limits for the public and nuclear energy workers.

With regard to emergencies, the Nuclear Safety Control Act allows CNSC to make any orders during a nuclear emergency that it considers necessary to protect the environment or the health and safety of people or to maintain national security and compliance with Canada's international obligations.[80] According to the Federal Nuclear Emergency Plan established by HC (2002) and the CNSC Emergency Response Plan (2010)[81] under the scheme of emergency management, CNSC has the following roles during a nuclear emergency: (1) to monitor the response of the licensee, (2) to evaluate response actions, (3) to provide technical advice and regulatory approval when required, (4) to provide field response to assist local authorities as needed, and (5) to inform the government and the public on its assessment of the situation.[82]

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[76] In addition to nuclear power plants, Uranium mines and mills, processing and research facilities, nuclear substances and radiation devices, and radioactive waste and waste management facilities are regulated by CNSC (CNSC, 2010a).

[77] The activities include security, dosimetry, packaging and transport of nuclear substances, and the import and export of nuclear substances (CNSC, 2010a).

[78] The Nuclear Safety and Control Act, Section 24-26

[79] The Nuclear Safety and Control Act, Section 29

[80] The Nuclear Safety and Control Act, Section 47

[81] CNSC, 2010b

[82] CNSC, 2012b

Following the Fukushima Daiichi NPP accident, CNSC immediately activated its Emergency Operation Center to monitor the situation and to provide advice to the Canadian government. Later, CNSC launched a review of all major nuclear facilities in Canada, and established an action plan to strengthen the defenses at Canada's nuclear power plants and to minimize risk further.[83]

2.3.3. Canadian Food Inspection Agency (CFIA)

The Canadian Food Inspection Agency (CFIA) is an agency under the Agriculture portfolio established in 1997 by the Canadian Food Inspection Agency Act (S.C. 1997, c. 6)[84] and dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.[85] The act defines the responsibilities of CFIA as administration and enforcement of the following acts related to sanitary and phytosanitary measures, for instance, the Food and Drugs Act (parts regarding food), the Feeds Act, the Fertilizers Act, the Health of Animals Act, the Plant Protection Act, the Meat Inspection Act, and the Agriculture and Agri-Food Administrative Monetary Penalties Act.[86]

The CFIA is in charge of enforcing the food safety policies, regulations and standards established by HC,[87] including the enforcement of the Canadian Guidelines for the Restriction of Radioactively Contaminated Food and Water Following a Nuclear Emergency issued by HC in 2000. Following the Fukushima Daiichi NPP accident, CFIA implemented the border controls on food and feed imported from Japan, and also tested the levels of radionuclides in domestic milk and domestic fish from British Columbia as well as in food imported from Japan.[88]

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[83] CNSC, 2013

[84] The Canadian Food Inspection Agency Act, Section 3

[85] CFIA, 2010

[86] The Canadian Food Inspection Agency Act, Section 11

[87] The Canadian Food Inspection Agency Act, Section 11

[88] CFIA, 2011a

3. Regulation framework related to food safety and radioactive contaminants

3.1. Regulation framework in Japan

In 2003, the Government of Japan passed the Food Safety Basic Act (Act No. 48 of May 23, 2003) in order to introduce the basic principles for a food safety regime: protection of health as a top priority, food-chain approach and risk analysis. There are three key players for risk analysis regarding food safety: FSC as a risk assessment body, and MHLW and MAFF as risk management bodies. FSC conducts risk assessment and notifies the risk management bodies of its results and recommendations.[89] MHLW ensures the safety and sanitation of foods mainly[90] by the administration of the Food Sanitation Act (Act No. 233 of December 24, 1947), for instance, prohibition of the sale of harmful food, prescription of standards for foods, and food monitoring with local governments. MAFF is responsible for (1) ensuring the safety of agricultural, forest and fishery products by measures taken on primary production, (2) improving production, distribution and consumption of food, drink, agricultural/forest/fishery products and agricultural inputs (e.g. feed, fertilizers, agricultural chemicals, veterinary medicines) and (3) preventing contamination of agricultural soil.[91] MAFF contributes to food safety by its implementation of laws related to regulations on agricultural inputs, such as the Act Concerning Safety Assurance and Quality Improvement of Feed (Act No. 35 of April 11, 1953),[92] by the prevention of contamination of agricultural soil, and by the improvement of practices in the food-chain.[93]

Two main laws pertaining to food safety, the Food Safety Basic Act and the Food Sanitation Act, will be explained in detail here. With regards to food labeling, two other

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[89] Food Safety Basic Act, Article 23

[90] The Abattoir Act (Act No. 114, August 1, 1953) and the Poultry Slaughtering Business Control and Poultry Inspection Act (Act No. 70, June 29, 1990) cover the regulation of livestock meat and fowl meat including inspection systems for meat.

[91] Act for Establishment of MAFF (Act No. 98 of July 16, 1999)

[92] This act aims to ensure feed safety and improve its quality, thereby contributing to safety for the public and a stable food supply by regulation of feed production, establishment of feed specification and standards and testing on them (Article 1).

[93] Improvement of practices in the food-chain can be made, for example, by establishing a Code of Practice to reduce contaminants/pathogens in food.

laws play a role as well as the Food Sanitation Act: the Act on Standardization and Proper Quality Labeling of Agricultural and Forestry Products (Act No. 175 of May 11, 1950) and the Health Promotion Act (Act No. 103 of August 2, 2002). However, laws regarding food labeling are out of the scope in this Chapter because they are not related to the safety of food contaminated by radioactive substances.

3.1.1.1. Food Safety Basic Act

The purpose of the Act is to comprehensively promote policies which ensure food safety. To achieve this purpose, the Act firstly sets the basic principles for a food safety regime: protection of health as a top priority, food-chain approach, and risk analysis. Next, the responsibilities of governments and food-related business operators[94] and the roles of consumers are clarified. Lastly, the Act states the basic direction for food safety policy formulation, for instance, application of food-chain approach and risk analysis, establishment of systems for emergency. The Act also defines the roles and organizations of FSC. FSC conducts risk assessment and notifies the risk management bodies of its result and recommendations.

3.1.1.2. Food Sanitation Act

The Act aims to prevent harmful sanitary effects resulting from eating and drinking by enforcing regulations and other measures necessary, from the viewpoint of public health, to ensure food safety and thereby to protect citizens' good health. MHLW and local governments are the responsible bodies for implementing the Act regarding food safety.[95] The main areas covered by the Act are as follows:

- Responsibilities of government and food business operators;[96]
- Principles of hygienic handling of food;
- Establishment of standards of food, etc., and requirements for methods of producing, processing, using, cooking, and preserving food;
- Ban on the sale of harmful foods, novel foods and non-compliant foods;

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[94] Food-related business operators are the business operators that produce, import, sell, or conduct other business for agricultural inputs that may have effects on food safety, food, additives, apparatus or containers and packaging.

[95] For food labeling, the Consumer Affairs Agency and local governments are responsible bodies.

[96] A food business operator is a person or a juridical person who/which is engaged in collecting, producing, importing, processing, cooking, storing, transporting, or selling food, additives, apparatus or containers and packaging, or a person or a juridical person who/which provides food to many and unspecified persons.

- Establishment of food monitoring and guidance plans;
- Establishment of requirements for and licensing of business facilities; and
- Withdrawal of food and suspension of business.

The Act delegates subordinate laws (i.e. cabinet order, ordinance of the ministry, ordinance of local government, notification, etc.) to define detailed matters including standards and requirements. For standards of food in particular, the Ministerial Ordinance on Milk and Milk products concerning Compositional Standards, etc. (MHLW Ordinance No. 52, December 27, 1951) and the Specifications and Standards for Food and Food Additives, etc. (Ministry of Health and Welfare Notification No. 370, December 28, 1959) are the main subordinate laws under the Food Sanitation Act.

3.1.2. Regulations of radionuclides in food

In Japan, two regulatory schemes are involved in the control of radioactive contaminated food: the scheme of the Basic Act on Disaster Control Measures and the scheme of the Food Sanitation Act (Figure 5).

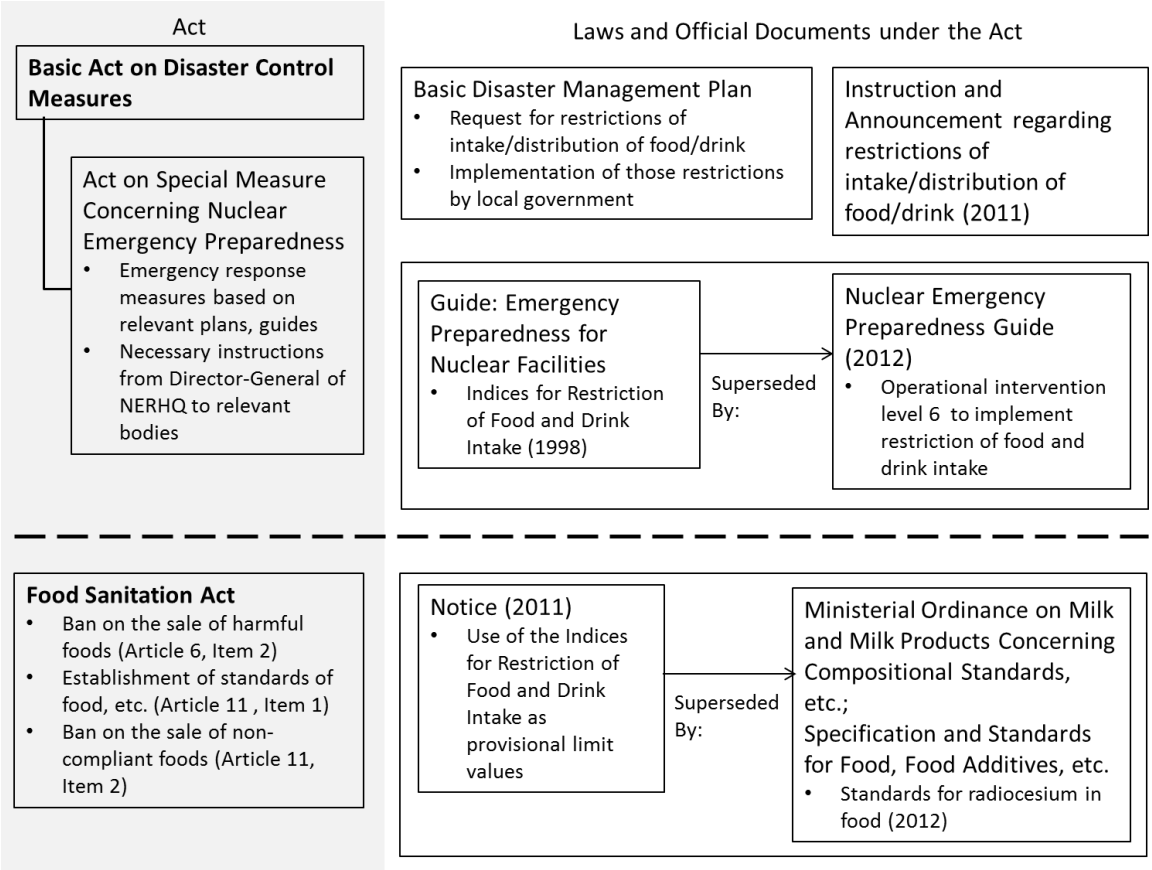

Figure 5: Two regulatory schemes in Japan regarding the control of radioactive contaminated food

The main law for food safety in general has been the Food Sanitation Act in Japan, but no standards which could directly regulate against radionuclides in food existed before the Fukushima Daiichi NPP accident. Outside the Food Sanitation Act, the laws and official documents under the scheme of disaster management were related to the restriction on the intake/distribution of contaminated food in a nuclear emergency. The Indices[97] for Restriction of Food and Drink Ingestion were provided by NSC in the Guide: Emergency Preparedness for Nuclear Facilities.

As a response to the Fukushima Daiichi NPP accident, MHLW quickly established the provisional regulation values of radionuclides in food under the Food Sanitation Act, by introducing the Indices for Restriction of Food and Drink Ingestion. The provisional regulation values were applied to the restriction on the distribution and/or intake of contaminated food based on the Act on Special Measures Concerning Nuclear Emergency Preparedness, which belongs to the scheme of disaster management. The provisional values for food were superseded by the new standards in 2012, which are still valid now.

After the accident, the laws and related official documents under the scheme of disaster management were revised in order to prepare for any future nuclear accidents. The new operational intervention levels (OILs)[98] for the restriction on the intake/distribution of contaminated food were set in the Nuclear Emergency Preparedness Guide issued by NRA, by using the Indices for Restriction of Food and Drink Ingestion.

3.1.2.1. Before the Fukushima Daiichi NPP accident

Before the Fukushima Daiichi accident in March 2011, no standard which could directly regulate against radionuclides in food existed under the scheme of the Food Sanitation Act. However, outside that scheme, some laws and official documents relevant to radioactive contaminated food existed before the accident, under the scheme of the Basic Act on Disaster Control Management (refer to Figure 5).

The Basic Act on Disaster Control Measures (Act No. 223 of November 15, 1961) has been the foundation of disaster management in Japan since 1961. It states that the Basic Disaster Management Plan (published in 1963, last revised in September 2012) shall be

[97] The Japanese government uses the word “Indices” as reference limits in official documents in English.

[98] They are already planned to be reviewed with the consideration of relevant IAEA publications in mind.

established[99] by the Central Disaster Management Council under the Cabinet Office. Chapter 11 of this plan defines measures against nuclear emergencies, including the restriction on food and drink ingestion/distribution. The old version of the plan stated that (1) the central government should request relevant bodies for the surveillance on radioactive contamination, and if necessary, the restriction of the distribution/intake of contaminated food and drink, and that (2) the local government should implement the restriction of the distribution/intake of contaminated food and drink based on the guidance and direction from the central government with consideration of the Guide: Emergency Preparedness for Nuclear Facilities (published in June 1980, last revised in August 2010, and abolished in 2012[100]) formulated by NSC. This Guide "should be respected enough with regard to professional and technical issues".[101] In this Guide, the Indices for Restriction of Food and Drink Ingestion (established in 1998 by a NSC Working Group) were provided as the limits to be used to start discussing whether NERHQ should direct the restriction of food and drink ingestion or not. It should be emphasized that the legal status of the Indices was vague because the Indices had no direct binding to acts and were "limits to start a discussion" on the needs of intake restriction (for details of values of the Indices, refer to Section 3.1.2.2.1).

The Act on Special Measures Concerning Nuclear Emergency Preparedness (Act No. 156 of December 17, 1999) was established after the JCO nuclear criticality accident in Japan, 1999. The purpose of this Act was to strengthen nuclear disaster control measures by providing, for instance, special measures related to the nuclear operators' obligations, the declaration of a nuclear emergency situation, the establishment of NERHQ and the implementation of emergency response measures which are taken based on the Basic Disaster Management Plan, etc. Based on this Act,[102] the Director-General of NERHQ may give necessary instructions to relevant bodies in order to implement emergency response measures; therefore, this Act could be used as the grounds for the instructions to restrict the ingestion/distribution of contaminated food and drink.

[99] Article 34, Item 1

[100] This Guide was replaced by the Nuclear Emergency Preparedness Guide issued by NRA in 2012.

[101] The old version of the Basic Disaster Management Plan.

[102] The former Article 20 Item 3 (the current Article 20 Item 2)

3.1.2.2. Response to the Fukushima Daiichi NPP accident

As a response to the Fukushima Daiichi NPP accident, provisional regulation values of radionuclides in food were quickly established by MHLW under the Food Sanitation Act, by the use of the Indices for Restriction of Food and Drink Ingestion. The provisional regulation values were applied to the restriction of the distribution and/or intake of contaminated food based on the Act on Special Measures Concerning Nuclear Emergency Preparedness. In 2012, MHLW abolished the provisional regulation values and set new standards for radionuclides (currently valid) in the Ministerial Ordinance on Milk and Milk products concerning Compositional Standards etc. and the Specifications and Standards for Food and Food Additives under the Food Sanitation Act (refer to Figure 5).

3.1.2.2.1. Provisional regulation values for food (abolished in 2012)

On March 11, 2011, the Prime Minister issued the declaration of a nuclear emergency situation due to the Fukushima Daiichi NPP accident and set up NERHQ as per on the Act on Special Measures Concerning Nuclear Emergency Preparedness. By March 15, MAFF had pressed MHLW to establish regulation values for radioactive substances in food under the Food Sanitation Act since it was concerned that contaminated agricultural products might be distributed.[103] MHLW subsequently established the provisional regulation values by the Notice on Handling of Food Contaminated by Radioactivity (No.0317-3, on 17 March 2011, from the Department of Food Safety, MHLW) under the Food Sanitation Act. This Notice stated that foods exceeding these values shall be deemed to be regulated by Article 6 Item 2[104] of the Food Sanitation Act, and measures shall be taken to ensure that such foods are not supplied to the public for consumption. The basic provisional regulation values were set by introducing the Indices for Restriction of Food and Drink Ingestion, without a risk assessment by FSC because an urgent response was required.[105]

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[103] Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company, 2012, Chapter V 5(1)c

[104] Article 6 (Extract): The following food and additives shall not be sold, or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of marketing:
(Item 2) Articles which contain or are covered with toxic or harmful substances or are suspected to contain or be covered with such substances; provided, however, that this shall not apply to cases where the Minister of Health, Labor and Welfare specifies that such articles involve no risk to human health;

[105] Food Safety Basic Act, Article 11

The provisional regulation values were applied to the restriction of the distribution and/or intake of contaminated food directed by NERHQ as per the Act on Special Measures Concerning Nuclear Emergency Preparedness. The Director-General of NERHQ started to issue instructions, addressed to the governors of the areas concerned, ordering the restriction of the distribution and/or intake of the relevant foods produced in the areas concerned from March 21,[106] based on the results of monitoring. In addition, NERHQ announced the Concepts of Inspection Planning and the Establishment and Cancellation of Items and Areas to which Restriction of Distribution and/or Consumption of Foods Concerned Applies on April 4.[107]

The provisional regulation values are summarized in Table 1. MHLW adopted the Indices for Restriction of Food and Drink Ingestion to set the provisional regulation values, and also provided the guidance that materials exceeding 100 Bq/kg of radioactive iodine should not be used in milk supplied for use in powdered baby formula or for direct drinking, in accordance with the current Codex guidance levels.[108]

[106] MHLW, 2011a

[107] MHLW, 2011b

[108] Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company, 2012, Chapter V 5(1)c

Table 1: Provisional regulation values for food in Japan

Nuclide	Provisional regulation values of radioactive materials in food (Bq/kg)			
	Infant foods	**Milk, Dairy products**	**Vegetables, grains, meat, eggs, fish, etc.**	**Drinking water**
Radioactive Iodine (representative nuclides: I^{131})	(2000)	300[a]	2000[b]	300
Radioactive Cesium	(500)	200	500	200
Uranium	20	20	100	20
Alpha-emitting nuclides of Plutonium and transuranic elements[c]	1	1	10	1

a. Provide guidance so that materials exceeding 100 Bq/kg are not used in milk supplied for use in powdered baby formula or for direct drinking.

b. For vegetables (except root vegetables and tubers) and fishery products only. The value of radioactive iodine in fishery products was added on April 5 by the Notice (No. 0405-1, April 5, 2011, Department of Food Safety, MHLW).

c. Total radioactive concentration of Pu-238,239,240,242, Am-241, Cm-242,243,244.

The Indices for Restriction of Food and Drink Ingestion, which were the grounds for the provisional regulation values, were established in 1998 by an NSC Environment Working Group based on the following concepts:[109]

- Radionuclides

The NSC Environment Working Group selected radionuclides which were considered (1) main radionuclides released in the nuclear facility accident and (2) radionuclides which could transfer into food and affect human health. A large amount of radioactive Iodine was considered to have been released in the early stage of the accident. Known as the radionuclides which contaminated food in the long-term, thanks to evidence from the Chernobyl accident, the index of radioactive Cesium (Cs-134, 137), taking into account the contribution of radioactive Strontium, was set with consideration of the need for quick emergency measurements. Radioactive Uranium was selected to prepare

[109] Information sources: NSC Environment Working Group, 1998; NSC 1980.

for the nuclear fuel plant accident, while alpha emitters[110] released in the re-processing plant accident were selected according to 1996 IAEA BSS.

- Food

The values of radioiodine were set only for milk and vegetables (except root vegetables and tubers) because radioactive iodine has a short half-life and thereby does not transfer into grain and meat so much. For radioiodine and radioactive Cesium, infant foods were not separated from other food groups because the effect on infants was already taken into consideration in the calculation of the values.

- Calculation

To determine the Indices, calculations were carried out to obtain Derived Intervention Levels[111] (DILs)[112] of each age group (i.e. infants (0–12 months old), young children (5 years old) and adults) for each food category. Then, the smallest value from the three age groups' DILs for a food category was taken as the index for the restriction of food intake. The equation for radioactive Iodine and radioactive Cesium[113] is described as follows:

$$DIL_{kj} = \frac{ILD/G}{F \times W_{kj} \times \sum_i S_{ij} \times f_i \times \{1 - e^{-\lambda_i t_0}\}/\lambda_i}$$

· DIL_{kj}

Derived intervention level (Bq/kg or Bq/l) of age group *j* for food group *k*.

· *ILD*

Annual intervention level of dose (mSv). "50 mSv × 2/3" and "5 mSv" were taken for radioactive Iodine and Cesium (and other nuclides groups), respectively, by taking into consideration ICRP publication 40 (1984). According to ICRP

[110] Alpha emitters are the radionuclides which decay by emitting alpha particles which are identical to a helium nucleus having two protons and two neutrons (EPA, 2012).

[111] Intervention level is the level of avertable dose at which a specific protective action is taken in an emergency or a situation of chronic exposure (IAEA, 2007).

[112] An index related to radioactive concentration in food and drink. If a person continues to consume food and drink containing radionuclides at DILs, the exposure dose will reach the Intervention Level of Dose (ILD) (NSC, Environment Working Group, 1998).

[113] For Uranium, the equation was unclear. For alpha emitters, a different equation was used (NSC, Environment Working Group, 1998). Here, the equations for Iodine and Cesium are used as examples.

publication 40, the minimum projected dose[114] in the first year for control of foodstuffs was 5 mSv for the whole body, and 50 mSv for individual organs (e.g. the thyroid, where ingested radioactive Iodine accumulates). “2/3” was multiplied by 50 mSv to give a safety margin.

- *G*
  Number of food categories. “3” for Iodine, “5” for Cesium.

- *F*
  Ratio of the annual average concentration and the peak concentration in order to take into consideration the radioactive decay and the rate of non-contaminated food. “0.5” was taken.

- W_{kj}
  Mass of food group *k* for age group *j* (kg/day). Average values were used.

- S_{ij}
  Ingestion dose coefficient[115] (mSv/Bq) for radionuclide *i* and age group *j*. Basically, values shown in the ICRP Publication 67 (1993) and IAEA 1996 BSS were applied.
- f_i
  Ratio of initial existing rate of radionuclide *i* to representative nuclide or nuclide group.

- *T*
  Duration of food intake (day). 365 days.

- λ
  Decay constant (day^{-1}).

[114] Projected dose is the dose that would be expected to be incurred if a specified countermeasure or set of countermeasures or, in particular, no countermeasures, were to be taken (IAEA, 2007).

[115] Dose coefficient means the committed effective dose of radiation resulting from intake of unit activity of a specified radionuclide in a specified chemical form. “Dose per unit intake factor” is a synonym (IAEA, 2007).

3.1.2.2.2. New standards for food (established in 2012)

Almost one year after the Fukushima Daiichi NPP accident, MHLW promulgated new standards of Cs-134 and Cs-137, (enforced in April 2012) by revising the Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards, etc. and the Specification and Standards for Food, Food Additives, etc., based on Article 11 Item 1 of the Food Sanitation Act.[116] Foods exceeding these standards shall be deemed to be regulated by Article 11 Item 2[117] of the Food Sanitation Act. As with the provisional regulation values, the new standards applied to the restriction of the distribution/intake of food and drink under the scheme of disaster management (refer to Figure 5). Table 2 shows the new standards for food under the Food Sanitation Act.

Table 2: New standards for food in Japan

Nuclide	New standards of radioactive cesium in food (Bq/kg)			
	Infant foods	Milk	General foods	Drinking water
Radioactive Cesium (Cs-134, Cs-137)*	50	50	100	10

*taking into account the contribution of other nuclides

- Scope

The new standards were established in order to (1) replace the provisional regulation values established just after the Fukushima Daiichi NPP accident and to (2) deal with the long-term situation following the accident.[118]

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[116] Notice: The Ministerial Ordinance Partially Revising the Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards, etc.; the Notification on Designating the Radioactive Substances Designated by the Minister of Health, Labor and Welfare under the Provisions of Item (I) (1) of the Attached Table 2 of the Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards, etc.; and the Notification on Partial Revision of Specification and Standards for Food, Food Additives, etc. (Notice No. 0315-1 on March 15, 2012, Department of Food Safety, MHLW).

[117] Article 11 Item 2 (Extract): When the criteria or standards have been established pursuant to the provisions of the preceding paragraph, food or additives shall not be produced, processed, used, cooked, or preserved using methods that do not conform to such criteria; food or additives that do not conform to such criteria shall not be sold or imported; and food or additives that do not conform to such standards shall not be produced, imported, processed, used, cooked, preserved, or sold.

[118] MHLW, 2011c. Also, according to the minutes of the meeting of Radiation Council in MEXT, the staff of MHLW mentioned that the new standards were established for the existing exposure situations.

- Radionuclides

Among all the radionuclides which were considered to be released into the air based on the evaluation by NISA, the radionuclides which have a relatively long-term physical half-life (more than 1 year) were selected first, namely, Cs-134, Cs-137, Sr-90, Ru-106, Pu-238, Pu-239, Pu-240 and Pu-241. It takes time to measure the concentration of radionuclides other than radiocesium; therefore, standards of radioactive Cesium (Cs-134 and Cs-137) were set, taking into account the contribution of other nuclides.[119]

- Food

The category "general foods" is used in the new standards in order to (1) minimize the effect of differences in individual food habits, (2) make standards understandable, and (3) make standards consistent with Codex guideline levels.[120] Additional categories, namely drinking water, milk and infant foods, are used because they need special consideration. Drinking water is consumed by all people in large quantities, has a WHO guidance level (10 Bq/kg of radioactive Cesium),[121] and can be controlled strictly (for tap water). For setting two of the groups, Milk and Infant Food, a remark about possibly higher sensitivity to radiation in childhood written in the risk assessment report by FSC (2011) was taken into consideration.[122]

- Calculation

A calculation was made to obtain the critical levels of each population group (i.e. 10 groups consisting of Infant, Pregnant, 1–6, 7–12, 13–18, and ≥19 years old for male and female) for all foods including infant foods and milk. Then, the smallest value from among the 10 population groups' critical levels was taken as the standard of radioactive Cesium in general foods. The equation is described as follows:[123]

$$CLf = min \frac{Df(t)}{\sum_{foods} DF_{total}(t) \times I \times 0.5}$$

[119] MHLW, 2011c. To take into account the contribution of other nuclides, the concentration ratio in each food type of each nuclide to Cs-137 was estimated by the use of following factors: the initial concentration ratio in the environment (e.g. soil, water) of each nuclide to Cs-137, the transfer factor of each nuclide from the environment to each food type, and the physical decay constant (MHLW, 2011d).

[120] The Codex guideline levels have two categories: infant foods and foods other than infant foods.

[121] The WHO guidance level was adopted as the standard for drinking water.

[122] MHLW, 2011c; FSC, 2011

[123] MHLW, 2011d

- *CLf*:
  Critical level (Bq/kg), same as DIL (derived intervention level).

- *Df (t)*:
  Annual dose from foods in year *t* (Sv/year). "1 mSv – [annual dose from drinking water]" was taken as *Df (t)*. "1 mSv" is the intervention exemption level in a year used in the Codex guideline levels, which was originally based on the ICRP publication (1999).[124]

- $DF_{total}(t)$
  Ingestion dose coefficient of all regulated nuclides (Sv/Bq), which means the dose attributed to all regulated radionuclides (Cs-134, Cs-137, Sr-90, Ru-106, Pu-238, Pu-239, Pu-240 and Pu-241) when a person ingests 1 Bq of radioactive cesium via foods in year t. $DF_{total}(t)$ is calculated by the use of following factors: the concentration ratio in each food type of each nuclide to Cs-137, and the ingestion dose coefficient of each radionuclide shown in ICRP Publication 72 (1995).

- *I*
  Annual Mass of each food group (kg/year). Average values were used.

- *0.5*
  Assumed rate of contaminated foods. The rate was assumed as 50% (0.5) by taking into account the monitoring results and the share of import foods in the market. For infant foods and milk, the rate of food contamination is 100% (1.0).

The minimum critical level was 120 Bq/kg; therefore, the rounded value 100 Bq/kg was adopted as the standard of radioactive Cesium in general foods. 50 Bq/kg, half of the value for general foods, was taken as the standard for infant foods and milk in order to cover the extreme case that the rate of food contamination is 100%.

For the discussion on the new standards, MHLW deterministically estimated the annual exposure dose attributed to radioactive Cesium[125] in food by monitoring the results

[124] FAO, 2011

[125] Exposure from the other radionuclides was not taken into account.

from August to November 2011, and the data for the average food intake of all the population.[126]

- *Case 1: The new standards are applied, and a person consumes foods contaminated at the median level of radiocesium for a year*

  Estimated exposure dose: 0.043 mSv/year

- *Case 2: The new standards are applied, and a person consumes foods contaminated at the 90 percentile level of radiocesium for a year*

  Estimated exposure dose: 0.074 mSv/year

- *Case 3: The provisional regulation values are applied, and a person consumes foods contaminated at the median level of radiocesium for a year*

  Estimated exposure dose: 0.051 mSv/year

Based on the estimation, MHLW recognized that the provisional regulation values are well able to ensure public health; however, MHLW introduced the reference level "1 mSv/year" instead of "5 mSv/year" in view of the ALARA principle of food safety[127] and consistency with the Codex guideline levels, and then established the new standards. It was also pointed out that the estimated exposure doses meet the content of the risk assessment report issued by FSC (2011), saying that more than 100 mSv of the extra cumulative effective doses of radiation during a lifetime could increase the risk of negative effects on health (not including radiation from the natural environment and medical exposure).

In the process of setting the new standards, the draft standards were consulted by the Radiation Council in MEXT (now in NRA) in December 2011 in accordance with Article 6 of the Act on Technical Standards for Prevention of Radiation Hazard (Act No. 162 of May 21, 1958). After a long discussion, in February 2012 the Council reported that the draft standards proposed by MHLW could be adopted as the technical standards in view of the basic policy defined in the Act: "the exposure dose of radiation for the operational workers and the public should be lower than the dose which is unlikely to pose radiation hazards to them". However, the Council attached the following opinions[128] to the report:

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[126] MHLW, 2011d

[127] MHLW showed the non-compliance rate against the provisional regulation values and the expected non-compliance rate against the new standards to explain that these rates had been declining well.

[128] Radiation Council, 2012

- *Opinion 1: Optimization of radiological protection and consideration of opinion from stakeholders*
  - It is unlikely that the establishment of new standards would be the measure to greatly enhance the effects of radiation protection because the exposure dose from foods is already far below the 1 mSv/year.
  - The Council agrees with the introduction of 1 mSv as the reference level, but the values of the food standards are set on the safe side in view of the concept of radiological protection due to over-assumption on the rate of contaminated foods and special safety margins for children to set standards for infant foods and milk.
  - According to the concept of radiological protection, values should be treated as reference levels in the beginning, then should gradually be set lower, and finally should be set as regulation standards.
  - In order to maintain normal social and economic activities in affected areas, the opinions from stakeholders should be taken into account to the maximum in the establishment and implementation of the standards for foods, along with consideration of the ICRP recommendations.
- *Opinion 2: Standards for infant foods and milk*
  - According to the calculation of CLs, the CL of infants was 460 Bq/kg. This indicates that it is possible to keep the annual exposure dose of children including infants below 1 mSv/year, if 100 Bq/kg is adopted as the standard for general foods. Even though the specific standard 50 Bq/kg would not be set for infant foods and milk, the Council thinks that the consideration of children is already enough.
  - Low radiation levels might make it difficult to keep the necessary measurement accuracy and the required number of samples; therefore, it is crucial to establish a proper monitoring system (e.g. facilities, human resources).

3.1.2.3. Latest regulation framework

After the Fukushima Daiichi NPP accident, laws and related official documents under the scheme of disaster management were reviewed and revised in order to prepare for any future nuclear accidents (refer to Figure 5).

The Act on Special Measures Concerning Nuclear Emergency Preparedness, which is used as the grounds for the restrictions on the distribution/intake of food, was revised in June 2012, for example, for the purposes of strengthening the functions of NERHQ in a

nuclear emergency situation, to enshrine the Nuclear Emergency Preparedness Guide into law, which replaced the Guide: Emergency Preparedness for Nuclear Facilities.

The Basic Disaster Management Plan was most recently revised in September 2012. As to the instructions regarding the restrictions on the distribution/intake of food, the revised plan states that (1) the central government should ask local governments for surveillance of radioactive contamination if necessary, and ask relevant bodies for enforcement of the restrictions on the distribution/intake of contaminated food and drink with consideration of the Operational Intervention Levels (OILs) in the Nuclear Emergency Preparedness Guide and the standards under the Food Sanitation Act if appropriate; and that (2) the local governments should implement – and cancel – the restrictions on ingestion/distribution based on the guidance and direction from the central government or by their own decision.

In October 2012, NRA established the Nuclear Emergency Preparedness Guide as the replacement for the Guide: Emergency Preparedness for Nuclear Facilities in October 2012.[129] The Guide aims to ensure radiological protection measures in order to minimize the effect of radiation on people around the nuclear facilities in the event of an emergency. The latest revision was carried out in February 2013. With regard to radiological protection measures covering food and drink, the Guide provides the default values[130] of Operational Intervention Levels (OILs) as follows, which are designated by modifying the OILs concept in IAEA GSG-2 (2011b) and by using the data and experiences from the Fukushima Daiichi NPP accident:[131]

- *OIL2*: *20 μSv/h (radiation dose rate measured at 1 m in height from the ground)*
  The level at which to implement the restriction of the intake of local produce.

- *Levels for screening related to food and drink: 0.5 μSv/h (radiation dose rate measured at 1 m in height from the ground)*
  The level at which to determine the areas where the surveillance of radionuclide contamination in foods and drinks shall be carried out.

[129] Article 6-2 Item 1, the Act on Special Measures Concerning Nuclear Emergency Preparedness.

[130] Default value means that the value is used as OIL in the beginning of the emergency. If necessary, the value can be revised when the component of radionuclides deposited on the ground is revealed.

[131] NRA, 2012a; NRA, 2012b

· *OIL6: refer to Table 3 (value of radionuclide concentration in food and drink)*
The level at which to implement the restriction of food and drink intake in the event of an emergency. The Indices of Restriction Food and Drink Intake were adopted as OIL6 because it was considered that the Indices worked properly as the radiological protection measure in the Fukushima Daiichi NPP accident. The background of the OIL6 (i.e. the Indices) is described in Section 3.1.2.2.1. The Guide states that the current values and targeted radionuclides will be reviewed, taking into consideration the examples of OIL6 values proposed in IAEA GSG-2 (2011).

Table 3: Default values of operational intervention level 6 (OIL6) to implement the restriction of food and drink intake in Japan

Nuclide	**OIL6 (Bq/kg)**	
	Drinking water, Milk, Daily products	**Vegetables, grains, meat, eggs, fish, etc.**
Radioactive Iodine	300	2000*
Radioactive Cesium	200	500
Alpha-emitting nuclides of Plutonium and transuranic elements	1	10
Uranium	20	100

* For vegetables, root vegetables and tubers are excluded.

NRA, which is responsible for summarizing all results from emergency monitoring, shall inform local governments via NERHQ of actions to be taken related to these OILs.

3.2.Regulation framework in Australia

3.2.1. Regulations of food safety in general

In 1995, the Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards (the Treaty) was signed to establish the Australia New Zealand Food Standards Code (the Code) and the bi-national governmental agency.[132] Food Standards Australia New Zealand (FSANZ) is now the statutory authority to develop food standards included in the Code and codes of practice based on risk analysis, according to the Food Standards Australia New Zealand Act 1991 (the FSANZ Act).[133] In Australia, food standards in the Code are given legal force by being called up in the food acts of the six States and two Territories, and it is a breach of those acts to sell or manufacture food that does not comply with the Code. In Australia, the Commonwealth also exercises control on imported food through the Imported Food Control Act 1992, which, broadly, operates by reference to the standards established by the Code. New Zealand adopts the standards in the Code by amending regulations under its (national) Food Act.

In Australia, FSANZ, which belongs to the Health and Ageing portfolio, develops food standards and codes of practice but also facilitates the harmonization of State and Territory food laws, coordinates the monitoring, surveillance and recall of foods, and develops assessment policies related to imported food.[134] Moreover, other bodies in the Commonwealth government also have responsibilities regarding food safety. The Legislative and Governance Forum on Food Regulation (the Forum), which consists of Ministers from Australian Commonwealth government, New Zealand government and Australian States and Territories governments, is responsible for developing domestic food regulatory policies and policy guidelines for setting domestic food standards.[135] The Department of Health and Ageing (DoHA) supports the development of food standards and food regulatory policies by coordinating the Forum and providing advice to the Forum and FSANZ, and also controls foodborne diseases.[136] The Department of Agriculture, Fisheries and Forestry (DAFF) is in charge of the imported food inspection at the border under the Imported Food Control Act 1992, and works with key

[132] FSANZ, 2013a

[133] The FSANZ Act Section 13 and 18

[134] The FSANZ Act Section 13

[135] DoHA, 2012a

[136] DoHA , 2012b

organizations (e.g. DoHA, FSANZ) and industries in developing standards for primary products.[137] The Australian Pesticides and Veterinary Medicines Authority (APVMA), which is in the Agriculture, Fisheries and Forestry portfolio, also contributes to food safety by assessing and registering agricultural and veterinary chemicals, by setting maximum residue limits (MRLs) for agricultural and veterinary chemicals in food and animal feedstuffs,[138] and by conducting risk assessments of dietary exposure to chemical residues with experts from DoHA and FSANZ.[139] These governmental organizations are risk management bodies, but experts in these organizations also work as risk assessors.

Two main food laws (the FSANZ Act 1991 and the Imported Food Control Act 1992) and the Code will be explained in detail here. Other food-related laws, such as the Agricultural and Veterinary Chemicals Act 1994 (Act No. 36 of 1994) and the Competition and Consumer Act 2010 (Act No. 51 of 1974) will not be considered because they are not related to radioactive contaminants in food nor the countermeasures against the Fukushima Daiichi NPP accident.

3.2.1.1. Food Standards Australia New Zealand Act 1991

The purpose of the FSANZ Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of FSANZ.[140] To achieve this purpose, the act gives FSANZ powers to perform its functions, for example, developing and reviewing food regulatory measures (i.e. food standards in the Code and codes of practice), issuing assessment policies related to imported food in Australia, and coordinating the monitoring, surveillance and recall of food in Australia.[141] Food regulatory measures[142] can include:

- Composition of food, including (1) maximum amounts of contaminants or residues in food, (2) maximum or minimum amounts of additives in food, (3) microbiological status and safety, and (4) method of sampling and testing of food;
- Production and handling of food;
- Prohibition of the sale of food;

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[137] FSANZ, 2013b; DAFF, 2012b

[138] APVMA, 2013a

[139] APVMA, 2013b

[140] The FSANZ Act, Section 3

[141] The FSANZ Act, Section 13 and 14

[142] The FSANZ Act, Section 16 and 17

- Information about food including labeling, promotion, and advertising;
- Knowledge, skill, health, and hygiene requirements for people handling food;
- Responsibilities of businesses; and
- Design, construction, maintenance, and cleanliness of premises, equipment, and vehicles.

The FSANZ Act requires FSANZ to develop and review food regulatory measures with consideration of three objectives, namely protection of public health and safety, provision of adequate information, and prevention of misleading or deceptive conduct, and the following factors:[143]

- Need for standards to be based on risk analysis using the best available scientific evidence;
- Promotion of consistency between domestic and international food standards;
- Desirability of an efficient and internationally competitive food industry;
- Promotion of fair trading in food; and
- Written policy guidelines.

Then, the act determines the processes for developing[144] and reviewing food regulatory measures, and, lastly, the administrative matters of FSANZ.

3.2.1.2. Imported Food Control Act 1992

The Imported Food Control Act 1992 aims to provide for the compliance of food imported into Australia with Australian food standards and the requirements of public health and safety.[145] Under the act, importers are responsible for ensuring that the food imported into Australia complies with relevant standards in the Code,[146] and also must not import food which poses a risk to human health.[147]

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[143] The FSANZ Act, Section 18

[144] The processes for developing food regulatory measures start either by an application from a body or person to FSANZ or by a proposal initiated by FSANZ (The FSANZ Act, Part 3).

[145] The Imported Food Control Act, Section 2A

[146] DAFF, 2013; the Imported Food Control Act Section 8

[147] The act states that "food poses a risk to human health if: (a) it contains: (i) pathogenic micro-organisms or their toxins; or (ii) micro-organisms indicating poor handling; or (iii) non-approved chemicals or chemical residues; or (iv) approved chemicals, or chemical residues, at greater levels than permitted; or (v) non-approved additives; or (vi) approved additives at greater levels than permitted; or (vii) any other contaminant or constituent that may be dangerous to human health; or (b) it has been manufactured or transported under conditions which render it dangerous or unfit for human consumption"

The act, together with the Imported Food Control Regulations 1993 (Statutory Rules 1993 No. 100), constitutes the Imported Food Inspection Scheme (IFI Scheme) which is run by DAFF. In the IFI Scheme, DAFF may determine foreign government certificates stating that food meets standards and does not pose a risk to human health,[148] and may make orders classifying foods as "risk food" (if FSANZ advises that the food has a potential to pose a high or medium risk to public health), "compliance agreement food", or "surveillance food" by consultation with FSANZ.[149] This classification affects the rate of inspection and the holding of food until the results of the test are known.[150] Additionally, the act describes the treatment, destruction or re-export of failing food, and the enforcement of the act by DAFF.

3.2.1.3. Australia New Zealand Food Standards Code

Food standards in the Australia New Zealand Food Standards Code (the Code) developed by FSANZ are given legal effect by the Australian State and Territory and New Zealand government laws, and by the Imported Food Control Act 1992 (for the food imported into Australia) and the other applicable laws. The Codes consist of four Chapters, as follows:

- Chapter 1 "General Food Standards" covers standards applied to all food, for instance, general prohibitions, labeling requirements, substances added to food, contaminants[151] and chemical residues (Maximum Residue Limits [MRLs] for agricultural and veterinary chemical residues are applied in Australia only), pre-market clearance of novel food and genetically modified organisms, microbiological limits and processing requirements (Australia only).

(Section 3).

[148] The Imported Food Control Act, Section 18

[149] The Imported Food Control Act, Section 16 and 17; The Imported Food Control Regulations, Part 3

[150] DAFF, 2013

[151] In Standard 1.4.1, it is said that (1) regardless of whether or not a Maximum Level (ML) exists, the levels of contaminants in foods should be kept As Low As Reasonably Achievable (the ALARA principle), that (2) an ML has been established only where it serves an effective risk management function and only for those foods which provide a significant contribution to the total dietary exposure, and that (3) MLs have been set at levels that are consistent with public health and safety and which are reasonably achievable from sound production and natural resource management practices with consideration of international trade obligations.

- Chapter 2 “Food Product Standards” contains the standards which are applied to certain groups of foods.
- Chapter 3 “Food Safety Standards (Australia only)” deals with food hygiene matters.
- Chapter 4 “Primary Production and Processing Standards (Australia only)” sets the food safety and suitability requirements in primary production and processing of certain groups of primary products.

3.2.2. Regulations of radionuclides in food

Food is controlled by each State or Territory and the Commonwealth in accordance with the Code and it is illegal to manufacture food that does not comply with the Code or is “unsafe” (insofar as it presents a risk of harm to consumers) or “unsuitable” (more a consumer affairs issue). There are also powers to make emergency orders where food presents a serious danger to public health. These include the power to warn the public, seize and destroy the food that is subject to the order. However, the Code currently has no standards for radionuclides in foodstuffs. On the other hand, the Recommendations: Interventions in Emergency Situations Involving Radiation Exposure (Radiation Protection Series No.7, ARPANSA, 2004), which were published under the framework of the Australian Radiation Protection and Nuclear Safety Act 1998 (the ARPANS Act), and which is written in “non-regulatory style”, has “General Action Levels (GALs)” and “Operational Intervention Levels (OILs)” for radionuclides in foodstuffs during a nuclear emergency. The Recommendations do not mention how to interpret legally the food exceeding the GALs and OILs, but the author expects that such food would be recognized as “unsafe” by the Imported Food Control Act and the food acts of States and Territories.

Based on the ARPANS Act aiming to protect the health and safety of people and environment from the harmful effects of radiation,[152] ARPANSA have issued publications related to radiation protection (called as the Radiation Protection Series[153]) which are divided into four categories, namely, standards, codes of practice, recommendations, and safety guides:[154]

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[152] The ARPANS Act, Section 3

[153] There are currently 26 publications (http://www.arpansa.gov.au/publications/codes/rps.cfm).

[154] ARPANSA, 2004

- *Radiation Protection Standards* set fundamental requirements for safety and may contain key procedural requirements for best international practice in radiation protection and fundamental quantitative requirements such as exposure limits.
- *Codes of Practice* contain practice-specific requirements that must be satisfied to ensure an acceptable level of safety in dealings involving exposure to radiation.
- *Recommendations* provide guidance on fundamental principles for radiation protection which are applied in related Radiation Protection Standards and Codes of Practice, and are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of best international practice.
- *Safety Guides* provide practice-specific guidance on achieving the requirements set out in Radiation Protection Standards and Codes of Practice.

The Radiation Protection Series is adopted through the legal processes in the State, Territory or Commonwealth jurisdictions. Among the publications in the Radiation Protection Series, the Recommendations: Interventions in Emergency Situations Involving Radiation Exposure (Radiation Protection Series No.7, ARPANSA, 2004, the Recommendations) give guidance regarding radioactive contamination in foodstuffs in emergency situations.

The Recommendations are in conformity with the requirements of the IAEA Safety Standards GS-R-2 (2002) and aim to provide guidance on radiation protection criteria for use in mitigating the consequences of emergencies involving radiation exposure.[155] They are intended to be used in the preparation of emergency plans and during the implementation of the plans in emergency situations by the Commonwealth, State and Territory governments and local authorities.[156] With regard to the radioactive contamination of food, the restriction of feedstuffs for animals (e.g. transfer from pasture to indoor feeding) in the early[157] and intermediate[158] phase, food and water control, restriction and discarding of foodstuffs and control of contaminated livestock in intermediate and late (or recovery)[159] phase, and restrictions or prohibitions on the use of contaminated products (for fertilization, soil improvement, etc.) in the late phase are

[155] ARPANSA, 2004, Section 1.1 and 1.2

[156] ARPANSA, 2004, Section 1.3

[157] The early phase extends into the first few hours following the event.

[158] The intermediate phase is the period from the first few hours to a few days or weeks after the commencement of the emergency.

[159] The late phase may extend for a considerable period beyond the intermediate phase.

recommended as protective measures which may be considered after the event.[160] For the control on foodstuffs during an emergency, some numeric recommendations are provided, namely the Generic Action Levels (GALs) and Operational Intervention Levels (OILs).

3.2.2.1. Generic Action Levels for foodstuffs

Generic Action Levels (GALs) are the optimized levels of activity concentration in a foodstuff at which controls should be placed on foodstuffs, water and crops in emergency situations.[161] Table 4 summarizes the GALs written in the Recommendations. The numbers are applicable for the foods prepared for consumption.[162]

Table 4: Recommended Generic Action Levels for foodstuffs in Australia

Radionuclides	**Values of Generic Action Levels (kBq/kg)[a]**	
	Food destined for general consumption	**Milk, infant food and water**
Cs-134, Cs-137, Ru-103, Ru-106, Sr-89	1	1
I-131		0.1
Sr-90	0.1	
Am-141, Pu-238, Pu-239, Pu-240, Pu-242[b]	0.01	0.001

a. The GALs apply to the sum of the activity of the isotopes in each group independently. The numbers are applicable for foods prepared for consumption.

b. Pu and Am isotopes should not be important sources of ingestion dose for reactor accidents.

- Scope

The GALs are for use in any emergency situations involving radiation exposure.[163] The values of GALs were taken from those in the IAEA Safety Standards GS-R-2 (2002) and IAEA Publication No. 109 (1994), and are based on and are consistent with the old

[160] ARPANSA, 2004, Section 4.7

[161] ARPANSA, 2004, Section 3.2.1 and 3.2.2

[162] ARPANSA, 2004, Section 4.8

[163] ARPANSA, 2004, Section 1.3

Codex guideline levels established in 1989[164] which were intended to be used for one year following an accident resulting in contamination of foodstuffs to be traded internationally. The Recommendations say that the values of GALs are "for guidance only", and that it is permissible for governments to (1) set higher levels for foods such as tea or spices, which contribute to only a very small part of the food intake, and to (2) exert some discretion in the domestic application of the GALs (i.e. setting higher value(s)) if one essential foodstuff is scarce.[165]

The GALs might not be applied directly in the early phase of an emergency if the data on specific radioactive materials concentrations in foodstuffs is limited. In this case, Operational Intervention Levels (OILs), which are derived from GALs, can be used in a reactor emergency.[166]

- Radionuclides

Radionuclides included in the GALs are the same as those in the IAEA Safety Standards GS-R-2 (2002) and IAEA Publication No. 109 (1994) which added Pu-238, 240 and 242 to radionuclides written in the old Codex guidelines (1989) (i.e. Cs-134, Cs-137, Ru-103, Ru-106, Sr-89, I-131, Sr-90, Am-141 and Pu-242). They were selected as representative radionuclides with consideration of the release characteristics of nuclear facilities and the possibilities of significant contamination problems in food. In order to retain simplicity and practicality, the radionuclides were grouped according to their degrees of radiological hazard; in other words, the "dose per unit intake factor (Sv/Bq)".[167]

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[164] Pu-238, Pu-240 and Pu-242 are not included in the old Codex guideline levels established in 1989.

[165] ARPANSA, 2004, Section 4.8. This Section also mentions that any differences between Australian requirements and those of Codex must be capable of being justified on scientific grounds under World Trade Organization Sanitary and Phytosanitary provisions and that both imported and domestically produced foods should meet the same set of standards.

[166] ARPANSA, 2004, Section 4.8

[167] IAEA, 1994 p.56 and Annex 1. Dose per unit intake factor means that the committed effective dose of radiation resulting from intake of unit activity of a specified radionuclide in a specified chemical form. "Dose coefficient" is a synonym (IAEA, 2007).

- Food

The GALs use two food groups: "Food destined for general consumption" and "Milk, infant food and water,[168]" which are the same groups as in the IAEA Safety Standards GS-R-2 (2002). The reason why milk and infant food were separated from general food is that the dose per unit intake factor (Sv/Bq) for infants was used in the calculation of GALs for milk and infant food in order to reflect the infants' sensitivity to radiation.

- Calculation

The values of GALs are based on the old Codex guideline levels (1989) which were obtained by the use of the following formula (the obtained values were rounded as 1, 10, 100 or 1000 Bq/kg):[169]

$$Level = \frac{RLD}{m \times d}$$

· *RLD: Reference Level of Dose (Sv)*

For all radionuclides except I-131, 5 mSv (= $5*10^{-3}$ Sv) was adopted as the reference level[170] of dose in the first year after an accident. Due to the extremely conservative assumptions used, it is most unlikely that the application of obtained levels will result in a exposure dose to an individual greater than 1 mSv. For I-131, a dose of 50 mSv to the thyroid, which is the organ where radioactive iodine can accumulate, was adopted as RLD. These values of reference levels are considered to be based on ICRP publication 40 (1984).

· *m: mass of food consumed (kg)*

It was assumed that 550 kg of food would be consumed in a year, all of which would be contaminated.

· *d: dose per unit intake factor (Sv/Bq)*

Dose per unit intake factor means the dose attributed to a radionuclide when an individual ingests 1 Bq of the radionuclide via food. The factors for the nuclides concerned could be divided into three classes.

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[168] Water is not included in the old Codex guideline levels (1989) nor in IAEA Publication No. 109 (1994).

[169] CAC, 1989

[170] Reference level means the level of avertable dose at which a specific protective action is taken in an emergency or a situation of chronic exposure (IAEA, 2007).

3.2.2.2. Operational Intervention Levels for foodstuffs in a Reactor Accident

Operational Intervention Levels (OILs) are the operational parameters that can easily be measured during an emergency for the prompt decision-making on protective actions. In the Recommendations, default values of OILs for foodstuffs in a reactor accident are provided based on the GALs and on assumptions such as the isotopic composition of the source; also, they need to be reviewed when more detailed isotopic information becomes available during the course of an accident.[171]

- OIL5 based on the ambient dose rate from ground deposition (μSv/h)

OIL5 is an operational intervention level for precautionary restrictions on food and milk. In other words, OIL5 can be used to identify areas where an initial restriction on foodstuffs could be required. The default value is 1 μSv/h.

- OIL6 and OIL7 based on the ground deposition concentration of marker radionuclide (I-131, Cs-137) (kBq/m^2)

OIL6 and OIL7 are operational intervention levels of the ground deposition above which restrictions on food and milk are recommended. OIL6 is expressed in terms of the I-131 ground deposition concentration (default values are 10 kBq/m^2 for food, 2 kBq/m^2 for milk), and OIL7 is the concentration of Cs-137 in ground deposition (default values are 2 kBq/m^2 for food, 10 kBq/m^2 for milk).

- OIL8 and OIL9 based on marker radionuclide (I-131, Cs-137) concentration in food, milk and water (kBq/kg)

OIL8 and OIL9 are operational intervention levels of the radionuclide concentration in food/drink above which restrictions on food and milk or water are recommended. OIL8 is based on I-131 activity concentration in food and milk or water, while OIL9 is based on that of Cs-137. The default values of OIL8 and OIL9 are shown in Table 5.

· Scope

  OIL8 and OIL9 are for use in a reactor emergency only. The values of OILs are only appropriate if a food supply is readily available.

· Radionuclides

  I-131 and Cs-137 are likely to be dominant radionuclides due to a severe reactor accident, which can be easily measured and assessed. The other less significant

[171] ARPANSA, 2004, Section 4.8 and Annex C

radionuclides can be assumed to be in a fixed ratio to I-131 and/or Cs-137; therefore, decisions on protective actions can be made by reference to the measurement of the marker radionuclides alone.

- Food

  OIL8 and OIL9 have two food categories: General Food (including food items for babies) and Milk and Water.

- Calculation

  Default values of OIL8 and OIL9 for foodstuffs in a reactor accident are provided based on the GALs. In a reactor accident, I-131 concentration is assumed to dominate among radionuclides[172] early in an accident; therefore the values of OIL8 are equal to the GALs for the I-131 concentration.

  For the calculation of OIL9 regarding Cs-137, the radioactive release mix is assumed to be without any Iodine.[173] In calculation of OIL9 in General Food, the ratio of Cs-137 to the total of Cs-134, Cs-137, Ru-103, Ru-106 and Sr-89 is estimated to be ≈ 0.2. For OIL9 in Milk and Water, the ratio of Cs-137 to those radionuclides is estimated to be ≈ 0.3 by the use of cow transfer factors. Thus, OIL9 can be derived from the following equations:

  (GAL)×(estimated ratio of Cs-137)

  = 0.2 kBq/kg (General Food) or 0.3 kBq/kg (Milk and Water)

Table 5: Default operational intervention levels (OILs) for food in a reactor accident in Australia

OILs	Marker radionuclides	Values of OILs (kBq/kg)[a]	
		General food[b]	Milk and water
OIL8	I-131	1	0.1
OIL9	Cs-137	0.2	0.3

a. The numbers are applicable for foods prepared for consumption.

b. Including infant foods (ARPANSA, 2012).

[172] I-131 is assumed to dominate in the group of Cs-134, Cs-137, Ru-103, Ru-106, Sr-89 and I-131, and in the group of Sr-90 and I-131, for calculating OIL8 of General Food and Milk and Infant Food, respectively (ARPANSA, 2004, Annex C).

[173] This assumption should be valid for old fission product mixes (spent fuel or core releases > 2 months after shutdown) (ARPANSA, 2004, Annex C).

3.3. Regulation framework in Canada

3.3.1. Regulations of food safety in general

Since 1997, the federal government bodies which lead food safety matters in Canada have been Health Canada (HC) and the Canadian Food Inspection Agency (CFIA). HC sets food safety policies, regulations and standards of all food sold in Canada, conducts risk assessments, pre-market reviews and evaluations regarding food safety, and regulates pest control products and veterinary drugs, mainly under the framework of the Food and Drugs Act.[174] In addition, it is the responsibility of HC to monitor the food safety activities of CFIA. CFIA takes responsibility for the enforcement of the food safety policies, regulations and standards established by HC, the federal food inspection service, and the enforcement of acts related to the agricultural inputs, such as the Feeds Act and the Fertilizers Act. In addition to the two leading bodies, the Public Health Agency of Canada (PHAC) and Agriculture and Agri-Food Canada (AFFC) also play roles relevant to food safety. PHAC is the agency under the Health portfolio which aims to protect and improve the health of Canadians and to help reduce pressure on the health-care system.[175] With regard to food safety, PHAC conducts outbreak surveillance and epidemiology and provides advice to protect people's health.[176] AAFC is the agency belonging to the Agriculture portfolio which is responsible for providing information, research/technology, and policies/programs to achieve an environmentally sustainable, competitive, and innovative agriculture, agri-food and agri-based products sector.[177] AAFC contributes to food safety in Canada by providing information and guidance to industry groups on food policy and regulatory issues.[178] These four federal organizations work as food safety risk management bodies, and only HC conducts "food-related health risk assessments" as a food safety risk assessment body in order to determine if the presence of a certain substance or microorganism in food poses a health risk to consumers.[179]

In Canada, the main federal legislation covering food safety is the Food and Drugs Act and Regulations, which will be explained in this Section. Other food-related laws, for

[174] AAFC, 2012a

[175] PHAC, 2013a

[176] PHAC, 2013b

[177] AAFC, 2012b

[178] AAFC, 2010

[179] Health Canada, 2008b

instance, the Pest Control Products Act and the Feeds Act, will not be described here because they are not related to radioactive contaminants in food nor the countermeasures relevant to food against the Fukushima Daiichi NPP accident.

3.3.1.1. Food and Drugs Act

The Food and Drugs Act (R.S.C., 1985, c. F-27) covers food, drugs including veterinary drugs, cosmetics, and therapeutic devices for humans and animals. The purpose of the act is to protect the public against health hazards and fraud from the sale of food, drugs, cosmetics, and devices.[180]

With regard to food, the act prohibits the sale of food which (1) has in or on it any poisonous or harmful substance, (2) is unfit for human consumption, (3) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance, (4) is adulterated, or (5) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions,[181] and to sell food with labeling or advertisement which is false, misleading or deceptive.[182] Moreover, it is not allowed to import, sell, label or package food which does not comply with prescribed standards.[183] Next, the Act mentions the administration and enforcement of the Act, for example, inspections by inspectors,[184] analysis and issuance of certifications/reports of the results by analysts,[185] and development of regulations by the Governor in Council relating to the following matters,[186] for instance:

- Labeling and packaging for sale of food, etc.;
- Sale or conditions of sale of any food, etc.;
- Use of any substance as an ingredient in food, etc.;
- Standards of composition, purity, quality or other property of food, etc.;
- Import of foods, etc. in order to ensure compliance;
- Method of manufacture, preparation, preserving, packing, storing and testing of any food, etc.; and

[180] AAFC, 2010

[181] The Food and Drugs Act, Section 4

[182] The Food and Drugs Act, Section 5

[183] The Food and Drugs Act, Section 6

[184] The Food and Drugs Act, Section 23

[185] The Food and Drugs Act, Section 29

[186] The Food and Drugs Act, Section 30

- Assessment of the effect on the environment or on human life and health of the release into the environment of any food, etc., and the measures to take before importing or selling it.

3.3.1.2. Food and Drugs Regulations

The Food and Drugs Regulations (C.R.C., c. 870) prescribe the standards of composition, strength, potency, purity, quality or other property of the article of food or drug to which they refer.[187] Part A of the Regulation prohibits the import of food or drugs the sale of which would constitute a violation of the Act or the Regulations,[188] and gives powers to inspectors and analysts, such as taking samples from imported food and drugs, and conducting examinations and analysis on them.[189] Part B focuses the standards about food as follows:

- General standards including food labeling requirements and conditions of adulterated food due to unauthorized additives, toxic compounds, etc.;
- Standards of nutrition labeling, nutrient content claims, and health claims;
- Standards for each food group including those regarding ingredients, methods for manufacture, etc., microbiological criteria, and analytical methods;
- Standards of food colors, food additives, salt, and sweetening agents;
- Standards about adulteration of food, including the regulatory limits of contaminants, unregistered pesticide residues,[190] and veterinary drug residues; and
- Standards of food packaging materials, food irradiation, novel food and food for special use.

These standards for the safety and nutritional quality of food sold in Canada are established by HC, and enforced by CFIA.

3.3.2. Regulations of radionuclides in food

Currently the Food and Drugs Regulations have no standards for radionuclides in food. However, in 2000, HC published the Canadian Guidelines for the Restriction of Radioactively Contaminated Food and Water Following a Nuclear Accident containing the recommended action levels for radionuclides in food and water in a nuclear emergency. In the event of radioactive contamination in food, the parts of the Guidelines

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[187] The Food and Drugs Regulations, Section A.01.002

[188] The Food and Drugs Regulations, Section A.01.040

[189] The Food and Drugs Regulations, Section A.01.041 and 042

[190] The regulatory limits for registered pesticide residues are listed in the Pest Control Products Act.

referring to foods will be implemented under the authority[191] of the Food and Drugs Act.[192] Additionally, HC developed the Federal Nuclear Emergency Plan: Part 1: Master Plan[193] in 2002 under the emergency management scheme in Canada. This plan outlines the role, organization and capability of the federal government in responding to a nuclear emergency,[194] and mentions the need for protective actions on the food supply in emergency situations in accordance with the Guidelines.[195]

The purpose of the Guidelines is to guide emergency response organizations at the federal and provincial levels on decisions concerning the withdrawal and substitution of contaminated food and water within Canada in order to minimize the health risk associated with the consumption of contaminated food and water, and to preserve public confidence in the safety of the commercial food supply following a nuclear emergency in Canada or abroad.[196] At the federal level, CFIA is responsible for implementing and enforcing the Guidelines based on the Canadian Food Inspection Agency Act.[197] In the Guidelines, "action levels" are set for food and water controls as the intervention for radiation protection. In an emergency when the action levels are raised, the expected radiation doses to populations should be assessed and monitored, and the safety of the food supply should be confirmed by federal and/or local governments.[198]

Recommended action levels for radionuclides in food and water

Action levels are defined as the activity concentration above which protective actions are generally recommended.[199] In other words, food and water containing radionuclides at concentrations above "action levels" would normally be withdrawn from sale or distribution and replaced by alternative supplies.[200] Table 6 summarizes the recommended action levels for radionuclides of *potential significance* to dose from the

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[191] Authority of the Section 4(a) of the Food and Drugs Act. Section 4(a) states that no person shall sell an article of food that has in or on it any poisonous or harmful substance.

[192] Health Canada, 2000

[193] Health Canada, 2002

[194] Health Canada, 2011b

[195] Health Canada, 2002, Advice on the Alteration of Action Levels

[196] Health Canada, 2000, Foreword

[197] The Canadian Food Inspection Agency Act, Section 11

[198] Health Canada, 2000,

[199] Health Canada, 2000, Intervention Levels vs Action Levels

[200] Health Canada, 2000, Introduction

ingestion of contaminated food. The Guidelines also provide the recommended action levels for radionuclides of *lesser significance* to dose from ingestion, as "supplementary action levels", but they will not be described here.[201]

- Scope

The action levels are intended to be used for the control of food offered for sale and public drinking water supplies that have been contaminated following a nuclear emergency in Canada or abroad.[202] The valid period of the action levels is not determined. It is simply written in the Guidelines that the food and water controls may be in place for "extended periods".[203]

The periodic re-assessments of the appropriateness of the action levels can be performed in terms of public confidence and availability of alternate supplies; however, the alteration of the values of action levels shown in Table 6 generally should be precluded because it could lead to a loss of public confidence and/or international trade disputes. The values of action levels could be modified with caution and sufficient justification under special situations, for instance, (1) where food controls could result in severe shortages of essential foods or nutritionally adequate alternatives for extended periods of time (the values may be higher than those given in Table 6), and (2) where the public concern is the overriding factor (the values may be lower than those given in Table 6). The rationale for the alteration of the recommended values of action levels must be clear.[204]

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[201] Health Canada, 2000, Supplementary Action Levels for Other Radionuclides. "Supplementary action levels" include the following radionuclides: H-3, C-14, Cr-51, Fe-55, Fe-59, Co-60, Zn-65, Y-91, Zr-95, Nb-95, Mo-99, Ag-110m, Te-132, Ba-140, La-140, Ce-141, Ce-144, Np-237, Np-239, Pu-241, Pu-244.

[202] Health Canada, 2000, Foreword

[203] Health Canada, 2000, Advice on the Alteration of Action Levels

[204] Health Canada, 2000, Advice on the Alteration of Action Levels

Table 6: Recommended action levels in Canada for radionuclides of potential significance to dose from the ingestion of contaminated food

Radionuclide	Action levels (Bq/kg)[a]		
	Fresh liquid milk	Other commercial foods and beverages	Public drinking water
Sr-89	300	1000	300
Sr-90	30	100	30
Ru-103	1000	1000	1000
Ru-106	100	300	100
I-131	100	1000	100
Cs-134, Cs-137	300	1000	100
Pu-238, Pu-239, Pu-240, Pu-242, Am-241	1	10	1

a. If the several radionuclides are present in a sample, the following summation criterion must be satisfied: $\sum_i \left(\frac{A_i}{AL_i}\right) \leq 1$

where A_i is the measured activity of radionuclide i, and AL_i is its corresponding action level. In this summation criterion, all radionuclides are assessed collectively. It should be noted that this methodology differs from the old Codex guidelines levels adopted in 1989,[205] which allow the summation of activities within each of three independent radionuclide groups, but not between groups. The action levels are applied to food as prepared for consumption.[206]

- Radionuclides

The radionuclides shown in Table 1 (Sr-89, Sr-90, Ru-103, Ru-106, I-131, Cs-134, Cs-137, Pu-238, Pu-239, Pu-240, Pu-242 and Am-241) are those which typically have the most significance to radiation dose from the ingestion of contaminated food and water, and are therefore selected based on IAEA Publication 109[207] (1994).[208] They are divided into 7 groups in Table 6 according to the values of action levels, but this grouping is not related to the screening of samples for compliance with action levels. In

[205] CAC, 1989

[206] Health Canada, 2000, Screening of Food Samples for Compliance with Action Levels

[207] In IAEA Publication 109, Pu-240 and Pu-242 are not included.

[208] Health Canada, 2000, Summary of Methodology for Calculating Action Levels

other words, all radionuclides in 7 groups are assessed collectively for checking compliance, not assessed within each of the groups.

- Food

The food groups considered here are: Fresh liquid milk, Other commercial foods and beverages and Public drinking water. "Fresh liquid milk" was established as a separate food group because fresh milk is important in infant diets, and because its marketed supplies typically come from local sources. "Public drinking water" was also separate since it also generally comes from a local source and is contaminated by pathways different from those for the other food groups. Unlike Fresh liquid milk and Public drinking water, "Other commercial foods and beverages" should be composed of less local products.[209]

- Calculation

Action levels for these radionuclides were calculated for six age groups[210] per food group because age-specific factors (i.e. consumption rates and dose coefficients for ingestion) were used for calculation with the following formula. A single action level was chosen for each radionuclide per food group and rounded to the values of 1, 3, 10, 30, 100, 300 or 1000, with consideration of the lowest calculated value among the six age groups and the harmonization with the old Codex Guideline levels adopted in 1989.[211]

$$AL_{i,j,k} = \frac{IL}{M_{j,k} \times DC_{i,k} \times f_j}$$

· $AL_{i,j,k}$: action level for radionuclide i in food group j and age group k (Bq/kg)

[209] Health Canada, 2000, Calculation of Action Levels

[210] The six age groups are 3 months, 1 year, 5 year, 10 year, 15 year and Adults. This grouping is employed by the ICRP Publication 72 (1996).

[211] Health Canada, 2000, Calculation of Action Levels for Radionuclides in Food. Action levels for Other commercial foods and beverages were harmonized with the old Codex guideline levels adopted in 1989 for the similarly grouped Foods destined for general consumption, with the exception of Ru-106. Values for several radionuclides in Fresh liquid milk were significantly lower than the old Codex guideline levels for Milk and infant foods, and were thus not harmonized. As fresh milk is not traded internationally in general; therefore this situation is unlikely to cause trade disputes. The old Codex guideline levels do not contain those for drinking water.

- *IL* : intervention level (Sv)
  Intervention level defines the committed effective dose received by an individual consuming contaminated foods over a specified time period[212]. In the Guidelines, an intervention level of 1 mSv per each of three food groups (i.e., 3 mSv apportioned equally among three food groups) was applied. This choice of the intervention level is based on the judgment that the maximum dose from the total dietary consumption above which intervention would be required is in the range of 1-10 mSv per year,[213] and on the assumption that the food controls would be completely effective at averting dose. The needs for protecting public health, ensuring public confidence and maintaining commercial food supply, particularly with regard to infants and children, were primarily considered in the choice of the intervention level. Action levels were calculated with the use of conservative assumptions, and therefore, the Guidelines state that the actual doses to the public in an emergency will be unlikely to exceed the intervention level.

- $M_{j,k}$: mass of food group *j* consumed by age group *k* over the assessment period (kg)
  Average annual age-specific consumption rates are based on recommended Canadian reference values derived from Canada-wide surveys. The assessment period depends on the half-lives of targeted radionuclides: a period of one year for long-lived radionuclides and 2 months for radionuclides with half-lives less than about 300 hours (12–13 days). For the calculation of *M* for short-lived radionuclides, the annual consumption rates should be divided by 6 because the assessment period is 2 months, or one-sixth of a year.

- $DC_{i,k}$: ingestion dose coefficient for radionuclide *i* and age group *k* (Sv/Bq)
  Ingestion dose coefficients are the estimates of the integrated dose expected to be imparted to the whole body of an individual over a defined time period following a single intake by ingestion of 1 Bq of activity of a radionuclide. They are dependent on the radiological and biological half-lives of the radionuclide, and the age of the individual at intake. In the calculation of the action levels, the age-specific dose

[212] The intervention level is assessed over a period of one year for long-lived radionuclides and 2 months for radionuclides with half-lives less than about 300 hours (12–13 days).

[213] The Guidelines state that the range of 1–10 mSv/year is consistent with intervention levels recommended by the international agencies. However, the reference(s) used to determine this range is (are) unclear.

coefficients (i.e. dose coefficient for each of the six age groups) for each radionuclide, which were taken from the ICRP Publication 72 (1996), were used.

- f_i : contamination factor

  The contamination factor describes the average fraction of an individual's intake of a food group that is assumed to be uniformly contaminated to the full value of the action level for the duration of the assessment period. In general, individuals are likely to eat most of their food from a variety of sources; therefore, only a portion of the total diet is likely to be directly contaminated as a result of an accident. But, the fresh milk, seasonal vegetables, and water and locally bottled beverages can be produced and consumed locally. In the calculation of action levels, a contamination factor of 1 (i.e. 100%) was assumed for the food groups Fresh liquid milk and Public drinking water since individuals are likely to obtain them from a single contaminated source. For the group Other commercial foods and beverages, a contamination factor of 0.2 (i.e. 20%) was assumed. This is based on the expectation by OECD that normally less than 10% of the annual dietary intake could consist of food directly affected by the emergency, and on the application of a factor of 2 to account for sub-groups that might be more dependent on local foods.

4. Countermeasures taken after the Fukushima Daiichi NPP accident

On March 11 in 2011, a nuclear accident happened in Fukushima Daiichi NPP Japan, which was triggered by the Great East Japan Earthquake and the subsequent enormous tsunami. NISA of Japan provisionally classified this accident as level 7 on the International Nuclear Event Scale, which is the same level as the Chernobyl accident, but NISA also mentioned that the estimated amount of emission of radioactive substances in the Fukushima Daiichi NPP accident was around 10% of that in the Chernobyl accident.[214] Due to the release of radioactive substances from the plant into the environment, radiological protection measures on public health were taken including the measures against radioactive contamination of food.

As described in previous Chapters, the Prime Minister issued the declaration of a nuclear emergency situation due to the Fukushima Daiichi NPP accident on March 11, and set up the NERHQ to implement the emergency response measures. On March 15 in 2011, the Fukushima Prefecture Government detected highly contaminated wild plant samples taken at points more than 30 km from the Fukushima Daiichi NPP. Based on this information, the NERHQ and the Fukushima Prefecture Government started monitoring food, as did MAFF and other concerned local governments.[215] Also, MHLW recognized the need for countermeasures against radioactive contamination of food, and then established the provisional regulation values for food on March 17 (refer to Section 3.1.2.2).

NERHQ has since issued instructions about the restrictions on the distribution/intake of contaminated food and also instructions about the restriction on rice planting/shipment to local governments. Organizations in the central government, especially MHLW and MAFF, have played their role under the NERHQ in collaboration with local governments. For instance, MHLW set the provisional regulation values and the new standards of radionuclides in food and has arranged the monitoring of food, while MAFF has arranged restrictions on rice planting/shipment, has given technical advice to reduce the contamination of food, has issued the certificates of export of food, and has set the provisional regulation values of radionuclides in feed and fertilizers.

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[214] METI, 2011

[215] Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company, 2011, V5(1)b

4.1.1. Restrictions on the distribution/intake of food and drink

On March 21 in 2011, NERHQ issued the first instrument of restriction on food distribution, regarding some commodities produced in four prefectures,[216] based on the evaluation of monitoring results.[217] On April 4, NERHQ issued the Concepts of Inspection Planning and the Establishment and Cancellation of Items and Areas to which Restriction of Distribution and/or Consumption of Foods Concerned Applies (lastly revised in April 2013), with the use of the provisional regulation values. This document[218] consists of three elements:

- Inspection planning of the local government
- Requirements for establishing items and areas to which restriction of distribution and/or consumption of foods concerned applies by the government
- Requirements for cancelling items and areas to which restriction of distribution and/or consumption of foods concerned applies by the government

Local governments have planned and implemented monitoring on foods according to this document, and NERHQ have issued the instructions of restrictions on distribution/intake of foods based on the monitoring results.

4.1.2. Monitoring on radionuclides in food

In the Notice from MHLW to the local governments issued on March 17 in 2011,[219] MHLW announced the provisional regulation values together with a manual for measurement of radionuclides in food. After NERHQ issued the Concept document on April 4, MHLW asked local governments to make their monitoring plan and supported them to find the facilities for carrying out radiation measurements.[220] MHLW collected monitoring results from local governments and unified them to report to NERHQ in order to consider the restriction on distribution/intake of food. The food exceeding the

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[216] Prefectures of Japan are the country's 47 first-order subnational jurisdictions. Local governments asked NERHQ to restrict distribution of foods on a per-region basis rather than on a per-prefecture basis.

[217] Investigation Committee on the Accident at Fukushima Nuclear Power Stations of Tokyo Electric Power Company, 2011, V5(1)b; MHLW, 2011a. Local governments report monitoring results to MHLW, and then, MHLW summarizes them to report to NERHQ.

[218] This version is available in MHLW (2011b). After the publication of this document, several revisions have been made.

[219] Notice: Handling of Food Contaminated by Radioactivity (Notice No.0317-3, on 17 March 2011, from the Department of Food Safety, MHLW).

[220] MHLW, 2011e

provisional regulation values has been dealt with based on the Food Sanitation Act (refer to Section 3.2).

The monitoring of radionuclides in foods has been implemented up till now, and the results have been accumulated since 2011. The non-compliance rates of main foods against the provisional regulation values and the new standards are summarized in Table 7. It should be mentioned here that the efforts to reduce contamination in foods on the market have been made by farmers via the restriction on rice planting, voluntary restriction of the shipment of certain types of fish from certain areas, good agricultural practices to prevent radioactive contamination, etc. As seen in Table 7, non-compliance rates are mostly below 1.5% and are decreasing in general; however, non-compliance rates of mushrooms and wild plants against the new standard are high, more than 10%.

The new standards shall be applied to the imported food as well as domestic foods. On March 29 in 2012, MHLW issued the Notice on Monitoring and Directing of Imported Foods following Nuclear Power Plant Accidents in the Former Soviet Union to the quarantine station chiefs, saying that the quarantine stations should direct importers to conduct voluntary testing on certain foods imported from certain countries. According to the results of monitoring imported foods at the border from April 2012 till March 2013, seven blueberry products, which were made from blueberries produced in Poland and Ukraine, and one fresh mushroom from France, exceeded the new standard.[221]

4.1.3. Other countermeasures

MAFF has performed countermeasures which have not directly used the provisional regulation values and the new standards established by MHLW. MAFF has arranged restrictions on rice planting/shipment, has given technical advice and information to local governments and farmers in order to prevent and reduce radioactive contamination in foods, has issued the certificates of export of food, and has monitored radioactive contamination of feed and fertilizers based on the provisional regulation values of radionuclides in them.

[221] Based on the data of MHLW website [Japanese]
(http://www.mhlw.go.jp/topics/yunyu/ihan/)

Table 7: Non-compliance rates of main foods[222] against the provisional regulation values and the new standards in Japan (data are obtained from MAFF website[223])

Food categories	From March 2011 to March 2012 (Provisional regulation values of radioactive cesium in food)			From April 2012 to March 2013 (New standards for food)		
	Number of sample	Number of non-compliance	Rate (%)	Number of sample	Number of non-compliance	Rate (%)
Rice	3,217	1	0.03	10,310,000[a]	84	0.0008
				9.213[b]	0	0
Soy beans	534	0	0	4,069	23	0.6
Vegetable	11998	139[c]	1.2	18,544	5	0.03
Fruit	2,724	28	1.0	4,466	13	0.3
Tea[d]	2,232	192	8.6	867	13	1.5
Milk	1,914	1[e]	0.05	2,375[f]	0	0
Beef	90,661	157	0.2	72,908[g]	0	0
				92,334[h]	2	0.002
Pork, Poultry, Egg	1,173	0	0	1,847	1	0.05
Shiitake mushroom	1,081[i]	71	6.6	1,353[ik]	206	15.2
	358[j]	1	0.3	722[jk]	0	0
Wild plant	522	59	11.3	1,746[k]	197	11.3
Aquatic product	Number of sample (from March 2011 till January 2013): 24,848 Number of sample exceeding 100 Bq/kg: 2,467 (9.2%)					

a: samples taken in Fukushima Prefecture and a part of Miyagi Prefecture;

b: samples taken from 16 prefectures; c: mostly up until June 2011;

d: samples up until March 2012 were tea leaves, while since April 2012 samples were tea as a drink;

e: a violation sample was found in March 2011; f: samples up until February 2013;

g: samples until September 2012, until when the provisional regulation value was applied;

h: samples since October 2012; i: cultivated with tree logs; j: cultivated with mushroom bed;

k: samples until January 2013.

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[222] Results of some foods (wheat, beans other than soy, soba, horse meat, etc.) are not shown in Table 7

[223] Summarized by the author based on the data of MAFF website [Japanese] :
<http://www.maff.go.jp/j/kanbo/joho/saigai/s_chosa/index.html> and
<http://www.maff.go.jp/j/syouan/soumu/saigai/pdf/2_taisaku_130214.pdf>

4.2. Countermeasures in Australia regarding radionuclides in food

In Australia, DAFF, which is the Commonwealth department responsible for imported food inspection, has carried out testing on imported food from Japan for radionuclides based on advice from FSANZ and ARPANSA since just after the Fukushima Daiichi NPP accident in March 2011.[224]

Following the Fukushima Daiichi NPP accident in March 2011, FSANZ provided the assessment policy to DAFF[225] to advise that (1) foods originating from some prefectures in Japan had the potential to be contaminated with radionuclides,[226] that (2) the risk of Australian consumers being exposed to higher than internationally acceptable levels (i.e. the current Codex guideline levels) of radionuclides in food imported from Japan was negligible because there was very little food imported from Japan,[227] and that (3) certain fresh or frozen foods (milk and milk products, fresh fruit and vegetables, seaweed and seafood) originating from certain Japanese prefectures should be tested with the use of the acceptable levels consistent with the current Codex guideline levels as follows:[228]

- Total Cs-137 and Cs-134 must not be more than 1000 Bq/kg; and
- I-131 must not be more than 100 Bq/kg.

After receiving the assessment policy from FSANZ on the risk to human health posed by radionuclides in food from Japan, DAFF started testing on food imported from Japan and requiring documentary evidence confirming the source of the imported food under the Imported Food Inspection Scheme.[229] These requirements for testing food imported from Japan were announced via the Imported Food Notice.[230]

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[224] FSANZ, 2013c

[225] Considered to be based on the FSANZ Act, Section 13 (1) (l)

[226] ARPANSA, 2012

[227] Australian Customs and Border Protection Service, 2011. Imports from Japan are limited to a small range of specialty products, for example, seafood, seaweed-based products, and sauces.

[228] Australian Customs and Border Protection Service, 2011; FSANZ, 2013c. The GALs shown in Section 3.2.2.1, which are based on the old Codex guideline levels (1989), were not referred to as acceptable levels.

[229] Considered to be based on the Imported Food Control Act, Section 16(2) and 17(1). The risk classification of food imported from Japan (refer to Section 3.2.1.2) is unknown.

[230] According to the GAIN Report AS1109 (USDA, 2011), the first notice was on March 28, 2011.

FSANZ has continued to monitor the situation in Japan (e.g., data provided by the Japanese government) and to give advice to DAFF on the monitoring of food from Japan, while ARPANSA has provided advice to FSANZ on which Japanese prefectures, foods and radionuclides to target. ARPANSA selected prefectures where their measured radionuclide deposition data were above the OIL6 and/or OIL7 described in Section 3.2.2.2, and selected certain foods which were most likely to be contaminated based on previous testing results in Japan and Australia and the expected impact of radioactive contamination in foods.[231] Also, ARPANSA provided risk-based assessment advice on radionuclide contaminates in food with consideration of the reference level of 1 mSv per year for the public.[232]

According to the report issued by ARPANSA (2012), the food contamination pathway in affected Japanese prefectures can be described by three different time phases: immediate, delayed, and long-term contamination. In immediate contamination, radioactive material directly settled on plant produce above ground and surface waters and was ingested by animals and marine species via soils and sea water. The delayed contamination occurred later in 2011 and early 2012 in foods like fruit and tea because the radionuclides in plants were absorbed, stored and/or remobilized into fruit and leaves as they grew. The long-term contamination happens by the transfer of radionuclides with long half-life (e.g. Cs-134 and Cs-137) from the soil to the roots of plants, and from sediment to marine species. It also impacts on the wild species which eat contaminated plants. The requirements for testing food imported from Japan have been amended as the food contamination pathway has changed over time. By the Imported Food Notice 19/11 announced by DAFF in December 2011, I-131 was removed from the targeted radionuclides, and targeted foods[233] and prefectures were changed.

In March 2012, ARPANSA assessed the mean internal radiation dose to the public from foods imported from Japan and concluded that the Codex guideline levels were still sufficient to ensure the dose below 1 mSv per year, which is the dose limit for the

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[231] ARPANSA, 2012

[232] ARPANSA, 2012. According to this document, "1 mSv" is based on the dose limit per year for the public as defined by the Recommendations for Limiting Exposure to Ionizing Radiation (1995), which is mainly based on ICRP Publication 60 (ARPANSA, 2002).

[233] Milk and milk products were removed, and tea, rice, and cereals were added.

public.[234] Therefore, the acceptable levels were maintained as before (i.e. the total Cs-134 and Cs-137 must not be more than 1000 Bq/kg). In September 2012, DAFF issued the Imported Food Notice 07/12 to update the targeted food and Japanese prefectures for testing in accordance with the updated assessment policy provided by FSANZ, and has monitored radioactive Cesium in tea (fresh and dried), dried mushrooms, and fish (fresh, frozen, and dried) originating from eight prefectures. From March 2011 to August 2012, no foods tested under the monitoring program by DAFF exceeded the acceptable levels.[235]

In New Zealand, the Ministry for Primary Industries (MPI, formerly the Ministry of Agriculture and Forestry (MAF)) had conducted the border control on foods imported from Japan,[236] but terminated it in July 2012. Post-border testing is still taking place on specific products and the results are assessed against the following Codex guideline levels:[237]

- Strontium-90 must not be more than 100 Bq/kg; and
- Total Caesium-137 and Caesium-134 must not be more than 1000 Bq/kg.

Although MPI of New Zealand had been working with FSANZ,[238] the countermeasures taken by MPI against the Fukushima Daiichi NPP accident are not consistent with those taken by DAFF in Australia, which still conducts testing on food imported from Japan based on the advice from FSANZ, and which does not analyze Strontium-90 in food.

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[234] Defined in the Recommendations for Limiting Exposure to Ionizing Radiation (1995) (ARPANSA, 2002)

[235] DAFF, 2012a

[236] At the time of August 2011, MAF of New Zealand assessed the test results against the current Codex guideline levels (Cs-134 and Cs-137, and I-131) as DAFF of Australia did. But MAF's monitoring program was different from that of DAFF (Ministry of Agriculture and Forestry, 2011).

[237] Ministry for Primary Industries, New Zealand, 2012

[238] Ministry for Primary Industries, New Zealand, 2012

4.3. Countermeasures in Canada regarding radionuclides in food

In Canada, CFIA, which is the agency responsible for enforcing the food safety policies, regulations and standards established by HC, including the Canadian Guidelines for the Restriction of Radioactively Contaminated Food and Water Following a Nuclear Emergency, took countermeasures following the Fukushima Daiichi NPP accident on March 11 of 2011. Their countermeasures include the enhanced import controls on food and feed from Japan, monitoring radiation levels of domestic milk and fish from British Columbia[239] as well as of food imported from Japan, and assessing the situation in Japan. HC monitored regularly for radionuclides in food sold in Canada through its Total Diet Study.[240]

On March 23, 2011, CFIA published a press release saying that CFIA, in collaboration with the Canada Border Services Agency (CBSA)[241] and HC, was implementing enhanced import controls.[242] In the import control, CFIA did not allow food and animal feed from affected Japanese prefectures to enter Canada without the required documentation or the results of testing for radionuclides conducted by CFIA. In addition, radiation levels in domestic milk and domestic fish from British Columbia were monitored by CFIA. The results of testing on food imported from Japan and domestic food from British Columbia were assessed against the action levels of I-131, Cs-134 and Cs-137 recommended in the Guidelines (refer to Section 3.3.2),[243] and all food samples (more than 200 samples until June 15, 2011) were found to be below them.[244] By taking account of such results, CFIA lifted the enhanced import controls on June 13,

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[239] British Columbia is a Canadian province which faces the Pacific Ocean.

[240] CFIA, 2011a

[241] CFIA maintains rigorous controls and tracking systems for imported food, while CBSA routinely monitors radioactivity levels in shipping containers.

[242] CFIA, 2011b

[243] These actions taken by CFIA are considered to be based on the following laws:

- the Food and Drugs Act, Section 4(a), 23 and 29
- the Food and Drugs Regulations, Section A.01.040, 041 and 042
- the Canadian Food Inspection Agency Act, Section 11

[244] CFIA, 2011a. Minimum Detectable Concentration is typically around 2 Bq/Kg. The sample size used for the test is generally around 120 g and the method used is High Resolution Gamma Spectroscopy (CFIA, 2011c).

2011. After June 2011, CFIA continued to monitor the situation in Japan and to assess any potential impacts on the food supply in Canada.[245]

HC played its role following the Fukushima Daiichi NPP accident, too. In addition to the atmospheric radiation level monitoring, HC monitored the radionuclides in food sold in Canada through its Total Diet Study, which provides the estimate levels of exposure to chemicals (including radionuclides) that Canadians in different age-sex groups accumulate through the food supply.[246] The results of the Total Diet Study in 2011 have not been published yet.

[245] CFIA, 2011a; and MAFF, 2013

[246] CFIA, 2011a; Health Canada, 2009

5. Comparative analysis

From Chapter 2 to Chapter 4, the radiation protection organizations, regulatory frameworks regarding radioactive contamination in food, and countermeasures against the Fukushima Daiichi NPP accident in Japan, Australia and Canada were analyzed. Combined with the study by Wahidin (2013) on the EU, the US and the Codex, the present study conducts a comparative analysis of them in these five countries with the use of the radiation protection framework regarding food control at international level and the Codex guideline levels as the baselines; in addition, it uses the Codex Working Principle for Risk Analysis and the ICRP and IAEA publications as the criteria.

5.1. Baselines and Criteria for comparative study

5.1.1. Baseline and Criteria for comparative study of organizations related to control of radioactive contaminated food

In the comparative analysis of organizations related to control of radioactive contaminated food, the radiological protection framework regarding food control at international level is used as a baseline, and the Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007), called the Codex Working Principles, are used as criteria.

At the international level, the radiological protection framework in general can be seen in Fig. 6, which shows UNSCEAR providing scientific summaries of exposure levels and effects of ionizing radiation from various routes, ICRP providing science-based principles based on UNSCEAR publications, and international organizations developing standards based on ICRP recommendations.[247] The radiation protection framework regarding food control also follows the system shown in Fig.6, and can be utilized as the baseline for the comparison with the national governmental organizations related to control of radioactive contaminated food.

[247] Clarke and Valentin, 2009

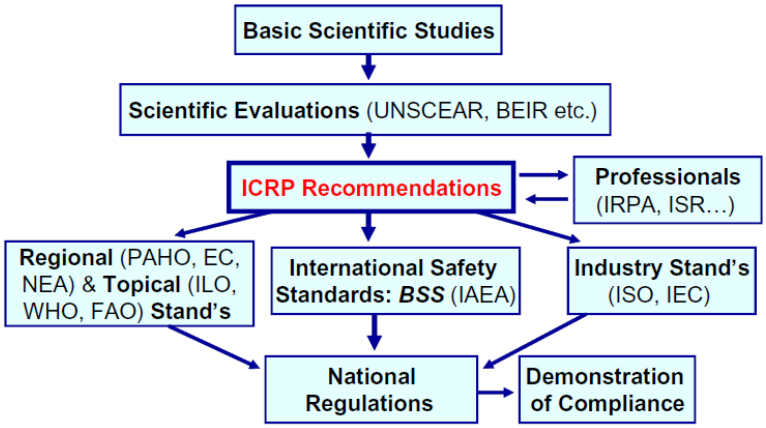

Figure 6: Radiological protection framework at international level (adapted from Clarke and Valentin, 2009)

The Codex Working Principles, which provides guidance to national governments for risk analysis, are used as criteria in order to clarify the task of each organization. The SPS Agreement of WTO states that Members shall base their sanitary measures on international standards, guidelines or recommendations, where they exist, and names the Codex as the relevant international organization; therefore, the countries targeted by the present study are considered to follow the Codex Working Principles to some extent in controlling radioactive contaminated food. The Codex Working Principles apply to national governments, not to the international framework, but it will not be a problem because the idea of risk analysis written in the principles is same as that of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.[248]

5.1.1.1. Radiological protection framework regarding food control at international level

CAC set the Codex Guideline Levels for radionuclides in food traded internationally, first in 1989 and then revised them in 2006 (still valid). CAC has decided that the preferred format of a Codex standard is a maximum level, not a guidance level, and that the existing guidance levels shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by JECFA,[249] if appropriate.[250] So

[248] CAC, 2013

[249] The 50th Executive Committee noted that scientific advice concerning radionuclides might be required from bodies other than JECFA. (FAO, 2011)

[250] General Standard for Contaminants and Toxins in Food and Feeds (CODEX STAN 193-1995)

far there has been no request for a risk assessment to establish maximum levels for radionuclides in food, but the Codex Guideline Levels are based on scientific work including the expert meetings held by IAEA, WHO and FAO. In drafting the guideline levels, ICRP publications were taken into account.[251]

Radioactive contamination in food following a nuclear or radiation emergency is a food safety issue, but also a problem in view of radiation protection. IAEA, which establishes requirements for the protection of people from the harmful effects of ionizing radiation, also provides a requirement and guidance related to limits for food control. IAEA states that the regulatory body shall consider the guideline levels for radionuclides contained in food traded internationally following an emergency as the Codex Guidance Levels,[252] and also provides the examples of the default Operational Intervention Levels (OILs) for food control[253] with the use of the scientific basis obtained from ICRP publications.

ICRP provides science-based policy recommendations regarding radiation protection with the use of the summaries of basic scientific studies provided by UNSCEAR[254]. Most importantly, ICRP recommendations present reference levels, representing the level of dose (1) above which it is judged to be inappropriate to plan to allow exposures to occur and (2) below which optimization of protection should be implemented, with consideration of the finding that there is an increased likelihood of deterministic effects and a significant risk of cancer at doses higher than 100 mSv.[255] Also, ICRP serves dose coefficients (used as a synonym for dose per unit intake of a radioactive substance)[256] which is the effective dose resulting from intake by ingestion of unit activity of a specified radionuclide in a specified chemical form.[257] These factors (i.e. reference levels and dose coefficients) are essential in setting the limits for food control in CAC and IAEA.

As mentioned above, UNSCEAR provides the science regarding radiation protection which can be utilized by ICRP. The most significant work of UNSCEAR referenced by

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[251] FAO, 2011

[252] IAEA, 2011a

[253] IAEA, 2011b

[254] Clarke and Valentin, 2009

[255] ICRP, 2007

[256] Refer to Table 9 which summarizes the ICRP publications.

[257] IAEA, 2007

ICRP is the publication[258] describing the sources and effect of ionizing radiation. After the Fukushima Daiichi NPP accident in 2011, UNSCEAR carried out the investigation and research, and then the report on radiological impact of the Fukushima-Daiichi NPP accident was adopted by UNSCEAR in May of 2013.[259] WHO also published the health risk assessment paper in February of 2013.

For setting the food standards related to contaminants such as heavy metals and natural toxins, CAC and JECFA are the primarily responsible players of risk analysis at the international level;[260] however, the framework regarding radionuclides in food includes radiation protection organizations but has not included JECFA up until now.

5.1.1.2. Codex Working Principles for Risk Analysis

The Codex Working Principles provide guidance to national governments for risk analysis consisting of the three following components. Risk analysis should be applied consistently; should be open, transparent and documented; and should be evaluated and reviewed as appropriate in the light of newly developed scientific data.

- Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification,[261] (ii) hazard characterization,[262] (iii) exposure assessment,[263] and (iv) risk characterization.[264] Risk assessment should be conducted based on the risk assessment policy established by the risk managers.
- Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment

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[258] UNSCEAR, 2008

[259] The report will be published after the United Nations General Assembly in 2013 (UNSCEAR, 2013).

[260] CAC, 2013

[261] The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods (CAC, 2013).

[262] The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable. (CAC, 2013)

[263] The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.(CAC, 2013)

[264] The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment. (CAC 2013)

and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.[265] Different from risk assessment, risk management should take into account the economic consequences and the feasibility of risk management options.

- Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[266]

The present study will compare the central government organization in each country related to the control of radioactive contaminated food with the international organizations under the radiation protection framework regarding food control (refer to Section 5.1.1.1). To make the comparative analysis more understandable, the present study uses the Codex Working Principles in order to categorize the national and international organizations into risk assessment bodies and/or risk management bodies and to clarify their tasks relevant to control of radioactive contaminated food. A national or international risk assessment body can be involved in a whole or a part of a risk assessment project on radionuclides in food (1) in a normal situation or (2) following an emergency to provide a scientific basis for the decision making on food control as a countermeasure.[267] Meanwhile, a national or international risk management body can be involved in giving policies for setting the limits, setting the limits intended to be used for food control, determining the need for food control, and implementing it based on the limits following an emergency, by taking into account the result of a whole or a part of a risk assessment project.

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[265] CAC (2013)

[266] CAC (2013)

[267] The present study understands that any activities which can be labeled as "risk assessment" have not been performed at national and international level for setting limits of radionuclide concentrations in food in terms of emergency preparedness. Countries have directly used ICRP publications as a scientific basis for legislation of such limits for food control, and exposure assessment on artificial radioactive substances cannot be performed before an accident.

5.1.2. Baselines and criteria for comparative study of limits on radionuclide concentrations used for food control

In the comparative analysis of limits on radionuclide concentrations used for food control, the current Codex Guideline Levels are used as baselines, while the ICRP and IAEA publications are used as criteria.

There are two reasons for selecting the Codex Guideline Levels as baselines:

- The SPS Agreement of WTO states that Members shall base their sanitary measures on international standards, guidelines or recommendations, where they exist, and names the Codex as the relevant international organization.
- Under the radiation protection framework, national standards should be set based on the publication of IAEA etc., and IAEA BSS (2011) requires countries to consider the guideline levels for radionuclides contained in food traded internationally following an emergency as the Codex Guidance Levels.

In addition, the publications of ICRP and IAEA have been used by national governments and international organizations for setting the limits of radionuclide concentrations used for food control, under the radiation protection framework. It is necessary to be aware of the list of essential publications of ICRP and IAEA because the applications of those publications for setting limits are checked in this comparative analysis.

5.1.2.1. Codex Guideline levels

CAC has a reference for food contaminated following a nuclear accident in the General Standard for Contaminants and Toxins in Food and Feeds (CODEX STAN 193-1995) (GSCTFF). The name of the reference is the Guideline Levels for Radionuclides in Food Contaminated Following a Nuclear or Radiological Emergency (Codex Guideline Levels), which was developed in 1989 after the Chernobyl accident in 1986, and was revised in 2006 (the current version).[268] The previous and current versions of the Codex Guideline Levels are summarized in Table 8. No specific guidance on methods of analysis and sampling has been developed in the Codex.

[268] FAO, 2011

Table 8: Codex guideline levels (previous version and current version)

Previous version (1989-2005)			Current version (2006-)		
Representative radionuclides	Guidance levels (Bq/kg)[a]		Representative radionuclides	Guidance levels (Bq/kg)[a]	
	Food destined for general consumption	Milk and infant food		Foods other than infant food	Infant foods
Am-241, Pu-239	10	1	Pu-238, Pu-239, Pu-240, Am-241,	10	1
Sr-90	100	100	Sr-90, Ru-106, I-129, I-131, U-235	100	100
I-131	1000				
Cs-134, Cs-137		1000	S-35, Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192	1000	1000
			H-3, C-14, Tc-99	10000	1000

a. The guideline levels have been developed with the understanding that there is no need to add contributions from radionuclides in different groups. Each group should be treated independently. However, the activity concentrations of each radionuclide within the same group should be added together. These levels apply to food prepared for consumption. This is because of the different times of appearance and concentration of radionuclides after a nuclear accident.[269]

- Scope

The Codex Guideline Levels apply to radionuclides in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency (including both accidents and malevolent actions[270]). In line with the general definition of a "guideline level" in GSCTFF,[271] the application of the Codex Guideline Levels for radionuclides is described in GSCTFF as follows:

· When radionuclide levels in food do not exceed the corresponding Guideline Levels,

[269] FAO, 2011

[270] FAO, 2011

[271] A guideline level is the maximum level of a substance in a commodity which is recommended by the CAC to be acceptable for commodities moving in international trade. When the guideline is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction (GSCTFF).

the food should be considered safe for human consumption.

- When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.

The previous version stated that the Codex Guideline Levels would remain applicable for one year following a nuclear accident,[272] but the current version does not mention the valid duration of the levels. The Codex Guideline Levels allow national governments to adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply, for example, in the case of widespread radioactive contamination, and for foods consumed in small quantities, such as spices.

- Radionuclides

By the revision of the Codex Guideline Levels in 2006, the list of representative radionuclides was extended from 6 to 20. Radionuclides included in the list are those (1) important for uptake into the food chain; (2) usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods, and; (3) which could be accidentally released into the environment from typical installations or might be employed in malevolent actions. Radionuclides of natural origin are generally excluded from consideration in this document as they are not associated with emergencies.

For the previous and current Codex Guideline Levels, radionuclides are divided into three and four groups respectably, based on their Dose per Unit Intake factors (Sv/Bq).[273]

- Food

The Codex Guideline Levels have two food groups: “infant foods” and “other foods”. The category “infant foods” is established in order to reflect differences in radionuclide absorption, metabolism, sensitivity to radiation, and food consumption rate between infants and adults.[274]

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[272] CAC 1989

[273] CAC 1989; FAO, 2011

[274] FAO, 2011

- Calculation

The current values of Guideline Levels for these radionuclides were calculated for two age groups (i.e. infants and adults) by using the following formula which assumes that all the foodstuffs imported from foreign areas with residual radioactivity are contaminated with radionuclides at the Guideline Levels. The factor "IPF (import to production factor)" was added in the revision in 2006. For convenience, values obtained from calculations were rounded off to the values of 1, 10, 100, 1000 and 10000. In consequence, the radionuclides with ingestion dose coefficient of similar magnitudes have the same values of Guideline Levels.[275]

$$GL = \frac{IED}{M(A) \times IPF \times e_{ing}(A)}$$

· *GL*: guideline Level (Bq/kg)

· *IED*: intervention exemption level of dose (mSv/year)
Previously an intervention exemption level 5 mSv/year was applied[276], but the revised level is 1 mSv/year in accordance with the ICRP Publication 82 (1999).

· *M(A)*: age-dependent Mass of food consumed per year (kg/year)
The current version assumes that 550 kg of food is consumed by an adult in a year, and that the value of infant food and milk consumption during the first year of life is equal to 200 kg based on contemporary human habit assessments (the previous version used the value of 550 kg only).

· *IPF*: import to production factor (dimensionless)
This factor is included in the formula for the current Codex Guideline Levels only. It is assumed that the mean fraction of major food quantities imported by all countries is 0.1, in accordance with FAO statistical data. The current Codex Guideline Levels note that the assumption of IPF value of 0.1 may not always apply, in particular to infants who have a diet essentially based on milk with little variety, and consider that the fraction of imported contaminated food will decrease in the long term as a result of food control, agricultural countermeasures, changes to other produce, and decay.

[275]CAC, 1989; FAO, 2011; and GSCTFF

[276] To calculate the value for I-131 of the previous Guideline Levels, a dose of 50 mSv to thyroid and a mean life of ingested I-131 of 11.5 days were used (CAC, 1989).

· e_{ing} *(A)*: age-dependent ingestion dose coefficient (mSv/Bq)
The most conservative values of age-dependent ingestion dose coefficient were selected for each radionuclide from the IAEA BSS (1996) and ICRP Publication 72 (1996). It is unclear which ICRP publication was referred to for selecting the dose coefficient in the calculation of the previous version of the Codex Guideline Levels.

5.1.2.2. ICRP and IAEA publications

ICRP, as an independent, international organization, has been providing recommendations regarding radiation protection to the international or national regulatory agencies. In particular for setting the limits of radionuclide concentrations for food control, the following ICRP publications have been used because they provide the reference dose and the ingestion dose coefficient[277] (Table 9).

[277] Definitions of "reference dose" and "dose coefficient" are given in Section 5.1.1.1.

Table 9: ICRP Publications providing recommendations regarding the reference dose for the public and the ingestion dose coefficient

Publication No. (year), title	Contents
No. 119 (2012): Compendium of Dose Coefficients based on ICRP Publication 60.	(It provides dose coefficients based on the primary radiation protection guidance given in ICRP Publication 60. The coefficients tabulated in this publication will be superseded in due course by values based on ICRP Publication 103.) (It includes dose coefficients for intakes of radionuclides by 3-month-old infants, 1-, 5-, 10-, and 15-year-old children, and adults, as compiled in ICRP Publication 72, calculated using the Publication 66 model of the human respiratory tract and the Publication 30 model of the gastrointestinal tract.[278])
No. 111 (2009): Application of the Commission[279]'s Recommendations to the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or a Radiation Emergency	The reference level[280] for people living in contaminated areas should be selected in the lower part of the 1–20 mSv/year band (ICRP Publication 103) for the management of existing exposure situations. Past experiences show that a typical value used in long-term post-accident situations is 1 mSv/year. (It also mentions food control in existing exposure situations and the use of the Codex Guideline Levels.)
No. 109 (2007): Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations	The reference level for emergency exposure situations should be set in the band of 20–100 mSv effective dose (acute or per year) (ICRP Publication 103). The reference level represents the level of residual dose or risk above which it is generally judged to be inappropriate to plan to allow exposures to occur. It is not appropriate to treat averted dose levels defined by ICRP as absolute criteria that prescribe when each protective measure should be included in a plan. However, the corresponding quantified values can be used as triggers to initiate appropriate protective measures. (It also mentions food control in emergency exposure situations.)

[278] Doses from radiation exposure, H-G. Menzel, J.D. Harrison (2012).

[279] ICRP is called "the Commission" in its publications.

[280] For all exposure routes, not limited to ingestion of contaminated food and water.

No. 103 (2007): The 2007 Recommendations of the International Commission on Radiological Protection	In developing response plans for emergency exposure situations, reference levels between 20 and 100 mSv effective dose (acute or per year) for the public are recommended. Reference levels for existing exposure situations should be set typically in the 1-20 mSv/year band of projected dose. (It also explains the principles for radiation protection.)
No. 82 (1999): Protection of the Public in Situations of Prolonged Radiation Exposure	The following values are recommended: · Generic reference level for interventions almost always justifiable (above which intervention should be considered almost always justifiable): <100 mSv(existing annual dose) · Generic reference level for interventions not likely to be justifiable (above which intervention may be necessary): <10 mSv (existing annual dose) · Exemption from intervention in commodities (criterion for deriving intervention exemption levels for dominant commodities): 1 mSv (additional annual dose) (It also mentions the previous Codex Guideline Levels)
No. 72 (1995): Age-dependent Doses to the Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients	(It serves age-dependent committed effective dose coefficients for the public (3-month-old infants, 1-, 5-, 10-, and 15-year-old children, and adults) from intakes by ingestion of radioisotopes.)
No. 63 (1992): Principles for Intervention for Protection of the Public in a Radiological Emergency	For any single foodstuff, an intervention level that is almost always justified is an averted effective dose of 10 mSv in a year (in special situations, intervention may be justified only at levels of projected dose much higher than 10 mSv per year). (It also mentions the previous Codex Guideline Levels.)

No. 60 (1991): 1990 Recommendations of the International Commission on Radiological Protection	The Commission now recommends that the dose limit[281] for public exposure should be expressed as an effective dose of 1 mSv per year (in special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year). However, the dose limits are intended for use in the control of practices, not for intervention. (It does not clarify the exact intervention level for the public in an emergency.)
No. 56 (1990): Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 1	(It provides age-dependent committed effective dose coefficients for public (3-month-old infants, 1-, 5-, 10-, and 15-year-old children, and adults) from intakes by ingestion of radioisotopes. The number of radioisotopes is limited to 19.)
No. 40 (1984): Protection of the Public in the Event of Major Radiation Accidents - Principles for Planning	It may be appropriate to control the distribution of fresh foods if the projected dose within the first year otherwise exceeds the annual dose limit for members of the public. Projected dose-equivalent levels (in the first year) for food control in intermediate phase are: · Whole body: 5-50 mSv · Individual organs preferentially irradiated: 50-500 mSv
No. 26 (1977): Recommendations of the ICRP	The annual dose-equivalent limit of 5 mSv to individual of public is likely to result in an average dose of less than 0.5 mSv. In order to protect any one organ or tissue, an overriding annual dose-equivalent limit of 50 mSv should apply. However, these values are intended for use in the control of practices, not for intervention. Intervention levels should be treated as reference levels intended for guidance in making decisions and should be reassessed in the light of all the available information at the time of intervention. (It does not clarify the exact intervention level for the public in an emergency.)

[281] The value of the effective dose (the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body) or the equivalent dose (the dose in a tissue or organ) to individuals from controlled practices that shall not be exceeded. (ICRP, 2007)

IAEA, as an organization within the United Nations family, has developed nuclear safety standards. With regard to setting the limits of radionuclide concentrations used for food control, the key publications of IAEA are the following two series: General Safety Requirements (GSR) -2 and GSR-3, which determine the reference levels and the effective dose per unit intake (i.e. dose coefficients) and recommends the limits for food control with taking account of ICRP recommendations. GSR-2 and related Safety Guides cover the emergency preparedness and response, while GSR-3 is called the International Basic Safety Standards (BSS) for radiation protection and safety of radiation sources. Table 10 summarizes the key IAEA publications related to the setting of limits for food control.

Table 10: Key IAEA publication series providing recommendations regarding the reference dose and the limits for food control

Publication title (year)	Contents
Radiation Protection and Safety of Radiation Sources, International BSS 2011: GSR-3 Interim Edition (2011) (currently valid)	A reference level for the public in emergency exposure situations shall be set in the range of 20-100 mSv/year. For existing exposure situations, the reference level for the public shall be expressed in the range of 1-20 mSv (Based on ICRP Publication 103 (2007)). In existing exposure situations, specific reference levels for exposure via each of the commodities (e.g. food, water) shall typically be expressed as, or based on, an annual effective dose that does not generally exceed a value of about 1 mSv. The regulatory body shall consider the Codex Guideline Levels to be the guideline levels for radionuclides contained in food traded internationally following a nuclear or radiation emergency. (It also provides the effective dose per unit intake.)
GSG-2 Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency (2011) (currently valid, intended to assist Member States in the application of GSR-2)	The generic criteria replace the system of generic action levels (GALs) described in the previous standards. The set of generic criteria expressed in terms of the projected dose is compatible with reference levels within a range of 20–100 mSv. Examples of default Operational Intervention Levels (OILs) for food control are provided as follows: · OIL3: a measured value of ground contamination calling for immediate restrictions on consumption of some

	commodities · OIL5 and OIL6: measured values of concentrations in food for consideration of food consumption restrictions so as to keep the effective dose below 10 mSv/year. (It also provides the list of OILs for each radionuclide.)
GSR-2 Preparedness and Response for a Nuclear or Radiological Emergency (2002) (currently valid)	Action levels for countermeasures (including food control) shall be established. Default OIL (a type of action level that is used immediately and directly to determine the appropriate protective actions on the basis of an environmental measurement) for food concentrations shall be arranged. (It provides the generic action levels (GALs) as guidelines based on the previous Codex Guideline Levels with a few amendments.[282])
International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (1996) (superseded)	The estimated average doses to the public that are attributable to practices shall not exceed the following dose limits (the dose limits are not relevant for decisions on whether and how to undertake an intervention): · an effective dose of 1 mSv in a year · in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year; Action levels for the withdrawal and substitution of specific supplies of food and drinking water shall be specified in emergency plans as appropriate. If there is no shortage of food and there are no other compelling social or economic factors, the action levels shall be based on the generic action levels (GALs). (It provides the GALs as a guideline, based on the previous Codex Guideline Levels with a few amendments.) (It also provides the effective dose per unit intake.)
Intervention Criteria in a Nuclear or Radiation Emergency (1994) (superseded)	(It recommends the GALs which are based on the previous Codex Guideline Levels with a few amendments.)

[282] Amendments are (1) adding some radioisotopes to each radionuclide group and (2) adding drinking water to the food group Milk and infant food.

5.1.2.3. Other points for comparative analysis

As described above, the current Codex Guideline Levels will be used as a baseline for the comparative study on limits of radionuclide concentrations used for food control in nations, and the applications of publications of ICRP and IAEA in setting the limits will be key points in this comparative analysis. In addition, the following aspects of national limits used for food control will also be discussed: (1) the legal status of the limits (regulation or guidance?), (2) the legal interpretation of food exceeding the national limits (non-compliant food or unsafe food?), (3) applications of the limits following the Fukushima Daiichi NPP accident in 2011.

5.2. Results from comparative analysis

5.2.1. Comparative analysis of organizations related to control of radioactive contaminated food

This Section compares the national organizations related to the control of radioactive contaminated food with the organizational framework at international level. By taking into account the Codex Working Principles, this Section categorizes the national or international organizations related to the control of radioactive contaminated food as risk management bodies and/or risk assessment bodies which can be defined in this present study as follows:

- Risk assessment (RA) body: an authority which can be involved in a whole or a part of a risk assessment on radionuclides in food (1) in preparation for an emergency (before an accident occurs) or (2) following an emergency to provide a scientific basis for the decision making about the control of radioactive contaminated food.
- Risk management (RM) body: a body which can give policies for setting the limits, which can set the limits intended to be used for food control, and which can determine the need for food control and implement it based on the limits following an emergency, by taking into account the result of a whole or a part of a risk assessment.

Table 11 shows the categorization of the organizations related to the control of radioactive contaminated food in five countries (including one region, the EU) and the international framework based on the definition of RA body and RM body described above. Information in Table 11 is mainly based on Chapter 2 of the present study and Wahidin (2013). Overall, in all counties, not only the organizations related to general food safety issues but also the radiation protection organizations are involved with control of radioactive contaminated food, like the organizational framework at international level. The author recognizes that it would be helpful if both types of bodies can share their strength/expertise with each other in taking actions related to food control.

The present study details the similarities and differences between the national organizations and the international ones in the following small Sections.

Table 11: Analysis of organizations related to control of radioactive contaminated food

	Tasks	JP		AU	CA	EU	US	International level
		Pre-reform	Current					
RA Bodies	Performing assessment (HI, HC, EA and/or RC[a]) before an accident	[MHLW] [FSC]	[MHLW] [FSC] [NRA]	[FSANZ] [ARPANSA]	[HC_{food}] [$HC_{radiation}$]	[Article 31 Group of Expert]	[FDA] [USDA] [EPA]	UNSCEAR(continuously)(HI and HC on ionized radiation via all routes including food) [JECFA]
	Performing assessment after the Fukushima accident	MHLW (2011) (EA[b]) FSC(2011) (HI and HC)	MHLW (2012) (EA[b]) [FSC][NRA]	ARPANSA (2012) (EA on ionized radiation from all routes including food), [FSANZ]	[HC_{food}] [$HC_{radiation}$]	[Article 31 Group of Expert]	[FDA] [USDA] [EPA]	UNSCEAR(2013)(RA on ionized radiation from all routes including food), WHO (EA in 2012, RA in 2013 on ionized radiation from all routes including food) [JECFA]
RM bodies	Giving policies used for setting limits	Use ICRP (and IAEA)	Use ICRP (and IAEA)	Use ICRP (and IAEA)	Use ICRP (and IAEA)	Use ICRP (and IAEA)	Use ICRP (and IAEA)	ICRP(continuously)(use UNSCEAR) (IAEA(continuously)(use ICRP))
	Setting limits as guidance /recommendations	NSC (1998)	NRA (2012)	ARPANSA (2004)	$HC_{radiation}$ (2000)	$Commission_{DG\ ENER}$, (1987) [c]	$FDA_{radiation}$ adopted by FDA_{food} (1998)[d]	Codex (2006) IAEA (2011)
	Setting limits as regulation	MHLW (2011)	MHLW (2012)	[FSANZ]	[HC_{food}]	$Commission_{DG\ ENER\ and\ DG\ SANCO}$ (post Chernobyl and Fukushima)	[FDA_{food}]	-
	Implementing food control	MHLW (2011-) NERHQ (2011-)		DAFF (2011)	CFIA (2011)		FDA_{food} (2011) [USDA]	-

( ): the year when the organisation conducted the task most recently. [ ]: the organization which is competent to perform the task, but hasn't done it.

a. HI: Hazard Identification, HC: Hazard Characterization, EA: Exposure Assessment, and RC: Risk Characterization

b. MHLW performed the exposure assessment for setting the current standards and the total diet study.

c. The Council Regulation (EURATOM) No. 3954/87 (1987) provides pre-established levels applicable to a Regulation aiming to implement food control in the event of radiation emergencies which can be used as references to judge the acceptability of placing food on the market. By taking into account the nature of this Council Regulation, the present study categorizes the pre-established levels as guidance/recommendations.

d. FDA adopted Derived Intervention Levels as guidance levels from recommendations established by the Center for Devices and Radiological health, FDA, in 1998.

5.2.1.1. Risk assessment bodies performing assessments in preparation for an emergency (before an accident occurs)

For setting the Codex standards related to food contaminants, JECFA is the primary responsible player of risk assessment at the international level; however, no risk assessment specific to radionuclides in food has been carried out by JECFA yet. Under the radiation protection framework, UNSCEAR has issued scientific publications describing sources and effects of ionizing radiation, which can be recognized as hazard identification and hazard characterization of risk assessment on ionizing radiation from all exposure routes (including food ingestion). Exposure assessment and risk characterization have not been performed at international level in normal situations because contamination in food by artificial radionuclides would only happen following disaster events.

None of the countries (including one region, the EU) in Table 11 has performed assessments at national level in preparation for an emergency. They directly utilize ICRP recommendations (based on UNSCEAR's scientific findings) and IAEA standards (based on ICRP recommendations) in risk management activities (i.e., setting limits for emergency preparedness). This situation might not be consistent with one Codex principle stating that the three components of risk analysis should be applied within an overarching framework for management of food related risks to human health; however, at least countries use the same scientific basis (UNSCEAR's findings) as the international framework.

5.2.1.2. Risk assessment bodies performing assessments after a nuclear/radiation accident

UNSCEAR and WHO conducted investigations and analysis on the effect of radiation exposure from all routes (including food) on human health following the Fukushima Daiichi NPP accident. In May of 2013, UNSCEAR adopted a risk assessment paper which will be presented to the UN General Assembly. WHO published a paper about the preliminary estimation on exposure dose in May of 2012, and a health risk assessment paper in February, 2013. JECFA has not performed any assessments on radionuclides in food.

The present study understands that no country performed a full risk assessment on the effect of radiation exposure from food and/or all routes following the Fukushima Daiichi NPP accident. In Japan, in 2011, FSC published a paper covering hazard

identification and hazard characterization of radionuclides in food, and MHLW estimated exposure dose via food in order to set new standards of radionuclides in food. Before the reform of organizations in 2012, it was not clear which organization(s) were responsible for radiation protection;[283] therefore, no governmental organization published an assessment on total radiation exposure covering all possible routes (external and internal) following the accident. From the point of view of radiation protection, the assessment of the individual dose distribution and the comparison of all doses with the reference level are necessary in the implementation of protective actions in existing exposure situations[284]. Also, CAC defines exposure assessment as the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant[285]. For these reasons, the author of the present study considers that the situation at international level (i.e., a full risk assessment papers on the effect of radiation exposure from all routes including food is available) is preferable comparing to the situation in Japan, 2011.

Japan is not a big exporter and has supplied a relatively small amount of foodstuffs to the world trade; therefore, the impact of the Fukushima Daiichi NPP accident on food supply has not been large.[286] Among the countries in Table 11 except Japan, only Australia's ARPANSA (responsible for radiation protection) provided a publication on the assessment of the radiation dose from all routes including food imported from Japan. The style of the assessment in Australia is close to that at international level. For Canada, the EU and the US, such publications which indicate the results of assessments on the radiation dose were unavailable on the Internet. It seems that both food safety authorities and radiation protection authorities can perform assessment on the radiation dose via food and via all routes (including food), respectively, following nuclear accidents or radiation emergencies, but there is an exception: EFSA, the EU risk assessment body for food safety. Following the Fukushima Daiichi NPP accident, EFSA explicitly stated that EFSA is not involved in risk assessment of radiation contamination, but can provide technical assistance and support in the area of food and feed safety as

[283] After the reform in 2012, NRA was established as the body responsible for radiation protection; therefore, NRA is expected to perform assessment of the total radiation exposure from all possible routes including food ingestion.

[284] ICRP, 2009.

[285] CAC, 2013

[286] OECD and FAO, 2011

required[287]. It is only the EU which states non-engagement of food safety risk assessment body with radiation contamination.

5.2.1.3. Risk management bodies giving policies for setting limits

In the framework at international level, ICRP provides science-based policy recommendations, such as the selection of reference levels to be used for setting the limits, based on the summaries of basic scientific studies provided by UNSCEAR. IAEA, as a body under the UN, publishes standards mentioning the reference levels etc. which are recommended by ICRP. Under the radiation protection framework shown in Fig.6, the countries in Table 11 directly utilize the contents of ICRP recommendations and IAEA standards for setting limits for food control. In this point, it can be said that the international and national organizations share common policies for setting limits.

5.2.1.4. Risk management bodies setting limits as guidelines/recommendations

At international level, CAC set the Codex Guideline Levels for radionuclides in food traded internationally based on scientific work including the expert meetings held by IAEA, WHO and FAO with the use of ICRP publications. In addition, in 2011, IAEA provided the examples of the default Operational Intervention Levels (OILs) for food control by national governments with the use of the scientific basis obtained from ICRP publications. IAEA also states that the guideline levels for radionuclides contained in food traded internationally following an emergency shall be considered as the Codex Guidance Levels.

At national level, the limits intended to be used for food control were developed as guidelines/recommendations in each country by organizations responsible for radiation protection, not by organizations responsible for food safety, with the use of ICRP and IAEA documents. Instead, the national organizations responsible for food safety have the authority to set limits as regulations (only Japan and the EU have limits as regulations).

With regard to the EU, it should be noted that the Council Regulation (EURATOM) No. 3954/87 does not mention the Directorate(s)-General responsible, which is (are) (a) department(s) of the Commission.[288] The present study assumes that the

[287] EFSA, 2011

[288] The European Commission is the EU's executive body. The Commission is divided into several departments (known as Directorates-General) and services, each of which is responsible for a particular

Directorate-General for Energy (DG ENER) developed this Council Regulation because (1) this Council Regulation was established under the Treaty of the European Atomic Energy Community (EURATOM) which requires the Council to establish uniform safety standards to protect the health of the public,[289] not under any European food laws, and (2) DG ENER is responsible for developing the legal framework for nuclear energy including the legislation concerning radioactive levels in food.[290] Also, it should be mentioned that this Council Regulation laid down only the procedure for determining MPLs, in other words, a new Regulation should be issued in order to apply MPLs for countermeasures following an emergency. In this respect, MPLs in this Council Regulation work as guideline levels and are not given a power as regulations.

5.2.1.5. Risk management bodies setting limits as regulation

Only in Japan and the EU were the limits intended to be used for food control set as regulation. In both countries, the organizations responsible for food safety (i.e. MHLW and DG SANCO) are involved in the legislation of the limits for food control, and the process for setting limits includes the consultation with the experts on radiation protection. Only in the EU is it assumed that a radiation protection organization (i.e. DG ENER) is also involved.

In Japan, MHLW, which is a food safety management body and in charge of setting food standards, established the provisional regulation values by introducing the guidance limits just after the Fukushima Daiichi NPP accident, and revised them in the current standards in 2012. No radiation protection organization is responsible for setting standards; however, in the process for setting the current standards, the draft was sent to the Radiation Council in MEXT (now the Council belongs to NRA) for consultation. The experts in the Radiation Council are required by the relevant act[291] to assess the draft standards based on the "limited" policy: the exposure dose should be lower than the dose which is unlikely to pose the radiation hazards to them. This "limited" policy does not cover the ICRP fundamental principles for radiation protection. The Radiation Council adopted the draft standards proposed by MHLW, but also attached the opinion on them which revealed the difference between the point of view of a food safety body and that of experts of radiation protection (this point will be discussed in Chapter 6).

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policy area. (European Commission, 2013)

[289] Article 2(b), Treaty for establishing EURATOM

[290] DG ENER, 2013 ; EFSA, 2011

[291] Act on Technical Standards for Prevention of Radiation Hazard

In the EU, Regulations for determining the maximum levels and implementing the control of radioactive contaminated food have been established following the Chernobyl accident and the Fukushima Daiichi NPP accident by adopting the pre-established levels in the Council Regulation (EURATOM) No. 3954/87[292]. These Regulations do not mention the Directorate(s)-General responsible, but the author assumes that not only the DG for Health and Consumers (DG SANCO) but also DG ENER have been involved with the legislation of maximum levels and food control for the following reasons:

- After the Fukushima Daiichi NPP accident, the Commission Implementing Regulations[293] were established under the General Food Law[294], not under the Treaty for establishing EURATOM.
- The Commission Implementing Regulations following the Fukushima accident mentions the use of the Rapid Alert System for Food and Feed (RASFF) and the involvement of the Standing Committee on the Food Chain and Animal Health in determining countermeasures.
- In general, DG ENER is responsible for the legislation concerning radioactive levels in food and for introducing a safeguard clause to impose radioactive testing if necessary.[295]

According to the Council Regulation (EURATOM) No. 3954/87, the consultation of the Group of Experts referred to in Article 31 of the Treaty for establishing EURATOM is required in the process for determining the maximum levels in a new Regulation.

Comparing between Japan and the EU, the EU has the system which is more likely to reflect the view of radiation protection on the limits as regulations and operation of food control because DG ENER, a responsible body for radiation protection, could be involved and because the Group of Experts can give advice in the view of radiation protection principles..

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[292] The Commission Implementing Regulation No. 297/2011 used the pre-established levels for control of imported food from Japan; however, the amending Regulations introduced the maximum levels in the Japanese legislation (Wahidin, 2013).

[293] The Commission Implementing Regulation No. 297/2011, No. 351/2011, No. 996/2012, etc.

[294] Article 53 of Regulation (EC) No 178/2002 which provides for the possibility of adopting appropriate Community emergency measures for food and feed imported from a third country in order to protect public health, animal health or the environment, where the risk cannot be contained satisfactorily by means of measures taken by the Member States individually.

[295] EFSA, 2011

5.2.1.6. Risk management bodies implementing food control by the use of limits

In all countries in Table 11, organizations in charge of general food safety issues are involved in the control of radioactive contaminated food. In addition to that, the NERHQ of Japan, which is established in a nuclear emergency, also plays a role in food control based on the Act on Special Measures Concerning Nuclear Emergency Preparedness. In the EU, DG ENER can introduce a safeguard clause to impose radioactive testing if necessary[296] and may be involved with the legislation of implementation of food control with DG SANCO. With the involvement of NERHQ and DG ENER, measures for food control could have more variety.

5.2.2. Comparative analysis on limits of radionuclide concentrations used for food control

This Section compares the national limits of radionuclide concentrations used for food control, which are currently valid, with the current Codex Guideline Levels, in the light of the following aspects:

- Scope of setting the limits
- Targeted radionuclides/food and grouping of them
- Assessment of test results
- Formula for calculation of limits and factors in formulas
- Values of limits.

In this analysis, the applications of ICRP and IAEA publications in setting the limits are also checked carefully. Moreover, the national limits intended to be used for food control are compared to each other in view of the following aspects: (1) the legal status of the limits, (2) the legal interpretation of food exceeding the national limits, and (3) applications of the limits following the Fukushima Daiichi NPP accident in 2011.

5.2.2.1. Analysis of the scope of limits

As seen in Table 12, there are variations in the name of the national limits of radionuclide concentrations used for food control and in the document providing those limits; in other words, the legal status of these limits and the application of these limits after an emergency are different. This issue will be discussed in Section 5.2.2.5.

With regard to the year of establishment of the limits which are currently valid, the limits of the EU are the oldest which were established following the Chernobyl accident, before the establishment of the previous version of Codex Guideline Levels. The Codex

[296] EFSA, 2011

Guideline Levels were revised in 2006 most recently; however, no national limits except Japanese standards have been revised since then. This means that it is likely that the national limits, which have not been revised recently, do not reflect the latest science-based ICRP recommendations and/or IAEA publications.

The limits shown in Table 12 in general are intended to be used for food control, but they have small differences in scope. Firstly, the Codex Guideline Levels apply to food traded internationally, while the standards of Japan[297] and the limits of in Canada[298], the EU, the US and Codex are intended to be applied for food on the market, and the Japanese OILs and the Australian limits can be used for the restriction of any food, including the food that is not on the market.[299] Secondly, different phrases are used in order to explain the contents of food control, for instance, "determination if food should be placed on market" (limits of Codex, the EU and the US), "ban for sale, import, produce and use of food" (Japanese standards), "food restriction" (Japanese and Australian OILs) and "withdrawal and substitution of food" (Canadian limits). Thirdly, the targeted situations applicable for the limits differ between the countries and Codex in Table 12. Japanese standards were established in 2012, when one year had passed since the Fukushima Daiichi NPP accident, in order to deal with the long-term, existing exposure situations. The other limits are basically intended to be used following a radiation emergency (i.e., be used from the emergency exposure situations), but it is not clear whether they can be applied for the existing emergency situations. In addition, the Australian OILs specify the types of emergency (i.e. a reactor accident), and it is not apparent that the Japanese OILs and the Australian GALs and OILs are applicable to emergencies in abroad. The author considers that national limits intended to be used following an emergency should be able to apply not only for food on the market but also for food that is not on the market in order to prepare for any possible countermeasures. Also, it should be clarified in what kinds of accidents and in which exposure situations the limits can be used.

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[297] By using the framework of the Act on Special Measure Concerning Nuclear Emergency Preparedness, these limits can be used for restricting intake of food not for sale.

[298] Canadian guidelines (Health Canada, 2000) also mention that they may be used to provide advice applicable to individuals producing or harvesting their own food.

[299] In some cases, NERHQs of Japan directed intake restriction which required consumers not to eat/drink concerned commodities, including food produced or harvested for their own consumption.

Table 12: Analysis of the scope of limits

Country	**Japan**		**Australia**		**Canada**	**EU**	**US**	**Codex**
Name of limits:	Standards	Operational Intervention Levels (OILs)	Generic Action Levels (GALs)	Operational Intervention Levels (OILs)	Action Levels (ALs)	Maximum Permitted Levels (MPLs)	Derived Intervention Levels (DILs)	Guideline Levels (GLs)
Document:	Ministerial Ordinances (laws)	Guide	Recommendations		Guidelines	Council Regulation (law)	Compliance Policy Guides (CPG)	General Standard
Last updated/ established:	2012	2012, but based on Indices (1998)	2004	2004	2002	1987	1998, adopting the FDA Recommendations(1998)	2006
Scope: Use of limits	To ban for sale, import, produce and use of food for sale[a]	To determine and implement the restriction of food and drink intake	To determine and implement food and water restriction		To implement the withdrawal and substitution of food for sale and drinking water	To determine if food should be placed on market (including food from 3rd country)	To determine if domestic / imported food for sale present a safety concern (FDA may initiate an enforcement action[c])	To be applied to food to be traded internationally; To ask a country to decide if the food should be distributed
Applicable Situation	In long-term, existing exposure situation after the Fukushima accident[b]	Following an emergency of a nuclear facility or during nuclear transportation	Following any radiation emergency situations	Following a reactor emergency; Especially in early phase	Following a nuclear emergency in Canada or abroad	Following a nuclear accident or any radiological emergency	Not mentioned in the CPG[d]	Following a nuclear or radiological emergency

a. Under the Food Sanitation Act. By using the framework of the Act on Special Measures Concerning Nuclear Emergency Preparedness, these limits can be used for restricting food and drink intake/distribution.

b. This is not written in the Ministerial Ordinances, but in the discussion papers in setting these standards.

c. In addition, the FDA Recommendations (1998) states that the DILs are intended to be used for temporary embargoes for food and actions to reduce contamination.

d. The FDA Recommendation (1998) stated that the DILs are for the radiological emergencies.

5.2.2.2. Analysis of radionuclides and food targeted by limits

Table 13 summarizes the results from the comparative analysis of the targeted radionuclides/food and their group divisions. The Codex selected the 20 representative radionuclides based on the following criteria: radionuclides which (1) are important for uptake into the food chain; (2) are usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods; and (3) could be accidentally released into the environment from typical installations or might be employed in malevolent actions. The idea of the Codex criteria is shared among all countries in Table 13, but they have limits for a part of, not a whole of, radionuclides included in the Codex Guideline Levels[300]. Japanese standards and OILs, Australian OILs and US DILs have relatively lesser radionuclides because the governments of those countries considered (1) the need for the quick/easy measurement and (2) the release of radioactive substances due to the Fukushima Daiichi NPP accident (for Japanese standards only). Considering the experience of the Fukushima Daiichi NPP accident, it seems difficult for countries to measure several types of radionuclides at the same time in emergencies probably due to a lot of samples of food and other materials and the limitation of measurement facilities. The author considers that the selection by national governments of prioritized radionuclides from the radionuclides listed in the Codex GLs is reasonable, and that the less-targeted radionuclides are not likely to result in a low level of protection in practical because the measured radionuclides are expected to be limited. It should nevertheless be mentioned that the Japanese OILs intended to be used following the accident, which are the only limits not covering Ru and Sr, might have less ability to manage an event in which that Ru and Sr contribute considerably to the exposure.

The Codex Guideline Levels have 4 radionuclide groups divided in accordance with their Dose per Unit Intake values. As seen in Table 13, many countries have 4-5 radionuclide groups, but the way of grouping differs between countries. The radionuclide grouping is related to the assessment of results from measurement of radionuclide concentration in food. In assessing the results of measured concentrations of radionuclides in food based on the Codex Guideline Levels, each group should be treated independently; in other words, the concentrations of each radionuclide within the

[300] Exceptionally, Australian OILs and Canadian ALs cover Pu-242 which is not included in Codex GLs. AU-OILs and CA-ALs are consistent with the Generic Action Levels (GALs) provided by IAEA (2002, 1996, 1994). Now, IAEA GSG-2 (2011) states that the GALs are out of use; therefore, the importance and need of Pu-242 are not discussed in this study.

same group should be added together. Many countries introduced the same system of result evaluation into their limits; however, Canada introduces a different system where all nuclides are assessed collectively. The author considers that the difference in grouping of radionuclides is not likely to change the level of protection in practice because (1) the appearance and concentration of each radionuclide in food changes over time due to their decay[301] (i.e. the priority of radionuclides for measurement changes over time) and (2) the measured radionuclides are expected to be limited during an emergency (i.e. it is unlikely that several types of radionuclides are measured at the same time). But the diversity in the grouping of radionuclides might be confusing in the event that the results of multiple radionuclides in each sample are available.

Codex set two food groups, Infant food and General food. Drinking water is out of scope of the Codex GLs, while all countries cover drinking water probably due to consideration of IAEA publications (refer to Table 10). Only the US does not divide food into groups, while the other countries divide food into 2-5 groups, taking into account several factors. If a country prefers to minimize the effect of food habit diversity among individuals and the complexity of limits, less food groups are suitable.

The group for milk, not included in the Codex GLs, is set in all limits except the US DILs. The reason why CAC did not establish the category of milk in the revision in 2006 may be that milk is not likely to be traded internationally. On the contrary, national governments with the exception of the US set the category for milk based on the following reasons: (1) milk is important in infant diets; and/or (2) milk is likely to be consumed locally. This situation looks as if the US does not take care of infants and exposure via milk, but this is not true. In the calculation of the Japanese standards and the Canadian ALs for milk, the ratio of contamination was set at 1 (100%) instead of 0.5 or 0.2 (refer to Table 14), and the lowest calculated value of each nuclide in milk was taken among all population groups including infants. Australia and the EU applied the ratio of contamination of general food (1 and 0.1, respectively) for that of milk. Meanwhile, the US used 1 (100%) as the ratio of contamination factor of I-131 in and infant diet mostly consisting of milk, and selected the lowest calculated value for each nuclide in the total diet among all population groups. If the calculated value for infant is the lowest, it would be selected as a DIL. From these points, the US has the concept to give a high level of protection to infant from the exposure of I-131 in milk. Australia and the EU deal with milk food and other food categories equally, without special

[301] FAO, 2011

consideration of the ratio of contaminated milk.

The Codex GLs, the Japanese standards, the Australian GALs and the EU's MPLs have a category for infant food. Among these limits, only the Japanese standards adopt 1 (100%), not 0.5 (50%), as the ratio of contaminated food for infant food in order to make "special safety margin for children", but radiation experts in Japan stated that consideration of children is already enough without setting "safety margin".[302] From this, one question is raised: "Do the limits with the infant food category (like the Codex GLs) provide a higher level of protection for infants than the limits without the infant food category?" The answer is "no" because the limits of each radionuclide in general food are based on the lowest calculated value among all population groups including infants. If the calculated value of the infant population group is the lowest, it would be selected as a limit for general food.

In summary, having groups of milk and infant does not always mean the higher level of protection for infant. The level of protection depends on the application of ratio of contaminated food specific to milk and infant food.

[302] Radiation Council, 2012

Table 13: Analysis of radionuclides and food targeted by limits

Country	**Japan**		**Australia**		**Canada**	**EU**	**US**	**Codex**
Name of limits:	**Standards**	**OILs**	**GALs**	**OILs**	**ALs**	**MPLs**	**DILs**	**GLs**
Radionuclides	-	Alpha-emitting nuclides	$Pu^{238,239,240,242}$ Am^{241}	-	$Pu^{238,239,240,242}$ Am^{241}	Alpha-emitting nuclides	$Pu^{238,239}$ Am^{241}	$Pu^{238,239,240}$ Am^{241}
	-	U	-	-	-	-	-	U^{235}
	-	I	I^{131} (for general food, included in Cs groups)	I^{131}	I^{131}	I	I^{131}	$I^{129,131}$
	-	-	Sr^{90}	-	Sr^{90}	Sr	Sr^{90}	Sr^{90}
	-	-	Ru^{106}	-	Ru^{106}	(included in all other nuclides)	Ru^{106}	Ru^{106}
	-	-	Ru^{103}	-	Ru^{103}		Ru^{103}	Ru^{103}
	-	-	Sr^{89}	-	Sr^{89}	(included in Sr)	-	Sr^{89}
	$Cs^{134,137}$ (including the contribution of other nuclides)	Cs	$Cs^{134,137}$	Cs^{137}	$Cs^{134,137}$	All other nuclides of half-life >10days	$Cs^{134,137}$	$Cs^{134,137}$, S^{35}, Co^{60}, Ce^{144}, Ir^{192}
	-	-	-	-		-	-	H^3, C^{14}, Tc^{99}
No. of group	1 (assessment of results: same as Codex)	4 (assessment of results: same as Codex)	4(assessment of results: same as Codex)	2(assessment of results: same as Codex)	1 (All nuclides are assessed collectively)	4(assessment of results: same as Codex)	5(assessment of results: same as Codex)	4 (Sum of activity of nuclides in each group is assessed)
Food group	Drinking water	Drinking water	Water	Water	Drinking water	Liquid food	All components of diet	-
	Milk	Milk, Dairy prod.	Milk	Milk	Milk	Dairy prod.		(included in groups below)
	Infant foods	Other foods	Infant food	General food	Other food and beverages	Baby food		Infant food
	General foods		General food			Other food*		General food
No. of group	4	3	2	2	3	4+1*	1	2

*Specific limits for “Minor foods” are set in the Commission Regulation (EURATOM) No. 944/89

5.2.2.3. Analysis of the calculation for deriving the values of limits

Table 14 compares the calculations to derive values of limits for food control. To obtain the Codex Guideline Levels, a value of a level specific for each radionuclide in each food group (i.e., infant food and general food) was calculated with consideration of two age groups (i.e., infants and adults) and intake for the duration of one year. The obtained value was rounded off to the values of 1, 10, 100, 1000 and 10000. As seen in Table 14, all countries except Australia set more than two age groups for calculations to derive the values for limits; therefore, they needed to select the minimum value obtained from calculations for all age groups in order to set the limits of radionuclides in food consumed by all generations. As to the duration of the intake of radionuclides, some countries use 2 months as intake duration for short-life radionuclides. Additionally, as shown in Table 15, which summarizes the values of limits, countries except Australia rounded the values obtained from calculations in a different way from the Codex. The way to round up the obtained values should be chosen carefully in order to reflect the uncertainty on the assumptions underlying the calculated values[303] and in order to reduce the difference in the values of limits.

In the calculation to obtain the Codex Guideline Levels, the following formula was used:

$$GL = \frac{IED}{M(A) \times IPF \times e_{ing}(A)}$$

where *GL* is the guideline level (Bq/kg); *IED* is the intervention exemption level of dose (mSv/year) which is same as reference dose, *M(A)* is the age-dependent mass of food consumed per year (kg/year); *IPF* is the import to production factor (dimensionless) which can be recognized as the ratio of contaminated food; and e_{ing} *(A)* is the age-dependent ingestion dose coefficient (mSv/Bq). All countries have the factors described above in their formulas to calculate the values of the limits, but a few countries introduced additional factors in their formulas. The author considers that the basic concept and components (factors) of the equation deriving the Codex GLs are shared with national limits; however, it must be noted that the selection of the value for each factor varies among the Codex and countries. The Codex Guideline Levels allow a country to select different values of the of *IPF* (i.e. the ratio of contaminated food), but do not mention selecting different values for other factors including the reference dose, mass of food and ingestion dose coefficient. The author of this study considers that it is reasonable for national governments to choose their own food consumption data in order to reflect their food habits. In the event that a country has national food consumption data for

[303] In 2012, the Article 31 Group of Experts recommended that, in the event of future calculation of MPLs, the MPLs be rounded to just one significant digit in order to reflect the uncertainty on the assumptions underlying the calculated values. (Article 31 Group of Experts, 2012)

several age groups[304], the country can use the ICRP dose coefficient values exact for each age group in the calculation.

On the other hand, the difference in citing scientific basis from ICRP and IAEA publications (i.e. intervention level, dose coefficient) between the Codex GLs and national limits should be reviewed. The Codex GLs directly introduce the latest ICRP/IAEA recommendations for intervention levels and dose coefficient into the calculations. On the other hand, many countries have not revised their limits for a long time; therefore, the old/superseded publications from ICRP have remained as the scientific basis of their limits. In addition, Canada selected the original value, 3 mSv in total, as the intervention level.

In ICRP and IAEA publications, it is clear that 1 mSv/year is recommended as the reference level specific for foods in existing exposure situations (after the emergency exposure situations); on the contrary, the reference level specific for foods in the emergency exposure situation is not clear (refer to Table 9 and 10). The Codex GLs and Japanese standards are based on the reference dose of 1 mSv, while the other limits are mostly based on 5 mSv[305]. The recommended reference level (for total exposure route) in the emergency exposure situation is the band of 20-100 mSv; therefore, the use of 5 mSv as intervention level in calculation of limits can be acceptable in emergency exposure situations. However, the interpretation of 5 mSv should be reviewed based on the latest ICRP/IAEA publications if a country wants to keep the use of 5 mSv, or, the intervention level should be changed to 1 mSv if a country considers that the limits cover not only the emergency exposure situations but also the existing exposure situations.

The selection of the value for each factor in the calculation varies greatly between the Codex and countries; therefore, the different choices of intervention level are not the only factor affecting the calculated value. However, the intervention level should be chosen carefully because it directly shows the level of protection set by national governments.

[304] Codex uses the food consumption data for only two age groups (infant and adult).

[305] Following the Fukushima Daiichi NPP accident, these countries assessed the need for food control based on the reference level of 1 mSv, not 5 mSv or 3 mSv.

Table 14: Analysis of the calculations for deriving the values of limits

Country	**Japan**		**Australia**		**Canada**	**EU[306]**	**US**[306]	**Codex**
Name of limits:	**Standards**	**OILs**	**GALs**	**OILs**	**ALs**	**MPLs**	**DILs**	**GLs**
Basic idea for calculation								
Population group[a]	10 groups	3 groups	2 groups	2 groups	6 groups	3 groups	6 groups	2 groups
Intake duration	a year	a year	a year	a year	a year/ 2months	a year	a year/ 2months	a year
Factors in formula								
Intervention level[b] in duration	Food:1 mSv – [dose from drinking water] Water: 0.1 mSv	Iodine:50mSv× 2/3 (organ) Others:5 mSv	Iodine: 50 mSv (organ) Others: 5 mSv		1 mSv for each food groups (i.e., 3 mSv in total)	5 mSv (additional exposure dose: not to exceed 1 mSv)	50 mSv (organ) or 5 mSv	1 mSv
Ingestion dose coefficient	Based on ICRP No. 72 with amendments	ICRP No.72 (1995)	Based on the values provided in the previous Codex GLs		ICRP No. 72 (1995)	(information not available)	ICRP No. 56 (1990)	ICRP No. 72 (1995)
Ratio of contaminated food	0.5 (1 for Milk, Infant food, Water)	0.5	1	1	0.2 (1 for Milk, Water)	0.1	0.3 (1 for I^{131} in infant diets)	0.1
Mass of food in duration	Based on national survey, average	Based on national survey, average	550 kg	550 kg	Based on national survey, average	Based on EU survey, with range	Based on national survey, average	Adult: 550 kg Infant: 200 kg
Other factors		Number of food group, Ratio of a nuclide to a nuclide group; Decay		Ratio of a radionuclide to others		Correction factor to allow for additivity of food within "other foods"		

a. When the number of population groups is more than 2 (two groups consist of infants and adults), a calculation was made for each population group to derive the value of the limit for each food category and radionuclide, and then the minimum value was chosen and rounded to set the limit.

b. Reference dose of 1 mSv is consistent with the ICRP No. 111 (2009), 109 (2007), 103 (2007) and 82 (1999) and the latest IAEA BSS (2011), while 5 mSv and 50 mSv (organ) are consistent with ICRP No. 40 (1984) and 26 (1977).

[306] Commission of the European Communities, 1991; European Commission, 1998; FDA, 1998

5.2.2.4. Analysis of values of limits

Table 15 summarizes the values of limits for radioactive Iodine, Cesium and alpha emitter nuclides in Milk, Infant food and General food.

It should be noted that the Japanese standards clearly differs from the other limits in terms of the targeted radionuclides (Cesium only) and values of radioactive Cesium concentration (lowest values). This is because the Japanese standards aim to deal with the long-term, existing exposure situation after the Fukushima accident (i.e. the emergency exposure situation is out of the scope). The values of Japanese standards differ from those of the Codex GLs by a factor of 10-20.

In Table 15, the factor of difference in values between national limits and the Codex level for each radionuclide and each food group is shown in a square bracket. By focusing the attention on food groups, the factor of difference in limits for infant food is lower (1-2.5, excluding Japanese standards) than that for milk (1-10, excluding Japanese standards) and general food (1-20, excluding Japanese standards). When looking at the radionuclides, the factor of difference in limits of Cesium (1-5, excluding Japanese standards) is lower than that of alpha-emitters (1-10) and that of Iodine (1-20). In particular, the national limits of radioiodine in general foods are very different from the Codex GLs. By comparing countries, it is evident that the values of the US DILs are closest to the Codex GLs (the factor of difference in limits is 1.2-5). It should be noted that the DILs of the US were derived by the calculation with the use of an intervention level of 5 mSv, dose coefficient based on ICRP No. 56, and ratio of the contamination food of 0.3, which are different from those of the Codex GLs, and do not categorize food into groups. In other words, having close value of limits does not mean having similar concepts in setting limits.

In international trade, generally the difference between the national standards and the Codex standards may cause trade barriers. Milk is unlikely to be traded internationally due to its perishability, and radioactive Iodine I-131 has a short physical life-time (i.e. it is easy to decay); therefore, the differences in limits for milk or radioactive iodine are unlikely to pose problem in trade at international level. On the contrary, some commodities categorized as general food can be exported/imported in large amounts, and radioactive Cesium has a long life-time and is relatively easy to measure. It should be recognized that the differences in limits for general food or Cesium might lead to trade barriers and affect the food supply at international level when a radiation emergency has occurred in a big exporter country. (The factor of difference in values between national limits and Codex is from 1 to 10. Japan is not a big food exporter, so the Fukushima accident has not posed large problems in international trading.)

Table 15: Analysis of values of limits for radioactive Iodine, Cesium and alpha emitters

Countries, / Food, Limits / Radionuclides		**Japan**		**Australia**		**Canada**	**EU**	**US**	**Codex**
		Standards	**OILs**	**GALs**	**OILs**	**ALs**	**MPLs**	**DILs**	**GLs**
Milk	I	-	300 [3]	100[b] [1]	100 [1]	100 [1]	500 [5]	170[d] [1.7]	(100)[af]
	Cs	50 [20]	200 [5]	1000[c] [1]	300 [3.3]	300 [3.3]	1000 [1]	1200 [1.2]	(1000)[ag]
	α-emitter	-	1 [10]	1 [10]	-	1 [10]	20 [2]	2 [5]	(10)
Infant food	I	-	(2000)[a]	100[b] [1]	(1000)[ad]	(1000)[a]	150 [1.5]	170[d] [1.7]	100[f]
	Cs	50 [20]	(500)[a]	1000[c] [1]	(200)[ae]	(1000)[a]	400 [2.5]	1200 [1.2]	1000[g]
	α-emitter	-	(10)[a]	1 [1]	-	(10)[a]	1 [1]	2 [2]	1
General food	I	-	2000 [20]	1000[c] [10]	1000 [10]	1000 [10]	2000 [20]	170[d] [1.7]	100[f]
	Cs	100 [10]	500 [2]	1000[c] [1]	200 [5]	1000 [1]	1250 [1.3]	1200 [1.2]	1000[g]
	α-emitter	-	10 [1]	10 [1]	-	10 [1]	80 [8]	2 [5]	10

(unit: Bq/kg)

* The number in a square bracket shows the factor of difference in values between national limits and the Codex level for the same radionuclide and food group.

a. No specific OIL for this food group exists, so OILs for general food are assumed to be applied.

b. This radionuclide group includes Sr-90.

c. This radionuclide group includes Sr-89, Ru-103 and Ru-106.

d. I-131 only.

e. Cs-137 only.

f. This radionuclide group includesSr-90, Ru-106 and U-235.

g. This radionuclide group includes S-35, Co-60, Sr-89, Ru-103, Ce-144 and Ir-192.

How do differences in calculations result in differences in values?

As described above, the values of limits for food control vary among the Codex and countries, and in particular the difference in values of limits for radiocesium in general food might lead to trade barriers at the international level. Table 16 shows how differences in calculations result in difference in values of limits for cesium in general food.[307] From this table, it seems that the selection of intervention level and the ratio of contaminated food have significant impacts (by a factor of 5 at maximum) on the calculated value in general. Also, it should be mentioned that the calculated value by Canada is 741 Bq/kg, which is almost half of the calculated value by the Codex; however, the Canadian AL and the Codex GL have the same value in the end. If the countries follow the same path as the Codex to round calculated values, there will be a chance to reduce the difference in the values of limits from the Codex GLs. It seems difficult to harmonize the values completely, but at least the efforts for harmonization in calculation (i.e., selection of factors, rounding the calculated results) should be made.

[307] Only Japanese standards, Canadian ALs, the US DILs and Codex GLs are shown in Table 16 due to the availability of information on the Internet (Radiation Council, 2012b; Health Canada,2000; FDA, 1998; FAO, 2011).

Table 16: Comparison of the calculations and values of limits for radiocesium-137 in general foods

	Japan	**Canada**	**US**	**Codex**
	Standard	**AL**	**DIL**	**GL**
Population group resulting in the minimum calculated value	13-18 year-old (male) (among 10 groups including infant)	12-19 year-old (among 5 groups)	Adult (among 6 groups including infant)	Adult
Intake duration	1 year	1 year	1 year	1 year
Food groups	-Drinking water -Milk -Infant food -General foods	-Drinking water -Milk -Other food and beverages	-All components of diet	-Infant food -General food
Denominator in equation				
Intervention level in duration	0.881 mSv/year ([1mSv]-[dose from drinking water])	1 mSv/year for this food category	5 mSv/year for this food category	1 mSv/year for this food category
Numerator in equation				
Ingestion dose coefficient	1.53-3.06*10^{-5} mSv/Bq (Use dose coefficient for each small food group (taking into account the contribution from other nuclides))	1.3*10^{-5} mSv/Bq	1.3*10^{-5} mSv/Bq	1.3*10^{-5} mSv/Bq
Ratio of contaminated food	0.5	0.2	0.3	0.1
Mass of food	749 kg/year in total (Use mass of each small food group)	519 kg/year	943 kg/year	550 kg/year
Result				
Calculated value	129 Bq/kg	741 Bq/kg	1360 Bq/kg	1399 Bq/kg
Value used as limits (after being rounded)	100 Bq/kg	1000 Bq/kg	1200 Bq/kg (taking into account calculated value of Cs-134: 930)	1000 Bq/kg

Only Japanese standards, Canadian ALs, the US DILs and Codex GLs are shown in this table due to the availability of information on the Internet (Radiation Council, 2012b; Health Canada,2000; FDA, 1998; FAO, 2011).

5.2.2.5. Analysis of the legal status and application of limits

The present study compares the national limits for food control to each other in view of following aspects: (1) the legal status of the limits, (2) the legal interpretation of food exceeding the national limits, and (3) applications of the limits following the Fukushima Daiichi NPP accident in 2011 (Table 17).

Only the Japanese standards and the MPLs of the EU are provided in documents categorized as laws (e.g., Ministerial Ordinances in Japan, Council Regulation in the EU). It should be noted that this Council Regulation[308] of the EU laid down only the procedure for determining MPLs, in other words, a new Regulation should be issued in order to apply MPLs for countermeasures following an emergency. In this respect, MPLs in these Council Regulations are kinds of pre-established guideline levels to prepare for the future accidents. Other limits shown in Table 17 are provided in documents issued as Guides, Recommendations or Guidelines[309] which were not published as laws; therefore, the limits provided by them cannot be called regulations. With regard to the flexibility of changing the limits, the national limits except the Japanese standards are allowed to be changed in implementing countermeasures in the presence of scientific and/or social reasons.

Based on the documents providing limits and the experiences after the Fukushima Daiichi NPP accident, the legal interpretation of the food exceeding each limit in order to conduct food control is summarized in Table 17. The food containing radionuclide amounts above the Japanese standards and the EU MPLs is interpreted as the non-compliant food based on a Japanese food law and a newly established EU Regulation; while the food exceeding the other limits is dealt with as the food containing harmful substances, etc. to be regulated by the food law of each country. On this point, the Guides, Recommendations and Guidelines listed in Table 17 can give interpretations on the food containing harmful substances, the food posing a risk, or adulterated food which is noted in national food laws.

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[308] Council Regulation (EURATOM) No. 3954/87

[309] The purposes of documents shown in Table 17 are as follows:

- The Guide in Japan: to determine the technical issues which can support the decision making and the implementation of countermeasures by relevant bodies in nuclear emergencies
- The Recommendations in Australia: to provide guidance on fundamental principles for radiation protection, which are written in an explanatory and non-regulatory style
- The Guideline in Canada: to guide emergency response organizations on decisions concerning food controls
- The Guide in US: to provide a convenient and organized system for statements of FDA compliance policy, which are intended for internal guidance

Following the Fukushima Daiichi NPP accident, the Canadian ALs, the US DILs and the Japanese Indices (established in 1998, the previous version of the Japanese OILs) were applied for the control of contaminated food. The EU introduced the pre-established MPLs in the Council Regulation (EURATOM) No. 3954/87 into the Commission Implementing Regulation regarding the import control at first, but later, the Japanese limits (e.g., the provisional regulation values and the new standards) were adopted as limits applied for food from Japan by the subsequent Implementing Regulations. Council regulations governing the Chernobyl accident are still valid with the different limits (e.g. 600 Bq/kg for food products, 370 Bq/kg for milk and milk products).[310] Australia used the Codex Guideline Levels for the border control of Japanese food, instead of the GALs and OILs written in the Recommendations.[311] All limits except Japanese standards in Table 17 can be changed into different values for taking actions. The author considers that countries set limits as guidelines which are able to assure the flexibility in selecting values of limits following the accident based on the situation in each event and based on the optimization principle. On the contrary, the Japanese new standards cover all domestic and imported food and have less flexibility for use.

[310] Council Regulation (EC) No 733/2008; Council Regulation (EC) No 1048/2009

[311] The reasoning of this decision by the Australian government is not provided in available documents.

Table 17: Analysis of legal status and application of limits

Country	**Japan**		**Australia**		**Canada**	**EU**	**US**	**Codex**
Name of limits	**Standards**	**OILs**	**GALs**	**OILs**	**ALs**	**MPLs**	**DILs**	**GLs**
Document providing limits:	Ministerial Ordinances(laws)	Guide	Recommendations		Guidelines	Council Regulation (law)	Compliance Policy Guides	General Standard
Limits = national/regional regulation?	Yes	No	No		No	No (MPLs need to be adopted in a new Regulation)	No	
Flexibility of limits (based on documents or the experience after Fukushima)	No	Values can be changed in implementation	Values can be changed in implementation		Values can be changed in implementation	Different values can be selected in a new Regulation	FDA may not use these values for actions	A country can adopt different values for internal use within its territory
Legal interpretation on food exceeding the national limits (based on documents or experiences after Fukushima)	Non-compliant food (Food Sanitation Act)	Food containing harmful substances (need to be adopted as provisional regulation values) (Food Sanitation Act)	Food posing a risk (Import Food Control Act); Unsafe food (under State/Territory laws)*		Food containing harmful substances (Food and Drugs Act)	Non-compliant food (a new Regulation)	Adulterated food containing deleterious substances (US Code Title 21)	
Application of limits after Fukushima	Applied (2012.4-) under Food Sanitation Act and Act on Nucl. Emergency Preparedness	(Indices (1998) which is the previous ver. of OILs) Adopted as provisional regulation values; Applied (-2012.3) under Food Sanitation Act and Act on Nucl. Emer. Preparedness	Not applied (AU used the Codex GL for import control from the beginning)		Applied under Food and Drugs Act	Adopted in an Implem. Regulation; Later, JP limits were adopted in Implem. Regulations; Implem. Regulations concerning Chernobyl are still valid	Applied under United States Code Title 21	Directly used in AU and NZ

*This is just an assumption because no document explaining this issue was found, and no action was taken by States/Territories after the Fukushima accident.

6. Discussion

CAC states that the Codex guideline levels (GLs) for radionuclides in food are intended to be applied for food to be traded internationally.[312] IAEA under the UN requires member countries to consider the guideline levels for radionuclides in food traded internationally following an emergency as the Codex GLs.[313] However, in fact, countries set their national limits which are different from the Codex GLs, and mostly they applied their own limits for imported food control after the Fukushima Daiichi NPP accident in 2011. Therefore, exporters should comply with the limits set by the importing countries instead of the Codex GLs. Even though there have been no serious trade conflicts at international level after the Fukushima accident (this is because Japan is not a big food exporting country), the differences in national limits might cause problems in the international trade and the food supply in the event that a big food exporting country suffer from a nuclear accident and sets limits higher than those of importing countries, and that two or more than two areas suffered from different nuclear accidents exist at the same time. The author considers that promoting harmonization of limits for radioactive contamination in food and ensuring the flexibility of limits are important to avoid possible problems in the international trade.

How can the harmonization of limits be carried out?

The SPS Agreement of WTO states that the Members shall base their sanitary measures on international standards, guidelines or recommendations, where they exist, and names the Codex as the relevant international organization. From this point and also the following practical reasons, the Codex GLs should be recognized as the foundation for harmonizing national limits of radionuclides in food: (1) the main components (factors)[314] of the equation deriving the Codex GLs are shared with existing national limits; and (2) the Codex GLs are consistent with the latest ICRP and IAEA publications.

It would be difficult to harmonize the national limits completely. Firstly, the Codex GLs allow national governments to adopt different values for internal use in order to set limits suitable for the situation in each country.[315] Secondly, the existing national limits,

[312] The GSCTFF of Codex

[313] IAEA BSS 2011

[314] Intervention level, mass of food, dose coefficient, and ratio of contaminated food.

[315] FAO, 2011

which are set as a part of radiation protection planning, have different scopes, for instance, intended nuclear accidents and intended exposure situations. Lastly, the SPS Agreement also states that Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification.[316] However, the efforts for harmonization of the methods deriving national limits can be made with the use of the Codex GLs as the foundation. The following efforts may give a chance to reduce the difference in values between national limits and the Codex GLs.

- The rounding of calculated values can be reviewed by national governments. CAC rounded the calculated values to just one significant digit. This way of rounding will cover the uncertainty for assumptions in calculations.[317]

- Like the Codex GLs, the intervention level and the dose coefficients used for national limits should be consistent with the latest ICRP and IAEA recommendations. The previous Codex GLs (1989) assumed the annual intervention level as 5 mSv based on the old/superseded ICRP publications which had not introduced the situation-based approach.[318] After the revision in 2006, the current Codex GLs adopted 1 mSv per year which has been consistent with the latest ICRP and IAEA publications recommending (1) 1 mSv/year as the reference level specific for foods in existing exposure situations,[319] (2) the band of 20-100 mSv/year as the reference level (for total exposure route) in emergency exposure situations, and (3) the band of 1-20 mSv/year as the reference level (for total exposure route) in existing exposure situations. The countries shown in this study have been keeping 5 mSv as the intervention level for the calculation of limits for food control based on the old/superseded ICRP publications. The use of 5 mSv can be acceptable in emergency exposure situations in consideration of the band of 20-100 mSv/year, and the current national limits including Japanese OILs worked well to keep the annual radiation exposure via food under 1 mSv after the Fukushima Daiichi NPP accident (therefore stricter limits are not desired). However,

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316 Article 3 (3)

317 Article 31 Group of the Experts, 2012

318 ICRP publication 103 (2007) introduced the situation-based approach to characterize possible situations where radiation exposure may occur as planned, emergency and existing exposure situations.

319 Reference level specific for foods in the emergency exposure situations is not determined.

the intervention level of 5 mSv should be changed to 1 mSv if a country considers that limits are able to cover not only the emergency exposure situations but also the existing exposure situations,[320] or the interpretation of 5 mSv should be reviewed by using the latest ICRP and IAEA recommendations if a country wants to keep 5 mSv. It should be clarified by national governments for which exposure situations their limits can apply.

- The Codex GLs allow a country to select different values of the ratio of contaminated food, but it should be selected carefully by national governments because of its large impact on the final calculated value. Selecting different values for mass of food is not mentioned in the GSCTFF, but the author considers it reasonable that national governments calculate limits by using their own food consumption data for several population groups in order to set more precise limits.

- It is reasonable that selection/grouping of radionuclides and grouping of food differ between countries in order to make national limits suit to situation in each country. The difference of radionuclides might be confusing but is not likely to result in trade conflict in practice because (1) countries selected prioritized radionuclides from those listed in the Codex GLs; (2) importing countries are expected to decide which nuclide(s) to measure for food control based on the information provided by the affected country; (3) it is unlikely that several types of radionuclides in one sample are measured at the same time; and (4) long-term trade conflicts may be caused by only the difference of limits for radionuclides which are easy to measure and having a long half-life (e.g. Cesium). The difference of food is also unlikely to result in trade problems because the amount of "Milk" and "Infant food" traded internationally is estimated to be much less than that of food categorized as "General food". In addition, the difference in food/radionuclide grouping is ethically accepted because such differences do not directly affect the difference in level of protection (refer to Section 5.2.2.2). For these reasons, the harmonization on radionuclides and food is not an urgent issue.

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[320] When the Codex GLs was revised in 2006, mostly the value of GLs were not changed because CAC introduced the ratio of contaminated food (0.1) when they changed the intervention level from 5 mSv to 1 mSv. If the countries changes the intervention level to 1 mSv, it is recommended to reconsider the ratio of contaminated food carefully because these factors in calculation have a big impact on the final calculated values.

It should be noted that the difference in values of limits for radiocesium in General food is most likely to cause a trade conflict; therefore, the national governments should pay attention especially on them in the opportunity to revise their limits.

At the meeting of the 7th Codex Committee on Contaminants in Foods (CCCF), IAEA informed attendees that an Inter-Agency Working Group including FAO and WHO would work towards publishing a Technical Document in 2014 providing a full explanation of various existing national and international limits of radionuclides in foods. To facilitate the harmonization, the author of this study expects that the Technical Document will also provide the guidance (1) explaining how to review national limits with the use of the Codex GLs as the foundation and (2) describing the interpretation of the intervention level for food in emergency exposure situations.

Why is it important to ensure the flexibility of limits?

This study revealed that the countries have the limits as guidelines which can assure the flexibility in selecting values of limits based on the situations in each event. Such flexibility is considered to be convenient to avoid the trading conflict in certain circumstances. For instance, if a big food exporting country suffers from a nuclear accident and sets limits higher than those of an importing country, this importing country may consider the impact of its strict limits on the food supply and the need to select different values as limits. In the event that two or more than two areas suffered from different nuclear accidents exist at the same time, there might be differences among such areas in distribution of radionuclides concentrations in food, major radionuclides contributing contamination, exposure situations, economic and societal conditions, etc. Based on the optimization principle which involves keeping exposure dose as low as reasonably achievable, such a situation is likely to result in different limits between affected areas. Then, how can the third countries importing food from those affected areas deal with this situation? For example, the EU currently adopts different limits for the food affected by the Fukushima Daiichi NPP accident (i.e., the Japanese limits have been introduced into the Commission Implementing Regulation) and the food affected by the Chernobyl accident.

The SPS Agreement states that Members shall ensure that their sanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members.[321]

[321] Article 2 (3)

As to general contaminants in food, each national standard should apply for all domestic and imported food equally based on the SPS Agreement. With regard to the radioactive contamination in food, however, the EU currently adopts different limits for the food affected by the Fukushima Daiichi NPP accident and the food affected by the Chernobyl accident, by introducing the limits set in the affected areas. The author considers that radioactive contamination of food has unique characteristics. Firstly, the radioactive contamination in food occurs following a nuclear accident only, in a limited area. Second, the impact of the accident on food (e.g. type of radionuclides, distribution of radionuclides concentrations, size of affected area) should differ case by case; moreover, radionuclides in the environment decay as time passes. When taking into account these characteristics, the author does not recognize the EU's countermeasures as the discrimination written in the SPS Agreement because nuclear accidents cannot cause the identical or similar conditions prevailing in member countries. The EU's approach, which applies different limits for different accidents by introducing the limits set in the affected areas, seems not in breach of the SPS Agreement, not to hamper the export from the affected areas, and consistent with the optimization principle of radiation protection.

The EU's approach might be an extreme example; however, the author can recommends countries to set national limits as guidelines which can assure the flexibility in selecting values of limits in order to make it possible to deal with any situations regarding radioactive contamination of food by various possible countermeasures. The Inter-Agency Working Group is expected to explain the difference of flexibility between the limits as regulations and the limits as guidelines/recommendations in the Technical Document to be published in 2014.

How can organizations work towards better harmonization of limits and implementation of food control?

In general, national organizations are recommended to introduce the scientific basis and principles established by international organizations (e.g. UNSCEAR, ICRP, IAEA and the Codex) into national standards and guidelines. With regard to control on radioactive contaminated food, ICRP and IAEA have issued recommendations presenting the reference doses and dose coefficients which have been used in the calculation of limits for food control, but also principles about the emergency preparedness and response to be implemented by national authorities. ICRP states that an emergency response plan should provide "triggers" for initiating protective actions (including food control) in the

early phase and that there may be a need to modify the planned protective actions depending on the characteristics of the emergency exposure situations that occurs.[322] Following the transition from emergency to existing emergency situations, national authorities are recommended to assess the dose distribution with radiation monitoring, compare all dose with the reference level and investigate the main exposure pathways in order to decide whether to continue/modify their protective actions or not. Appropriate implementation of the optimization principle and communication with stakeholders are required for the management of contaminated food, and contamination criteria in food may be reduced step by step to take the progressive improvement of the situation into account[323].

From the point of view of food safety, Codex states that MLs should be set as low as reasonably achievable (ALARA) necessary to protect the consumer and be set at a level which is (slightly) higher than the normal range of variation in levels in food that is produced with current adequate technological methods.[324] The Codex Working Principles say that risk management should be based on risk assessment and take into account the economic consequences and the feasibility of risk management options. Throughout the risk analysis, the effective communication and consultation with all interested parties should be ensured.[325].

When setting the pre-calculated limits and adopting/modifying the limits after an accident occurs, national governments should take into account these principles provided by international organizations in order to promote harmonization of national limits. The present study revealed that not only the organizations related to general food safety issues but also the radiation protection organizations are involved in the control on radioactively contaminated food in the countries shown in this study. The author considers that the involvement of two types of organizations is preferable for countries to facilitate the introduction of principles provided by all key international organizations. National organizations in each country divide tasks regarding the limits for food control;[326] however, the task division about the assessment of exposure via all routes

[322] ICRP, 2007. Same contents are stated by IAEA (2011b).

[323] ICRP, 2009

[324] The GSCTFF of Codex.

[325] CAC, 2007

[326] For instance, radiation protection bodies set limits as guidelines for food control, while food safety bodies set limits as regulations if necessary and implement those limits.

and via food ingestion following an accident is not clear in some countries. The author recommends that the regular communication between two types of bodies (i.e. radiation protection bodies and food safety bodies) is essential to clarify the task division on exposure assessment following an accident and to share their principles and knowledge about radiation protection and food safety. Such communication is expected to promote consistency with principles provided by international organizations in setting the pre-calculated limits and adopting/enforcing/modifying the limits after an accident occurs, and to result in harmonization of national limits themselves.

After the Fukushima Daiichi NPP accident, the organizations responsible for setting limits as regulations and implementing food control in Japan and the EU (i.e. MHLW of Japan, and DG SANCO and DG ENER in the EU) consulted with experts in radiation protection. In both Japan and the EU, the revised limits were brought down from the original ones (Japan set new standards for existing exposure situations, and the EU introduced the Japanese new standards into the Implementing Regulations). The experts in radiation protection in Japan and the EU gave opinions as follows:[327]

- Lower limits were not necessary from the point of view of radiation protection.
  - *Japan:* It is unlikely that the establishment of new standards would be the measure to largely enhance the effect of radiation protection because the exposure dose from foods is already far below the 1 mSv/year. The Council agrees with the introduction of 1 mSv as a reference level, but the values of the food standards are set on the safe side in view of radiological protection. Low radiation levels might make it difficult to keep the necessary measurement accuracy and the number of samples.
  - *EU:* The small amount of food imported from Japan in to the EU does not necessitate, from the point of view of radiation protection, lower levels than those pre-established in Regulation 3954/87. Public and political understanding is that any level is a borderline between safe and unsafe food. This, together with the fact that Japan is committed to not exporting food above the levels applied in Japan, are good grounds to continue checking compliance with this commitment at the same levels. The continued need for such controls, or any other measures where applicable, should be assessed on the basis of the optimization principle.

[327] Radiation Council in Japan, 2012; Group of the Experts of Article 31, 2011

- Stakeholders should be involved with in the decision making process.
  - *Japan:* The opinions from stakeholders should be taken into account to the maximum in the establishment and implementation of the standards for foods, with consideration of ICRP recommendations.
  - *EU:* In order to prepare for the event of a future accident affecting the European territory, the Experts recommend that national authorities, together with the European Commission, explore approaches based on stakeholder involvement in the decision making process.

These opinions from radiation protection experts seem as if the experts could not be satisfied with the proposal from the national organizations (i.e. MHLW, DG SANCO and DG ENER) responsible for setting limits as regulations and implementing food control. This might be due to the differences between the Codex ALARA principle written in the GSCTFF and the optimization principle defined by ICRP 2007 Recommendations. Codex states that maximum levels should be set as low as reasonably achievable and be set at a level which is (slightly) higher than the normal range of variation in levels in food that is produced with current adequate technological methods. Based on this principle, the food safety authorities are likely to focus on the distribution of radionuclides concentrations in food and the non-compliance rates. Also, the food safety authorities may watch carefully the changes of concentration distribution and non-compliance rates due to the application of adequate technical methods and the decay of radionuclides, when modifying the limits. On the contrary, ICRP says that the exposure dose should be as low as reasonably achievable; therefore, the experts of radiation protection are likely to look at the change of exposure dose distribution. Moreover, the ideal stakeholder involvement might differ between food safety issues and radiation protection issues. It would be helpful to have a discussion about interpretation and application of the Codex ALARA principle and optimization between food safety authorities and radiation protection authorities at national and international level, with stakeholders. Such discussion may facilitate unified principles for setting, implementing and modifying limits used for food control, resulting in harmonization of national limits.

7. Conclusions and Recommendations

This study performed a comparative analysis of the organizations related to control on radioactive contaminated food, and on the limits of radionuclide concentrations used for food control in order to find the way to harmonize the existing limits. This is based on a systematic review on the legal and policy documents and secondary literatures about the radiation protection/food safety organizations at national and international levels, regulatory frameworks regarding radioactive contamination in food, and countermeasures against the Fukushima Daiichi NPP accident in four countries (Japan, Australia, Canada and the US), one region (the EU) and the Codex. The radiological protection framework regarding food control at international level and the Codex guideline levels (GLs) for radionuclides in food were used as the baselines, while the Codex Working Principle for Risk Analysis and the ICRP and IAEA publications were used as the criteria for comparison.

The present study revealed that two types of organizations are involved in risk assessment and risk management related to the control of radioactive contaminated foods: organizations responsible for radiation protection and organizations responsible for general food safety issues. In the radiation protection framework at international level, UNSCEAR has performed a part of risk assessment before an accident happens, and a full of risk assessment following a nuclear/radiation accident. JECFA has not performed one yet. As risk management bodies, ICRP provides policy recommendations, which include essential factors used for setting limits (i.e. reference levels and dose coefficient) and the emergency preparedness/response based on the scientific findings of UNSCEAR, while IAEA issues standards based on ICRP publications and recommends Member countries to consider the guideline levels for radionuclides in food traded internationally as the Codex GLs, which were established by CAC based on the ICRP and IAEA recommendations. At national level, governments have not performed risk assessment in preparation for a future accident (i.e. they directly use the UNSCEAR's findings), but the exposure assessment has been carried out by the food safety authority or the radiation protection authority in a few countries after the Fukushima accident. The task division about the assessment of exposure via all routes and via food ingestion following an accident is still unclear in some countries. Mostly, limits as guidelines to be used for food control have been made by radiation protection bodies, while setting limits as regulations and implementing limits as guidelines or regulations are the responsibilities of food safety bodies. The author recommends that the regular

communication between two types of bodies (i.e. radiation protection bodies and food safety bodies) is essential to clarify the task division on exposure assessment following an accident and to share their principles provided by key international organizations. Especially, it would be helpful to have a discussion about interpretation and application of the Codex ALARA principle and ICRP optimization principle between two types of bodies with stakeholders. These activities are expected to promote consistency with principles provided by key international organizations in setting/implementing the limits, and to result in harmonization of national limits themselves.

Based on the comparative analysis of the limits of radionuclide concentrations used for food control, it was revealed that national limits are not harmonized with the Codex GLs, but the basic concept of calculation deriving the Codex GLs was shared with the national limits. In other words, the components of the equation deriving the Codex GLs, namely the intervention level, dose coefficient, mass of food and ratio of contaminated food, are included in the equations deriving the national limits of five countries/regions shown in this study. The Codex GLs are appropriate as the foundation for harmonizing the limits for radionuclides in food because of its basic concept shared with existing national limits and its consistency with the latest ICRP and IAEA recommendations. By comparison between national limits and the Codex GLs, it is clear that grouping of radionuclides and food, the selection of the values for each component of equations, the rounding of calculated values, and the values of limits are not harmonized. It would be difficult to harmonize the national limits completely because the Codex GLs allow national governments to adopt different values for internal use in order to set limits suitable for the situation in each country and because the existing national limits have different scopes. However, the efforts for harmonization of the methods deriving national limits can be made with the use of the Codex GLs as the foundation in order to reduce the difference in values between national limits and the Codex GLs. In particular, the rounding of calculated values should be harmonized, and the intervention level and dose coefficient should be adopted from the latest ICRP and IAEA publications. In addition, the ratio of contaminated food should be selected carefully by national governments because of its large impact on the final calculated values. To facilitate the harmonization of the intervention level used for calculation of the limits for food control, it is recommended that ICRP and IAEA clarify their interpretation of the intervention level for food in emergency exposure situations.

When looking at the legal status of the national limits and the countermeasures after the Fukushima Daiichi NPP accident, it was found by this study that the most countries have the limits as guidelines/recommendations, which can give the interpretation of the "unsafe" food written in the national food laws. The limits as guidelines/recommendations are convenient to avoid the trading conflict because they can assure the flexibility in selecting values of limits following the accident based on the situations in each event. Also, the limits as guidelines can cover not only food on the market but also food that is not on the market in order to prepare for any possible countermeasures.

Even though there have been no serious trade conflicts at international level after the Fukushima accident (this is because Japan is not a big food exporting country), the differences in national limits might cause problems in the international trade and food supply. In order to reduce the possible problems in the event of radiation emergency, the following recommendations for harmonization of limits can be provided.

Recommendations on the harmonization of limits for radionuclides in food

<For international organizations>

- When the Inter-Agency Working Group[328] drafts the Technical Document in 2014 explaining existing national and international limits, it is recommended that the Working Group (1) provides the guidance explaining how to review national limits with the use of the Codex guideline levels as the foundation, (2) clarifies the interpretation on the intervention level for food in emergency exposure situations, and (3) describes the difference between the limits as regulations and the limits as guidelines/recommendations. The following should be included in the guidance:
  - The rounding of calculated values should follow the Codex method that rounds the calculated values to just one significant digit.
  - The intervention level and the dose coefficients should be consistent with the latest ICRP and IAEA recommendations. If a country considers that the limits cover not only the emergency exposure situations but also the existing exposure situations, the intervention level should be changed to 1 mSv. If a country wants to keep 5 mSv which originated from the old/superseded ICRP and IAEA recommendations, the interpretation on 5 mSv should be reviewed based on the latest ICRP and IAEA recommendations.

[328] Organized by IAEA, including FAO and WHO.

- The values for the ratio of contaminated food should be selected carefully by national governments because of their large impact on the final calculated results.
- It is reasonable for national governments to use their own food consumption data for calculation. Also, the harmonization of grouping radionuclides and food is not an urgent issue.
- It is recommended that national limits are established as guidelines because they can assure the flexibility in selecting values of limits and in application of them. Limits as guidelines are convenient to avoid the trade conflicts and to deal with any possible situations.

· It is recommended that a discussion on the interpretation and the implementation of the Codex ALARA principle and the ICRP optimization principle is held in the Working Group.

<For countries>

· It is recommended that countries revise their national limits based on the guidance in the Technical Document described above.

· The regular communication between radiation protection bodies and food safety bodies is essential to clarify the task division on exposure assessment following an accident and to share their principles provided by key international organizations. It is recommended that a discussion on the interpretation and the implementation of the Codex ALARA principle and the ICRP optimization principle is held between food safety authorities and radiation protection authorities, with stakeholders.

Recommendations on the future plan of this study

· After the publication of the Technical Document by the Inter-Agency Working Group in 2014, contents of the Technical Document and reactions by Member countries should be monitored.

· In this study, the guidelines and recommendations are recognized as the documents providing the interpretation of unsafe food as detailed in food laws. Also, the application of limits as guidelines is considered to be more flexible than limits as regulations. It would be interesting to explore “What are guidelines?” and “How useful are guidelines?” in food safety.

· Limits for radionuclides in feed and fertilizers can be new research topics.

8. Terminology used in radiation protection

Action levels

The activity concentration above which the protective actions are generally recommended (HC, 2000).

Alpha emitter

The radionuclide which decays by emitting alpha particles which are identical to a Helium nucleus having two protons and two neutrons (EPA, 2012).

Dose coefficient

The committed effective dose of radiation resulting from intake of unit activity of a specified radionuclide in a specified chemical form. “Dose per unit intake factor” is a synonym (IAEA, 2007).

Dose limit

The value of the effective dose (the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body) or the equivalent dose (the dose in a tissue or organ) to individuals from controlled practices that shall not be exceeded (ICRP, 2007).

Emergency exposure situations

Unexpected situations such as those that may occur during the operation of a planned situation, or from a malicious act, requiring urgent attention (ICRP 2007).

Existing exposure situations

Situations that already exist when a decision on control has to be taken, such as those caused by natural background radiation. Situations of exposure due to residual radioactive material that derives from past practices that was not subject to regulatory control or that remains after an emergency exposure situation (ICRP 2007).

External exposure

The exposure which may occur from radionuclides released from installations and which are present in the air, soil, or water (ICRP 2007).

Generic action levels (GALs)

The optimized levels of activity concentration in a foodstuff at which control should be placed on foodstuffs, water, and crops in emergency situations (ARPANSA, 2004).

Internal exposure

The exposure which can occur by inhalation of airborne radionuclides from a cloud, inhalation of re-suspended radionuclides, and by ingestion of contaminated food or water (ICRP 2007).

Intervention level

The level of avertable dose at which a specific protective action is taken in an emergency or a situation of chronic exposure (IAEA, 2007).

Ionizing radiation

Radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionized (WHO, 2013).

Operational intervention level

A type of action level that is used immediately and directly to determine the appropriate protective actions on the basis of an environmental measurement (IAEA, 2007).

Physical half-life

The time that it takes for half the radionuclides to disintegrate or decay (IAEA, 2013b).

Principle of radiological protection

Namely justification, optimization and application of dose limits (ICRP 2007):

- Justification: Any decision that alters the radiation exposure situation should do more good than harm.
- Optimization: The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal factors.
- Application of dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by ICRP.

Projected dose

The dose that would be expected to be incurred if a specified countermeasure or set of countermeasures or, in particular, no countermeasures were to be taken (IAEA, 2007).

Radiological protection

The protection of people from the effects of exposure to ionizing radiation, and the means for achieving this (IAEA, 2007).

Reference level

The level of dose or risk above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimization of protection should be implemented (ICRP 2007).

Sv (Sievert)

The special name for the SI unit of equivalent dose (a measure of the absorbed dose delivered by radiation to a tissue or organ designed to reflect the amount of harm caused) and effective dose (the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body). The unit is joules per kilogram (J kg-1) (ICRP, 2007; IAEA, 2007).

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