RADIOACTIVE CONTAMINATION ON FOODS AND FEEDS

A COMPARATIVE STUDY ON FOOD SAFETY-RELATED RADIOLOGICAL PROTECTION SYSTEM IN THE EU, THE USA, INDONESIA, AND AT INTERNATIONAL LEVEL



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STUDENT REPORT

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ABSTRACT

The EU, the USA, Indonesia, and CAC have their own established food safety-related radiological protection system. Each system has its own characteristics as a result of different approach in 3 (three) judgment components (Science, Experience, and Value). This student report analyses food safety-related radiological protection systems by comparing the EU, the USA, Indonesia, and International system. The author used Codex Working Principles for Risk Analysis Application for Food Safety for Governments as the baseline to compare the standards and related stakeholders and ICRP Recommendation as the baselines to compare the standards particularly on the guideline level within the standard.

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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

LIST OF ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
BAPETEN	BadanPengawasTenagaNuklir (Nuclear Energy Regulatory Agency)
Bq	Becquerel
CAC	Codex Alimetarius Commission
CPG	Compliance Policy Guide
DG-Energy	Directorate-General for Energy
DG-Research	Directorate-General for Research
DG-SANCO	Directorate-General for Health and Consumers
DILs	Derived Intervention Levels
EC	European Commission
EURATOM	European Atomic Energy Community
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization
FDA	United States-Food and Drug Administration
FSANZ	Food Standards Australia New Zealand
FSIS	Food Safety Inspection Services
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
INA	Indonesia
INES	International Nuclear and Radiation Event Scale
IRPA	International Radiological protection Association
MHLW	Japan Ministry of Health, Labour, and Welfare
MPL	Maximum Permitted Levels
mSv	Millisievert
NADFC	National Agency for Drug and Food Control
NRC	Nuclear Regulatory Commission
PAG	Protective Action Guidance
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
USA	United States of America
WHO	World Health Organization

1. INTRODUCTION

1.1 Problem statement

Chernobyl nuclear power plant accident which is also known as "Chernobyl accident" in April 1986 was still the worst ever recorded nuclear power plant's accident which was significantly influenced all aspects of life especially for the population lived near to the nuclear power plant (Russia, Ukraine, and Belarus). Radiation[1] exposures were not only experienced by power plant workers but also by thousands of people surrounding the contaminated areas. Furthermore, people throughout Europe were also having a huge impact following the Chernobyl accident particularly relating with their health status. A report from UNSCEAR that published in 2008 on Chernobyl accident describes that several thousand people were having external exposures[2] and internal exposures[3] that caused early and late health effects. External exposures which came from accumulated radionuclide on land and internal exposures which came from radionuclide contaminated food ingestions are the main radiation exposure on human. The most important radionuclide contaminants are the group of long half-life radionuclide such as ^{134}Cs & ^{137}Cs, ^{231}Pu, ^{241}Am, and ^{90}Sr.

At the time of the Chernobyl accident, there were still no comprehensive radioactive contamination on foods and feeds[4]standards nor structured authorities to deal with harmful radiological effect on food safety-related issues as an integrated radiological protection system (CAC, 2006). The Chernobyl accident became a starting point for the establishment of an integrated food safety-related radiological protection system. At that time, principles used to establish the system were driven mainly by considering factors of high levels of exposures and predominantly central decisions resulting from a nuclear accident or any other radiological emergency. However, current research development on the radioactive health effect on humans has brought new advanced approaches into the radiological protection system to be more science- based, transparent, systematic, and dynamic. All researches are aimed to improve living quality of the people and to reduce radiation exposures as low as reasonably achievable (ALARA) given the situation by considering socio-economic and environment factors (ICRP, 2009).

[1]The radiation that will be the focus of this study is ionizing radiation. According to WHO, "Ionizing radiation is 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).

[2]External exposure is defined as radioactive exposure which come from released of radionuclide from installations and which exist in the air, soil, and water (ICRP, 2007).

[3] Internal exposure is defined as radioactive exposure which come from inhalation of airborne radionuclide in a cloud, inhalation of re-suspended radionuclide and by ingestion of contaminated food or water (ICRP, 2007).

[4] According to article 1(2) of the Council Regulation No 3954/87: For the purposes of this Regulation, 'foodstuffs' means products which are intended for human consumption either immediately or after processing and 'feedingstuffs' means products which are intended only for animal nutrition.

Recent nuclear power plant accident in Fukushima, Japan in March 2011 has opened our eyes once more to the precedence of better public health's protective system from the radiation contamination on foods and feeds. The protective measures shall be supported by applicable standards, reliable related stakeholders, and proper radiological protection application that shall be governed by using 3 elements of risk analysis (risk assessment, risk management, and risk communication). In the aftermath of the accident, food originating or consigning from Japan are receiving high concern from many importing countries particularly on the extent of radioactive contamination levels. Protective measures such as food ban and radiation contamination on foods and feeds standard establishment becomes the only option to minimize radiation exposures.

A wide range of standards and responsible food safety-radiological protection stakeholders' schemes are established by different countries. However, there is still no deep study on how far is the difference of the standards and the responsible stakeholders between the EU, the USA, Indonesia, and at International level.

1.2 Study Objectives

The aims of this study are:

1. To assess the differences between the EU, the USA, Indonesia and at International level radiological protection system in the perspective of Codex Working Principles for Risk Analysis Application for Food Safety for Governments and ICRP Recommendation;
2. To assess how far is the application of Codex Working Principles for Risk Analysis Application for Food Safety for Governments and ICRP Recommendation in the EU, the USA, Indonesia, and at International level and also to assess the probability harmonization;
3. To describe protective measures performed by the radiological protection related stakeholders in the EU, the USA and Indonesia in the aftermath of Fukushima accident.

1.3 Research Questions

The following questions will serve as guidelines throughout this study,

1. Who are authorities on food safety-related radiological protection in the EU, the USA, Indonesia, and at International level?
2. How different is the radioactive contamination standards on foods and feeds between the EU, the USA, Indonesia, and at International level by using Codex Working Principles for Risk Analysis Application for Food Safety for Governments and ICRP Recommendation?
3. What are protective measures taken by the EU, the USA, and Indonesia in the aftermath of the Fukushima accident?

1.4 Methodology

This study is performed using legal data, policy documents, measures and sampling data from NADFC, literatures, and also requesting more detailed information by email to related stakeholders such as EU, US-FDA, Codex Committee of Food Contaminant, NADFC, etc. The literature review is carried out from books, journals, publications particularly from ICRP, IAEA regulations, and other sources such as web pages and newspapers etc.

1.5 Report Framework

The remaining of the chapters of this report is organized as follows:

- Chapter 2 describes food safety-related radiological protection authorities;
- Chapter 3 describes the regulatory frameworks;
- Chapter 4 describes the comparative analysis;
- Chapter 5 describes the protective measures taken by the EU, the USA, and Indonesia following the Fukushima accident;
- Chapter 6 presents the discussion; and
- Chapter 7 presents the conclusion and recommendations.

2. FOOD SAFETY-RELATED RADIOLOGICAL PROTECTION AUTHORITIES

2.1 Authorities in the EU

There are two main organizations related to radiological protection in Europe, first is the European Atomic Energy Community (EAEC/EURATOM) and second is the Article 31 Group of Expert.

2.1.1 European Atomic Energy Community (EURATOM)

Treaties of Rome which signed in Rome in March 1957 consist of EC treaty establishing the European Economic Community (EEC) and the EURATOM Treaty establishing the European Atomic Energy Community (EAEC/EURATOM). Since the establishment, EURATOM Treaty is never experienced any significant revision. The Treaty is still unchanged even after the Treaty of Lisbon was signed in 13 December 2007. The member states and the institutions of EURATOM are the same as the EU. The establishment of the Treaty of European Union has only caused less effect on the EURATOM Treaty; thus, it changes only for budgeting but did not affect the essence of the Treaty. Figure 1 describes the unique relationship between TEU/TFEU and EURATOM Treaty which shows that the EURATOM treaty stands alone as an independent treaty which possesses its own legal personality.

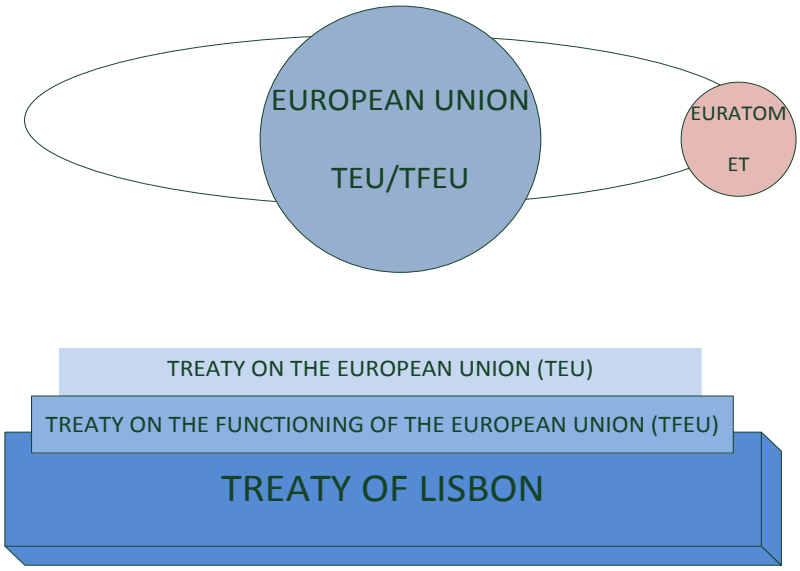


Figure 1 The structure of the European Union, adapted from http://globalgovernanceprogramme.eui.eu

According to Article 1 of the EURATOM Treaty, the establishment of the European Atomic Energy Community is to obtain an important role in the efforts to create and develop the Europe's nuclear industries for the sake of all Member State's development of atomic energy and to ensure the continuity of energy supply. At the same time, the Treaty ensures the protection of the citizens

by the establishment of high and uniform safety standards and the utilization of nuclear energy only for the civil purposes and not for the military purposes[5].

According to Article 2 of the Treaty, the main tasks of the EURATOM are:

a. To promote research and ensure the dissemination of technical information;
b. To establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied;
c. To facilitate investment and ensure, particularly by encouraging ventures on the part of undertakings, the establishment of the basic installations necessary for the development of nuclear energy in the Community;
d. To ensure that all users in the Community receive a regular and equitable supply of ores and nuclear fuels;
e. To make certain, by appropriate supervision, that nuclear materials are not diverted to purposes other than those for which they are intended;
f. To exercise the right of ownership conferred upon it with respect to special fissile materials;
g. To ensure wide commercial outlets and access to the best technical facilities by the creation of a common market in specialized materials and equipment, by the free movement of capital for investment in the field of nuclear energy and by freedom of employment for specialists within the Community; and
h. To establish with other countries and international organizations such relations as will foster progress in the peaceful uses of nuclear energy[6].

As been described before, the unique characteristic of the EURATOM's institutions which uses the EU's institution; thus institutions consist of triangle structure: Parliament, Council, and Commission. Beside those 3 institutions, there are also Court of Justice of the European Union and The Court of Auditors. The functions of above institution can be described as follow:

a. The Council: decision making and coordinate national measures;
b. The Commission: guard the treaty implementation by the member states, legal initiative, own power of decision, recommendations or opinions.
c. Parliament: advisory (consultation) and supervisory power, may request proposal, handle petitions from citizens
d. Court of Justice: interpretation and application of Treaty and secondary law
e. Court of Auditors: control on budget

[5] http://europa.eu/legislation_summaries/institutional_affairs/treaties/treaties_EURATOM_en.htm
[6] EURATOM treaty

f. The Economic and Social Committee: advisory body[7]

Member states through the Council and Commission gained a very great authority concerning decision making process in all aspect of nuclear legislation and policies; in addition, a close relationship between nuclear energy and the military precedence in the past and also the practice of secrecy has created a burden in the implementation of the Treaty. Major efforts are needed to have a better in the management of nuclear policy in the EU using the principles of transparency and democracy; even though, the success story of the treaty implementation still localized in the field of creating basic safety standards and has not reach other main tasks.

Ever since the nuclear power plant catastrophic in Chernobyl, the potential risk hold by the utilization of nuclear as the backbone of energy supply in the Union is always attract the Citizen's attention; Moreover, the radiation hazards and the long term of impact of a nuclear accident has worsened the public perception. In order to flourish the transparency and democracy within the Treaty, the European Parliament will have to revise the Treaty; in other words, the revision's aim is to put the parliament in a position of co-decision makers together with the Council such as in the Treaty of European Union. Related with the establishment of uniform safety standards which further implemented in the form of Basic Safety Standards (BSS) as one of the EURATOM main tasks as described in Article 2(b) and clearly mentioned in the Article 30 of the Treaty, The Council through the mechanism in the Article 31 of the Treaty has published Council Directive (EURATOM) no 29/1996 of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation which currently undergo a recast based on the proposal COM (2011) 593 final of 29 September 2011 which is submitted by the Commission through the DG-Energy and DG-SANCO. Besides that through the same mechanism, the Council also published the supplementary legislation products related to radioactive contamination on foods and feeds such as, Council regulation (EURATOM) 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency, Council regulation (EURATOM) No 994/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency and Commission regulation (EURATOM) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency.

[7] http://globalgovernanceprogramme.eui.eu

2.1.2 Article 31 Group of Experts

The Article 31 Group of Experts is a group of public health expert that elected by the technical and scientific commission. The task of the Article 31 Group of Experts is attached to the Commission and shall have advisory status (European Commission, 2013). The Group's main task is to provide scientific advice and to analyze related information which later on is used as the main consideration on the establishment of radiological protection policies. Thus, the Article 31 Group of Experts shall also carry out the risk assessment for the food safety-related radiological protection system. In other words, EFSA does not have any authority to conduct risk assessment for that specific issue.

2.2 Authorities in the USA

The food safety-related radiological protection in the USA is carried out by NRC, FDA and EPA.

2.2.1 NRC

NRC is an independent regulatory commission created in 1974 which is aimed to ensure the safety of the radioactive materials utilization for the civilian benefits and in the same time stands up for the public protection from the radioactive exposures (Walker & Wellock, 2010). The organization was aimed to replace previous ineffective and incompetent nuclear regulatory organization which is known as the Atomic Energy Commission and focus their work on the general aspect of the nuclear energy. The US-NRC's regulatory function consists of 5 elements:

a. Regulations and guidance (including guidance and standards development);
b. Operational experience;
c. Oversight (including inspection and enforcement);
d. Licensing, decommissioning, and certification; and
e. Support for decisions.

At the present time, the US-NRC puts a lot of attention on the safety of nuclear power plants, particularly on all aspects of countermeasures of the emergency related accident and on the establishment of basic safety standards.

2.2.2 FDA

FDA is a scientific-regulatory federal agency within the US Department of Health and Human Service. The agency is responsible for the safety of the locally produced and imported foods, cosmetics, drugs, biologics, medical devices, and radioactive-emitting products. Related to food's scope, FDA is authorized for all domestic and imported foods except meats, poultry, and processed eggs product which is the responsibility of USDA-FSIS. The agency is managing at least 4

Acts: Federal Food, Drug, and Cosmetic Act (FFDCA), the Public Health Service Act, the Egg Products Inspection Act. The function of FDA to achieve the national public health goals are expressed in 6 offices within the organization:

a. Office of the Commissioner
b. Office of Foods
c. Office of Global Regulatory Operations and Policy
d. Office of Medical Products and Tobacco
e. Office of Operations

The responsibility of FDA in the food safety-related radiological protection of the members of the public is carried out through the Office of foods. Thus, Centers for Food Safety and Applied Nutrition (CFSAN) within the Office of foods are responsible to provide international food standards and safety harmonization efforts[8].

2.2.3 EPA

The organization was established in 1970 due to increased concern on the quality of the environment (air, water, and soil). The missions of the organization are to ensure the human health and the environment by establishing the regulations, and to execute the enforcement of the regulations. The human health protection from the radiation hazard is done by two offices within the organization. First, the Office of Air and Radiation (OAR) which is focused on the establishment of the national programs, policies, and regulations to control the unnecessary exposure of radiation. Second, the Office of Radiation and Indoor Air (ORIA) which is focused on the implementation of the human protection from radiation risk by having cooperation with other federal, state, tribal, and non-governmental organizations. Moreover, the agency is also having roles in the radiation risk assessment and to issue the federal guidance for other federal agencies which is signed by the President. Besides that, the agency is also providing the technical issue related with the latest radiation dose and risk assessment scientific and technical information which help the harmonization of standard and risk assessment methodologies[9] in the USA. Related with food safety issues, the agency is responsible for the safety uses of pesticides and drinking water. Furthermore, due to the FDA-new Food Safety Modernization Act (FSMA), EPA, FDA, and FSIS through the inter-agency mechanism are establishing the priority issues concerning the environmental contamination including the radiation contamination on foods.

[8] Adapted from http://www.fda.gov
[9] Adapted from www.epa.gov

2.3 Authorities in Indonesia

There are 4 main food safety-related radiological protection organizations in Indonesia: Nuclear Energy Regulatory Agency (BAPETEN), Ministry of Health, Ministry of Agriculture, and National Agency of Drug and Food Control (NADFC).

2.3.1 BAPETEN

Based on the Nuclear Energy Act No 10 of 1997, the supervision function of nuclear energy utilization is carried out by the Nuclear Energy Regulatory Agency (BAPETEN).

BAPETEN as the supervisory agency has the main purpose to ensure the public and environmental safety especially on the area of nuclear energy usage. Its main tasks are described as follows:

a. Regulation management

BAPETEN is responsible to create safe use of the radioactive regulations including the basic safety standards in the form of maximum dosage levels.

b. Licensing

The usage of nuclear energy has to get permission from BAPETEN. Until 2005 BAPETEN has issued 3162 industrial activities, 2958 permits for medical activities and 3383 working licenses for radioactive protection officer.

c. Inspection and regulation enforcement

BAPETEN's officers have been doing inspection to all nuclear facilities to make sure the compliance of their measures related to the permission that has been given to them and to ensure that the radioactive exposures which come from their facility do not exceed the permitted maximum dose limit.

The functions of BAPETEN are described as follows:

a. Formulation of national policies in the field of supervision of the use of nuclear energy; preparation and creation of national plans and programs in the field of supervision of nuclear energy utilization;
b. The management and preparation of regulations and the review of the implementation of nuclear safety, radioactive safety, and security of nuclear materials;
c. Implementation of licensing and inspection of construction and operation of nuclear reactors, nuclear installations, nuclear materials facilities, and sources of radioactive as well as the development of nuclear preparedness; implementation of cooperation in the field of monitoring of the use of nuclear energy by government agencies or other organizations both inside and outside of the territory of Indonesia;

d. Implementation of surveillance and control of nuclear materials; implementation of guidance and information concerning the efforts to ensure the safety and health of the workers, the members of the public as well as environmental protection;
e. Implementation of the improvement of human resources development and quality in the BAPETEN; implementation of administrative guidance, control and supervision within BAPETEN environment;
f. Implementation of other tasks given by the President[10].

2.3.2 Ministry of Health -NADFC, Ministry of Agriculture, Ministry of Fisheries and Marine Affairs

According to Government Regulation No. 28 Year 2004 on Food safety, Quality, and Nutrition, there are four authorities dealing with food safety issue. First is the Ministry of Health. The Ministry acts as regulator for wide range national's health issues. The ministry regarded radiation contamination on food and feed as national food safety issue especially in the aftermath of Fukushima accident. Therefore, in 27 Mei 2011, the Ministry published Ministry of Health Decree No 1031/MENKES/PER/V/2011 laying down the maximum level of radioactive contaminant in foods. The decree acts as general standard that applied for all imported radiation contaminated food product.

Second, the NADFC that works under the Ministry of Health as food control authority. In the aftermath of the Fukushima accident, NADFC carries out sampling and monitoring imported food products from Japan especially processed food in all import entry points. Thus, NADFC takes the sample to BAPETEN to be analysed for the radiation contamination level. Both NADFC and BAPETEN use the Ministry of Health Decree No 1031/MENKES/PER/V/2011 as the standard to implement protective measures.

Third, the Ministry of Agriculture that carries out control on fresh food such as vegetables, fruits, and meats and also feeds control. The Ministry has representative offices in all import entry points. The office's main task is to ensure the safety of imported fresh food product before entering the market. In the aftermath of Fukushima accident, the Ministry of Agriculture has published Ministry of Agriculture Decree No 20/Permentan/OT.140/3/2011.

Finally, the Ministry of Fisheries and Marine Affairs that carries out food safety control on marine products. The Ministry has representative offices at all import entry point. In the aftermath of the Fukushima accident, the office carries out sampling and monitoring on radiation contaminated marine products from Japan.

[10] Adapted from http://www.bapeten.go.id/

2.4 Organizations at the International Level

In the international levels, the organizations which mainly involve in the radioactive protection issues are: UNSCEAR, ICRP, IAEA and IRPA.

2.4.1 UNSCEAR

As a response to the increasing concerns on the effect of radioactive contamination on human health and environment, the UN established the United Nations Scientific Committee on the Effect of Atomic Radiation (UNSCEAR) on 3 December 1955 based on resolution 913(X). For more than a half century, UNSCEAR regards as the worldwide leading body on the risk assessment of ionizing radiation[11] health effect. The publications from UNSCEAR uses by the other international bodies such as the International Atomic Energy Agency (IAEA), the International Labor Organization (ILO), the World Health Organization (WHO) and the International Commission on Radiological Protection (ICRP) to develop the radiological protective measures. The 2008 UNSCEAR's publication on the sources and effects of ionizing radiation is used by ICRP to establish its latest recommendation. Besides that, related to the recent Fukushima accident, UNSCEAR is carrying out the investigation and research on the effect of ionizing radiation on the members of public in the contaminated area.

As mentioned in resolution 913(X), the mandates of UNSCEAR are:

a. To receive and assemble in an appropriate and useful form the following radiological information furnished by States Members of the United Nations or members of the specialized agencies:

   (i) Reports on observed levels of ionizing radioactive and radioactivity in the environment;

   (ii) Reports on scientific observations and experiments relevant to the effects of ionizing radioactive[11] upon man and his environment already under way or later undertaken by national scientific bodies or by authorities of national Governments;

b. To recommend uniform standards with respect to procedures for sample collection and instrumentation, and radioactive counting procedures to be used in analyses of samples;

c. To compile and assemble in an integrated manner the various reports, referred to in sub-paragraph (a) (i) above, on observed radiological levels;

d. To review and collate national reports, referred to in sub-paragraph (a) (ii) above, evaluating each report to determine its usefulness for the purposes of the Committee;

e. To make yearly progress reports and to develop a summary of the reports received on radioactive levels and radioactive effects on man and his environment together with the

[11] Ionizing radiation defined 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, 2012).

evaluations provided for in sub-paragraph (d) above and indications of research projects which might require further study; and

f. To transmit from time to time, as it deems appropriate, the documents and evaluations referred to above to the Secretary-General for publication and dissemination to States Members of the United Nations or members of the specialized agencies.

2.4.2 ICRP

The increased attention on the detrimental effects of radiation which came from medical usage of X-Ray and Radium drove the establishment of International Congress of Radiology of the International X-Ray and Radium Protection Committee in 1928. Later on in 1950, the organization was renamed as International Commission on Radiological Protection (ICRP) (Wrixon, 2008). The organization has been continuously establishing, developing, and consolidating a radioactive protection system that used as the science-based principles of standards, guidelines, programs, and practice worldwide (ICRP, 2007). The ICRP has evolved as the leading body in the protection against the ionizing radiation. The main aim of ICRP's Recommendations is to contribute on an appropriate level of protection for people and the environment against the detrimental effects of radioactive exposures without unduly limiting the desirable human actions that may be associated with such exposures. The Recommendation provides dose coefficient (dose per unit exposures), dose limits, constraints, and reference levels that use in the establishment of radiological protection system. Until the present time, ICRP has published more than 118 publications in the area of radioactive protection in a practical and fundamental concept's recommendation on radioactive protection issues. The foundation of the system created by ICRP on the basis of the latest understanding on health effect of radioactive exposure on humans and the additional judgments which considers societal expectations, ethics, and gained experiences on the application of the system.

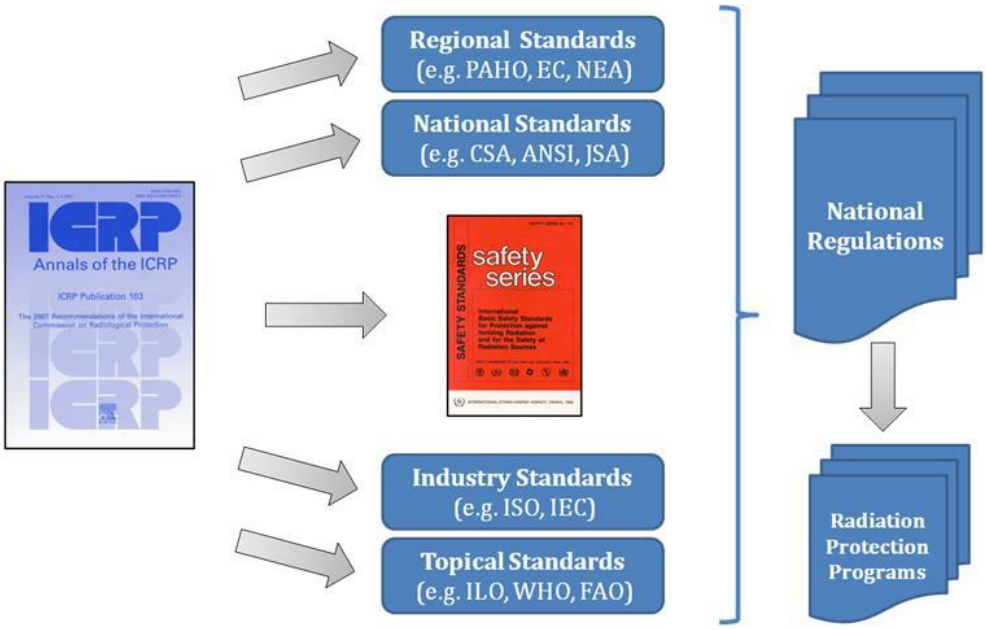


Figure 2 Impact of ICRP recommendation on standards of radioactive protection worldwide (ICRP, 2011).

Figure 2 describes the elaboration of the ICRP principles in the protection of the public health in the form of radioactive protection Regulations/Standards in many regulatory and advisory bodies such as IAEA and ILO and also most of the countries in the world. According to the Commission 1990 Recommendation and the latest 2007 Recommendation, the radiological protection system is always build based on 3 famous principles: Justification, Optimization, and limitation.

2.4.3 IAEA

IAEA was created in 1957. The establishment is inspired by US President Eisenhower's proposal to the General Assembly of the UN on 8 December 1953. The proposal led to the creation of IAEA statute which was unanimously approved by 81 nations in October 1956. Based on the IAEA statute, the main purpose of IAEA is to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world. It shall ensure that the assistances provided by it or at its request or under its supervision or control is not used in such a way on any military purposes. The functions of IAEA as mentioned in the same statute are:

a. To encourage and assist research on, and development and practical application of, atomic energy for peaceful uses throughout the world; and, if requested to do so, to act as an intermediary for the purposes of securing the performance of services or the supplying of materials, equipment, or facilities by one member of the Agency for another; and to perform any operation or service useful in research on, or development or practical application of, atomic energy for peaceful purposes;
b. To make provision, in accordance with this Statute, for materials, services, equipment, and facilities to meet the needs of research on, and development and practical application of,

atomic energy for peaceful purposes, including the production of electric power, with due consideration for the needs of the under-developed areas of the world;

c. To foster the exchange of scientific and technical information on peaceful uses of atomic energy;
d. To encourage the exchange of training of scientists and experts in the field of peaceful uses of atomic energy;
e. To establish and administer safeguards designed to ensure that special fissionable and other materials, services, equipment, facilities, and information made available by the Agency or at its request or under its supervision or control are not used in such a way as to further any military purpose; and to apply safeguards, at the request of the parties, to any bilateral or multilateral arrangement, or at the request of a State, to any of that State's activities in the field of atomic energy;
f. To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property (including such standards for labor conditions), and to provide for the application of these standards to its own operation as well as to the operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision; and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangements, or, at the request of a State, to any of that State's activities in the field of atomic energy; and
g. To acquire or establish any facilities, plant and equipment useful in carrying out its authorized functions, whenever the facilities, plant, and equipment otherwise available to it in the area concerned are inadequate or available only on terms it deems unsatisfactory[12].

IAEA is an independent organization; it has 3 pillars of work: Safety and Security; Science and Technology; and Safeguards and Verification. In terms of relation with the UN, IAEA reports annually to the UN General Assembly and when appropriate to the Security Council regarding non-compliance by States with their safeguards obligations as well as on matters relating to international peace and security. The main product of IAEA as the international nuclear regulatory bodies related with food safety is the 2011 International Basic safety standard (BSS) which is published in 12 September 2011.

[12]Adapted from: http://www.iaea.org/

2.4.4 Codex Alimentarius Commission/CAC (FAO & WHO)

The FAO conference in 1961 was the beginning era of the CAC as the single international body on the establishment of the Codex Alimetarius as the international reference point for food standards (Commission Codex Alimentarius, 2012). The establishment of the Codex Alimentarius involved all member countries' representatives in diverse FAO/WHO joint conferences. The aims of the Codex Alimentarius Commission are to establish internationally accepted food standards by endorsing all countries to participate in the process, to develop food standards harmonization by encouraging all countries to adopt the Codex Alimentarius as far as possible into their national food law and standards.

The radioactive contamination guideline is included in codex standards 193-1995: Codex General Standards for Contaminants and Toxins in Food and Feed which is updated recently in 2010. The establishment of the standards' recommendation proposal is carried out by the Codex Committee on Contaminants in Foods (CCCF) based on risk assessment from Joint FAO/WHO Expert Committee on Food Additives (JECFA)(Commission Codex Alimentarius, 2007). Later on, the proposal is submitted to CAC to be implemented into a risk management product such as guidelines or standards. Recent IAEA International Basic Safety Standards (BSS) of 2011 which applied the latest ICRP 2007 Recommendation is the main trigger for CAC to update the codex standards 193-1995 to be relevant with the latest IAEA International BSS.

2.4.5 IRPA

International Radioactive Protection Association (IRPA) is the international professional association on radioactive protection which has a membership of almost 17,000 individuals who are members of 47 national societies in 60 countries worldwide and strives to enhance the radioactive protection cultures and practices (Kase, 2012). Based on its vision, IRPA wants to be recognized by its members, stakeholders, and publics as the international voice of the radioactive protection profession worldwide.

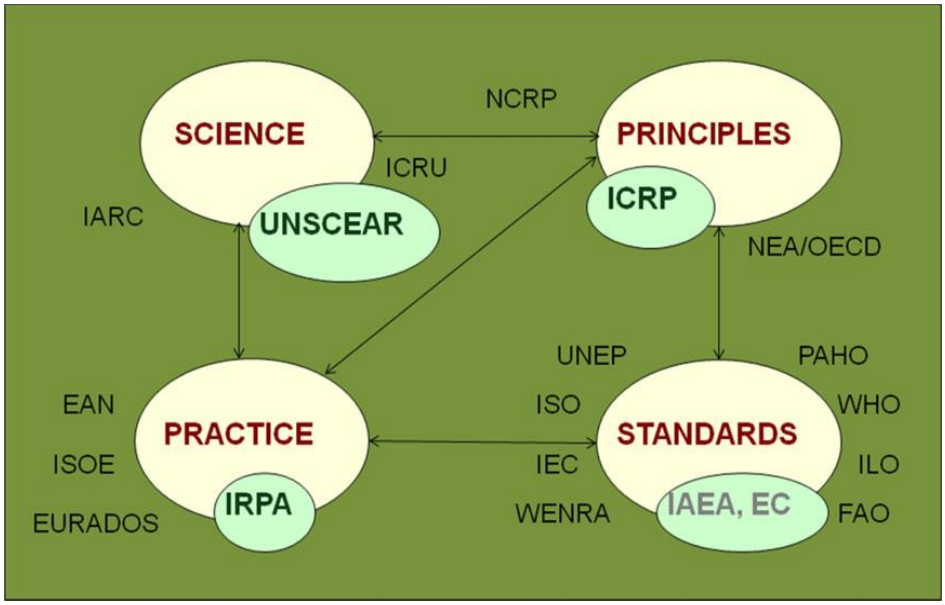


Figure 3 Four pillars of radiological protection stakeholder (www.irpa.net)

The objectives of IRPA are:

a. To encourage establishment of radioactive protection societies throughout the world as a means of achieving international cooperation;
b. To provide for and support international meetings for discussions of all aspects of radioactive protection;
c. To encourage international publications dedicated to radioactive protection;
d. To encourage research and educational opportunities in support of radioactive protection; and
e. To encourage and participate in the establishment and continuous review of universally acceptable radiation protection standards or recommendations through the international bodies concerned.

On the basis of point e, IRPA builds a very close connection with ICRP by positioning themself to participate in and facilitate the implementation of ICRP Recommendations. As for international cooperation, IRPA held the 13th International Congress of IRPA in Glasgow in 14-18 May 2012. The next congress will be held in Cape Town, South Africa in 2016. IRPA describes its perspective concerning the radioactive protection system (four pillars of radioactive protection) particularly in the terms of responsibility, function, and relationship with other regional and international bodies in Figure 3.

3. THE REGULATORY FRAMEWORK

3.1 The Framework of the EU Regulations

3.1.1 Current Regulations

According to Article 2(b) of the EURATOM Treaty, one of the main tasks of the EAEC is to establish uniform safety standards to protect the health of workers and the general public and ensure that the standards are applied. The universal safety standards are implemented in the form of Basic Safety Standards (BSS) which is clearly described in Article 30 of the EURATOM Treaty. The mechanism of the BSS establishment is explained further in the Article 31 and 32 of the EURATOM Treaty. The product of the treaty is the Council Directive (EURATOM) No 29/1996 of 13 May 1996 laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation[13] which is also known as the BSS Directive. The reference levels and ingestion dose coefficient in the Directive are implemented in the various radioactive contaminations on foodstuffs and feedingstuffs related regulations. The relationship of the BSS Directive and others supplementary regulations is described in Figure 4.

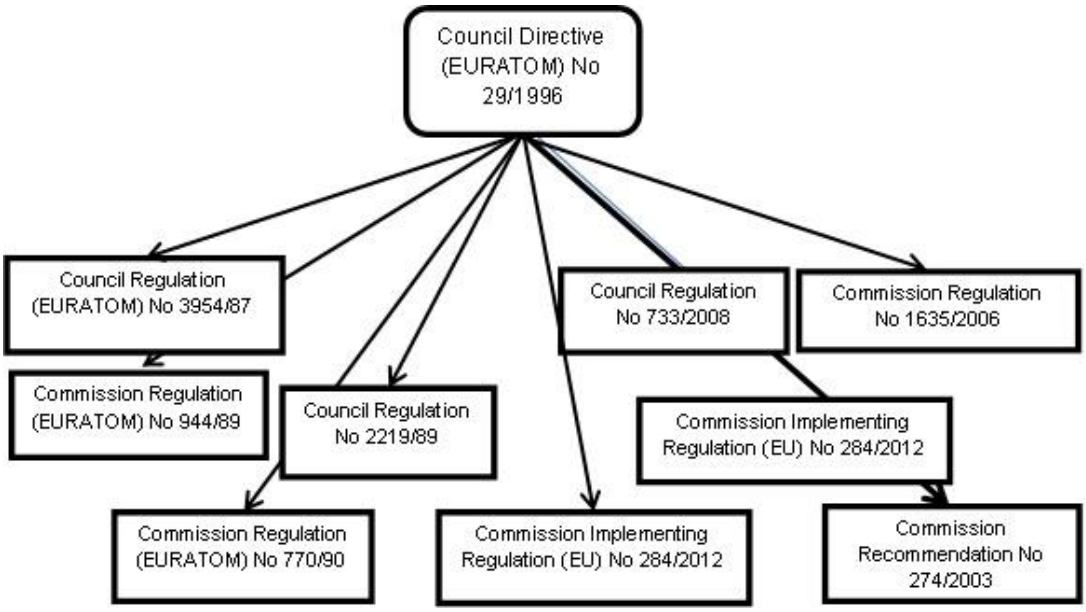


Figure 4 Regulations related with radiation contamination on foods and feeds

Moreover, the supplementary legislation to the BSS Directive particularly on maximum permitted level of radioactive contamination on foods and feeds, the legislative products are Council Regulation (EURATOM) No 3954/87 of 22 December 1987 which is amended by the Council Regulation (EURATOM) No 2218/89 of 18 July 1989 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedstuffs following a nuclear accident or any other

[13] OJ L-159 of 29/06/96 page 1

case of radiological emergency[14]. The regulation accompanied by three related regulations: first is Commission Regulation (EURATOM) No 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency[15], this regulation explains about the maximum permitted level of radioactive contamination for minor foodstuffs which are considered to have a maximum permitted level ten times higher than other foodstuffs category in the Council Regulation (EURATOM) No 3954/87. Second is the Commission Regulation (EURATOM) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency[16]. Finally is the Council Regulation No 2219/89 of 18 July 1989 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency[17].

Following the nuclear accident in Fukushima on 11 March 2011, the EU has issued Commission Implementing Regulation (EU) No 297/2011 of 25 March 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station[18] which is amended by the Commission Implementing regulation (EU) No 351/2011 of 11 April 2011[19]. Next is the Commission Implementing Regulation (EU) No 961/2011 of 27 September 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Regulation (EU) No 297/2011[20] and finally the Commission Implementing Regulation (EU) No 284/2012 of 29 March 2012 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Commission implementing regulation (EU) No 961/2011[21].

All above regulations are used in emergency exposure situations. As for the existing exposure situations, the regulations are Council Regulation No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (codified version); the Council Regulation (EC) No 1048/2009 extends its validity until 31 March 2020)[22]; the Council regulation No 1048/2009 of 23 October

[14] OJ L 371, 30.12.1987, p. 11; OJ L 211, 22.7.1989, p. 1–3
[15] OJ L 101, 13.4.1989, p. 17–18
[16] OJ L 83, 30.3.1990, p. 78–79
[17] OJ L 211, 22.7.1989, p. 4–5
[18] OJ L 80, 26.3.2011, p. 5–8
[19] OJ L 97, 12.4.2011, p. 20–23
[20] OJ L 252, 28.9.2011, p. 10–15
[21] OJ L 92, 30.3.2012, p. 16–23
[22] OJ L-201 of 30/07/2008, page 1

2009 amending Council Regulation (EC) No 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station[23]; the Commission Regulation No 1635/2006 of 6 November 2006 laying down detailed rules for the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station[24]; the Commission Regulation No 1609/2000/EC of 24 July 2000 establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station[25]; the Commission Recommendation No 274/2003 of 14 April 2003 on the protection and information of the public with regard to exposure resulting from the continued radioactive Cesium contamination on certain wild food products as a consequence of the accident at the Chernobyl nuclear power station[26].

3.1.2 Regulations History

Efforts to establish maximum permitted levels of radioactive contamination on foodstuffs and feedingstuffs regulations have been carried out by the EU since the Chernobyl accident which happened in 26 April 1986. In addition, increased public concern on the negative health effects of the radioactive exposures from contaminated foodstuffs and feedingstuffs became the trigger for the EU to publish Council Regulation (EURATOM) No 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingtuffs following a nuclear accident or any other case of radiological emergency[27], as amended by Council Regulation (EURATOM) No 2218/89[28]. The establishment of Council Regulation (EURATOM) No 3954/87 began with the information from IAEA Convention on Early Notification of Nuclear Accident of 26 September 1986 to the EC concerning abnormal levels of radioactivity in Chernobyl and maximum permitted levels have been established from the international scientific seminar on foodstuff intervention levels after a nuclear accident which was organized by the EC which held in Luxembourg on 27 to 30 April 1987[29]. The next step taken by the EC was to have a consultation with the Economic and

[23] OJ L-290 of 06/11/2009, page 4
[24] OJ L-306 of 07/11/2006 page 3
[25] OJ L-185 of 25/07/2000, page 27
[26] OJ L-99 of 17/04/2003 page 55, amended by corrigendum published in OJ L-109 of 01/05/2003 page 27
[27] OJ L 371, 30.12.87
[28] OJ L 211 , 22.07.89 p.1
[29] The Convention on Early Notification of a Nuclear Accident was adopted by the General Conference at its special session, 24-26 September 1986, and was opened for signature at Vienna on 26 September 1986 and at New York on 6 October 1986. It entered into force on 27 October 1986, i.e. thirty days after the date (26 September 1986) on which three States expressed their consent to be bound by the Convention, as required under Article 12 thereof (http://www.iaea.org/Publications/Documents/Infcircs/Others/infcirc335.shtml).

Social Committee. The response is the opinion of The Economic and Social Committee of 13 May 1987 on the draft proposal for a Council regulation laying down maximum permitted radioactivity levels for agricultural products and drinking water. Following these sequence, the EC submitted a proposal for the Council Regulation laying down maximum permitted levels for foodstuffs, feedingstuffs and drinking water in the case of abnormal levels of radioactivity or of a nuclear accident on 16 June 1987. The maximum level of radiation contamination on food which is listed within the regulation was produced from the consultation with the Article 31 group of experts. The next event was the opinion given by the Parliament on 16 December 1987. Finally the Council agreed a final draft of the regulation and published Council Regulation No 3954/87 laying down maximum permitted levels of radioactive contamination on foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency on 22 December 1987.

Currently Council Regulation No 3954/87 is in the process of codification[30] with other two supplementary regulations: Council Regulation (EURATOM) No 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency and the Council Regulation (EURATOM) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency. The new regulation will supersede all those three regulations. Recent nuclear accident in Fukushima, Japan on March 2011 has been an issue raised in the Article 31 group of experts meeting on 8-9 June 2011. The issue was about the validity of the maximum permitted levels listed in the Council Regulation No 3954/87 which came to the conclusion that the levels are still valid and there was no need to have a recalculation as long as the dose coefficient in the ICRP publication does not change.

Council Regulation No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power plant is set up by the council to counteract the radiation contaminated imported food. The regulation is a product of codification which has been through several amendments from its original regulation, Council Regulation (EEC) No 737/90 of 22 March 1990. It was the continuation of Council Regulation (EEC) No 3955/87 with the same title which expired on 31 March 1990. The Council regulation No 733/2008 expires on 31 March 2010; however the regulation was amended

[30] COM(2010)184 final

by Council Regulation (EC) No 1048/2009 of 23 October 2009, particularly on the Article 7 which extends the regulation until 31 March 2020. This extension was based on two main reasons[31]:

a. According to the recent scientific report the level of radioactive contaminant Cs-137 on particular foodstuffs originating from third countries is still above maximum permitted levels of the Council Regulation No 733/2008.
b. The radioactive contaminant Cs-137 following the Chernobyl accident still exists in the environment due to its long physical half-life of which is approximately 30 years.

3.2 The Framework of the USA's Regulations

3.2.1 Current Regulations

The new Food Safety Modernization Act (FSMA) which is signed by President Obama on 4 January 2011 has given revolutionary impacts related with the food safety framework and implementation in the USA. The new paradigm is more focusing on the prevention of risk and not reliance on the inspection and giving more power to FDA to ensure the prevention measures, for instance by providing the authority to order mandatory recall for incompliant food products. Moreover, in section 104 of FSMA, FDA shall issue the contaminant-specific and science-based guidance documents. In other words, the guidance has to be updated continuously based on the latest study or information.

The 1998 FDA Document which was established long before the FSMA entry into force brought significant changes to the 1986 FDA Document. The most distinguish one is the scope of the products regulated. The current Compliance Policy Guide (CPG) is included domestic foods in the interstates trade besides the imported foods. Moreover, the term "Derived Intervention Levels (DILs)" is used in the current CPG replacing "Level of Concerns (LOCs)" in the previous CPG. Based upon the current CPG, FDA published the latest import alert 99-33 on 25 July 2012 related with the Fukushima accident laying down the detention without physical examination of products from Japan due to radionuclide contamination.

3.2.2 Regulations History

In 1979, the USA suffered from a nuclear power plant accident which is known as the Three miles island accident however the magnitude and extent of radionuclide released to the environment was much less than the Chernobyl accident. Furthermore, the Three miles island accident did not cause any injuries or adverse health effect towards the surrounding population (US-NRC, 2012; World Nuclear Association, 2012b). The regulation related with the guidance levels of radioactive

[31] OJ L 290, 6.11.2009, p. 4–4

contamination in foods were not yet established at the time the Three miles island accident happened but it was established just after the Chernobyl accident. Following those accidents, FDA and FSIS created a task group to determine the guidance levels as the Levels of Concern (LOC) by FDA and Screening Levels by FSIS.

Furthermore, on June 1986 FDA released a recommendation which was known as 1986 FDA Document which is further implemented the guidance levels in the CPG sec. 560.750 Radionuclide in Imported Food; Levels of Concern (CPG 7119.14). The LOCs are derived from the Protective Action Guides (PAGs) in the 1982 FDA Document. Later on, the CPG replaced by FDA; Compliance Program entitled "Toxic Elements in Food and Food ware and Radionuclide in Food" in accordance to the 1998 FDA document entitled: Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies. The recommendation is still in force until the present time and has also been used by FDA to take protective measures in the aftermath of the Fukushima accident.

3.3 The Framework of Indonesia's Regulations

3.3.1 Current Regulations

There are two regulations related with basic safety standards in Indonesia. There are BAPETEN Chairman's Decree No 02/Ka-BAPETEN/V-99 on standard of radioactivity levels in the environment and BAPETEN Chairman's Decree No 01/Ka-BAPETEN/V-99 on the requirement for radiation safety. Furthermore, The Regulation on the maximum permitted level of radioactive on foods is managed by the Ministry of Health Decree No 1031/MENKES/PER/V/2011 on the maximum permitted levels of radioactive contamination on foodstuffs which is came from countries/areas which are experiencing a nuclear emergency situation. Besides that, there is a regulation that applies only for fresh products of animal and vegetable origins which are originated from Japan, the regulation is the Ministry of Agricultural Decree No 20/Permentan/OT.140/3/2011. Both regulations are in the level of the Central Government Regulation.

Food Act No 18 of 2012 acts as one of the Primary law for food safety in Indonesia. According to Article 47 point 2: "food safety is aimed to prevent the possibility of the biological, chemical or any other food contaminant which are injurious to human's health" and in the Article 90 point 1: "contaminated foods are prohibited to enter the market". Another primary law for food safety is Health Act No 36 of 2009 (state gazette of 2009 No 144 and additional state gazette No 3452) particularly Article 111 (6) about prohibition to put into the market and recall for incompliant foods and beverages. Under those two laws, there are two supplementary laws: Government

Regulation No 69 of 1999 on Food labelling and Advertising and second and Government Regulation No 28 of 2004 on food safety, quality, and nutrition.

3.3.2 Regulations History

Following the Chernobyl accident, Indonesia had also set a regulation on the maximum permitted level of radioactive contamination on foods through the Health Ministry Decree No 00474/B/JI/87 of 1987 on the obligation to accompany the suspected contaminated imported food with a health and radioactive certificate. The context of the regulation did not specify the imported foods from certain countries or any other radiological emergency suspected country. Later on, following the Fukushima accident, the Ministry of Health established Health Ministry Decree No 1031/MENKES/PER/V/2011 on the maximum permitted levels of the radioactive contamination on foods which is entered into force on 27 May 2011. The regulation replaced the Ministry of Health Decree No 00474/B/JI/87. The scope of the current regulation is more specific on the provision for countries which are suspected to have a nuclear emergency situation. Besides that, there is also another regulation specifically applied for certain foods (meats, seafood, fruits and vegetables) originating in Japan following the Fukushima accident. The regulation is the Ministry of Agriculture Decree No 20/Permentan/OT.140/3/2011 on the surveillance on animal origin and vegetables/fruits product originating in Japan toward the radioactive contamination levels.

3.4 The Framework of the International Regulations

3.4.1 Current Regulations

The current regulation in the international level that uses as guideline or model by many countries is the Codex Standard 193-1995; it has revised five times in 1997, 2006, 2008, 2009, and 2010. The standard regulates the contamination and toxic substance on foods and feeds, the guideline levels, and also the associated sampling plan.

3.4.2 Regulations History

At the international level following the Chernobyl accident, CAC through the Codex Committee on food Additive and Contaminant (CCFAC) set the guideline levels for radiation contamination on foods following a nuclear or any radiological emergency in the General Standard for Contaminants and Toxins in Food and Feed (Codex Standard 193-1995). The main purposes of the establishment of (Codex Stan 193-1995) are to avoid trade barriers between countries; while, maintaining high level of protection on human health related with radioactive contamination on foods and feeds. The EU, the USA, and Indonesia as members of FAO-WHO and WTO should have harmonized standards by adapting the ICRP Recommendations and Codex Stan 193-1995 as a model. However,

due to differences on standards interpretation, risk analysis implementations, socio-economic and environment factors, and the magnitude and extend of nuclear accidents, the guidance levels of the radioactive contamination on foods and feeds standards are different between countries. Despite the differences, the Chernobyl accident is the primary trigger for FAO, WHO, and IAEA interagency workgroup through the CAC to establish Codex standard on the contaminants of foods and feeds including the radioactive contaminant in order to have a global harmonization toward measures and emergency plans in 1989 (FAO, 2011). The standard is called the CODEX/GL 5-1989; it was originally a product of several joint meetings between WHO, FAO, IAEA with other organizations involving many experts to formulate the establishment of dose limits for radiation contaminants to be used by all member countries.

The standard was revised in 2006 at the 29th CAC's meeting in Geneva, Switzerland. The revision was done on the addition of new regulated radionuclides; the use of intervention exemption levels of 1 mSv per year and the use of Import to production factor (IPF) 0.1 (10%); and the application of 10 times higher guideline levels for spices or herbs and for all minor diet component (FAO, 2011).

4. THE COMPARATIVE ANALYSIS

The Codex Working Principles for Risk Analysis Application for Food Safety for Governments and the 2007 ICRP Recommendation are used as the baselines to analyze the disparities of food safety-related radiological protection systems in the EU, the USA, Indonesia, and at International level. The baselines are used as the meta-frameworks or frameworks of frameworks. In the other words, the international/regional/national legal system is expected to adopt those meta-frameworks in their food safety-related radiological protection system establishment. Codex Working Principles for Risk Analysis Application for Food Safety for Governments mainly focused on the application of risk analysis is used on the comparison of the food safety–related radiological protection systems and the ICRP Recommendations is used particularly on the comparison of guideline level establishment within the standard.

First, Codex Working Principles for Risk Analysis Application for Food Safety for Governments consists of 3 distinct but closely related components (risk assessment, risk management, and risk communication[32]). The components should be regarded as integral parts of the food safety system[33]. Furthermore, in practice, the risk assessment and the risk management should be completely separated in function to avoid conflicts of interest and also to ensure the scientific integrity of risk assessment[34]. The roles of risk assessors at international level are mainly carried out by UNSCEAR and ICRP. The products of risk assessment are reports or recommendations which are used by risk managers together with other factors such as socio-economic factors, environmental factors, and trade restriction factors to establish the protective measures. The aim of the protective measures establishment is to minimize radiation contamination on foods and feeds and to endorse a continuous effort on the best practice concept application (Schneider, Ollroge, Clauberg, & Schuhmacher-Wolz, 2007).

Second, 2007 ICRP Recommendation that established on exactly the same 3 principles of the radiological protection system in the previous 1990 ICRP Recommendation (the principles of

[32] Definition of Risk assessment, risk management, and risk communication according to Codex:
a) Risk assessment: A scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.
b) Risk management: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment 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.
c) 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. (WHO, 2006. Food Safety Risk Analysis: A guide for National Food Safety Authorities, p. 7)
[33] CODEX/GL 62-2007 laying down Working Principle for Risk Analysis for Food Safety for Application by Governments, point 4, p. 1.
[34] CODEX/GL 62-2007 laying down Working Principle for Risk Analysis for Food Safety for Application by Governments, point 11, p. 1.

Justification, Optimization, and Limitation)[35]. However, in 2007 ICRP Recommendation, the principles are applied using the situations-based approach which is completely different from the previous Recommendation which used the processes-based approach. The situations-based approach consists of 3 distinct situations: planned exposure situations, emergency exposure situations, and existing exposure situations. Planned exposure situations are defined as the situations where the dose accepted or the extent and the level of exposures can be predicted and the radiological protection can be done in advance. In contrast, Emergency exposure situations are defined as the situations where the extent and level of exposures cannot be predicted and the origin of the situations could be from planned exposure situations or any other radiation emergency situations and the action to overcome the situations has to be done immediately. The existing exposure situations are defined as the situations where the exposures already exist in the environment, including prolonged exposures after emergency exposure situations (Weiss, 2009). The emergency and existing exposure situations are the main exposure situations which contribute in the public exposures. On the other hand, the planned exposure situations are contributes in the worker exposures.

The principle of justification and optimization are applied for all exposure situations; however the principle of limitation is only applied for planned exposure situations (ICRP, 2007). Furthermore, the constraint of the optimization (reference levels) has to be led by the best practice concept to avoid an excessive scientific uncertainty. The reference levels in the emergency exposure situations are defined as the residual doses or committed doses of the public exposures in a certain periods of time in accordance with the magnitude and extent of the situations. The optimization measures should also cover a situation where the exposures exceed the reference levels (Weiss, 2009). In other words, the reference levels should be placed as the benchmarks in the radiological protection system. Beside those ICRP radiological protection principles, there are other important factors such as the societal and economic factors and the environmental factors which are also important to the radiological protection system establishment (Wrixon, 2008).

The food categorization system is also important to obtain a more plausible and integrated comparative study. The categorization system is the aggregation of various foods into groups in

[35] a. Justification means that the use of a new radioactive source has to consider by minimizing existing exposures or minimizing the risk of potential exposures so that the benefit of the new source is greater than the detrimental effect to the society (apply for all exposure situations);

b. Optimization means that the protection has to be done on the best margin of benefit than harm (apply for all exposure situations); and

c. Limitation consist of : Dose limit/constraint is only applicable for planned situation not in the emergency situation where the limit/constraint is determined by the regulatory authority and Reference level which is applicable for existing and emergency situations (ICRP Publication 103, 2007).

certain methods and parameters. Furthermore, the categorization systems used in the EU, the USA, Indonesia, and at International level are different since a single food categorization system cannot fulfill all requirements on the radiological protection system (Schneider et al., 2007).

4.1 The Radiological Protection Authorities

ICRP sees radiation exposures on humans as a network of events and situations (ICRP, 2007). Therefore, all stakeholders related with radiological protection should establish a system of protection which covers the sources of the radiation exposures, the pathway of the exposures from the sources to the environment, the transmission of the radiation from the environment to the human, and eventually the doses on human due to the exposures (ICRP, 2007). The protective measures can be carried out starting from the sources, at the point of the exposures pathway, or sometimes by modifying the characteristic or the location of the exposed humans. In other words, the ICRP radiological protection principles primarily apply on the "Source" intervention in the multistage radiation transmission. The most important intervention is the establishment of the reference levels which are used as benchmarks of the protection level.

IAEA General Safety Requirements part 1 identified that every government (member) has to establish a radiological protection system consists of related authorities and standards. The aims of the establishment of the authorities as the risk manager and/or risk assessor are to establish comprehensive standards, appropriate supervisions and reliable risk scientific evaluations. Besides that, an independent risk assessor is also important in order to have a reliable and integrated risk assessment. Codex Working Principles for Risk Analysis Application for Food Safety for Governments is used as the baseline to compare the radiological protection competent authorities.

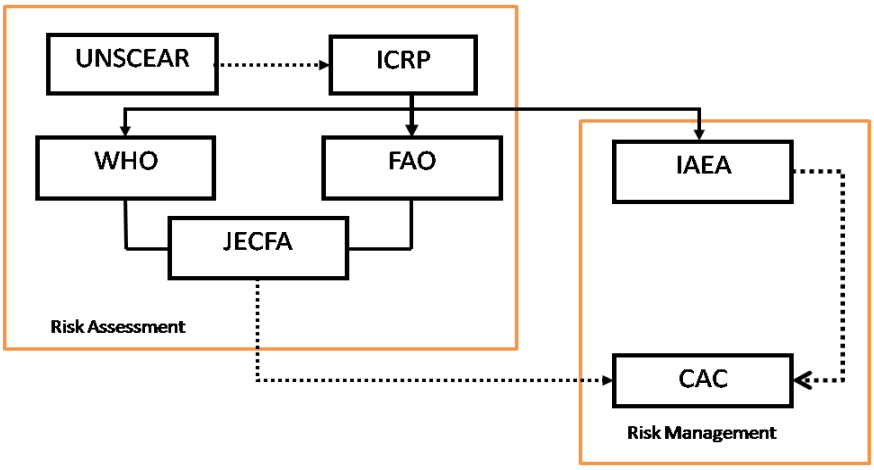


Figure 5 International food safety-related radiological protection stakeholders

Food safety-related radiological protection stakeholders at international level are described in figure 5. There are two processes in the establishment of food safety-radiological protection standards. First, the risk assessment, the process begins with the scientific report from the UNSCEAR related with the effect of radiological exposure on human and environment. The UNSCEAR report is used by ICRP on the development of the Recommendation. FAO/WHO through JECFA is using the UNSCEAR reports to establish their risk assessment. Second, the risk management is produced by CAC and IAEA. CAC through the Codex Committee on Food Contaminants (CCFC) uses the risk assessment from JECFA to establish the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF). On the other hand, IAEA uses the ICRP Recommendation directly to establish the International BSS and the General Safety Requirement. IAEA as the regulator has established the International BSS since 1996 and currently the standard has been replaced by the 2011 IAEA International BSS according to the latest 2007 ICRP Recommendation.

At the EU level, the EC plays a central role in risk management. On the other hand, the risk assessment is carried out by the Article 31 Group of Experts. The group consists of respected scientific experts who are specialized in radiological protection and public health issues. Furthermore, the task of the group of experts is to advice the EC on the establishment, revision and supplementing Council Directive No 29/1996 of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation which is also known as the BSS Directive and also for its supplementary regulations. The reference levels and weighing factors in the BSS Directive become the basis for the maximum permitted levels (MPL) calculation in Council Regulation No 3954/87, Council Regulation No 944/89 and Council Regulation No 770/90. At the present time, the EC has submitted a proposal to revise the current BSS Directive through the risk assessment evaluation from the Article 31 Group of Experts and also the current codification process of Council Regulation No 3954/87 on 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedstuffs following a nuclear accident or any other case of radiological emergency.

According to Article 22 paragraph 2 of the General Food Law[36], the European Food Safety Authority (EFSA) has a mission to provide risk assessments on food and feed safety issues related with community's legislation and policies. However, EFSA does not provide risk assessment on the issue of radioactive contamination but it is carried out by the Article 31 Group of Experts.

[36] Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Moreover, many member states carry out their own risk assessments on the issues of health effect of low dose radiation which is caused ineffectiveness in budgeting and research priorities program. In order to overcome this situation, the DG-Research and DG-Energy established the High Level of Experts Group (HLEG). The group is aimed to combine the scattered risk assessment on the health effect of low dose radiation and to develop a guidance and road map on the particular risk assessments.

In the USA, protective measures in nuclear facilities including standard setting, nuclear facilities inspection, and decommissioning to ensure the safety practice in the nuclear power plant (risk management) are carried out by the NRC based on the Energy Reorganization Act of 1974. Besides that, NRC also carried out research programs on the issues of nuclear reactors, nuclear materials, and radioactive waste safety. From the aspect of food borne illnesses due to radiation contamination, the USA has three agencies in charge, the US-FDA, USDA-FSIS, and US-EPA. Each agency has specific authority on the risk assessment and risk management on certain food products. The US-FDA has the authority on the processed food products, The USDA-FSIS has the authority on meat, poultry and egg products, and the US-EPA has the authority on the drinking waters safety. The coordination between the competent authorities particularly in an emergency situation is carried out through the Food Emergency Response Network (FERN). The mission of the network is to integrate the federal, states, and local food testing laboratories to detect, identify, respond, and overcome bioterrorism, or public health emergency/outbreaks involving the food supply (FDA, 2012a). Despite the existing coordination, the complexity of the multi-agency system and a continuous increase of imported foods often accused as the factors responsible on the high number of food borne illnesses in the USA (CRS, 2012). According to a report from the Government Accountability Office (GAO), there are at least 15 federal agencies collectively managing more than 30 food safety issues related laws and the numbers of imported foods is accounted for about 17 percent (USDA, 2012).

According to 1996 IAEA International BSS, Indonesia established Nuclear Energy Act No 10 of 1997. According to the Act, there are two principles of nuclear energy policy in Indonesia: the utilization of a nuclear energy and the supervision of nuclear facilities. Each pillar is held by different agency, as for utilization responsibility including research, general investigation, exploration and exploitation of nuclear mining, raw material processing for producing nuclear energy, radioisotope production for the purpose of research, and radioactive waste management are under the authority of National Nuclear Energy Agency (BATAN). The supervision responsibility including regulation, licensing, inspection, and decommissioning is under the authority of Nuclear Energy Regulatory Agency (BAPETEN). The radioactive exposure guidance levels on humans are

determined by BAPETEN in the year of 1999 according to 1977 ICRP Recommendation (ICRP Publication 26). In other words, the principle used to build a nuclear protection framework including human's protection system is not up to date with the latest 2007 ICRP Recommendation (ICRP Publication 103). In the scope of food borne illnesses due to radionuclide contamination, according to the Health Act No 36 of 2009 the competent authorities which have the authority on the risk assessment and risk management of public health including the food safety-related radiological protection issues are the Ministry of Health and NADFC. The ministry carries out the measures according to the general public health issues except for agricultural product, the risk assessment and the risk management is carried out by the Ministry of Agriculture. The authority division between the ministries and agency is regulated in the Government regulation No 28 of 2004 laying down food safety, quality, and nutrition. The regulation describes the controlling and regulatory function of the safety of processed foods including the radioactive internal exposures risk[37] which is sourced from the processed food[38] is in the responsibility of NADFC, in the scope of fresh foods[39] and feeds is in the authority of the Ministry of Agriculture and in the scope of fast foods and restaurant foods are in the authority of the Ministry of Health. The lack of coordination often results in a lot of overlapping measures and policy control duplication between the Ministry of Health, NADFC and Ministry of Agriculture. Besides that, the overlap is also evoked from a high expectation from the public to have a better food safety assurance on NADFC's responsibility despite the authority division. In addition, there is still no regulation explicitly mentioning the separation of the risk assessment and the risk management which worsened the coordination and policy execution between the competent authorities in Indonesia.

The radiological protection competent authorities in the USA are more or less similar to Indonesia. Both the USA and Indonesia applied the multi-agency system by dividing the authority in different agencies. Moreover, the function of risk assessment and risk management are carried out within the same agency. On the other hand, the radiological protection competent authorities in the EU are more centralized in the hand of the EC through DG-Energy. Moreover, the function of risk assessment and risk management are completely separated. This is similar with the International level however the risk management is carried out by two major organizations (CAC and IAEA).

[37] According to ICRP Publication 103, "Internal exposures can occur by inhalation of airborne radionuclide from a cloud, inhalation of re-suspended radionuclide, and by ingestion of contaminated food or water".
[38] Processed foods are defined as foods and beverages which processed by certain ways or methods with or without additives (Article 1(3) of Government Regulation No 28 of 2004).
[39] Fresh foods are defined as foods which have not been through any process and can be directly consumed and/or its can become raw material for processed foods (Article 1(2) of Government Regulation No 28 of 2004).

4.2 Standard Comparison

The common framework of the national radiological protection standard establishment is described in Figure 6. The scientific reports on the negative effect of radiation exposure on human health mostly come from UNSCEAR. The latest report which is published in 2012 is the Biological Mechanism of Radiation Actions at Low Doses: A white paper to guide the Scientific Committee's future program. The reports are used by ICRP to develop the ICRP Recommendation that is used by International Organizations such as IAEA, FAO, WHO, etc. to develop radiological protection standards related with their field of work.

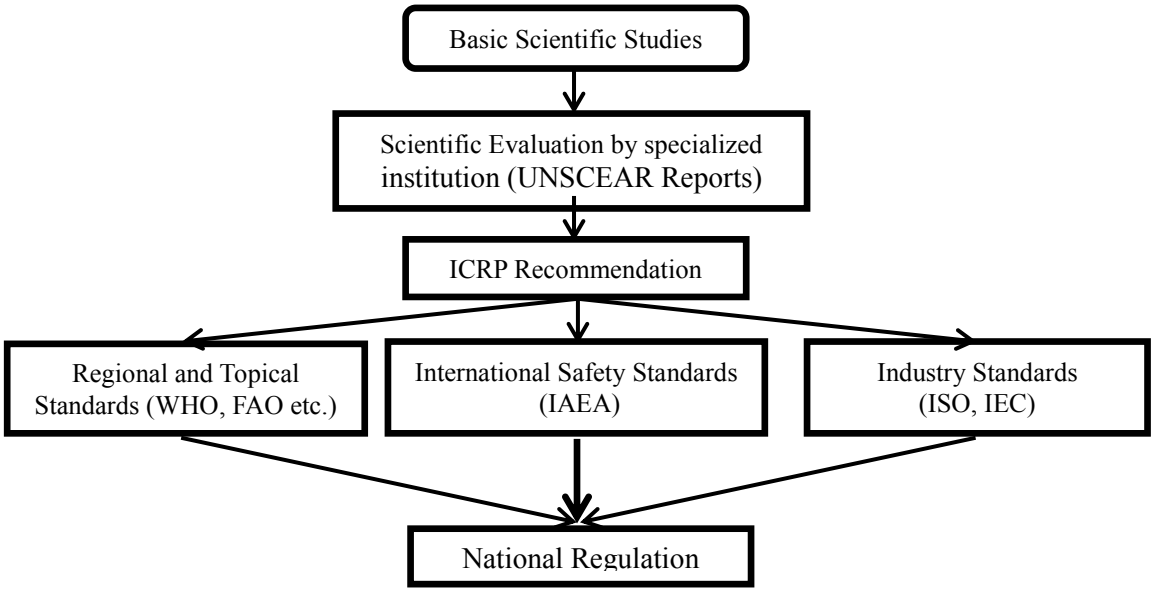


Figure 6 Framework of Radiological Protection Standard

The guidance levels[40] of the radiation contamination on foods and feeds in a nuclear accident or any other radioactive emergency regulations/standards between the EU, the USA, Indonesia, and at International level are identified and described in Table 1.

Table 1 Guidance levels of radiation contamination on foods in the EU (Council Regulation No 3954/87), the USA (CPG 560.750), Indonesia (Ministry of Health Decision No 1031/MENKES/PER/V/2011), and CODEX (Codex Stan 193-1995).

Radionuclide	Foods (Bq/kg)											
	Infants food				Dairy / Dairy Produce [1]				Other food [2]			
	EU	USA	INA	CODEX	EU	USA	INA	CODEX	EU	USA	INA	CODEX
^{231}Pu & ^{241}Am	1	2	-	1	20	2	-	-	80	2	-	10

[40] The Codex Stan 193-1995, the guideline level (GL) is used for limit levels and defined as "the maximum level of a substance in a food or feed commodity which is recommended by the CODEX to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction". According to 1998 FDA Document, DILs (Derived Intervention Levels) is defined as the recommended levels for concentration of radioactive contaminant on foods in absence of any intervention and certain period of time which could lead to an individual to receive the radiation dose equal to the PAG (in the international level the term used is the intervention level of dose).

^{90}Sr	75	160	-	100	125	160	-	-	750	160	-	100
^{131}I	150	170	50	100	500	170	100	-	2000	170	1000*	100
^{134}Cs & ^{137}Cs	400	1200	100	1000	1000	1200	150	-	1250	1200	500	1000

(-) : not regulated
[1] In Codex Stan, there are no dairy foods or liquid food category.
[2] Other foodstuffs in Indonesia are consist of fresh fruits and vegetables, fish and other marine products, meat, sealable drinking water, cereals including corn and barley, and other foodstuffs according to definition in Food Act No 7 of 1996.
*Only for fruits and vegetables.
**for the EU, the category is more general including all other radionuclide which has half-life greater than 10 days except for ^{3}H and ^{14}C and for Indonesia ^{134}Cs is excluded.

Table 1 described the comparison of guideline levels from four different standards. The parameters consisting type of radionuclide and type of foods are taken from Council Regulation No 3954/87 due to the regulation provides the most complex parameters compared to other standards. Furthermore, the scope of the EU's regulated food products are broader than in the USA, Indonesia, and International standards due to the addition of feedingstuffs[41] and minor foodstuffs[42]. The maximum permitted levels of the minor foodstuffs is set to be ten times higher than the other foodstuff category in Council regulation No 3954/87.

The guidance levels which are listed in Table 1 are applied in the emergency exposure situations. The EU established Council Regulation No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station which is applied in the existing exposure situations for only imported products. In Article 2 (2) of the Regulation, the accumulative maximum permitted levels of radionuclide ^{134}Cs & ^{137}Cs are set for 370 Bq/kg in milk, milk product, and infant's food and in other foodstuff category, the level of ^{134}Cs & ^{137}Cs is set for 600 Bq/kg.

4.2.1 Guidance Level

The guidance levels of the radiation contamination on foods and feeds are aimed to protect public health particularly in the situation following a nuclear power plant accident using the ICRP's reference levels and dose coefficients[43](Icrp, 2007). Requirement 51 point 5.23 of the 2011 IAEA International BSS described that IAEA encourages all regulatory bodies and other related parties to consider guideline levels from the Codex general standard for contaminants and toxins in foods and feeds (Codex standard 193-1995) to be applied as far as possible into their national standards; however, the EU, the USA, and Indonesia set the guidance levels using their own methods.

[41] Council Regulation No 770/90
[42] Council Regulation No 944/89
[43] Reference level is used as the constraint of exposures received by a person in emergency and existing situations (ICRP, 2007).

The guidance levels of the radiation contamination on foods and feeds in the EU, the USA, and Codex are established using almost similar equation; however the purposes, the contributing factors, the scope of the guidance levels, and the consideration on the equation factors are set differently. A special case in Indonesia, the guideline levels are set without using the equation due to different method of risk assessment application. Thus, Indonesia adapted the FSANZ's standards into their national standards establishment.

One of the most important elements in the guidance levels' equation is the reference level. According to the latest 2007 ICRP Recommendation, the reference level is aimed to be used as the main tool of the radiological protection system. In the other words, the aim of the radiological protection system is to prevent the deterministic and stochastic effects by using the principle of optimization in the form of reference levels.

The reference levels are expressed in different terminologies depending on the type of exposure situations. In the emergency exposure situations, the reference levels are expressed as total residual doses and in the existing exposure situations the reference levels are expressed as the annual effective doses (ICRP, 2007). The current ICRP's reference levels in the emergency exposure situations are set from 20 – 100 mSv and the reference levels in the existing exposure situations are set from 1-20 mSv (ICRP, 2007). Furthermore, the reference levels for the specific pathway such as foods and feeds are set for 1 mSv in accordance with the principle of optimization (IAEA, 2011; ICRP, 2007).

The reference levels for the food pathway are identified as Intervention Exemption level of Doses (IED) by CAC, Protective Action Guides (PAG) by the USA and reference level of individual effective dose (E) by the EU. The reference levels have a unique feature as the prospective exposure dose; in other words, the level is set as the benchmark of the level of protection for the future nuclear accident.

The radionuclide exposures through the food and feed pathways can be determined based on the following equations:

The CAC uses the term Guideline Levels (GL) for the guidance levels. The factors used to calculate the Guideline Levels are the Intervention Exemption level of Dose [IED], mass of food consumed per year [M], ingestion dose coefficient [e_{ing}], and import to production factor [IPF].

$$\boldsymbol{GL = \frac{IED}{M\ x\ eing\ x\ IPF}}$$

Where:

IED is the Intervention Exemption level of Dose (mSv/year)

M(A) is the mass of food consumed per year (kg/year)

e_{ing}(A) is ingestion dose coefficient (dose per unit intake, mSv/Bq)

IPF is the import/production factor (dimensionless)[44]

Second equation is the Derived Intervention Levels calculation (DILs) which is the guidance levels terminology used in the USA.

$$DILs = \frac{PAG}{f \; x \; food \; intake \; x \; DC}$$

Where:

PAG is protective action guide (mSv)

DC is dose coefficient; the radiation dose received per unit of activity ingestion (mSv/Bq).

F is fraction of the food intake assumed to be contaminated.

Food Intake is Quantity of food consumed in an appropriate period of time (kg).

Similar equation is also used in the EU however the term is called Maximum Permitted Level (MPL). Besides that, there is one another additional component in the EU equation which is the correction factor (C) corresponding to the additivity[45] of foods.

$$MPL = \frac{E}{f \; x \; D \; x \; I \; x \; C}$$

Where:

E is the reference individual effective dose arising from consumption of contaminated foods in a year subsequent to the accident

MPL is the activity concentration limit specified in the Regulation for a given radionuclide category and food group

f is factor which reflects a judgment that the average annual concentration in food actually consumed by the individual is a fraction of the activity concentration limit

[44] Codex Stan 193-1995 for contaminant and toxin in food and feed. p.36.
[45] Additivity represents the correction factor as a result of food variation and consumption behavior.

D is the ingestion dose coefficient in Sv/Bq

I is the annual consumption rate of the relevant food in kg, and

C is a correction factor to allow for the additivity of foods within the category other foods, taken as 5 for all radionuclides with physical half-life greater than a few weeks, and as 1 for radionuclide, e.g. iodine-131, with half-life of days or shorter.

In short, the reference level is one of the essential elements of the equation calculation. Codex and EU's guidance level applied the reference level from the 1990 ICRP Recommendation but USA still used the reference level from the 1977 ICRP Recommendation.

4.2.2 Criteria of Comparison

Based on the equation in the previous sub-chapter and risk assessment steps (hazard identification, hazard characterization, exposure assessment, and risk characterization), a comprehensive comparison of the standards is established on 5 parameters:

a. Radionuclide types

The concept of emitter groups is a framework developed by CAC in the Codex standards 193-1995 to establish the regulated radionuclide list. The concept defines the regulated radionuclide as the representative of two emitter groups (Alpha and Beta/Gamma). The type of emitters is not used in the regulated radionuclide classification, but the final list should include representatives from those two emitter groups. For instance, Codex used the Dose per Unit (DPU) value[46] as the framework to choose the representative radionuclide to be collected in group. From the point of view of risk assessment, there are two reasons on the determination of regulated radionuclide. First, the regulated radionuclide is the most probable radionuclide released in a nuclear accident or any other radiological emergency and also the most probable radioactive contaminants through the food pathways. Second, the regulated radionuclide is the most injurious radionuclide to health (radio-toxicity) which is also related with their biological half-life. More importantly, this concept provides a safeguard measures on the other radionuclide which are not included in the regulation to have the same guidance level with the regulated radionuclide within the group. In the existing exposure situations such as in the prolonged exposures after the emergency exposure situation, there are two additional reasons in the regulated radionuclide's selection. First is the physical half-life of the radionuclide. In other words, all radionuclide which has physical half-life less than one year are excluded from the Regulation list. Second is the capability of the radionuclide to travel great distances which are represented by Cesium (^{134}Cs &^{137}Cs) and Strontium (^{90}Sr) (Beta/Gamma

[46] Dose Per Unit (DPU) value defined as the amount of radionuclide dose received per unit of radionuclide activity (mSv/Bq).

emitters). The Alpha emitters such as ^{234}Pu and ^{241}Am are only affecting the location near to the nuclear accident or any other radiological emergency.

The radionuclide released from the Chernobyl nuclear accident were ^{131}I- (short physical half-life radioisotope), (^{95}Zr and 95Nb), ^{103}Ru, ^{106}Ru, (^{132}Te and ^{132}I), (^{140}Ba and ^{40}La, ^{141}Ce, ^{144}Ce, ^{134}Cs and ^{137}Cs (ground deposited radionuclide as external exposures), ^{134}Cs and ^{137}Cs (ingested radionuclide as internal exposure), and long physical half-life radionuclide from fuel particle ^{238}Pu, ^{242}Pu, ^{241}Am, ^{243}Am and 90% of the ^{89}Sr, ^{90}Sr (European Commission, 2011). Moreover, the 1998 FDA Document also described the type of important radioactive contamination sources:

a. Nuclear reactors (^{131}I; ^{134}Cs & ^{l37}Cs; ^{l03}Ru & ^{106}Ru);
b. Nuclear fuel reprocessing plants (^{90}Sr; ^{137}Cs; ^{239}Pu & ^{241}Am);
c. Nuclear waste storage facilities (^{90}Sr; ^{37}Cs; ^{239}Pu & ^{241}Am);
d. Nuclear weapons (i.e., dispersal of nuclear material without nuclear detonation) (^{239}Pu);
e. Radioisotope thermoelectric generators (RTGs) and radioisotope heater units (RHUS) used in space vehicles (^{238}Pu).

The radionuclides released from the Fukushima accident are mainly ^{131}I, ^{134}Cs, and ^{l37}Cs (Taira et al., 2012). The radionuclides that are mentioned above are the main radionuclides in the internal exposures through the inhalation and food ingestion pathways and in a smaller amount of ^{90}Sr (Balonov, Anspaugh, Bouville, & Likhtarev, 2007; Fushiki, 2012). More importantly, the health effect of the radionuclide is not affected only by physical half-life[47] but also by their biological half-life[48] (Table 2). ^{131}I has a short half-life but it stays in the thyroid for quite a long time (120 days) and from all those three radionuclide, ^{90}Sr is the most dangerous radionuclide because its long physical half-life and biological half-life and it is absorbed into the bone (Shigematsu et al., 2012). Besides that, the Beta and Gamma emitters are the most injurious radionuclide to health.

Table 2 Physical and Biological Half-life of I-131, Cs-137, and Sr-90

Radionuclide	Physical half-life	Biological Half-life
^{131}I	8 days	120 days
^{137}Cs	30 years	70 days
^{90}Sr	29 years	49 years

[47] ICRP defined the Physical half-life as "The time interval required for an amount of a certain radioactive nuclei to decay to half of its original levels. The units of time are second-s, minute-m, hour-h, day-d, and year-y."(Eckerman, Harrison, Menzel, & Clement, 2012).

[48] Biological half-life describes the elimination of the radioisotope from human body through the feces, urine, and perspiration (Shigematsu, Fukada, Ohashi, Kawaguchi, & Kawata, 2012)

b. Age groups

The determination on the compliance of public exposures with the reference levels is carried out by selecting the representative persons. The selection is done by using considerations as follow:

- Holistic approach toward relevant pathway of exposures;
- Included the persons who have higher exposures;
- Habit data in the exposed population has to be done by using common senses, sustainability, and compatibility concept; and
- Appropriate dose coefficient is applied on a certain age group.

Related with the last point, the age group of the representative persons is divided into three categories: Infants (0-5 years), Child (6-15 years), and Adults (16-70 years) (ICRP, 2006). Children and pregnant woman have to be considered as high risk population (Fushiki, 2012). However, related to the limited food consumption and a higher radioactive sensitivity in infants, the risk in this group should be regarded as the highest priority (Chen, 2010; CAC, 2010; Wakeford, 2012). Moreover, the sensitivity of the infants' age group to a radionuclide exposure can be tracked down from the relative ratio between dose coefficient of infants and dose coefficient of adults (ICRP, 1996). Besides that, the infants and children group are considered as the most vulnerable age group due to their higher radioactive sensitivity and longer life span (Sakai, 2012).

c. Food categories

Based on the age groups in point c, foods can be classified in two categories. First is infant's food which is defined as the foods intended to fulfill the nutrition requirement of the infants during the first four to six months of life and it is clearly identified and labeled (food preparation for infants) in the package retail sale[49]. Second is the non-infants foods which is included dairy and dairy products, liquid foods (tap water, etc.), and other foods. The food categories used in the regulations are reflecting the population's major components of diet.

d. Mass of food consumed

Food consumption relates with the nature of individual habits. It is also one of the essential components of the exposure assessment besides the occurrences of radioactive contaminations on foods or feeds. The food consumption is mainly influenced by type of foods available in the surrounding area and the amount of certain food consumptions. In a larger scope such as in the national level, the types of food can be divided into two distinct components, first is the local foods and second is the imported foods which the contribution is described in the term of IPF

[49]Council Regulation (EURATOM) No 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingtuffs following a nuclear accident or any other case of radiological emergency , as amended by Council Regulation (EURATOM) No 2218/89. (1987).

(Import/Production Factors). In the emergency exposure situations and/or in the existing exposure situations, the sum of exposures received by the affected population raised by the daily and episode intake of food ingestions. The types of food mostly contained radionuclide are milk, vegetables, meats, and fishes (ICRP, 2009). For instance, the people in the surrounding area of the Chernobyl accident are still having an annual effective dose around 0.1 mSv which consists of ^{137}Cs. The exposures also come from wild mushroom and berries consumption for 10-20 Bq daily intake and several hundred Bq from episode intake (ICRP, 2009). A more clear description on internal exposures from foods can be described on this example, assume that we consumed 1 Liter of milk every day in one year; moreover the radioactivity in that milk is detected ^{137}Cs in the level of 10.000 Bq/L with the effective dose coefficient 1.3 x 10^{-8}. The level of ^{137}Cs in 100 mL milk is 1000 Bq, so that the effective dose calculation is: 1000 x 1.3 x 10^{-8} x 365 = 0.0047 Sv = 4.7 mSv, means that it will be approximately 5 mSv is absorbed through the consumption of milk in a year (Shigematsu et al., 2012).

e. Other factors

Other factors used for the comparison such as:

- Potential exposures

  The existence of radioactive contamination sources in a country can be considered as the prospective exposure doses, such as the existence of the nuclear power plant or other nuclear facilities and the natural radiation background.

- Socio-economic, environmental and other related factors

  The societal factors such as public perception on radioactive risk, culture, and also economic factor such as high dependency on imported product or foods are also involved in the regulation's establishment. Free trade area concept can also serve as one of the deterministic factors for the establishment of radioactive contaminant on foods regulations/standards. The local environment such as the weather condition also determines the levels setting. Besides that, good agricultural practice, food processing, etc. also contribute to the complexity of the guidance levels calculation.

4.3 The Guidance Levels Comparative Analysis

4.3.1 Numerical Comparison

The guidance levels on foods and feeds in a nuclear emergency situation between countries are compared on four specified radionuclide groups: ^{239}Pu & ^{241}Am; ^{90}Sr; ^{131}I, and ^{134}Cs & ^{137} Cs and three food categories: infant's food, dairy/dairy produce, and other food (Table 1). The levels ^{239}Pu & ^{241}Am group in the EU and Codex are the same for infant's food category, but in other food

category, the EU's levels are higher than Codex's levels (2 times higher for dairy and 8 times higher for other foodstuffs). As for ^{90}Sr, in the category of infant's food, the EU's levels are lower than Codex but in other foods category the EU's levels are higher than Codex (7.5 times higher for other foodstuffs). The level of ^{239}Pu & ^{241}Am group in the USA is two times higher than in Codex for infant's food category, but the level is five times lower than in Codex for other food category. As for ^{90}Sr, the USA's level is 1.6 times higher than in Codex for infant's food and other food category. In Indonesia, ^{239}Pu & ^{241}Am and ^{90}Sr group are not regulated.

Next, the guidance levels of ^{131}I radioisotope in Indonesia are much lower than in Codex for infant's food category (half of the Codex level for infant's foods) but the level is 10 times higher for other food category. Furthermore, if we compare the guidance levels between Indonesia and Codex, the levels are lower only for infant's food (2 times lower) but the levels are higher for other foods category (10 times higher). On the other hand, the ^{131}I level in the EU is higher than in Codex for all food categories (1.5 times higher in infant's food and 20 times higher in other foods). Similar with the EU, the USA level is 1.7 times higher than in Codex both for infant's food and other food category. The ^{137} Cs level in Indonesia is lower than in Codex for all food categories. For infant's food, it is ten times lower than in Codex and for other foods category, it is two times lower than in Codex. Moreover, the ^{134}Cs & ^{137} Cs level in the EU is lower than in Codex for infant's food category (2.5 times lower) but the level is higher for other foods category (1.25 times higher). As for the USA, the ^{134}Cs & ^{137} Cs group level is 1.2 times higher than in Codex for infant's food and other food category.

The USA established a single level system which is defined as the guidance level of radiation contamination that applied for all food categories and age groups. In the other words, there is only one guidance level of a radionuclide that available for all food categories and age groups. Codex only applied a different guidance level of ^{239}Pu & ^{241}Am group between infant's food category and other food category but applied the same guidance levels of other radionuclides for all food categories and age groups. The two systems except ^{239}Pu & ^{241}Am group in Codex do not complied with the infants and adults age group distinction based on the dose coefficient in the ICRP Recommendation. Thus, the distinction between infants and adults age group is generally in the ratio of 1:10 (Eckerman et al., 2012). A different guidance levels application between infants and adults age group are conducted in the EU and Indonesia. Thus, on average the guidance levels for infants are 10 times higher than for adults. The lowest guidance levels for ^{131}I and ^{137} Cs are applied in Indonesia. If we use Codex guidance levels as benchmark, in general both the EU and the USA's guidance levels are less strict than Codex for all food categories. On the other hand,

Indonesia has guidance levels that more strict than Codex except for ^{131}I which is ten times higher than in Codex.

4.3.2 Guidance Levels

The guidance levels in the USA (DILs) are applied for approximately 1 year period after a nuclear accident or any other radiological emergency situation and if there is a situation where prolonged radiation exposure occurs, DILs will be evaluated accordingly to the level of emergency (FDA, 1998). Similar to the USA, the guidance levels for emergency exposure situations in Codex are also applicable for only 1 year period after a nuclear accident or any other radiological emergency. In contrast, the EU and Indonesia are not explicitly mentioning about the application time for the guidance levels in the emergency exposure situations. However, the EU established other guidance levels that applied in the existing exposure situations (prolonged exposure situations) for imported food product. Those guidance levels are described in Council Regulation No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (codified version);

Diverse guidance levels that are applied by those countries are established due to diverse reference levels and ingestion dose coefficient (e_{ing}) used in the equation. For instance, the USA and Indonesia still used reference levels[50] for food pathway from the old 1977 ICRP Recommendation (ICRP publication 26) which is 5 mSv per year; in contrast the EU and Codex have used the reference levels from the 1990 ICRP Recommendation (ICRP publication 60) which is 1 mSv per year. The equation used by the USA and CAC to calculate the guideline levels is just the same. The difference is only on the use of different terminology on the equation components. In general, the EU used a similar equation such as used by the USA and CAC; however, the EU used a correction factor (C) as additional component in their equation. The correction factor (C) represents the additivity of foods in the category of other foods.

Currently The EU uses the ratio of contaminated food for 0,1 (10%) which is the same value used by CAC. On the other hand, the USA add another factor of 3 to the factor of 0,1 (10%) resulting the ratio value to be 0.3 (30%). The additional factor of 3 is taken in the assumption that there are some sub-population that might be dependent on the certain food supplies (FDA, 1998). Next is the ingestion dose coefficient. The USA uses the ingestion dose coefficient from the ICRP Publication 56. However, The EU and Codex have used the ingestion dose coefficient from ICRP Publication 72.

[50] In the ICRP Publication 26 and Publication 60, the term dose limit is used for reference levels.

All distinct factors which are used in the equation have produced different guidance levels. One interesting fact, the guidance levels establishment in Indonesia was not based on the equations which are used either by the EU, the USA, and Codex. The guidance levels are established using the adoption principle by simply taking other country's (FSANZ's standard) and modify it to be more strict. This approach is aimed to substitute the incomplete application of risk assessment in the matter of scientific quantification on the absence of the national consumption data but it is expected to provide a high level of public health's protection.

4.3.3 Other Criteria Comparison

Besides the equation, there are three other important components in the guidance levels establishment (Table 1). First, the regulated radionuclide group's classification that is mainly based on two reasons:

a. The most probable radionuclide contaminants in a nuclear accident or in any other radioactive emergency; and
b. The most probable transferred radionuclide in foods and feeds.

Codex standard 193-1995 and the Council Regulation No 3954/87 present the most fit radionuclide groups classification and feeds standards due to their intensive risk assessment on the Chernobyl accident. There are three radiation emitters consist of Alpha, Beta, and Gamma emitter group. In Codex, there are 20 radionuclides representing all emitter groups which are divided into 4 different groups. The division is based on the Dose per Unit (DPU) value. In other words, radionuclide that has similar or equal DPU value will be collected in the same group. Moreover, Codex used the term of representative radionuclide to describe the group; that is, the radionuclides which are not in the regulation's list shall have the same guidance level with the one in the list as long as they have the equal or similar DPU value. The EU also applies the same concept as the Codex. There are four radionuclide groups including isotopes of plutonium and trans-plutonium elements (^{239}Pu & ^{241}Am) represents Alpha emitters, isotopes of Strontium (notably 90Sr) represent Beta emitters, isotopes of iodine (notably ^{131}I) and all other radionuclide of physical half-life more than 10 days (notably ^{134}Cs &^{1} ^{37}Cs) except for isotopes ^{3}H and ^{14}C represents Beta/Gamma emitters; thus group encompasses a wide range of radionuclides. The USA also applies the concept of emitter groups but it does not use representative radionuclide concept. Instead of using that concept, the USA used definite regulated radionuclides concept. The USA's CPG has five radionuclide groups consisting nine different radionuclides. Thus, radionuclides that are not in the standard's list can be considered to have guidance levels if the radionuclides proved to have a significant adverse health effect. An evaluation of the radiation

dose is carried out (FDA, 1998) under the safety net provision of the Food, Drug and Cosmetic Act (FDCA) Title IV section 342 (a)(1) : "Food shall be deemed to be adulterated If it bears or contains any poisonous or deleterious substance which may render it injurious to health". Indonesia has the fewest regulated radionuclide with only put two definite radionuclides (^{131}I and ^{137}Cs) in its Regulation[51]. Both radionuclides are Beta/Gamma emitters. Similar to the USA, Indonesia also has safety net provision to cover radionuclides other than the regulated radionuclides. The Food Act No 18 of 2012 Title VII section 90 (2): "Food shall be deemed to be adulterated if it contains poisonous or dangerous substance or any substance which is injurious to human's health or life".

An updated report from the Chernobyl accident described that in the existing exposure situations especially on the prolonged exposure situations, ^{137}Cs should be regarded as the most important radionuclide contaminant in the internal exposures and other long half-life radionuclides such as ^{90}Sr-, ^{241}Am and ^{239}Pu are less significant contaminants (IAEA, 2006). The report is used as the basic for the EU radioactive contamination on foods and feeds Regulations in the existing exposure situations following the Chernobyl accident[52].

Second, the age group's classification which is recommended by the ICRP Publication 101 shall consist of three age groups: Infants (0-5 years), Children (6-15 years), and Adults (16-70 years). The EU and Codex based their guidance levels calculation only on two age groups: infants age group (1 year old) and adults age group(CAC, 2006; European Commission, 1998). However, the USA used six age groups [3 months, 1 year, 5 years, 10 years, 15 years and adults (>17 years)] in the calculation of DILs. The age groups determination in Indonesia is not applicable due to the application of incomplete risk assessment.

Finally, the food categorization which is based on national data consumption and consumption behavior; The EU regulations included baby foods, dairy produce, liquid foods and other foods[53] in its standard. Besides that, the guidance levels are also set for feeds, and minor foodstuffs in separate regulations[54]. Feeds considered as one of the radioactive contamination drivers due to the fact that there is a transfer of radionuclides from contaminated soil to livestock and ends up in human bodies. Besides that, a detailed list of minor foodstuffs is also regulated in the EU regulation. The complex EU measures in the aspect of food categorization reflect the holistic approach which is taken by the EU to facilitate all possible ingestion exposure pathways. As for

[51] Ministry of Health Decree No 1031/MENKES/PER/V/2011 on the maximum permitted levels of radioactive contamination on foodstuffs which is came from countries/areas which are experiencing a nuclear emergency situation
[52] Council Regulation No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.
[53] Annex of the Commission (EUROATOM) Regulation No 3954/87.
[54] Annex of the Commission (EURATOM) Regulation No. 770/90 and the Commission (EURATOM) Regulation No 944/89.

Indonesia, there are eight food categories consisting baby foods, dairy produce, fruits and fresh vegetables, fishes and other seafood, meats, water in package, cereals include corn flour and barley, and the last category is other foods. Similar to the EU, this food categorization is also developed based only from consumption behavior since Indonesia does not have national data consumption. Unlike the EU and Indonesia which has more than two food categories, Codex has only two food categories in the standard consist of infants foods and non-infants foods. Codex only mentioned general information related with the minor foodstuffs without having detailed list of minor foodstuffs. The guideline levels for minor foodstuffs were sets to be ten times higher than the guideline levels in other foods category but without put in detail on the list of the minor foods such as in the EU regulation. Feeds are not regulated in the Codex standard. In contrast, the USA does not have any food categorization in their regulation and chooses to use "all components of diet" term instead of the food categorization. The absences of the food categorization system in the USA's regulation indicates the simplification of major diets in the risk assessment process.

Different from the USA regulation that used guidance levels that cover all type of foods and all age groups. Regulations in the EU, Indonesia and Codex described and identified infant's food category as an independent parameter that is completely separated from adult's food category. The setting is based on the fact that infant's age group has higher vulnerability and radio-sensitivity compared to adult. Besides that, the nutrition fulfillments of these age groups are mainly come from specific foods with a small variation. Moreover, the higher radio-sensitivity of infant's age group is clearly described in the latest 2007 ICRP Recommendation and ICRP Publication119: the compendium of dose coefficient based on ICRP Publication of 1977. For example, the intestinal absorption (f_1 values) for the 3 months-infants are set higher than other age groups that used intestinal absorption of adult's age group.

In short, the latest 2007 ICRP Recommendation and the 2011 IAEA International BSS are not yet applied in the EU, the US, Indonesia, and Codex Regulations/Standards. Infants' age group is set as a different category that completely separated from adults' age group in the EU, Indonesia, and Codex Regulations/Standards. On the other hand, the USA's regulation sets single level system for all food types and age groups; thus, there is only one guidance level of radionuclide for all age groups and food categories.

4.4 Comparative Analysis of Other Provisions

The optimization principle in 2007 ICRP Recommendation should be applied in every exposure situations which means that guidance levels have to be provided for all types of exposure situations to ensure that the good practice concept is consistently applied to protect the public

health. Proper guidance levels should be established for emergency exposure situations and existing exposure situations. The requirement to establish a legal framework for the radiological protection in all possible exposure situations is also mentioned in the 2011 IAEA International BSS. The EU established distinct regulations on the radiological protection based on the type of exposure situations. In the emergency exposures situations, the EU uses the guidance levels from Council Regulation No 3954/87 and in the existing exposure situations; the EU uses the guidance levels from Council Regulation No 733/2008; even though, Council Regulation No 733/2008 applies only for imported foods. At the present time, based on the latest risk assessment, there are several food categories in the EU which have the same or even lower radiation contamination compared to the situation before the Chernobyl accident. Therefore, the amendment of Council Regulation No 733/2008 shall be carried out continuously. The guidance levels for the existing exposure situations are not regulated in the USA, Indonesia and Codex.

Apart from that, the reference levels from the 2007 ICRP Recommendation encompass the reference levels from the 1990 ICRP Recommendation, but with a wider application. In other words, the guidance levels in the EU and Codex which use the reference levels from the 1990 ICRP Recommendation are still relevant with the latest 2007 ICRP Recommendation. However, the guidance levels in the USA and Indonesia which still use reference levels from 1977 ICRP Recommendation need a significant adjustment to be in line with the latest 2007 ICRP Recommendation.

5. THE PROTECTIVE MEASURES TAKEN BY THE EU, THE USA, AND INDONESIA FOLLOWING THE FUKUSHIMA NUCLEAR ACCIDENT

The 9.0 magnitude earthquake on 11 March 2011 which was followed by a devastating tsunami has led to a nuclear accident in the Fukushima Daiichi Nuclear Power Plant in Japan which is also known as the Fukushima accident. The Japan Nuclear and Industrial Safety Agency (NISA) classified the Fukushima accident as level 7 of the INES which is the same level as the Chernobyl accident (Hamada, Ogino, & Fujimichi, 2012; Wang, Chen, & Yi-chong, 2013). The excessive amount of radionuclides were released into the environment mostly consists of ^{131}I, ^{134}Cs, and ^{137}Cs. The contamination level in the Fukushima accident was approximately 5.5% from the Chernobyl accident (Fitzgerald et al., 2012).

A series of inevitable radionuclide internal exposures on humans mainly come from the ingestion of radionuclide contaminated foods and drinking water. The latest measurement on 6 November 2012 described that the radiation contamination levels on certain foods are still above the Japanese standard's limit. Most of the contaminated foods are originating from Fukushima, Ibaraki, Gunma, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa, Iwate, Shizuoka, and Yamanashi prefectures (MHLW, 2012). Since March 2011, MHLW has carried out continuous sampling and monitoring on the radiation contamination on foods including the tap water and published the issuance and cancellation of instructions to restrict distribution and/or consumption of foods based on the Act on Special Measures Concerning Nuclear Emergency Preparedness. Besides that, the Japanese government has ensured the international community that the foods which are prohibited in Japan's market will be banned also for export.

Since 17 March 2011, MHLW puts the provisional regulation values as the standards limit of radionuclide in foodstuffs. The guidance levels were set without having any risk assessment from Japan Food Safety Commission (FSC) as the risk assessor. The actual risk assessment request was asked by MHLW to the FSC on 20 March 2011 and the FSC finished and submitted it on 27 October 2011. The new standards limit of the radioactive contamination on foods based on the actual risk assessment was published on 15 March 2012 and entered into force on 1 April 2012. The MHLW new standards are only applied to the sum of ^{134}Cs and ^{137}Cs and other radionuclides which have a physical half-life more than one year. The MHLW's standard set the reference levels of 1 mSv per year which is originated from four food categories (drinking water, infant's food, milk and dairy product, and general food). Besides that, the contaminated food is assumed 50 % of all marketed foods and 100% contaminated on drinking water, infants food, milk and dairy product. Different from the radioactive contamination levels calculation on foods, the levels' calculation on drinking water is based on the WHO's guidance levels for drinking water.

In conclusion, the new standard is established based on the actual condition of the radiation contamination on foods in the most affected prefectures and also based on the risk assessment and ALARA concept. This is reflected from the guidance levels in the new MHLW standard which only covered most important radiation contaminants (^{134}Cs and ^{137}Cs). The levels are stricter than the previous standard which is aimed to increase the public health protection level (Table 3). Besides that, the infant's food is also included in the new standard to assure that the infants' age group as the first priority in the radiological protection system.

Table 3 the guidance levels of ^{134}Cs and ^{137}Cs between the previous standard (provisional regulation) and the new standards

Foods	Provisional regulation (Bq/kg)	New standard (Bq/kg)
Infants food	-	50
Milk and dairy product	200	50
Drinking water	200	10
Other food	500	100

(-) : not regulated

5.1 The EU Countermeasures

The EU has carried out a series of protective measures following the Fukushima accident. On 12 March 2012, the EC activated the emergency team and transmitted an emergency alert to all member states through the ECURIE (European Community Urgent Radiological Information Exchange) just 24 hours after the Fukushima accident. Furthermore, the EC has imposed import condition for foods originating or consigning from Japan by establishing Commission Implementing Regulation No 297/2011 of 25 March 2011. The Regulation is continuously revised based on the latest MHLW's report. The latest one is Commission Implementing Regulation No 996/2012 of 26 October 2012. The revisions mostly related with the food exclusion from the Regulation application. The current regulation applies for emergency exposure situations due to Fukushima accident and used food ban as the main tool for the protective measures.

The principles of the Commission Implementing Regulation are:

a. The Regulation applies for all foodstuffs and feedingstuffs in accordance to the definition in Council Regulation No 3954/1987;
b. The protective measures is implemented by banning all foodstuffs and feedingstuffs originating in or consigning from certain prefectures in Japan; however, there are foodstuffs

and feedingstuffs which are excluded from the list of the Regulation based on the MHLW's reports (Article 1);

c. The establishment of the Regulation provision is based on the latest report of the level of radiation contamination on foodstuffs and feedingstuffs which is published continuously by the MHLW and also by using the new Japan's standard to assess the compliance; and

d. The Regulation applies until 31 March 2014.

However, there are some exceptions for the application:

- Products which left Japan before 28 March 2011;
- Products which have been harvested and/or processed before 11 March 2011;
- Alcoholic beverages falling within CN codes 2203 to 2208;
- Personal consignments of feed and food of animal origin which are covered by Article 2 of Regulation (EC) 206/2009;
- Personal consignments of feed and food other than of animal origin which are not-commercial and destined to a private person for personal consumption and use only. In case of doubt, the burden of proof lies with the recipient of the consignment.

The main reason of the exclusion is described on point c which shows that the EU has developed a closed communication with MHLW. Furthermore, the close cooperation is showed in the Article 6 of the Regulation: "the declaration of products has to be signed by the Japanese competent authorities". Furthermore, the declaration is intended for the consignment of all imported foods from Japan. Moreover, the analytical report containing the results of sampling and analysis shall be provided by the Food business operators together with the declaration form for a certain product, for example, tea and mushroom originating in Shizuoka prefecture. Until 31 December 2011, the member states' competent authority has carried out monitoring and sampling on 1967 imported foods from Japan and found 19 significant radiation contaminated foods (>10 Bq/kg) but there are still below the standard's limit (European Commission, 2012).

There is no definition on the time frame of the emergency exposure situations in the EU Regulation. However, Codex describes the time frame of emergency situation within 1 year period after the nuclear accident but each country can define the time frame based on their judgments on the level and the extent of the nuclear emergency. Point d showed that the EU extended the emergency exposure situations time frame up to 2014 which is more than three years after the Fukushima accident; however, the time frame is going to be reviewed on 31 March 2013.

Table 4 Radioactive Contamination Levels on foods following the Fukushima accident

Radionuclide	Foodstuffs (Bq/kg)											
	Commission Implementing Reg. No 297/2011				Commission Implementing Reg. No 351/2011				Commission Implementing Reg. No 996/2012			
	FI	MD	OF	LF	FI	MD	OF	LF	FI	MD	OF	LF
^{90}Sr	75	125	750	125	75	125	750	125	-	-	-	-
^{131}I	150	500	2000	500	100	300	2000	300	-	-	-	-
^{231}Pu & ^{241}Am	1	20	80	20	1	1	10	1	-	-	-	-
^{134}Cs & ^{137}Cs	400	1000	1250	1000	200	200	500	200	50	50	100	10

(-) : not regulated

* FI = Food for infants and young children
MD = Milk and dairy products
OF = Other foodstuffs except liquid foodstuffs
LF = Liquid foodstuffs

Commission Implementing Regulation No 297/2011 of 25 March 2011 imposing special conditions governing the import of feed and food originating in of consigned from Japan following the accident at the Fukushima nuclear power station still used the guidance levels from Council Regulation No. 3957/87; however, the amending Regulation (Commission Implementing Regulation No 351/2011 of 11 April 2011 used the guidance levels in the Japanese provisional standard except for ^{90}Sr which is taken from Council Regulation No 3954/87. Latest Commission Implementing Regulation No 996/2012 of 26 October 2012 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Commission Implementing Regulation (EU) No 284/2012 has completely used the guidance levels from the new Japanese standard. Besides that, the list of affected prefectures will be included in the restriction zone if there are evidences that the levels of contamination are still above the Japanese standard and it will be excluded if there is a clear evidences that the radioactive contamination levels are below the Japanese standard.The EU measures are carried out by considering reports from the MHLW who continuously updates the radiation contamination's on foods. The essence of the measures is that the level of exposures is kept as low as reasonable achievable (ALARA). Based on MHLW's reports, the numbers of contaminated foods above the standard limit are decreasing significantly since there is no incompliant food detected in the prefecture of Fukushima for more than one year[55].

5.2 The USA Countermeasures

Following the Fukushima accident, US-FDA published the import alert 99-33 which was continuously updated the prohibited food list based on reports from the MHLW. The first import alert was published on 23 March 2011 and continuously updated till the latest one which was

[55] OJ L 299, 27.10.2012, p. 31–41

published on 25 July 2012. FDA chooses DILs in the current CPG as the guidance levels used for sampling and monitoring of imported foods from Japan; although, the latest MHLW standard's guidance levels are lower than DILs (Table 5). The impact of the DILs application is the requirement of sampling and monitoring to be stricter in the aspect of the radionuclide types due to the CPG regulates more radionuclides than in the Japanese standard. Until 20 June 2012, US-FDA has tested 1313 samples (with 199 seafood or seafood products) and found that 1312 samples were free from radioactive contaminants and only 1 sample contained Cs radionuclide; however the contamination level is lower than the USA's standard (FDA, 2012b).

Table 5 Comparison of the guidance levels between CPG 560.750 (US) and the new Japanese Standard

Radionuclide	**Foodstuffs (Bq/kg)**				
	CPG 560.750 (US)	**Japanese standard**			
	All Diets Component	FI	MD	OF	LF
^{90}Sr	160	-	-	-	-
^{131}I	170	-	-	-	-
^{231}Pu & ^{241}Am	2	-	-	-	-
^{134}Cs & ^{137}Cs	1200	50	50	100	10

(-): not regulated
*Japanese standard takes into account the contribution of strontium, plutonium, and other radionuclide with a half-life more than 1 year.

The import alert always updates food types which may fall under the detention without physical examination. Furthermore, the import alert is applied on foodstuffs which classified on four categories (FDA, 2012b):

a. Category 1 consisting the foods and feeds which are restricted for sale and export by the Japanese government. The products are prohibited to enter the US market even though the levels of radioactive contamination are still below the DILs.
b. Category 2 consisting the foods and feeds from Fukushima, Ibaraki, and Tochigi prefecture which are not yet restricted for sale and export by the Japanese government. These specific products include dairy products and fresh produce. The foods may enter the US market if the levels of radioactive contamination are below the DILs.
c. Category 3 consisting the foods and feeds from Fukushima, Ibaraki, and Tochigi prefecture but are not covered in the FDA's Import Alert. FDA will do the sampling and monitoring of food and feed's radioactive contaminant level before entering the USA market; and
d. Category 4 consisting other food products originating in or consigned from Japan within the FDA regulation that are not listed in the Import Alert and do not belong to other categories. A

regular sampling and monitoring will be carried out by the authorities and the entering permit can be given if the food product complies with the US-FDA standard requirement.

More importantly, FDA relies on the cooperation with the Japanese government to prevent the radiation contaminated foods and feeds entering the USA's market. In other words, the import alert will continuously be updated in accordance to the MHLW reports. Besides that, to verify and ensure the compliance of the radiation contamination level on foods and feeds originating in and consigned from Japan, FDA through the FERN (Food Emergency Response Network) system has been doing the sampling and monitoring on the level of radionuclide of the imported foods at the import entry points. The time frame of the emergency exposure situations is not defined in the US-FDA import alert 99-33. Moreover, the latest update import alert is only focusing on the certain food types originating in and consigned from 3 prefectures (Fukushima, Ibaraki, and Tochigi).

5.3 Indonesia Countermeasures

NADFC published Circular letter on 4 April 2011 which is intended for food business operators (importers) about their obligation to accompany foods[56] originating in and consigned from Japan after 11 March 2011 with a radiation certificate[57]. In other words, foods within the definition of Food Act of 1996 originating in or consigned from Japan are prohibited to enter the market unless food business operators can provide a radiation certificate published by an accredited laboratory in Japan such as the Japan Food Research Laboratories, Japan Inspection Association of Food & Feed Industry Environment, Nippon Kaiji Kentei Kyokai, Shin Nihon Kentei Kyokai, and All Nippon Checkers Corporation. Food business operators could also bring their product sample to get a radiation certificate from BATAN. Moreover, to ensure the compliance of the circular letter, the NADFC food inspectors carried out sampling and monitoring of foods originating in or consigned from Japan at the import entry points. The requirement of a radiation certificate applies to foods originating from all Japan's prefectures without any exception. The radiation certificate is used by importer to obtain an import certificate from NADFC as the regulation requirement to put their product into the market[58]. Until 31 December 2011, 395 import certificates were released by the NADFC for Japan's food products with more than 3231 product items consisting 663 food raw materials, 362 food additives, and 2206 processed foods. Until 31 December 2011, there was no food found to contain a radioactive contamination above the MPL in the Ministry of Health Decree No 1031/MENKES/PER/V/2011 on the maximum permitted levels of radioactive

[56] Foodstuffs include food raw material, food additives, and processed food.
[57] Free radiation is defined as the level of radioactive contaminant is still below the maximum permitted levels in Ministry of Health Decree No 1031/MENKES/PER/V/2011.
[58] Food Act No 7 of 1996 Article 37

contamination on foodstuffs which come from countries/areas which is experiencing a nuclear emergency situation (Table 6).

Table 6 Comparison of the guidance levels between the Ministry of Health Decree No 1031/MENKES/PER/V/2011 and the Japanese Standard

Radionuclide	Foodstuffs (Bq/kg)							
	Ministry of Health Decree No 1031/MENKES/PER/V/2011				Japanese Standard			
	FI	MD	OF	LF/DW	FI	MD	OF	DW
^{90}Sr	-	-	-	-	-	-	-	-
^{131}I	50	100	500	100	-	-	-	-
^{231}Pu & ^{241}Am	-	-	-	-	-	-	-	-
^{134}Cs & ^{137}Cs	100	150	1000	150	50	50	100	10

(-): not regulated

The circular letter concerning the obligation of food business operators to provide the radiation certificate is still applied until now with no update related with the latest situation in Japan following the Fukushima accident. Despite this fact, the measures certainly put additional burden on the food business operators due to the strict requirements in the regulation without considering the real situation in Japan. The MHLW has asked the Indonesian government to lower down the requirements of the circular letter; however, the requirements are still applied until now. The MHLW report on the latest condition on the radioactive contamination on foods has been responded well by the EU and the USA. The status quo of the Indonesia's requirement is based on two main reasons. First is the control of the product in the market will be more effective causing fewer burdens on the monitoring and sampling of the suspected contaminated foods. Second is the government of Indonesia is still reluctant to use the MHLW's report and prefers to wait the WHO and UNSCEAR's report which are still in the assessing process which is expected to be completed at the end of 2013.

6. DISCUSSION

From the previous chapters, the author extracts several interesting findings such as described in Table 7.

Table 7 Summary of comparative analysis of the food safety-related radiological protection system

PARAMETER	The EU	The USA	Indonesia	CAC
Food Safety Control System	Centralized	Multi Agent system	Multi Agent System	Not Applicable
Separated function of risk assessor and risk manager	Comply	Not Comply	Not Comply	Comply
Guideline level classification	Discriminative	Non Discriminative (Single Level System)	Discriminative	Discriminative
ICRP Recommendation used	ICRP 1990	ICRP 1977	ICRP 1977	ICRP 1990
Reference level	1 mSv	5 mSv	5 mSv	1 mSv
Ingestion dose coefficient	ICRP Publication 72	ICRP Publication 56	Not applicable	ICRP Publication 72
Ratio of contaminated foods versus total foods	10%	30%	Not applicable	10%
Standard differentiation based on exposure situation	Applicable	Not Applicable	Not Applicable	Not Applicable

The comparative parameters used related with authorities in the radiological protection system are food control system and separation of function between risk assessor and risk manager. The risk manager in the EU is more centralized in the hands of the Council and Parliament in the legislation establishment and the Commission through DG-Energy and DG-Sanco for risk management. As for the risk assessor, the Article 31 Group of experts is given the mandate to provide the scientific advice and to analyze information. On the other hand, the USA used the multi-agency system as the food control system. This system is established on the basis of authorization division between federal agencies depending on the type of product. Currently, 15 federal agencies are administrating at least 30 federal laws and regulations to control radiological protection-food safety related issues in the USA (usgovinfo.about.com, 2012). Indonesia applies similar framework like in the USA. Some ministries such as the Ministry of Health, the Ministry of

Agriculture, the Ministry of Industry, the Ministry of Trade, the Ministry of Fisheries and Marine Affairs, and also agencies such as NADFC, and BAPETEN are dealing with the radiological protection food safety related policies. Both the USA and Indonesia are not applying the separation between risk assessor and risk manager; in other words, the authority could carry out both risk assessment and risk management. At the international level, the role of risk assessment is mainly carried out by UNSCEAR, WHO/FAO through JECFA, and ICRP. Risk management is carried out by IAEA and CAC especially on the establishment of the international standard such as International BSS and Codex standards.

Second finding is the non-discriminative guidance levels (DILs) in the USA's standard. The DILs are calculated for six different age groups (3 moths, 1 year, 5 years, 10 years, 15 years, and adults). The calculation is carried out using the PAGs and the ingestion dose coefficients relevant to the specific age group and radionuclide (FDA, 2004). The product of the calculation is the series of guidance levels for each radionuclide and age group. Thus, there is only one guidance level is chosen from the series as the DIL for each radionuclide. The DILs determination is carried out by choosing the guidance level that possessed the most limiting PAG. The author called this system, the single level system which has two main features. First feature is the simplicity of the DILs; in other words, the radionuclide-specific DIL is applied for all food categories and age groups. Therefore, monitoring and sampling of the suspected contaminated foods can be done easier than the system of the EU, Indonesia, and CAC. Second feature is the non-discrimination treatment of DILs. The guidance levels between infants' age group and adults' age group are the same. This measure is not relevant with the ICRP Recommendation because infant's age group has a lower ICRP's ingestion dose coefficient compared to adults' age group.

Third, the references used to establish guideline levels vary between countries. This fact is due to different judgment of the countries on three components of decision making. First component is the science. Each country including CAC has its own scientific evidence establishment and also information analysis method. Second component is the experience. Both the EU and USA have suffered direct impact from the nuclear power plant accident and also have a long history dealing with the incident. As for Indonesia, there is no direct impact from a nuclear power plant accident and has no experience dealing with the incident. Finally, the third component is value. Science is not the only value used in the decision making but there are also other reasons such as political, social, economy, and environmental reason.

Next, there is a clear line between standards that apply for emergency exposure situation and standards that apply specifically for existing exposure situations in the EU's regulation. On the other hand, there is no available standard that applied for the existing exposure situation in the USA, Indonesia, and CAC. For example, the USA applied the DILs for only emergency exposure situations. There are no regulated DILs for the existing exposure situations; in other words, DILs that applies for existing exposure situation are designed and evaluated based on the actual condition.

Finally, the guidance level for ^{137}Cs in the Indonesian regulation is stricter than Codex. It is contradictory with the fact that Indonesia has relatively less radiation contamination exposures compared to the EU and the USA. It is also against the SPS Agreement recommendation since Indonesia cannot provide science-based justification for having stricter guidance level compared to Codex.

7. CONCLUSSION AND RECOMMEDATION

This study is performed to compare and analyze the differences of food safety related radiological protection system in the EU, the USA, Indonesia and CAC. There are three parameters used in this comparative study. First, the multi-agency system in Indonesia and the USA is similar. Next, there is no risk assessment and risk management function separation in the USA and Indonesia. A centralized authority system is performed in the EU. EC act as the risk manager related with general and specific policies of the radiological protection and the Article 31 Group of Expert act as the risk assessor. In the international level, the risk assessments are carried out by UNSCEAR in the adverse health effect scope and ICRP in the framework of the radiological protection system. Those risk assessment results are used by IAEA and CAC to establish the risk management. IAEA works on general issues of the radiological protection and CAC on the food related radiological protection issues.

Second, the guidance levels in the EU, the USA, Indonesia, and CAC are different in many aspects. First, they carry out different approaches or judgments on the determination of three equation components (reference level, ingestion dose coefficient and ratio of the contaminated food). Second, the reference levels are taken from different ICRP Recommendations. The USA and Indonesia used the 1977 ICRP Recommendation, but the EU and CAC used the 1990 Recommendation. The situation is also similar with the ingestion dose coefficient. The USA used the ingestion dose coefficient from the ICRP Publication 56, but the EU and CAC have used the ICRP Publication 72. Both the EU and CAC used the ratio of contaminated food 0.1, but the USA used the ratio 0.3.Second, the exposure scenarios on the prospective dose exposure are different. The EU, USA, and CAC applied on-site and off-site radioactive contamination mind set, but Indonesia only applied the off-site mind set. In the aftermath of the Fukushima accident, the EU and the US follow the MHLW's reports to be used as the basis of their protective measure policies. In contrast, Indonesia chooses to neglect the MHLW's reports and prefer to use the UNSCEAR and WHO reports as the consideration to revise or modify their protective measure policies.

There are three recommendations based on this study. First, the harmonization effort can be done in certain guidance levels equation factors (reference level, ingestion dose coefficient and ratio of the contaminated food), but it is impossible to be carried out on the food intake factor because it is based on the national data consumption which is obviously different between countries. Particularly on the aspect of ICRP Recommendation, all countries or any related stakeholder should apply the latest 2007 ICRP Recommendation in order to have a harmonization on the Regulation/Standards and the National radiological protection system to avoid trade barriers and also to ensure high level protection of public health. Second, the single guidance level system in

the USA should be considered as an alternative system in the guidance levels establishment. The system possesses the simplicity properties which could increase the effectiveness of contaminated food monitoring and sampling in the emergency exposure situations. Next, a specific regulation for the existing exposure situations such as the one in the EU should be established to ensure high level protection of public health in all exposure situations and to comply with the 2011 IAEA International BSS requirement. Finally, General Standard for Contaminants and Toxins in Food and Feed (Codex Standard 193-1995) shall be applied as far as possible by the EU, the USA, and Indonesia to establish their food related radiological protection regulation and also should applied Codex Working Principles for Risk Analysis Application for Food Safety for Governments on the establishment of the food safety-related radiological protection system on the basis of risk analysis principle.

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APPENDICES

Appendix 1

Terminology used in radiological protection

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).

Beta emitter
The radionuclide which decays by emitting beta particle, the emission occurs when the ratio of neutrons to protons in the nucleus is too high. In this case, an excess neutron transforms into a proton and an electron. The proton stays in the nucleus and the electron is ejected energetically (EPA, 2012).

Gamma Emitter
The radionuclide which decays by emitting a very high-energy of ionizing radiation.

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).

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).

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).

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

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.

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).

Appendix 2

EU requirement in the form of Export Certification of food product originating in or consigned from Japan.

Declaration for the import into the Union of

…… (Product and country of origin)

Batch identification Code …… Declaration Number ……

According to the provisions of the Commission Implementing Regulation (EU) No 996/2012 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station the

……
……

(authorised representative referred to in Article 6 (2) or 6(3) of Implementing Regulation (EU) No 996/2012)

DECLARES that the

……
……

……

(products referred to in Article 1)

of this consignment composed of:

……

…… (description of consignment, product, number and type of packages, gross or net weight)

embarked at

……
.. (embarkation place)

on

……
……. (date of embarkation)

by

……
… (identification of transporter)

going to ……
(place and country of destination)

which comes from the establishment

……

(name and address of establishment)

is compliant with the legislation in force in Japan as regards the maximum levels for the sum of caesium-134 and caesium-137.

DECLARES that the consignment concerns feed or food

- **not falling under the transitional measures** provided in the Japanese legislation (see Annex III to Implementing Regulation (EU) No 996/2012) as regards the maximum level for the sum of caesium-134 and caesium-137

- **falling under the transitional measures** provided in the Japanese legislation (see Annex III to Implementing Regulation (EU) No 996/2012) as regards the maximum level for the sum of caesium-134 and caesium-137

DECLARES that the consignment concerns:

- feed or food that has been harvested and/or processed before 11 March 2011;
- feed or food that originates in and is consigned from a prefecture other than Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate, other than tea and mushrooms originating in Shizuoka prefecture and other than mushrooms originating in Yamanashi prefecture;
- feed and food that is consigned from Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate prefectures, but does not originate in one of those prefectures and has not been exposed to radioactivity during transiting;
- feed and food not listed in Annex IV to Implementing Regulation (EU) No 996/2012, that originates in and is consigned from Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate;
- tea or mushrooms or a compound feed or food containing more than 50 % of these products, originating in Shizuoka prefecture, and has been sampled on ..... (date), subjected to laboratory analysis on ..... (date) in the..... (name of laboratory), to determine the level of the radionuclide, caesium-134 and caesium-137. The analytical report is attached
- mushrooms or a compound feed or food containing more than 50 % of these products, originating in Yamanashi prefecture, and has been sampled on ..... (date), subjected to laboratory analysis on ..... (date) in the..... (name of laboratory), to determine the level of the radionuclide, caesium-134 and caesium-137. The analytical report is attached;
- feed and food listed in Annex IV to Implementing Regulation (EU) No 996/2012 or a compound feed or food containing more than 50 % of these products, that originates in Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate prefectures, and has been sampled on ..... (date), subjected to laboratory analysis on ..... (date) in the ..... (name of laboratory), to determine the level of the radionuclide, caesium-134 and caesium-137. The analytical report is attached;
- feed and food of unknown origin or containing more than 50 % of (an) ingredient(s) of unknown origin and has been sampled on ..... (date), subjected to laboratory analysis on ..... (date) in the ..... (name of laboratory), to determine the level of the radionuclide, caesium-134 and caesium-137. The analytical report is attached. Done at ..... on ..... Stamp and signature of the authorised representative referred to in Article 6(2) or (3) of Implementing Regulation (EU) No 996/2012,

Part to be completed by the competent authority at the border inspection post (BIP) or designated point of entry (DPE)

- The consignment has been accepted to be presented to the cUStom authorities for release into free circulation in the Union
- The consignment has NOT been accepted to be presented to the cUStom authorities into release for free circulation in the Union

.....
..
(Competent authority, Member State)
.....
..... Date
Stamp
Signature