INTERNATIONAL TRADE IN FOOD AFTER A NUCLEAR ACCIDENT

Doctoral Dissertation

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List of Abbreviations

Abbreviation	Description
AC	Alternating current
ADI	Acceptable daily intake
ALOP	Appropriate level of protection
APHIS	Animal and Plant Health Inspection Service
ASF	African swine fever
SBO	Station blackout
Bq	Becquerel
CCCF	Codex Committee on Contaminants in Food
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFAC	Codex Committee on Food Additives and Contaminants
CFR	Code of Federal Regulations
Codex	Codex Alimentarius Commission
DC	Direct current
DILs	Derived Intervention Levels
DPUI	Dose per unit intake
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Communities
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FDNPP	Fukushima Daiichi Nuclear Power Plant
FMD	foot-and-mouth disease
FSCJ	Food Safety Commission of Japan
GSCTFF	General Standard for Contaminants and Toxins in Food and Feed
Gy	Gray
GATT	General Agreement on Tariffs and Trade
GLs	Guideline Levels
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ILO	International Labour Organisation

IRALFs	Interim International Radionuclide Action Levels for Foods
JAEA	Japan Atomic Energy Agency
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
MAFF	Ministry of Agriculture, Forestry and Fisheries of Japan
MB	Market basket
MEXT	Ministry of Education, Culture, Sports, Science and Technology of Japan
MHLW	Ministry of Health, Labour and Welfare of Japan
MLs	Maximum levels
MOE	Ministry of the Environment of Japan
MRLs	Maximum residue limits
NISA	Nuclear and Industrial Safety Agency
NOAEL	No-observed-adverse-effect-level
NORM	naturally occurring radioactive materials
NRA	Nuclear Regulation Authority, Japan
mSv	Millisievert
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health (Office International des Epizooties)
OJ	Official Journal
PBq	Petabecqurels
PTWI	Provisional tolerable weekly intake
RCIC system	Reactor core isolation cooling system
SBO	Station Blackout
SENASA	*Servicio Nacional de Salud Animal* (National Animal Health Service)
SPS	Sanitary or phytosanitary
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
Standards Code	Agreement on Technical Barriers to Trade (Tokyo Round)
Sv	Sievert
TBT	Technical barriers to trade
TEPCO	Tokyo Electric Power Company
UN	United Nations
UNGA	United Nations General Assembly
UNSCEAR	United Nations Scientific Committee on the Effects of

	Atomic Radiation
UNTS	United Nations Treaty Series
US	United States
USDA	United States Department of Agriculture
USNRC	United States Nuclear Regulatory Commission
WHO	World Health Organization
WTO	World Trade Organization

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Australia – Apples	Appellate Body Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/AB/R, adopted 17 December 2010, DSR 2010:V, p. 2175
Canada – Continued Suspension	Appellate Body Report, *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R, adopted 14 November 2008, DSR 2008:XIV, p. 5373
EC – Hormones	Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, p. 135
India – Agricultural Products	Appellate Body Report, *India – Measures Concerning the Importation of Certain Agricultural Products*, WT/DS430/AB/R, adopted 19 June 2015, DSR 2015:V, p. 2459
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Japan – Apples	Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003, DSR 2003:IX, p. 4391
Korea – Radionuclides	Appellate Body Report, *Korea – Import Bans, and Testing and Certification Requirements for Radionuclides*, WT/DS495/AB/R and Add.1, adopted 26 April 2019
Russia – Pigs (EU)	Appellate Body Report, *Russian Federation – Measures on the Importation of Live Pigs, Pork and Other Pig Products from the European Union*, WT/DS475/AB/R and Add.1, adopted 21 March 2017, DSR 2017:I, p. 207
US – Continued Suspension	Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/AB/R, adopted 14 November 2008, DSR 2008:X, p. 3507

GATT/WTO Panel Reports

Short title	Full case title and citation
Australia – Apples	Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R, adopted 17 December 2010, as modified by Appellate Body

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Australia – Salmon (Article 21.5 – Canada)	Panel Report, *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 of the DSU by Canada*, WT/DS18/RW, adopted 20 March 2000, DSR 2000:IV, p. 2031
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EC – Hormones (US)	Panel Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, WT/DS26/R/USA, adopted 13 February 1998, as modified by Appellate Body Report WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:III, p. 699
EC – Seal Products	Panel Reports, *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, WT/DS400/R and Add.1, WT/DS401/R and Add.1, adopted 18 June 2014, as modified by Appellate Body Reports WT/DS400/AB/R, WT/DS401/AB/R, DSR 2014:II, p. 365
EC – Trademarks and Geographical Indications (Australia)	Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, Complaint by Australia*, WT/DS290/R, adopted 20 April 2005, DSR 2005:X, p. 4603
India – Agricultural Products	Panel Report, *India – Measures Concerning the Importation of Certain Agricultural Products*, WT/DS430/R and Add.1, adopted 19 June 2015, as modified by Appellate Body Report WT/DS430/AB/R, DSR 2015:V, p. 2663
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Korea – Radionuclides	Panel Report, *Korea – Import Bans, and Testing and Certification Requirements for Radionuclides*, WT/DS495/R and Add.1, adopted 26 April 2019, as modified by Appellate Body Report WT/DS495/AB/R
Russia – Pigs (EU)	Panel Report, *Russian Federation – Measures on the Importation of Live Pigs, Pork and Other Pig Products from the European Union*, WT/DS475/R and Add.1, adopted 21 March 2017, as modified by Appellate Body Report

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US – Continued Suspension	Panel Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/R and Add.1 to Add.7, adopted 14 November 2008, as modified by Appellate Body Report WT/DS320/AB/R, DSR 2008:XI, p. 3891
US – Poultry (China)	Panel Report, *United States – Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R, adopted 25 October 2010, DSR 2010:V, p. 1909

Introduction

On 11 March 2011, a tsunami wave triggered by a massive earthquake in eastern Japan caused a severe accident at the Fukushima Daiichi Nuclear Power Plant (FDNPP), which is located on the Pacific Coast of *Fukushima* Prefecture. As a result of this accident, a large amount of "radioactive materials" or "radionuclides"[1] was released into the atmosphere from the reactor, and then dispersed not only around the plant but also into the surrounding areas. Then, radioactive materials fell into the soil through rainfall, contaminating a wide range of areas, especially in *Fukushima* Prefecture.[2]

Radioactive materials continue to emit radiation for a certain period of time after an incidence, or even for years, depending on the type. Once the soil is contaminated, there is a risk that radioactive materials may be contained in agricultural products produced in these areas even several years after the accident. Since it is scientifically undisputed that the ingestion of foods containing radioactive materials above the certain level can cause adverse health effects to the human body (e.g. carcinogenesis),[3] many countries usually adopt a cautious attitude towards food products imported from the country where the nuclear accident occurred, or from the countries affected by the accident.

As soon as the accident of 2011 was reported, "54 countries and regions" in the world introduced some types of import restrictions against food products from Japan.[4] These import restrictions mainly took the form of (i) import ban, (ii) certificate of pre-export testing, and (iii) reinforced inspection at the border.[5] And food products subject to the import restrictions included, *inter alia*, rice, vegetables, fruits, tea, medicinal plants, dairy products, meats (beef, pork and poultry), fishery products and processed foods. Such protective and perhaps

[1] For the meaning of these terms, see Chapter 1.1.
[2] For an overview of the *Fukushima* accident including a map of the contaminated area, see Chapter 1.2.
[3] For the mechanism of the adverse effects of radiation on the human body, see Chapter 1.1.2.
[4] For the Japanese government's reference to this specific number of countries and regions, see Committee on Sanitary and Phytosanitary Measures, Current Status after the Nuclear Power Plant Accident: Communication from Japan (Revision), 16 July 2019, G/SPS/GEN/1233/Rev.1. For the specific names of these countries and regions, see also MAFF, *Lifting of the Import Restrictions on Japanese Foods following the Accident of Fukushima Daiichi Nuclear Power Plant (54 Countries and Regions) (April 2020)*, available at <https://www.maff.go.jp/j/export/e_info/pdf/thrm_en.pdf>, last visited 19 April 2020.
[5] For a detailed explanation of import restrictions on Japanese food products, see Chapter 4.1.

protectionist attitudes for food products from the country where the nuclear accident occurred was not particularly surprising, given the past experience the world faced 25 years ago, that is the *Chernobyl* accident. Shortly after the accident in April 1986, it became clear for the first time how seriously international trade in food could be affected by a nuclear accident.[6]

The following section firstly overviews how the *Chernobyl* accident led to the need for discipline on international trade in food containing radioactive materials. Secondly, it will be shown that, although an international agreement on such discipline was reached after the accident, it was designed in a way that gives importing countries excessively broad discretion. Meanwhile, international trade in food containing radioactive materials could also be regulated by the WTO Agreement that entered into force in 1995. Accordingly, the main question in this dissertation is to what extent the policy discretion given to importing countries regarding the regulation of imported food products containing radioactive materials will be harnessed and limited in the WTO, or to be more specific, the SPS Agreement.[7]

1 Origin of the Problem

On 26 April 1986, a sever accident occurred at the Unit 4 reactor of the *Chernobyl* Nuclear Power Plant, which was located in about 130 km north of Kiev, Ukraine.[8] As a result of the accident, the soil in Ukraine and Belarus, among others, was contaminated by radioactive materials.[9] Before this accident, according to one commentator, it was not anticipated that a single accident of a single reactor could affect an entire country, let alone other countries. The plans by the authorities operating nuclear reactors were based on the assumption that the effects of an accident would be limited within the country.[10] After the *Chernobyl* accident, however, a nuclear accident was interpreted to have a "transboundary" impact on

[6] There was another nuclear accident at the Three Mile Island nuclear power plant in Pennsylvania in March 1979, prior to the *Chernobyl* accident. While large amounts of radionuclides were also released from the reactor, it is noted that "the environmental releases and the resulting exposure of the public was small." UNSCEAR, *Ionizing Radiation: Sources and Biological Effects – 1982 Report to the General Assembly, with annexes* (United Nations Publication, New York: 1982), Annex F, para. 138.

[7] Agreement on the Application of Sanitary and Phytosanitary Measures, Multilateral Agreements on Trade in Goods, Annex 1A of the Agreement Establishing the World Trade Organization, 1867 UNTS 493, entered into force 1 January 1995.

[8] As to the detailed explanation of the *Chernobyl* accident and subsequent radioactive contamination of the environment, see UNSCEAR, *Sources, Effects and Risks of Ionizing Radiation: 1988 Report to the General Assembly, with annexes* (United Nations Publication, New York: 1988), Annex D.

[9] UNSCEAR (1988 Report) paras. 114-116.

[10] Gray, Paul S., 'Agriculture and Trade", in Boris Segerståhl (ed), *Chernobyl: A Policy Response Study* (Springer, New York: 1991) 61.

other countries. For example, in the Convention on Early Notification of a Nuclear Accident adopted by the IAEA in September 1986, immediately after the accident, a definition of "nuclear accident" set out as the applicable scope of this convention refers to any accident "which has resulted or may result in an international transboundary release that could be of radiological safety significance for another State."[11]

In addition to the fact that radioactive contamination of soil can be caused in other countries across the border, a nuclear accident is also "transboundary" in nature in that it can affect international trade in food.

Before the *Chernobyl* accident, almost no country had set out the permitted levels of radioactivity to be contained in imported food. To be precise, the need for such levels was not clearly recognized.[12] Therefore, when the possibility became apparent that agricultural products contaminated with radioactive materials as a result of the *Chernobyl* accident could be placed on the market, a number of countries moved to the import ban against agricultural products from Eastern European countries affected by the accident. On 12 May 1986, around two weeks after the accident, the EEC adopted the import ban as the provisional measures on agricultural products (e.g. meat, milk, fish and vegetables) from Bulgaria, Czechoslovakia (then), Hungary, Poland, Romani, the Soviet Union and Yugoslavia.[13]

Concerns about the EEC's import ban were expressed by contracting parties at the GATT meetings. At the Council held on 22 May 1986, Hungary, Poland and Czechoslovakia raised the issue, contending that the EEC's measure was not consistent with the GATT provisions.[14] As discussed below, since the EEC repealed the import ban at the end of May 1986, this issue was no longer raised at

[11] IAEA, Convention on Early Notification of a Nuclear Accident, 26 September 1986, 1439 UNTS 275.
[12] For example, in 1982, the USFDA issued recommendations with respect to accidental contamination of food products. See USFDA, *Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies*, 47 Fed. Reg. 47,073 (22 October 1982). However, the FDI did not recommend the limits of radioactivity in food, which are called Derived Intervention Levels (DILs), in its 1982 recommendations. Instead, the FDA only recommended 5 mSv/year of the Protective Action Guides (PAGs) for whole body as the acceptable level of risk from the consumption of food accidentally contaminated with radionuclides. For a detailed description of the 1982 FDA recommendations, see e.g. Schmidt, Gail D, 'Development of Guidelines for Safety Evaluation of Food and Water after Nuclear Accidents: Procedures in North America', in Melvin W Carter (ed), *Radionuclides in the Food Chain* (Springer, New York: 1988) 365, 367-371.
[13] Council Regulation (EEC) No. 1388/86, 12 May 1986 on the suspension of the import of certain agricultural products originating in certain third countries, 1986 OJ (L 127) 1.
[14] GATT, Council 22 May 1986, Minutes of Meeting Held in the Centre William Rappard on 22 May 1986, 12 June 1986, C/M/198, at 28-31.

the GATT meetings.[15]

In response to the *Chernobyl* accident, while imposing import bans temporarily, many countries urgently set out the acceptable levels of radioactivity in imported food and tested food products imported from certain Eastern European countries at the border.[16] On 30 May 1986, the EC Council adopted the regulation that sets out the permitted levels of radioactivity to be contained in imported food (i.e. maximum radioactive levels) in terms of the sum of cesium-134 and -137. Such levels were set as 370 Becquerel per kilogram (Bq/kg)[17] for milk, and 600 Bq/kg for all other products.[18] In exchange for introducing these radioactivity levels, the import ban, which had come into effect on 12 May, was repealed pursuant to this regulation.[19] It is important to note, however, that introducing the maximum radioactive levels in food does not mean that an import ban will no longer be relevant. Rather, an import ban may be imposed on imported food if the established levels are exceeded. For example, as set out in Article 5 of the Council Regulation No 1707/86, "repeated non-compliance with the maximum permitted levels" may trigger "the prohibition of the import of products originating in the third country concerned."[20]

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[15] With respect to the GATT consistency with the import ban taken in response to the *Chernobyl* accident, on 16 May 1986, Australia notified to the GATT that it had prohibited the import of food products from certain countries affected by the accident, "in accordance with Article XX(b)" of the GATT. GATT, Import Prohibition of Certain Agricultural Products: Recourse to Article XX(b): Notification by Austria, 27 May 1986, L/5998. Later on, like the EEC, Austria removed the import ban, and instead set out the radioactivity levels in imported food products. GATT, Import Prohibition of Certain Agricultural Products: Disinvocation of Article XX(b): Communication by Austria, 11 June 1986, L/5998/Add.1.

[16] According to the author's research, only three members (EEC, the Philippines, and Finland) notified their radioactivity levels in food to the GATT, pursuant to the Standards Code. For the Philippines, GATT, Committee on Technical Barriers to Trade, Notification, 22 September 1986, TBT/Notif.86.134, and GATT, Committee on Technical Barriers to Trade, Notification, 10 March 1987, TBT/Notif.87.27. For Finland, GATT, Committee on Technical Barriers to Trade, Notification, 16 August 1988, TBT/Notif.88.155, and GATT, Committee on Technical Barriers to Trade, Notification, 16 August 1988, TBT/Notif.88.156.

[17] Becquerel is a unit to describe the ability of a radioactive material to emit radiation, or the intensity of radioactivity in food, soil, water and so on. See Chapter 1.1.1.

[18] Council Regulation (EEC) No. 1707/86, 30 May 1986 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station, 1986 OJ (L 146) 88. The EEC notified this measure to the GATT pursuant to Article 2.6.1 of the Standards Code. GATT, Committee on Technical Barriers to Trade, Notification, 13 June 1986, TBT/Notif.86.85. Later, on 22 December 1987, the EEC adopted the regulation laying down the maximum permitted levels for foodstuffs on a permanent basis. For example, the maximum permitted levels in terms of the sum of caesium-134 and caesium-137 were set as (i) 1,000 Bq/kg for dairy products, and (ii) 1,250 Bq/kg for other general foods. Council Regulation (EURATOM) No. 3954/87, 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency, 1987 OJ (L 371) 11.

[19] Article 8 of the Council Regulation (EEC) No 1707/86.

[20] Article 5 of the Council Regulation reads that "[w]here cases of repeated non-compliance with the maximum permitted levels have been recorded, the necessary measures may be

At the time of the *Chernobyl* accident, however, there was no international agreement on the permitted levels of radioactivity in food products to be traded internationally. Therefore, while some countries simply followed the EEC's radioactivity levels, [21] many countries adopted the diversified levels of radioactivity applying to imported food products (see Table 1).[22]

taken…Such measures may even include the prohibition of the import of products originating in the third country concerned."

[21] For example, on 31 October 1986, six months after the accident, Japan set the levels of radioactivity in food products after the *Chernobyl* accident. See Chapter 4.2.1.1.

[22] Gray ('Agriculture and Trade') 74. As to a table of the maximum levels for radionuclides in milk and dairy products adopted by GATT members in response to the *Chernobyl* accident, see GATT, The Chernobyl Nuclear Accident and Dairy Trade: Note by the Secretariat, 11 March 1987, DPC/W/69.

Table 1 Concentration Levels Set by Countries for Imported Foods after the Chernobyl Accident

Country	Dairy products			Other foods		
	Cs-134	Cs-137	Total Cs	Cs-134	Cs-137	Total Cs
Group 1						
Finland	–	–	1,000	–	–	1,000
EC 12	–	–	370	–	–	600
Abu Dhabi	–	–	370	–	–	600
Brazil	–	–	370	–	–	600
Cyprus	–	–	370	–	–	600
Egypt	–	–	370	–	–	600
Hungary	–	–	370	–	–	600
Israel	–	–	370	–	–	600
Switzerland	–	–	370	–	–	600
USSR	–	–	370	–	–	600
Sweden	–	–	300	–	–	300–1,500
Belize	370	370	–	370	370	–
Algeria	267	302	–	267	302	–
Argentina	–	–	500	–	–	–
Group 2						
USA	–	–	370	–	–	370
Japan	–	–	370	–	–	370
Nigeria	–	–	370	–	–	370
Taiwan	–	–	277	–	–	–
Venezuela	–	–	250	–	–	300
Tunisia	–	–	100	–	–	500
Canada	100	100	–	300	300	–
Jordan	–	–	250	–	150–250	–
Group 3						
Malaysia	120	60	–	216	108	–
Indonesia	–	150	–	–	150–300	–
Syria	–	–	150	–	–	150
China	–	–	148	–	148	–
Group 4						
Australia	–	–	100	–	–	100
Morocco	–	100	–	–	100	–
Bangladesh	–	–	95	–	–	50
Kuwait	–	–	90	–	–	–
Qatar	–	–	30	–	–	75
Saudi Arabia	–	–	30	–	–	70
Philippines	–	–	22–33	–	–	6–28
Thailand	–	–	21	–	–	7
Iran	–	–	10	–	–	10
Singapore	–	–	0	–	–	0

Paul S. Gray, "Agriculture and Trade", in Boris Segerståhl (ed.), *Chernobyl: A Policy Response Study* (1991) at 74.

2 Research Question

As explained in the previous section, when the *Chernobyl* accident occurred, many countries temporarily banned imports of agricultural products from the countries affected by the accident. Meanwhile, they urgently set out the acceptable levels of radioactivity in imported foods, and then inspected these products at the border to see if the acceptable levels are exceeded. As is shown in Table 1, however, the radioactivity levels established for imported foods varied significantly from country to country, except for those that followed the EEC's

levels (i.e. 370 Bq/kg for dairy products, 600 Bq/kg for other products). The problem here is not the fact that radioactivity levels set out by countries were diverse in the absence of international standards and agreement. It is probably within the scope of sovereignty to decide what extent to protect its own citizens from ingesting radioactive materials contained in imported foods. Rather, the problem is that it was not always clear whether the radioactivity levels set by each country for imported foods were decided on a rational basis. Such decision would not be rational without taking into account the elements, such as (1) an assessment of adverse effects on human health arising from radiation exposure, (2) the actual extent to which imported foods from the countries affected by the Chernobyl accident were contaminated, and (3) policy considerations as to the acceptable level of health risk arising from the ingestion of imported foods containing radioactive materials.[23]

In response to these concerns, sometime after the *Chernobyl* accident, the need for an international agreement on the radioactivity levels in food to be traded internationally was explicitly recognized.

The development of international agreement on the acceptable levels of radioactivity in food to be used for international trade was mainly led by the Codex.[24] In 1989, the Codex adopted the Guideline Levels (GLs) as the levels of concentration for radionuclides in food to be traded internationally during one year after a nuclear accident on the basis of the ICRP's recommendations. For example, the GLs were set as 1,000 Bq/kg of caesium-134 for general food, excluding milk and infant food.[25] The GLs, which were later integrated into Codex standards, are merely voluntary and do not have legally binding effect on members.[26]

In the subsequent SPS Agreement, adopted in 1995, Codex standards are treated as constituting "international standards",[27] and WTO Members are obliged to base their SPS measures on Codex standards with respect to food safety.[28] With such provisions, trade restrictions possibly imposed on food products from the

[23] It is explained that the EEC's maximum radioactive levels were decided, taking into account the scientific basis provided by the ICRP. Gray ('Agriculture and Trade') 69.
[24] The Codex, a joint advisory body of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) with over 180 Members, was established at the Sixteenth World Health Assembly held in 1963. For details, see Chapter 3.
[25] As to the historical development and content of the Codex GLs, see Chapter 3.1.
[26] Codex, *FAQ: Are Codex standards mandatory?*, available at <http://www.fao.org/fao-who-codexalimentarius/about-codex/faq/faq-detail/en/c/454753/>, last visited 22 April 2020.
[27] Annex A(3)(a) of the SPS Agreement.
[28] Article 3.1 of the SPS Agreement. However, it does not mean that Codex standards are legally binding on WTO Members. See Appellate Body Report, *EC – Hormones*, para. 165.

country where a nuclear accident occurred or other countries affected by the accident would be expected to be convergent and harmonized.[29]

Although specific figures were agreed as to the acceptable levels of radioactivity in food for international trade, it is worth noting that the Codex standards were silent on the actions countries are entitled to take when imported foods exceeding the GLs are detected. In this regard, Codex standards contain the following provision:

> Guideline Levels are intended for use in regulating foods moving in international trade. When the Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction.[30]

It follows from this provision that it is within the wide discretion of the importing country to decide how to respond to the detection of imported food exceeding the GLs. Put differently, Codex standards do not appear to prevent the importing country from prohibiting future imports of this food, let alone lots containing the food samples exceeding the GLs, or from requiring additional testing of this food, if a sample above GL is detected at the border even once.

For example, as of 2 March 2020, 9 years after the *Fukushima* accident, the import ban against Japanese food products is still maintained according to government information by 6 countries and regions, while 34 out of the 54 countries and regions that had introduced import restrictions right after the accident have lifted them by that time.[31] If such an import ban is maintained as a response to the detection of Japanese food products exceeding the GLs, at least within the framework of Codex standards, it may not necessarily be a problem and in line with the Codex Guidelines.[32]

However, WTO Members do not enjoy such discretion that is widely granted to importing countries under Codex standards. If a WTO Member adopts import restrictions, including import bans, as a response to the detection of imported food that exceeds the GLs, such measures must be also subject to the disciplines of the SPS Agreement. In principle, such measures cannot be taken without

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[29] It is noted that WTO Members are not required to bring their SPS measures into line with international standards. In addition, in the SPS Agreement, Members are also entitled to deviate from international standards and to adopt more stringent levels of radioactivity for imported food than the Codex GLs. See Chapter 3.2.

[30] Codex Alimentarius Commission, Report of the 18th Session of the Codex Alimentarius Commission, ALINORM 89/40 (1989), para. 101 (emphasis added).

[31] MAFF, *Status of Countries and Regions Introduced Import Measures on Japanese Foods after the TEPCO's Fukushima Daiichi Nuclear Power Plant Accident (2 March 2020)*, available at <https://www.maff.go.jp/j/export/e_info/pdf/kisei_gaiyo_en.pdf>, last visited 19 April 2020.

[32] In the author's view, this is why Japan did not make a claim under Article 3 of the SPS Agreement in *Korea – Radionuclides*.

sufficient scientific evidence. Instead, they needs to be based an assessment of adverse effects on human health arising from radioactive materials in foods.[33] In addition, such measures must not be overly stringent. Rather, they must be taken only to the extent necessary to achieve the acceptable level of risk arising from the ingestion of imported food.[34] The legal disciplines for international trade in food products containing radioactive materials differ greatly between before and after the establishment of the WTO.

The 2015-2019 WTO dispute *Korea - Radionuclides*, in which the consistency of the import restrictions taken by Korea against Japanese fishery products after the *Fukushima* accident with the SPS Agreement was challenged, is placed in this context. This case dealt with the systematic issue of how the SPS Agreement could regulate the matters that are considered to fall within the discretion of importing countries under Codex standards.[35]

In light of the above, the main question to be addressed in this doctoral dissertation is to what extent a WTO Member enjoys policy space and discretion under the SPS Agreement when imposing import restrictions on food products imported from the country where a nuclear accident occurred, and other countries were affected by the accident.

[33] Articles 2.2 and 5.1 of the SPS Agreement. See Chapter 4.4.
[34] Article 5.6 of the SPS Agreement. See Chapter 4.5.
[35] As a literature analyzing this case, see e.g. Hamada, Taro and Ishikawa, Yoshimichi, 'Are Korea's Import Bans on Japanese Foods Based on Scientific Principles? Comments on Reports of the Panel and the Appellate Body on Korean Import Bans and Testing and Certification Requirements for Radionuclides (WT/DS495)' (2020) 11(1) European Journal of Risk Regulation 155.

Chapter 1

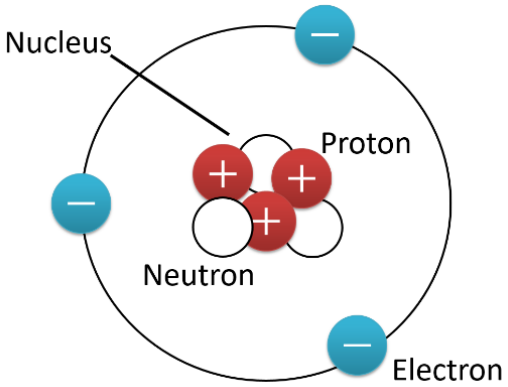
Background Information

An unstable nucleus, which is the central core of an atom, releases extra energy when it becomes a more stable nucleus. This energy, which travels in the form of particles or electromagnetic waves, is called "radiation". It is undisputed that radiation can have an adverse effect on the human body if the certain level is exceeded. In order to realize the biological effects of radiation, it is necessary to learn the mechanism of radiation by going back to the basic structure of an atom, and then to understand the phenomenon called "ionization" caused by radiation. Therefore, before turning to the details of the *Fukushima* accident (Chapter 1.2), this chapter will briefly overview the basic units and concepts relating to radiology (Chapter 1.1).[1]

1.1 Basic Understanding of Radiation

As illustrated in Figure 1, an atom is composed of a nucleus, which is the central core of an atom, and the electrons that orbit around the nucleus. The mass of an atom is almost equal to the mass of a nucleus.

Figure 1 Image of atomic system



A nucleus further consists of one or more (i) protons and (ii) neutrons. A proton is an elementary particle that is stable, bearing a positive charge equal in magnitude to that of an electron, which carries a negative electrical charge. As a result, the overall charge of an atom results in zero. Put it differently, when an atom is electrically neutral, it means that it contains the same number of protons and electrons.

[1] The description of this section relies heavily on the following work. Komatsu, Kenshi, *Contemporary Radiobiology* (Cambridge Scholars Publishing, Cambridge: 2019); Martin, Alan, Harbison, Sam, Beach, Karen, and Cole, Peter, *An Introduction to Radiation Protection*, 7th edn (CRC Press, Boca Raton, Florida: 2019); Law, Jonathan (eds), *A Dictionary of Science*, 7th edn (Oxford University Press, Oxford: 2017).

Each atom has its own atomic number, which is equal to the number of protons in the nucleus. This is so because a proton determines the chemistry of an atom. For example, the atomic number of caesium is 55, which means that the number of protons in caesium is 55. However, there are some atoms that have the same number of protons but different number of neutrons. For example, caesium can be caesium-133 if it contains 78 neutrons, while it can also be caesium-137 if it contains 82 neutrons.[2] Thus, they are called "isotopes" in the sense that they are the same type of substance.[3]

There are two types of isotopes; that is (i) "radioisotopes," which are unstable so that they decay and emit radiation,[4] and (ii) "stable isotopes," which are stable so that they do not emit radiation. Caesium-133 is the only stable and natural isotope of caesium, while caesium-137 is one of the unstable isotopes,[5] which was released into the atmosphere as a result of the *Fukushima* accident.

Moreover, the term "nuclide" is used to further specify an atom by the type of nucleus.[6] Caesium-133 and caesium-137 are isotopes, meaning that they have the same number of protons, but different number of neutrons. Therefore, in terms of the type of nucleus, they are different and thus are explained to be different nuclides.

1.1.1 Types of Radiation Emitted from Nuclear Decay

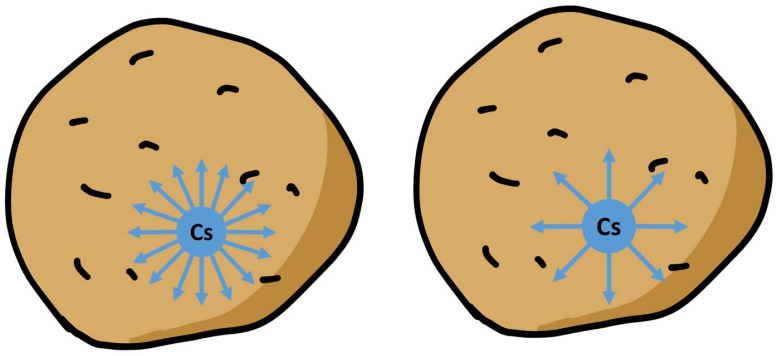
A nucleus that is unstable as it contains too many or few neutrons transforms into another stable nucleus.[7] This phenomenon is called "decay." The decay of a nucleus is accompanied by the emission of the following particles; that is (i) alpha particles, (ii) beta particles, or (iii) gamma radiation.[8] They are composed of particles with different properties. As explained below, alpha particles are helium nuclei, beta particles are electrons, and gamma radiations are photons or electromagnetic wave. Nevertheless, they are collectively referred to as radiation. Importantly, radiation travels with large amount of energy. When it enters into a substance, "ionization" occurs. And ionization will cause adverse effects on the

[2] The number 133, which is the sum of the number of protons and the number of neutrons, is called the "mass number".
[3] An isotope refers to one of two or more atoms that have the same number of protons in their nucleus with different numbers of neutrons. See Law (*Oxford Dictionary*) 494.
[4] For the meaning of radioactivity, see Chapter 1.1.1.
[5] There are 15 radioisotopes. See Law (*Oxford Dictionary*) 134.
[6] In other words, the type of nucleus is determined by the number of protons and neutrons.
[7] An original nucleus is also called a "parent nucleus." And a nucleus formed by the decay of the parent nucleus is called a "daughter nucleus."
[8] For example, caesium-137, which is an unstable isotope of caesium, emits beta particles and gamma radiation in the process of decay into a stable nucleus, which is barium-137. Radiation emitted from nuclei is not limited to these three types. For example, a particle called a neutron bean may be emitted.

human body.[9] Thus, to be more precise, radiation is called "ionizing radiation."[10]

The ability to emit radiation from a nucleus is called "radioactivity." A material that emits radiation, or in other words, that is radioactive, is called a "radioactive material." Likewise, a nuclide that emits radiation, or is radioactive, is called a "radionuclide." These two terms are often used interchangeably, but that is not a misuse. Caesium-137, for example, is a radionuclide, but is also called as a radioactive material in more general terms. The intensity of radioactivity is described by the unit of Becquerel (Bq). 1 Bq refers to the amount of radioactive materials that undergoes one decay of nucleus per second. For example, if 370 Bq/kg of caesium-134 and caesium-137 is detected from food, it means that 1 kg of this food contains radioactive materials or radionuclides with the decay of 370 nuclei per second. Therefore, the higher the Bq value, the greater the number of decaying nuclei will be. Hence, in that case, the level of radioactive contamination will be also high (see Figure 2).

Figure 2 Images of potatoes with high (left) and low (right) levels of radioactive contamination (Cs=caesium)



In this regard, the four types of radioactive materials released into the environment as a result of the *Fukushima* accident were iodine-131, cesium-134, cesium-137, and strontium-90. All of them emit beta or/and gamma rays when they decay.

Firstly, due to the decay of certain nucleus, (i) alpha particle, which is generally known as an alpha-ray or alpha-radiation, is emitted like a stream.[11] An alpha particle constitutes a helium-nucleus (i.e. 2 protons and 2 neutrons), and thus carries positive charge. Thus, the loss of an alpha particle from a nucleus due to the decay leads to a decrease of 2 in the atomic number, as well as 2 in the

[9] As to ionization, see Chapter 1.1.2.
[10] On the other hand, there are other types of radiation that do not have enough energy to generate ionization. Such type of radiation is called non-ionizing radiation (e.g. infrared ray, ultraviolet light). See Law (*Oxford Dictionary*) 486.
[11] Law (*Oxford dictionary*) 30.

nucleon number.[12] Alpha rays have the property of not penetrating the substance. They stop at the surface of the skin, and do not reach inside the body. Thus, for alpha rays, attention should be paid to exposure through the ingestion of radionuclides. It is estimated, however, that little of plutonium-239, which emits alpha rays during a decay process, was emitted in this accident.[13]

Secondly, (ii) beta particle is an electron emitted from a nucleus as a consequence of decay. To be more specific, when decay occurs, a neutron in the nucleus transforms into a proton as well as an electron. While the electron is released from an atom as a high speed, the proton stays inside the nucleus. An electron emitted from a nucleus in this process is called beta particle.[14] As a result of the beta decay, a nucleus will transform into the one with one more atomic number (because one proton increases) and one less neutron.[15] Whereas the human body can be protected from the alpha ray with just a single sheet of paper, a thin aluminum board or a glass board is needed to shield the beta ray. In addition, beta rays are extinguished when they travel a few meters through the air.

Thirdly, it may occur that a daughter nucleus formed as a result of alpha and gamma decay still contains excess energy, and remains in an excited state (i.e. excitation). In this case, the daughter nucleus further decays into a stable state by emitting this excess energy in the form of electromagnetic waves, which are called (iii) gamma radiation. Especially, beta decay frequently leads to an excited stage of the daughter nucleus.[16] For example, when nuclei of caesium-137 (i.e. protons 55, neutrons 82) decay with the emission of beta particle, it is only 5.6% of them that will directly transform into a ground state of barium-137 (i.e. protons 56, neutrons 81), whereas 94.4% of them will firstly transform into an excited state of barium-137, which is described as "barium-137m."[17] In the latter case, barium-137m is still in an unstable state. Thus, immediately after the occurrence of excitation, the excited daughter nucleus will further decay to achieve further stability with the emission of gamma radiation.

1.1.2 Biological Effects of Radiation

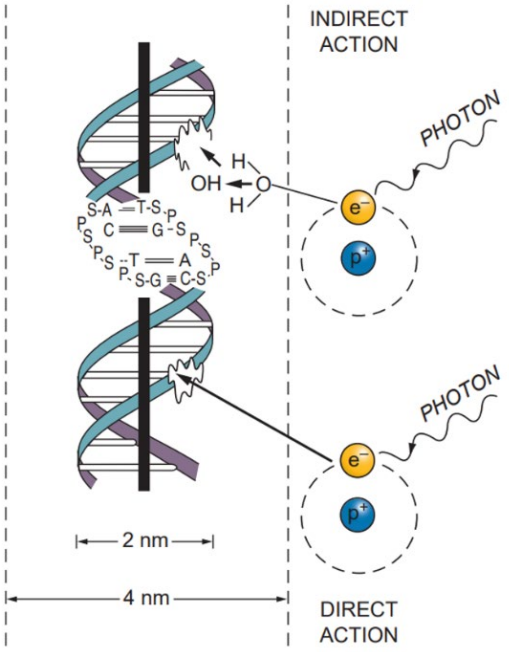
It is scientifically undisputed that a certain amount of radiation exposure causes

[12] For example, the decay of a nucleus in Uranium-238 (i.e. protons 92, neutrons 146) transforms into Thorium-234 (i.e. protons 90, neutrons 144) by emitting alpha particle.
[13] For the radionuclides released by the accident, see Chapter 1.2.
[14] Law (*Oxford Dictionary*) 93-94.
[15] For example, when a nucleus of Caesium-134 (protons 55, neutrons 79) decays with the emission of beta particle, it converts into Barium-134 (protons 56, neutrons 78).
[16] Grupen, Claus, *Introduction to Radiation Protection: Practical Knowledge for Handling Radioactive Sources* (Springer, New York: 2010) 20.
[17] Komatsu (*Contemporary Radiobiology*) 22-23.

some adverse effects on the human body. The following will overview how the human body is affected by exposure to radiation in terms of radiobiology.[18]

First of all, it must be emphasized that radiation itself does not directly damage the DNA in the body cell. To be exact, it is either electrons or "free radicals",[19] both of which are generated through ionization of water molecules caused by radiation, that lead to biological effects to the body cell (see Figure 3).

Figure 3 Direct/Indirect Actions of Radiation



Source: Hall, Eric J and Giaccia, Amato J, *Radiobiology for the Radiologist*, 7th edn (2012) 9.

Thus, radiation affects the cells of the human body via "ionization" of water molecules. Ionization is generally defined as "the removal of an orbital electron from an atom"[20] and occurs as follows. When radiation released from a nucleus as a result of decay is exposed to the human body and collides with water molecules in the body cell, its energy repels one or more orbital electrons of the molecules, and then separates them from positively charged atoms. In other words, unlike heat, light or radio waves, nuclear radiation contains sufficient energy to cause ionization in the cells of human body, and such radiation is specifically called

[18] See Hall, Eric J and Giaccia, Amato J, *Radiobiology for the Radiologist*, 7th edn (Wolters Kluwer Health, Lippincott Williams & Wilkins, Philadelphia: 2012). Radiobiology is the branch of biology concerned with radioactive compounds and ionization. Law (*Oxford Dictionary*) 776.
[19] See below.
[20] Martin et al (*Radiation Protection*) 17.

"ionizing radiation."[21]

Firstly, when radiation hits the human body, water molecules in cell absorb the energy, resulting in ionization explained above. Electrons repelled from an atom as a result of ionization might directly breaks links in chain molecules (i.e. direct effect). However, it is believed that the biological effects of radiation on body cells through ionization occur as the "indirect effect" described below.

Secondly, when radiation hits a substance, biological effects are also caused through the following steps; that is (i) a substance absorbs energy transferred from radiation, and then water molecules are ionized and excited (physical stage), (ii) the positive water ion (i.e. H_2O^+) formed through ionization reacts with other water molecules, and as a result, reactive products, called free radicals,[22] are created (physicochemical stage), (iii) such reactive radicals diffuse, and cause chemical reactions to important molecules of the body cell (chemical stage), and then (iv) the chemical reactions above damage the DNA, and as a result, a variety of biological effects are caused (biological stage).[23]

In light of the above, electrons or free radicals resulting from ionization triggered by radiation damage DNA in cells, which contains gene sequences as a basis for life information. Thus, when DNA is damaged by radiation (e.g. breaking DNA strand), its repair function is disrupted, causing cells to die or "mutations"[24] to accumulate. And they could eventually lead to cancer. The biological stage might occur even tens of years after the exposure of ionizing radiation.

1.1.3 Relevant Units

As explained in the previous section, when a substance is exposed to radiation, the substance absorbs the energy of the radiation mainly through ionization. In other words, radiation transfers energy to the substance.[25] The energy per unit mass absorbed by a substance through exposure is called "absorbed dose",[26] which is expressed in terms of Gray (Gy).[27] Although the term "dose" is generally

[21] Law (*Oxford Dictionary*) 485-486; Martin et al (*Radiation Protection*) 29.
[22] Free radical refers to "[a] fragment of an atom or molecule that contains an unpaired electron, which, therefore, make it very reactive." Hall and Giaccia (*Radiobiology*) 520.
[23] See Martin et al (*Radiation Protection*) at 29-30.
[24] Mutation refers to "[a] sudden random change in the genetic material of a cell that potentially can cause it and all cells derived from it to differ in appearance or behavior from the normal type…Mutations occur naturally at a low rate but this may be increased by radiation". Law (*Oxford Dictionary*) 614-615.
[25] However, it is noted that not all of the energy is transferred to the substance. Only some are absorbed by the substance.
[26] Law (*Oxford Dictionary*) 284.
[27] 1 Gy amounts to 1 Joule (J) per kilogram, which is the unit of work and energy. Law (*Oxford Dictionary*) 499.

used to measure the quantity of radiation, the unit of absorbed dose is concerned with the amount of energy.

However, the amount of energy absorbed in a substance from ionizing radiation does not correspond to the degree of adverse health effects. Even if the same amount of energy is absorbed, the adverse health effect will be different, depending on (i) the type of radiation, and (ii) the sensitivity of the tissues/organs exposed to radiation. Thus, the absorbed dose alone cannot be used to measure the adverse effects of ionizing radiation on the human body.

Firstly, there are differences in the degree of adverse effects on the human body, depending on the type of radiation exposed.[28] For example, according to the ICRP, 1 Gy of alpha particle is estimated to produce 20 times greater adverse effects than 1 Gy of beta particle or gamma radiation.[29] The correction factor that takes into account differences in biological effectiveness betweeen different types of radiation is called the "radiation weighting factor."[30] Therefore, the adverse effects of radiation on certain tissue and organ of the body can be correctly measured by multiplying the absorbed dose by the radiation weighting factor values. The dose calculated in this way is called "equivalent dose", which is expressed in terms of Sievert (Sv).[31]

Secondly, when the whole body is uniformly irradiated, all tissues and organs of the body are supposed to be exposed to the identical equivalent dose. However, some tissues or organs of the body are more sensible to radiation than others. Such a feature of the organ and tissue is called radiosensitivity.[32] According to the ICRP, the risk arising from radiation exposure is estimated to be four times greater for the thyroid gland, eight times greater for the gonads, and twelve times greater for the bone marrow, stomach, and lungs than for the skin.[33] The correction factor that takes into account differences in radiosensitivity betweeen different tissues and organs on the body is called the "tissue weighting factor"

[28] As noted by the ICRP, "[i]n order to relate the radiation dose to radiation risk (detriment), it is also necessary to take into account variations in the biological effectiveness of radiations of different quality." ICRP, The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37(2-4) (2007) para. 100.
[29] ICRP, Publication 103 (2007), para. 112.
[30] Hall and Giaccia (*Radiobiology*) 529.
[31] For example, in case that only the head is partially exposed to 100 mGy of gamma radiation, the extent of exposure for each tissue and organ of the head is determined by multiplying the radiation weighting factor value for gamma radiation, which is estimated to be one by the ICRP, by the absorbed dose. In this case, it is explained that the head was exposed to an equivalent dose of 100 mSv.
[32] It refers to "[a] relative susceptibility of cells, tissues, organs or organisms to the effects of radiation." Hall and Giaccia (*Radiobiology*) 529.
[33] ICRP, Publication 103 (2007), para. 126.

(see Table 2).[34] The equivalent dose multiplied by the tissue weighting factor value is called "effective dose", which is also expressed in terms of Sv.

Table 2 Tissue weighting factors recommended by the ICRP

	Tissue/Organs	Tissue Weighting Factor
(a)	Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues	0.12
(b)	Gonads	0.08
(c)	Bladder, Oesophagus, Liver, Thyroid	0.04
(d)	Bone surface, Brain, Salivary glands, Skin	0.01

Source: ICRP, Publication 103, para. 126.

On the one hand, if the whole body is exposed to 1 mGy of gamma radiation,[35] the effective dose is simply estimated to be 1 mSv.[36] On the other hand, assume that only the head is partially exposed to 1 mGy of gamma radiation. In this case, while the equivalent dose for the head is 1 mSv, the effective dose could be estimated to be 0.07 mSv, which consists of 0.04 mSv for the thyroid, 0.01 mSv for brain, 0.01 mSv for skin and 0.01 mSv for other tissues/organs of the head.

It means that when the unit of Sv is used, it needs to be clarified whether it means the equivalent dose, which is not corrected by differences in radiosensitivity for tissues and organs, or the effective dose. Unfortunately, however, the unit Sv is often used without clarifying this point. For example, the equivalent dose of 100 mSv to the thyroid is not the same as the effective dose of 100 mSv to this organ. The effective dose for the former case is estimated to be 4 mSv, given that the tissue weighting factor value for thyroid is set at 0.04.

1.1.4 Health Effects of Radiation on the Human Body

The previous section briefly surveyed the biological mechanisms by which radiation exposure affects the human body. It was shown that radiation eventually causes DNA damage in cells as a biological effect, and this would increase the risk of carcinogenesis.

For the purpose of radiological protection, health hazards caused by exposure to radiation are classified into (i) stochastic effects, and (ii) deterministic

[34] To be more exact, this factor refers to "the ratio of the risk of stochastic effects attributable to irradiation of a given organ or tissue to the total risk." Hall and Giaccia (*Radiobiology*) 533.
[35] The radiation weighting factor value for gamma radiation is one.
[36] This is the sum of 0.72 mSv for tissues/organs in category (a), 0.8 mSv for gonads in category (b), 0.16 mSv for tissues/organs in category (c), and 0.04 mSv for tissues/organs in category (d).

(non-stochastic) effects in terms of the relationship between exposure dose and the appearance of symptoms. The adverse effects on the human body caused through DNA damage (or, more precisely, subsequent mutations), such as cancer and leukemia, are classified into (i) stochastic effects, as they occur only in a probabilistic manner.

On the other hand, exposure to a large amount of radiation at once (e.g. nuclear accident, nuclear bomb) causes cell death in tissues, which can cause acute effects (e.g. bone marrow damage, hair loss, infertility) and late effects (e.g. cataracts) to tissues with high cell division. For the former, symptoms appear within a few weeks and for the latter, months later. Contrary to stochastic effects caused by mutations, these adverse effects occur only when the exposure is above a certain threshold. Thus, they are called "non-stochastic (deterministic)" effects.

As already explained,[37] however, this dissertation focuses on the discipline of international trade in foods containing radioactive materials released by a nuclear accident. And the risk at issue is the adverse effects on human health arising from the ingestion of food containing such radioactive materials, which can be broadly described as carcinogenic risk. Therefore, the issue here is limited to stochastic effects in the field of radiation protection.

1.1.4.1 Stochastic Effects

In 2007, the ICRP noted that the "nominal risk coefficient"[38] for the lifetime risk of death from cancer was 5.5% per Sievert (i.e. 5.5×10^{-2}/Sv) for the whole population, including both sexes and all ages.[39] It means that if 100 people are exposed to the radiation dose of 1 Sv (1,000 mSv) for a lifetime, 5.5 people (4.1 for adults, 1.4 for children) out of 100 are supposed to die of cancer. As noted by the ICRP, much of the epidemiological information on the risk of death from cancer due to radiation exposure is the result of a follow-up study of survivors of the 1945 atomic bombings in Japan, which is called "Life Span Study (LSS)."[40]

LSS aims to investigate the adverse effects of the acute exposure caused by the atomic bombs on the human body. Therefore, when calculating the effects of the lifetime exposure on human health based on the LSS, it is necessary to taken into

[37] See Introduction.
[38] It is sex-averaged and age-at-exposure-averaged lifetime risk estimates for a representative population. ICPR, Publication 103 (2007), at 26.
[39] ICRP, Publication 103 (2007), paras. 73, 83.
[40] ICRP, Publication 103 (2007), para. 68. The LSS is a research program to investigate lifelong health effects of radiation exposure based on epidemiological studies. The LSS reports are available from the webpage of the Radiation Effects Research Foundation (RERF) < https://www.rerf.or.jp/en/library/list-e/scientific_pub/lss/> last visited 26 April 2020.

account the rapidity of exposure. Even if the identical amount of radiation dose is exposed to the human body, cancer risk will be higher if it is an acute exposure with high dose rate, compared with that of prolonged exposure with low dose rate (i.e. dose rate effectiveness). Thus, the ICRP's estimation was based on the assumption that a dose and dose-rate effectiveness factor (DDREF) is 2.[41] It means that the risk of cancer death was assumed to be half in case of prolonged exposure, compared to the acute exposure.

As noted before, the ICRP estimated that the exposure of 1 Sv for a lifetime will result in the 5.5% increase of death rate for cancer. In addition, according to the ICRP, the risk of death from cancer increases or decreases in proportion to the amount of exposed radiation. Therefore, it follows that 5.5 out of 1,000 people will die of cancer due to the exposure of 0.1 Sv (100 mSv) for a lifetime. Furthermore, if 100,000 people were exposed to the low dose of 1 mSv (0.001 Sv) for a lifetime, it would be calculated that 5.5 people will die of cancer. In Japan, for example, the probability of dying from cancer in one's lifetime are estimated to be 24% for men and 15% for women based on the 2018 data.[42] Thus, for example, if a Japanese man is exposed to 100 mSv in his lifetime, the probability of dying from cancer increases to 24.55%.

In contrast, there has been scientific uncertainty about the stochastic effects on human health at doses below about 100 mSv.[43] Nevertheless, for the purpose of radiological protection, the ICRP has long taken the cautious assumption that, unlike deterministic effects, there exists no threshold dose for the risk of cancer or heritable effects, even in the low dose range below about 100 mSv.[44] Instead, the ICRP has adopted the assumption that, at low doses, radiation doses greater than zero will increase the risk of cancer and heritable disease in a simple proportionate manner, which is widely known as the "linear-non-threshold (LNT) model." According to the ICRP, the LNT model servers the best practical approach to managing risk from radiation exposure, and that its recommendations are based

[41] ICRP, Publication 103 (2007), para. 70.
[42] National Cancer Center Japan, The Latest Cancer Statistics, available at <https://ganjoho.jp/reg_stat/statistics/stat/summary.html>, last visited 26 April 2020.
[43] However, this does not mean that there is no evidence for radiation risk at doses below about 100 mSv. For example, the ICRP notes that "epidemiological and experimental studies provide evidence of radiation risk albeit with uncertainties at doses about 100 mSv or less." ICRP, Publication 103 (2007), para. 62. However, the ICRP also notes that biological or epidemiological information that unambiguously verifies the LNT model, which will be explained later, is unlikely to be forthcoming. ICRP, Publication 103 (2007), para. 66.
[44] ICRP, Publication 103 (2007), para. 64. This cautious assumption was already taken by the ICRP in Publication 9 (1965). The ICRP noted that "[t]he assumption is made that, down to the lowest levels of dose, the risk of inducing disease or disability increases with the dose accumulated by the individual. This assumption implies that there is not wholly 'safe' dose of radiation." ICRP, Recommendations of the International Commission on Radiological Protection. ICRP Publication 9 (Pergamon Press, Oxford: 1966), para. 29.

on this model.[45]

1.1.4.2 Deterministic Effects

High dose exposure in a short period of time (e.g. nuclear accident) causes the killing of cells, then leading to irreversible destruction of human tissues. As a result, symptoms such as hair loss, cataracts, and skin disorders appear. Such health effects are called "deterministic effect" or "tissue response".

Importantly, there is a threshold for deterministic effects, meaning that "[t]he probability of causing such harm will be zero at small doses".[46] To be more specific, unlike the common usage of the term "threshold" to mean zero risk below a certain level, the term "threshold dose" used by the ICRP for tissue reactions is defined as "dose estimated to result in only 1% incidence" of specified tissue or reactions.[47]

Although values of the threshold dose vary depending on the tissue or organ at issue, the ICRP made a general observation that "in the absorbed dose range up to around 100 mGy… no tissues are judged to express clinically relevant functional impairment" in either single acute exposure or prolonged exposure.[48] Put differently, deterministic effects are unlikely to occur below an "absorbed dose" of 100 mGy.[49] On the other hand, above the threshold dose, the severity of the injury increases with increasing exposure dose.[50]

1.1.5 Global Average of Radiation Exposure from Natural and Artificial Sources

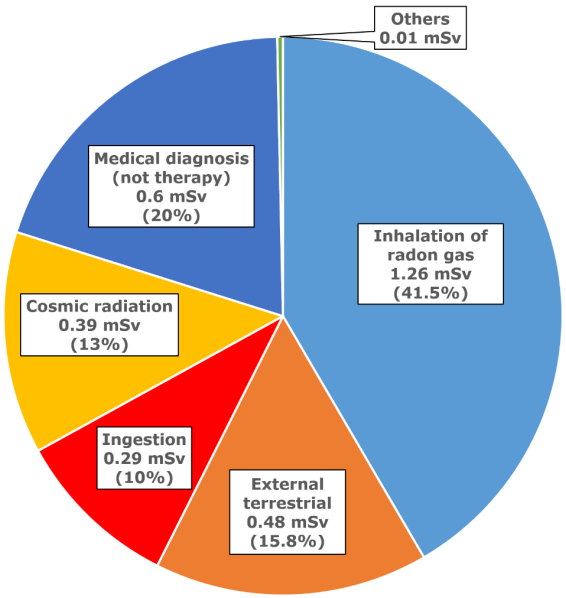
Irrespective of the radiation exposure resulting from a nuclear accident, we are routinely exposed to radiation through both "external exposure"[51] from natural radiation, as well as "internal exposure"[52] from the intake of foods containing naturally occurring radioactive materials (NORM). For example, potassium is an essential element for humans, animals and plants. However, 0.012% of it is

[45] ICRP, Publication 103 (2007), paras. 36, 65, 99.
[46] ICRP, 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21 (1–3) (1991), para. S6.
[47] ICRP Publication 103 (2007) at 34. See also ICRP, Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context. ICRP Publication 118, Part 2. Ann. ICRP 41(1/2) (2012) at 35.
[48] ICRP Publication 103 (2007), para. 60.
[49] The term "absorbed dose" refers to the amount of energy absorbed in tissues or organs through an exposure to ionizing radiation. Deterministic effects, which are caused by acute exposure to, for example, workers at the time of the nuclear accident, are normally measured based on the absorbed dose expressed in "Gray (Gy)".
[50] ICRP Publication 103 (2007), para. 58.
[51] It refers to the exposure to radiation from outside the body.
[52] It refers to the exposure inside the body from radioactive materials that are taken into the body through the intake or inhalation.

potassium-40, a radioactive isotope.[53] It means that all foodstuffs contain more or less potassium-40, and then the human body also contains it inside the body.

According to the UNSCEAR, the global average of annual effective dose to the public from natural sources of radiation is estimated to be 2.4 mSv.[54] There are four natural sources of exposure; that is (i) inhalation of radon-222, which is a radioactive isotope, through living and working indoors, (ii) ingestion of foodstuffs and drinking-water containing NORM (e.g. potassium-40), (iii) external exposure due to radiation from the earth's crust,[55] and (iv) external exposure from cosmic radiation[56] (see Table 3). The average annual effective dose for each is estimated to be (i) 1.26 mSv, (ii) 0.29 mSv, (iii) 0.48 mSv, and (iv) 0.39 mSv. In other words, members of the public are internally exposed to 1.55 mSv/year in effective dose from natural sources of radiation (see Table 3).

Table 3 Annual average of individual doses of ionizing radiation by source



Source: UNSCEAR 2008 Report at 4.

For the purpose of this dissertation, it is worth emphasizing that, on world average, members of the public are permanently exposed to 0.29 mSv/year from intake of foodstuffs or drinking-water containing NORM (i.e. 0.17 mSv from potassium-40,

[53] Sanders, Charles L, *Radiobiology and Radiation Hormesis: New Evidence and its Implications for Medicine and Society* (Springer, New York: 2017) 95.
[54] UNSCEAR, *Sources and Effects of Ionizing Radiation: UNSCEAR 2008 Report to the General Assembly with Scientific Annexes, Volume I* (United Nationals Publication, New York: 2010), para. 16, available at < https://www.unscear.org/unscear/en/publications/2008_1.html>, last visited 30 April 2020.
[55] Terrestrial radiation refers to gamma radiation emitted from naturally occurring radionuclides (e.g. potassium-40, rranium-238, thorium-232) in all environmental media, such as the soil. See UNSCEAR (*2008 Report Volume I*), para. 75.
[56] It is high-energy particles that fall on the earth from space. Law (*Oxford Dictionary*) 223.

0.12 mSv from other radionuclides), regardless of whether there is a nuclear accident or not.[57]

In addition to exposure from natural sources of radiation, we are also exposed to artificial sources of radiation, especially medical diagnosis (excluding therapy).[58] According to the UNSCEAR, the global average of annual effective dose to the public from artificial sources of radiation is estimated to be around 0.6 mSv.

It should be noted that all of the figures above are only global averages, and that the annual exposure from natural or artificial sources may vary greatly depending on the diet and lifestyle of the citizens of a country. For example, in Japan, while the annual exposure from natural sources of radiation is estimated to be, on average, 2.1 mSv, which is almost identical to the world average, the annual exposure from ingestion of foodstuffs is almost 1 mSv, which is three times higher than the global average. This feature might be attributed to the fact that the Japanese consume larger amount of fishery products that normally contain polonium-210. Moreover, the Japanese are more exposed to artificial sources of radiation than the global average through medical diagnosis, especially CT scans (i.e. 3.87 mSv/year). This value is 6 time higher than the global average.[59]

[57] See UNSCEAR (*2008 Report Volume I*), para. 16.
[58] The exposure from other artificial sources of radiation is very small compared to the exposure through medical diagnosis.
[59] The Cabinet Office, the Consumer Affairs Agency, the Reconstruction Agency, the Ministry of Foreign Affairs, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Economy, Trade and Industry, the Ministry of the Environment, the Secretariat of the Nuclear Regulation Authority, *Basic Information of Radiation Risk* (2016) 13, available at <https://www.reconstruction.go.jp/english/topics/RR/20160308BasicInformationRRen.pdf>, last visited 29 April 2020.

1.2 The *Fukushima* Accident[60] [61]

On 11 March 2011, at 14:46 local time, the Great East Japan Earthquake (magnitude 9.0) occurred off the northeastern coast of Honshu, the Japan's mainland.[62] The distance from the epicenter of the earthquake to the Fukushima Daiichi Nuclear Power Plant (FDNPP) operated by Tokyo Electric Power Company (TEPCO) in *Fukushima* prefecture was about 180 km in a straight line. At the time of the earthquake, Units 1-3 at were in operation at full power,[63] while Units 4-6 were undergoing routine inspections (see Figures 4 and 5). Although the power outage caused by the earthquake resulted in the loss of external power,[64] two emergency diesel generators were activated afterwards as designed. As a result, the control rods were inserted,[65] and each nuclear reactor in Units 1-3 automatically shut down. Therefore, it is fair to note that no damage was conferred to important equipment, such as emergency diesel generators, to cool the reactor. As explained below, it was not the earthquake itself that caused the sever accident, but a series of large tsunami waves created by the earthquake.[66]

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[60] To date, numerous reports have been released by relevant international organizations, such as UNSCEAR and IAEA describing the course of the accident, the causes of the accident, and the damage caused by the accident. See UNSCEAR, *Sources, Effects and Risks of Ionizing Radiation: UNSCEAR 2013 Report to the General Assembly with Scientific Annexes, Volume 1 (Scientific Annex A)* (United Nations Publication, New York: 2014), available at <https://www.unscear.org/docs/reports/2013/13-85418_Report_2013_Annex_A.pdf>, last visited 19 April 2020. See also IAEA, *The Fukushima Daiichi Accident: Report by the Director General*, GC(59)/14 (2015), available at <https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1710-ReportByTheDG-Web.pdf>, last visited 19 April 2020; IAEA, *The Fukushima Daiichi Accident, Technical Volumes 1-5* (2015), available at <https://www.iaea.org/publications/10962/the-fukushima-daiichi-accident>, last visited 19 April 2020.

[61] As a report on the *Fukushima* accident released by the Japanese government, see Investigation Committee on the Accident at the Fukushima Nuclear Power Station of Tokyo Electric Power Company, Final Report (2012), available at <https://www.cas.go.jp/jp/seisaku/icanps/eng/final-report.html>, last visited 19 April 2020. This is a committee to be established in the Cabinet Secretariat upon the decision by the Cabinet on 24 May 2011. See also, The National Diet of Japan, The Official Report of the Fukushima Nuclear Accident Independent Investigation Commission (2012), available at <https://warp.da.ndl.go.jp/info:ndljp/pid/3856371/naiic.go.jp/en/>, last visited 19 April 2020. This commission was appointed by the National Diet on 8 December 2011.

[62] For more information on the size and epicenter of the earthquake, see the following link. Japan Meteorological Agency, *News Release: The 2011 Great East Japan Earthquake (First Report)* (13 March 2011), available at <https://www.jma.go.jp/jma/en/News/2011_Earthquake_01.html>, last visited 17 April 2020.

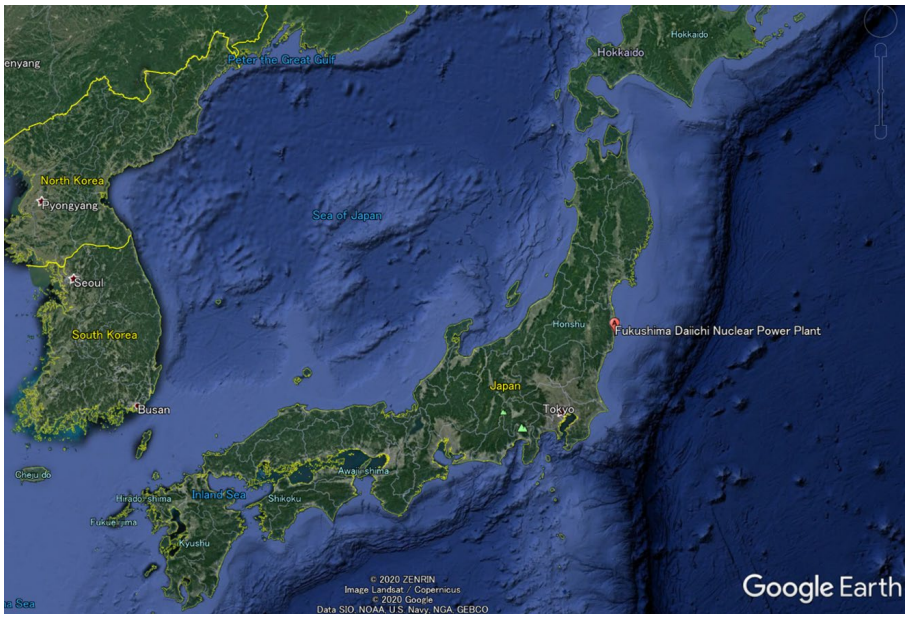
[63] The term "Unit" is usually used to refer to the entire facility, including the reactor building and the turbine building.

[64] At the FDNPP, electricity was drawn in from outside to cool the reactor, using wires that were used to transmit electricity made by the plant. It is called an external power source. However, those wires were damaged by the earthquake, then making it impossible to get electricity from the outside.

[65] A control rod contains a material (e.g. boron) that absorbs neutrons. Fission can be prevented by inserting the rod into nuclear fuel.

[66] For an overview of the status and transition of the accident in each Unit, see TEPCO, *The Development of and Lessons from the Fukushima Daiichi Nuclear Accident, 1st edn* (2013),

Figure 4 Location of the Fukushima Daiichi Nuclear Power Plant



Around 50 minutes after the earthquake, at around 3:36 p.m. on 11 March, the second and largest tsunami wave, which is estimated around 14-15 meter-high, reached the FDNPP, which is located along the Pacific Ocean coast,[67] causing the emergency diesel generators installed underground to be submerged in seawater, as well as damaging other equipment (e.g. batteries). The tsunami wave ultimately led to a total loss of AC power in Units 1-5, which is called "station blackout (i.e. SBO)".[68] With the loss of all power, the function to cool the reactor was lost, and it also became impossible to monitor and measure the condition inside the reactor.[69]

available at <http://210.250.6.22/en/decommision/accident/images/outline01.pdf>, last visited 19 April 2020.

[67] One might wonder why nuclear power plants are built on the coast in Japan, although there is a risk of tsunami. The types of nuclear reactors can be classified according to their cooling methods. Nuclear power plants in Japan adopt light water reactors, which need massive amount of light water (i.e. normal water) for cooling the reactor. Therefore, the plants are located in coastal areas where seawater is readily available.

[68] In Unit 3, on the other hand, the DC power supply facilities escaped flooding, so the DC power supply was not lost. Thus, the reactor core isolation cooling (RCIC) system using a DC power supply was able to continue cooling for about one and a half days until the DC power source (i.e. storage battery) was depleted. The RCIC system is a cooling system that pumps and pour water by using steam generated in a nuclear reactor. It works without AC power.

[69] As is shown in Figure 1, Units 5 and 6 were built in a different location from Units 1 to 4, and at a higher elevation, so the tsunami damage to Units 5 and 6 was lesser. The station blackout did not occur in Unit 6.

Figure 5 Fukushima Daiichi Nuclear Power Plant Just Before the Accident (March 2011)

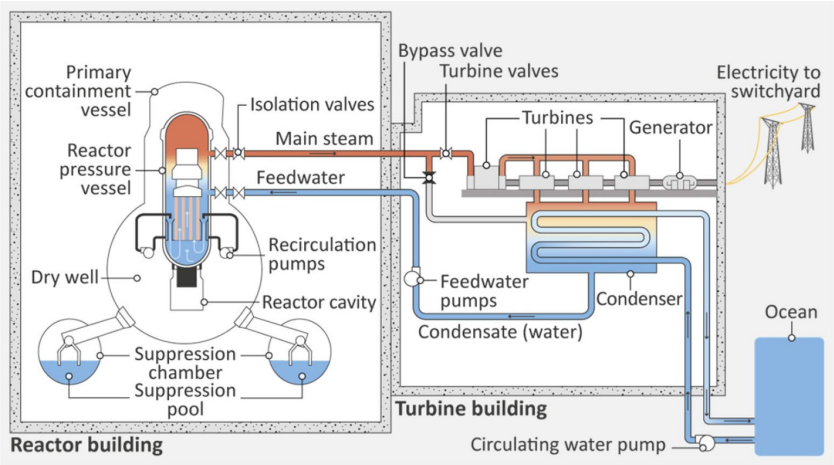
Without the cooling system, water cannot be poured into the reactor pressure vessels (RPV). If the water in the pressure vessel is depleted, the temperature of the fuel will rise. Although there was a time gap between Units 1 to 3, all of the reactors eventually fell into a situation where it was difficult to keep pouring water into the pressure vessel containing nuclear fuel. As a result, due to the high temperature inside the RPV, the reactor core, which is the central portion of a reactor consisting of nuclear fuel, control rods and so on,[70] began to melt. Melted fuel fell to the bottom of the RPV, and some of them further penetrated down to the floor of the primary containment vessels (PCV). Such a phenomenon is generally called a meltdown (see Figure 6).

In addition, the fuel rods reacted with the water vapor in the pressure vessel, producing a large amount of hydrogen. The hydrogen generated in the RPV leaked out of the area damaged by the meltdown, and pooled in the PCV that covers the RPV. As a result, the pressure inside the PCV increased, and then exceeded the designated level. At that time, there was a danger that the entire reactor building, including the RPV and PCV, would explode due to high pressure. If such explosion had occurred, a large amount of radioactive material would have been released into the environment,[71] and a much larger area than the present would have

[70] See USNRC, Full-Text Glossary (21 March 2019), available at <https://www.nrc.gov/reading-rm/basic-ref/glossary/full-text.html>, last visited 17 April 2020.
[71] That is exactly what happened with the *Chernobyl* accident in 1986. The entire reactor building in Unit 4 in the Chernobyl Nuclear Power Plant exploded on 26 April 1986. See

been contaminated by radioactive materials.

Figure 6 Structure of Nuclear Power Reactor



IAEA, *The Fukushima Daiichi Accident: Report by the Director General*, GC(59)/14 (2015) at 25.

In order to prevent the PCVs from exploding due to an increase in the pressure, the authorities decided to deliberately release the gas in the PCVs containing radioactive materials into the air through water,[72] and then to reduce the pressure in the PCVs of the Units 1 and 3 (i.e. wet venting).[73] Although venting was successful and the pressure inside the PCVs was reduced, certain amounts of radioactive materials were released to the area. In spite of venting, however, hydrogen leaking from the damaged part of the PCV accumulated in the upper part of the reactor building, and exploded at 3:36 p.m. on March 12. While a major destruction of the PCV was avoided, this led to the release of radioactive materials.[74]

Compared to Units 1 and 3, Unit 2 was put in a worse situation, especially after the RCIC system stopped its cooling function.[75] Wet venting failed in Unit 2, and the pressure inside the PCV rose to 1.5 times higher than the design limit. Around 15 March 2011, the gas could no longer withstand the pressure leaked from the damaged part of the PVC. However, the impact of the hydrogen explosion in Unit

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IAEA, *Frequently Asked Chernobyl Questions*, available at <https://www.iaea.org/newscenter/focus/chernobyl/faqs>, last visited 18 April 2020.

[72] It is said that, by going through water, the amount of radioactive material in the released gas can be reduced by several hundredths.

[73] Venting was carried out on the morning of March 12 for Unit 1, and the morning of March 13 for Unit 3.

[74] IAEA, *The Fukushima Daiichi Accident, Technical Volume 4, Radiological Consequences* (2015) 8.

[75] The reason why the pressure in the PCV of Unit 2 reached its limit a few days later than Unit 1 was that the RCIC system mentioned above had been activated just before the tsunami. Although a DC power supply was lost by the tsunami, the RCIC system continued to operate and pour water into the reactor for about three days.

1 opened a safety device originally installed in the wall of the reactor building, through which the gas was released into the air. Thus, while the hydrogen explosion in the entire reactor building of Unit 2 was fortunately averted,[76] at the cost of this, large amounts of radioactive materials were directly released into the air without passing through water.[77] They fell into the soil by rain, resulting in wet deposition mainly over the northeastern part of *Fukushima* Prefecture (see Figure 7[78]).

In sum, the main periods during which radioactive materials were released into the air during the *Fukushima* accident are estimated to cover (i) 12 March 2011 (mainly through venting and hydrogen explosion at Unit 1), (ii) around 15 March 2011 (mainly through the leakage of radioactive materials from the damaged PCV of Unit 2), and (iii) 20-22 March 2011 (relatively small).[79]

Although there is no definitive figure for the total amount of radioactive materials released into the atmosphere as a result of the *Fukushima* accident, according to the UNSCEAR,[80] it is estimated to fall roughly within the range of "about 100 to about 500 PBq" for iodine-131, and "6 to 20 PBq" for caesium-137.[81] They are

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[76] Mr. Masao Yoshida, the general manager of the FDNPP at the time of the Great East Japan Earthquake, responded to a later investigation by the government's Accident Independent Investigation Commission as follows. "[in response to a question about Unit 2, which was in crisis] With no water coming in, the No. 2 reactor was going to melt. All fuel was going to really override pressure in the containment vessel and escape outside. That would have been a worst-case accident, with corresponding amounts of radioactive substances all spewed outside. That would no longer be on a Chernobyl class – maybe not a 'China Syndrome,' but something like that."
The Asahi Shimbun, *The Yoshida Testimony: The Fukushima nuclear accident as told by p lant manager Masao Yoshida (Chapter 1)*, available at <http://www.asahi.com/special/yoshida_report/en/1-2.html >, last visited 19 April 2020.

[77] The amount of radioactive material released into the atmosphere by through venting in Units 1 and 3 was estimated to be sufficiently small, compared to the one released fro m Unit 2 that contributed to the major contamination. TEPCO, *Fukushima Nuclear Acciden t Analysis Report: Summary* (20 June 2012) at 36, available at <https://www.tepco.co.jp/en/press/corp-com/release/betu12_e/images/120620e0102.pdf>, last visited 17 April 202 0).

[78] See JAEA, *Airborne Monitoring in the Distribution Survey of Radioactive Substances*, av ailable at <https://emdb.jaea.go.jp/emdb/en/portals/b1020201/>, last visited 19 April 20 20. Figure 3 is based on the measurement results of the first and second airborne monit oring surveys by MEXT and the U.S. Department of Energy (DOE). This is a method of m easuring gamma rays from radioactive materials accumulated on the ground by installing highly sensitive radiation detectors on the aircraft. The first survey was conducted from 6 to 29 April 2011 for the area within 60 km of the FDNPP by DOE, and the area within 6 0-80 km of the FDNPP by MEXT. The second survey was conducted from 18 to 26 May 2 011 by MEXT with analytical cooperation from DOE for the area within 80-100 km of the FDNPP. See MEXT, *Monitoring Plan in the Area*, available at <https://www.mext.go.jp/en/incident/title01/detail01/sdetail01/sdetail01/1373113.htm>, last visited 19 April 2020.

[79] IAEA (*Radiological Consequences*) 8.

[80] UNSCEAR (*2013 Report*), paras. 25, 43. The release of caesium-134 is considered to be comparable with that of caesium-137.

[81] 1 PBq is equal to 10^{15} Bq. In a report submitted to the IAEA after the accident, the Ja panese government made a similar estimate. According to the Nuclear and Industrial Saf

about 10% and 20% respectively of the dose released from the *Chernobyl* accident.[82] On the other hand, the levels of plutonium deposited on the ground were estimated to be "very low and mostly below detection limits".[83] In addition, the levels of strontium deposited on the ground were also "significantly lower than those of" caesium-137.[84]

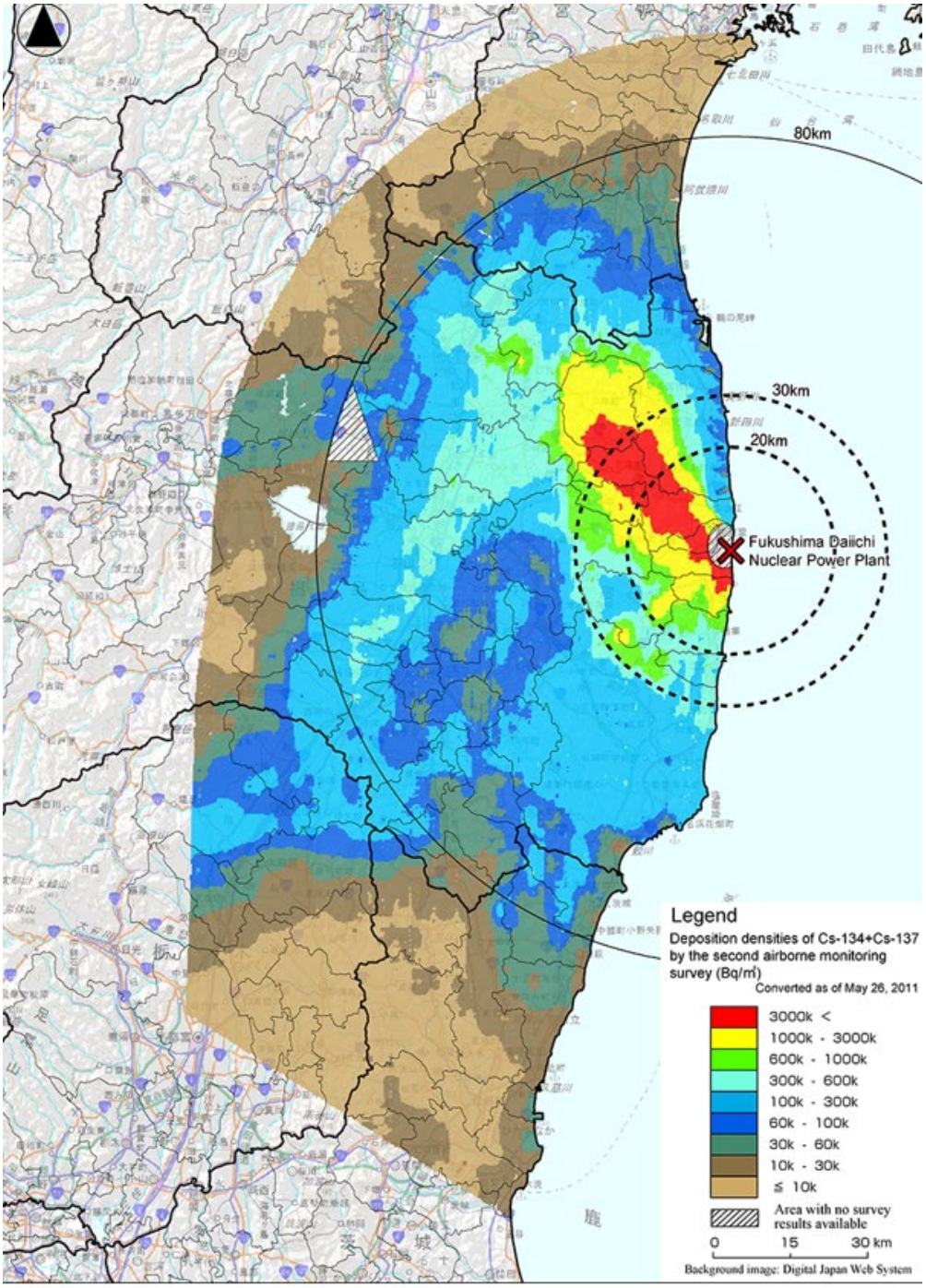
ety Agency, the predecessor of the current Nuclear Regulatory Authority (NRA), the amou nt iodine-131 released from the accident is estimated to be 160 PBq for iodine-131, and 15 PBq for caesium-137. Nuclear Emergency Response Headquarters, *Report of the Japan ese Government to the IAEA Ministerial Conference on Nuclear Safety: The Accident at T EPCO's Fukushima Nuclear Power Stations (June 2011) at VI-1*, available at <https://japa n.kantei.go.jp/kan/topics/201106/iaea_houkokusho_e.html>, last visited 19 April 2020.

[82] UNSCEAR (*Report 2013*) paras. 43, 206.

[83] UNSCEAR (*Report 2013*) para. 57.

[84] UNSCEAR (*Report 2013*) para. 57.

Figure 7 Results of Deposition of Radioactive Caesium



Source: JAEA, *Airborne Monitoring in the Distribution Survey of Radioactive Substances*

Chapter 2

International Trade in the ICRP's System of Radiological Protection

Introduction

Radiological protection, which is interchangeably referred to as radiation protection, is defined as "[t]he protection of people from harmful effects of exposure to ionizing radiation, and the means for achieving this."[1] For example, in the unfortunate event of a nuclear accident, the authorities need to implement various protective measures in order to protect the public from the harmful effects of radiation. Aside from accidents and other emergencies, the authorities are also required to develop and implement protective measures for workers at nuclear facilities and medical personnel on a daily basis.

Thus, the International Commission on Radiological Protection (ICRP), which is an independent, international organization with more than 250 experts from more than 30 countries,[2] has been making recommendations with the aim of providing a "guide"[3] to the authorities in developing and implementing radiation protection policies in a variety of situations, including in the aftermath of nuclear accidents. For example, radioactive materials released by the accident could be deposited in the soil, and the agricultural products produced there may contain radioactive materials. Therefore, the ICRP has provided guidance for authorities in restricting the distribution of food products (e.g. agricultural products) produced in the area affected by the accident.

On the other hand, the import restrictions imposed on food from the country where the accident occurred have been considered to be outside the scope of radiological protection, since the importing country maintaining such restrictions

[1] IAEA, *IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection*, 2018 edn (2019) 175 (Italic Omitted).
[2] ICRP, *Governance*, available at < https://www.icrp.org/page.asp?id=3>, last visited 15 May 2020.
[3] The ICRP notes that it "wishes to emphasize that its recommendations are intended to guide the experts responsible for putting radiation protection into practice." ICRP, Recommendations of the International Commission on Radiological Protection. ICRP Publication 9 (Pergamon Press, Oxford: 1966), para. 2.

is usually not directly affected by the nuclear accident. In other words, there is basically no intersection between radiological protection and trade restrictions by the importing country. In the following case, however, coordination between them may be required.

Once the accident is under control, the authorities may take a decision for the purpose of "radiological protection" allowing evacuees to return home, and then to permit the distribution of food products produced in the area to the market in order to provide them with a means of livelihood. However, since such food products can be exported through the domestic market to foreign markets, the importing country may impose import restrictions on such food products due to concerns over health risks. In this case, the need to lift the distribution restrictions on food products in terms of radiological protection would not be sufficient as a rational reason for the importing country to accept such food products. In other words, it is necessary to reconcile the need for radiation protection in the exporting country with the need for the importing country to determine the acceptable level of health risks arising from the consumption of imported food products.

Importantly, the occurrence of the *Chernobyl* accident in April 1986 that disrupted international trade in food, and the globalization of commodity markets, including food products, in the 1990s led to the inclusion of disciplines relating to international trade in the ICRP's recommendations. These disciplines were further developed in the 2000s. Therefore, this chapter will examine in detail the series of the ICRP recommendations that include the disciplines of international trade in food in relation to radiological protection.

2.1 ICRP's Early Recommendations: Lack of Reference to Distribution Restrictions on Foodstuffs

The early recommendations of the ICRP, such as Publication 9 (1965)[4] and Publication 26 (1977),[5] both of which will be addressed in this section, were framed by firmly relying on the distinction in a condition between (i) the condition in which the source of exposure is under control, and (ii) the condition in which the

[4] The first ICRP recommendations were adopted in 1958, and then published next year as Publication 1. Later, although the recommendations in Publication 1 were partially amended in 1959 and 1962, the ICRP did not revise them at the time of adopting Publication 6 in 1964 on the ground that there was "no change in the basic philosophy". In Publication 9 (1965), the ICRP attempted to provide a "complete and comprehensive account" of the basic principles of radiological protection by consolidating the publications that had been adopted before. ICRP, Publication 9 (1965), para. 1. Therefore, Publication 9 is taken as the starting point for the analysis of ICRP recommendations in this chapter.

[5] ICRP, Recommendations of the International Commission on Radiological Protection. ICRP Publication 26. Ann. ICRP 1 (3) (1977).

source of exposure is not under control (e.g. nuclear accident).[6] Since the focus of this dissertation is on international trade in food after a nuclear accident, the latter type of condition is more relevant.

As will be explained later, the focus of these recommendations was almost exclusively on the emergency stage right after the accident, and little attention was paid to the rehabilitation or recovery situation in which, while the source of exposure is under control again, the low level of radiation exposure still continues for a prolonged period of time due to radioactive residues.[7] Furthermore, it should be also noted that it was only in Publication 40 (1984) in which a reference was firstly made to the need for distribution restrictions on foodstuffs containing radioactive materials released by the accident.[8] Nonetheless, both Publication 9 and Publication 26 are considered to form the basic parts of the current ICRP's system of radiological protection.

2.1.1 ICRP Publication 9 (1965)

The recommendations made by the ICRP in Publication 9 (1965) are based on the distinction of two "conditions"[9] of exposures; that is (i) conditions in which the occurrence of the exposure is foreseen and the source of exposure is under control, and (ii) conditions in which the exposure is accidental (not planned) and thus the source of exposure is out of control.[10] Although the distinction between controllable and uncontrollable sources of exposure is not clearly defined, the ICRP notes that the uncontrollable sources include a situation "after a reactor accident or following nuclear weapon explosions."[11] Thus, it is fair to note that the exposure condition due to uncontrollable sources in Publication 9 almost corresponds to an "emergency situation" that was previously discussed by the ICRP.

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[6] It is worth noting that this distinction adopted in the early stages are conceptually not that far from that currently adopted by the ICRP, that is (1) a planned exposure situation, (2) an emergency exposure situation, and (3) an existing exposure situation. For example, the ICRP notes that "[t]he clearest distinction between planned exposure situations and emergency and existing exposure situations is the ability to choose a priori whether to accept a beneficial practice and its consequent exposures." ICRP, Scope of radiological protection control measures. ICRP Publication 104. Ann. ICRP 37 (5) (2007), para. 30.

[7] The first recommendation in which the main attention was paid to the long-term exposure situation after an accident was Publication 82 (1999) and subsequent reports. See Chapter 2.2.4.

[8] See Chapter 2.2.1.

[9] The term "condition" used in Publication 9 is quite similar to the term "situation" used in Publication 103. See Chapter 2.3.1. The term "condition" refers to "a state" or "[a] particular mode of being of a person or thing." *Shorter Oxford English Dictionary on Historical Principles, Volume 1 (A-M)*, 6th edn (Oxford University Press, Oxford: 2007) 483.

[10] ICRP, Publication 9 (1965), para. 46.

[11] ICRP, Publication 9 (1965), para. 97.

In order to protect members of the public from the biological risk of exposure in each condition, the ICRP recommends that the regulatory authorities use dose limits[12] for the condition in which the source of exposure is under control, and "action levels" for the condition in which it is not under control.[13] The following will overview the recommendations made by the ICRP in Publication 9 intended to provide guidance on how the regulatory authorities implement radiological protection in each different circumstance.

2.1.1.1 Loose Limits for Exposures from Controllable Sources

While the use of radiation benefits society, it is assumed that, no matter how low the level is, any exposure to radiation entails a risk of adverse effects to the human body. Thus, it is impossible to make such risk zero "unless man wishes to dispense with activities involving exposures to ionizing radiations."[14] Therefore, the ICRP explains that the national authorities should rather aim to limit the dose to a level at which "the assumed risk is deemed to be *acceptable* to the individual and to society in view of the benefits derived from such activities."[15] To be more specific, the ICRP recommends that all doses be kept "as low as is readily achievable," taking into account economic and social considerations.[16]

As a step toward achieving this objective, the ICRP recommends that the authorities establish specific dose limits and reduce the exposure from controlled sources to members of the public. According to the ICRP, once dose limits are established, the authorities should plan the use of sources in a way that such levels will not be exceeded.[17]

In Publication 9, the ICRP recommends the dose limits for members of the public for each organ or tissue group.[18] For example, it recommends 5 mSv/year for gonads and red bone-marrow, and 30 mSv/year for skin, bone, and thyroid.[19] As emphasized by the ICRP, its recommendations are only intended to provide guidance to the authorities on planning and implementing radiological protection.[20] Thus, in spite of the ICRP recommendations, the authorities are still entitled to establish the dose limits based on their policy decisions, taking into account the specific values presented by the ICRP.

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[12] The terms dose limits and "dose limitations" are used interchangeably in Publication 9.
[13] ICRP, Publication 9 (1965), para. 37.
[14] ICRP, Publication 9 (1965), para. 34.
[15] ICRP, Publication 9 (1965), para. 34 (Italic Added). Elsewhere, the ICRP also describes the objectives of radiological protection as "to limit the risks of late effects [stochastic effects] to *an acceptable level*" for society. ICRP, Publication 9 (1965), para. 3 (Italic Added).
[16] ICRP, Publication 9 (1965), para. 52.
[17] ICRP, Publication 9 (1965), para. 48.
[18] ICRP, Publication 9 (1965), at 14 (Table).
[19] This implies that the former group is more vulnerable to radiation than the latter group.
[20] ICRP, Publication 9 (1965), para. 2.

The four points below highlight the method and basis by which the ICRP derives the dose limits for members of the public.

Firstly, the ICRP derives the dose limits for members of the public based on the plain assumption that they "shall be one-tenth" of the corresponding dose limits for radiation workers (i.e. Maximum Permissible Dose).[21] In this case, the ICRP recommends the Maximum Permissible Dose of 50 mSv/year to radiation workers in terms of gonads and red bone-marrow.[22] Based on this, the ICRP derives the dose limit of 5 mSv/year for members of the public in terms of gonads and red bone-marrow by simply dividing 50 mSv/year by a factor 10.[23]

Secondly, one may wonder on what grounds the ICRP derives the Maximum Permissible Dose for radiation workers. As admitted by the ICRP at the time of adopting Publication 9, "the relationship between dose and risk is not known with precision"; it is not usually possible to make "quantitative evaluations of the benefit."[24] Thus, instead of providing a numerical basis, the ICRP only provides a general guide that the exposure risks to radiation workers should be equivalent to those accepted in other industries with high safety standards.[25]

Thirdly, one might also wonder on what grounds the ICRP considers it appropriate to set the dose limits for members of the public at 1/10 of that for radiation workers. In this regard, given that knowledge of radiobiology was not sufficient at the time of Publication 9's adoption, the ICRP notes that "[n]o undue biological significance should be attached to the magnitude of this factor."[26]

Nevertheless, "1/10" is not a random factor. The ICRP notes that the exposure risks to members of the public from controllable sources "should be less than or equal to other risks regularly accepted in every-day life."[27] In other words, the ICRP appears to understand that 1/10 of occupational exposure risk is almost equal to the risk that members of the public would usually accept in their normal lives. It is noted, however, that the ICRP recommendations are only intended to provide guidance to the regulatory authorities, and thus do not prevent them from setting more stringent levels as acceptable risks for members of the public.

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[21] ICRP, Publication 9, paras. 43, 72.
[22] ICRP, Publication 9, para. 56. It is noted that the ICRP recommends the dose limits in a unit of rem (i.e. 10^{-2} Sv). For example, the ICRP recommends 5 rem/year (i.e. 50 mSv/year) for gonads and red bone-marrow for radiation workers.
[23] Likewise, for the skin, bones and thyroid, the ICRP recommends the maximum permissible dose of 300 mSv/year for radiation workers and, based on this, the dose limit of 30 mSv/year for members of the public by dividing 300 by 10.
[24] ICRP, Publication 9 (1965), para. 36.
[25] ICRP, Publication 9 (1965), para. 47.
[26] ICRP, Publication 9 (1965), para. 43.
[27] ICRP, Publication 9 (1965), para. 47.

Lastly, it is noted that, in contrast to action levels explained in the next section, the dose limits represent the level of exposure risk from controlled sources that is acceptable to the individual and society. This understanding is further developed in the subsequent Publication 26 (1977).[28] In other words, establishment of dose limits closely involves a social judgement on "the degree of risk that would be acceptable, taking into account the particular circumstances," such as (i) a balance of the benefits or necessities of introducing the exposures against the risks, and (ii) the difficulties of limiting the exposure.[29]

2.1.1.2 Action Levels for Exposures from Uncontrollable Sources

In conditions in which the exposure is accidental and thus the sources of exposure are uncontrolled (e.g. after a nuclear accident), the ICRP repeatedly emphasizes that the dose limits are no longer applicable.[30] Instead, the ICRP notes that "the exposures and the risks resulting from them [uncontrolled sources] can only be controlled by remedial measures."[31]

As to a decision by the authorities to take remedial measures, the ICRP provides a general benchmark that taking such measures is appropriate "only when their social cost and risk will be less than those resulting from the exposure."[32] For example, although the scale of exposure from an uncontrolled source (e.g. nuclear accident) is very small, the authorities might request the residents living in the vicinity of the nuclear power plant to evacuate. In this case, the resulting social costs and risks may exceed those of exposure itself. This is the case, especially when requesting elderly people to evacuate. This measure might cause not only economic costs for the authorities, but also mental costs and medical risks for evacuees.

The ICRP recommends that the authorities establish dose levels at which the initiation of remedial measures is considered in advance as part of its emergency plan.[33] Such levels are called action levels in Publication 9.

However, the ICRP does not make quantitative recommendations as a reference

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[28] See Chapter 2.1.2.2.
[29] ICRP, Publication 9 (1965), para. 35.
[30] ICRP, Publication 9 (1965), paras. 49, 96, 99.
[31] ICRP, Publication 9 (1965), paras. 46, 51, 97. The terms "remedial measures" and "remedial actions" are used interchangeably in Publication 9.
[32] ICRP, Publication 9 (1965), para. 98. This benchmarks appears to come from ICRP's concern that remedial measures "in themselves might be more hazardous than the risks of the unplanned exposure." ICRP, Publication 9 (1965), para. 97. The core elements of the ICRP's system of radiological protection are the principles of justification and optimization of protection. But they appear only in Publication 26 (1977). Thus, no systematic criteria for taking remedial measures are presented in Publication 9.
[33] ICRP, Publication 9 (1965), para. 98.

for action levels, except a general action level beyond which remedial measures would always be needed (i.e. 1 gray (Gy) exposure for whole body).[34] This ICRP's approach contrasts with its recommendations to the authorities on dose limits, which are only applicable to limit the exposure due to controllable sources for members of the public, with specific values as a reference. This is so because, as admitted by the ICRP, exposure from uncontrolled sources presents "a much more complex problem" than exposure from controlled sources.[35]

As explained in the previous section, dose limits established by the authorities are supposed to represent the level of exposure risk from controlled sources which is acceptable to the individual and to society. On the other hand, the action levels embody the dose levels at which it is "considered"[36] whether to take remedial measures against the exposure from uncontrollable sources. It follows by definition that some authorities might decide not to take certain remedial measures based on policy considerations, even if the action levels established in advance are exceeded. Thus, dose limits and action levels have different purposes, and therefore function in a different way.

Lastly, it is noted that Publication 9 makes no reference to restrictions on the consumption of foodstuffs in an emergency situation following an accident, nor to restrictions on the placement of foodstuffs produced in contaminated areas in a rehabilitation (recovery) phase after an accident, which is the focus of this thesis.

2.1.2 ICRP Publication 26 (1977)

In accordance with the distinction adopted in Publication 9, the ICRP also makes recommendations in Publication 26 (1997) on the basis of the division between (i) the condition where the source of exposure is subject to control, and (ii) the condition where the source of exposure is not under control.[37] The latter condition is also termed "abnormal conditions" in Publication 26.[38]

In Publication 26, as will be examined later, the ICRP recommends "a system of dose limitation" consisting of three principles; that is (i) justification, (ii) optimization, and (iii) dose limits.[39] Then, the ICRP notes that the planned exposure in the former condition can be limited through the application of this

[34] ICRP, Publication 9 (1965), para. 104. Previously, the unit of rad was used. 100 rad equals 1 Gy.
[35] ICRP, Publication 9 (1965), para. 103.
[36] ICRP, Publication 9 (1965), para. 98.
[37] ICRP, Publication 26 (1977), para. 81.
[38] See Chapter 2.1.2.2.
[39] It should be noted that the unit "dose-equivalent" is used in Publication 26. Thus, when a reference is made to "dose limit" in this Section, it specifically means "dose-equivalent limit." As to dose-equivalent, see Chapter 1.1.3.

system. In other words, this system is not applicable to a situation where the source of exposure is not under control.[40] On the other hand, as to the latter condition, the accidental exposure can be limited only through remedial actions taken as an "intervention," not the system of dose limitation.

2.1.2.1 Limiting the Exposures from Controlled Sources through a System of Dose Limitation

According to the ICRP, the limitation of stochastic effects caused by radiation can be achieved through the application of a system of dose limitation it recommends.[41] Each of the three principles comprising this system is explained as follows:[42]

> (i) no "practice"[43] involving radiation exposure shall be taken unless its introduction produces a positive net benefit (i.e. principle of justification)
> (ii) all exposures shall be kept as low as reasonably achievable, taking into account economic and social factors (i.e. principle of optimization of protection)
> (iii) the "dose equivalent"[44] to individuals shall not exceed the dose limits recommended by the ICRP (i.e. principle of application of dose limits)

In this regard, the ICRP makes it one of the objectives of radiological protection to ensure that "practices involving radiation exposure are justified."[45] In addition, the ICRP notes that "no practice…shall be taken" unless it is justified. Therefore, it appears that, among three principles above, the (i) principle of justification is given the highest priority. It follows that, even if the other two principles are satisfied, practices or activities that are not justified (i.e. the benefit fails to exceed the detriment as result of introducing them) can never be introduced.[46]

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[40] The ICRP clearly notes that "the system of dose limitation recommended by the Commission does not apply" in a situation where the source of exposure is not under control. ICRP, Publication 40 (1984), para. 1. Although some parts of the recommendation in Publication 26 remain unclear, these unclear parts cane be somewhat solved by reading Publication 40.

[41] ICRP, Publication 26 (1977), para. 10.

[42] ICRP, Publication 26 (1977), paras. 12, 68. At the time of adopting Publication 26, these three features of this system are not clearly labelled as "principles." In subsequent recommendations, however, the ICRP uses the term "principle" to describe these features. See e.g. ICRP, Principles of Monitoring for the Radiation Protection of the Population. ICRP Publication 43. Ann. ICRP 15 (1) (1985), para. 13.

[43] While there is no specific definition for the term "practices" in Publication 26, it appears that it is used interchangeably with the term "activities." However, as will be explained in Chapter 2.2.2, the term "practice" had been treated as a key concept in the ICRP recommendations since Publication 60 (1990).

[44] See Chapter 1.1.3.

[45] ICRP Publication 26 (1977), para. 9.

[46] As to the (i) principle of justification, the ICRP only expresses its general view that justification should be determined through "cost-benefit analysis," which aims to ensure that the total detriment is small relative to the benefits as a result of introducing the proposed

These three principles still constitute the fundamental principles of the current ICRP's system of radiological protection regime (e.g. Publication 103 (2007)). While these principles are applicable only to the condition where the source of exposure is under control in Publication 26, they are considered to apply to all exposure situations in the current radiological protection system, including an emergency situation where the source of exposure is usually out of control.

Nevertheless, since the ICRP devotes most of its recommendations on a system of dose limitation to the explanation of the (iii) principle of dose limits in Publication 26, the following will overview the ICRP recommendations on dose limits.

2.1.2.1.1 The Dose Limits Recommended by the ICRP

As also confirmed in Publication 9, the objectives of the ICRP's radiological protection are set to prevent deterministic effects, and to limit stochastic effects to the acceptable level.[47] According to the ICRP, in the condition where the source of exposure is under control, the exposure can be limited by the application of dose limits. Therefore, once they are established, the authorities are required to plan the use of radiation sources in a way not exceeding these limits.

Firstly, deterministic effects, for which there is a threshold dose, can be prevented by setting dose limits so as not to reach the threshold dose.[48] In order to avoid deterministic effects, the ICRP recommends the dose limits of 500 mSv/year for radiation workers,[49] as well as 50 mSv/year for members of the public,[50] to all tissues except the lens.

Secondly, stochastic effects, for which there is no threshold dose, can never be zero. Instead, such effects can only be reduced to the acceptable level through dose limits. In other words, dose limits are established to enable activities or practices resulting in radiation exposure to be planned and implemented at acceptable levels.[51] In light of the above, the ICRP recommends the dose limits of 50 mSv/year for radiation workers,[52] as well as 5 mSv/year for members of the public.[53]

As will be demonstrated in the next section, the dose limits recommended by the

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practices. The detriment includes monetary, health and environmental costs and damage, while the benefits cover the ones accruing not only to individuals or particular groups but also to society. ICRP, Publication 26 (1977), paras. 69-71.

[47] ICRP, Publication 26 (1977), paras. 9, 103.
[48] ICRP, Publication 26 (1977), para. 10.
[49] ICRP, Publication 26 (1977), para. 103.
[50] ICRP, Publication 26 (1977), para. 126.
[51] ICRP, Publication 26 (1977), para. 135.
[52] ICRP, Publication 26 (1977), para. 104.
[53] ICRP, Publication 26 (1977), paras. 119-120.

ICRP for members of the public are derived in a way that reflects the acceptable level of risk regarding stochastic effects. Thus, the dose limits do not serve for dividing a line between safety and danger.[54] For example, assuming that the dose limit for public exposure is set at 1 mSv/year in Country X and 5 mSv/year in Country Y, it would not mean that the annual exposure dose of 3 mSv is dangerous in Country A, but safe in Country B. It is simply a matter whether the acceptable levels of risk are exceeded or not.

2.1.2.1.2 Basis for the Dose Limit of 5 mSv/year for the Public

One might wonder on what grounds the ICRP considers the dose limit of 5 mSv/year for members of the public as representing the acceptable level of risk regarding stochastic effects.

Firstly, the ICRP notes that the average risk in radiation occupations (i.e. mortality from malignancies induced by occupational radiation exposure) can be socially acceptable if it is comparable with the average risk in other safe industries.[55] As noted by the ICRP in Publication 27 (1977), if "the average annual mortality due to occupational hazards does not exceed 10^{-4}," which means 1 in 10,000 deaths, such industries are recognized as having "high standards of safety."[56] Then, since the annual mortality rate would be below 10^{-4} for being exposed to radiation at the dose levels of 50 mSv/year, the ICRP recommends this value as a dose limit representing the acceptable level of risk regarding stochastic effects for occupational exposure.

Secondly, the ICRP assumes that "the level of acceptability for fatal risks to the general public is an order of magnitude lower than for occupational risks."[57] It means that "a risk in the range of 10^{-6} to 10^{-5} per year," which is an order of magnitude smaller than 10^{-4}, can be acceptable to members of the public in everyday life.

In light of the above, the ICRP recommends the dose limit of 5 mSv/year for public exposure, which is simply one order of magnitude smaller than 50 mSv/year for occupational exposure based on the annual mortality rate of 10^{-4}.

Lastly, it is important to recall that the dose limits recommended by the ICRP are only references for the authorities. These values represent the level of risk that, *the ICRP considers*, is acceptable to individuals or society. Thus, the authorities are not required, or even expected, to adopt these values as its own dose limits.

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[54] ICRP, Publication 26 (1977), para. 81.
[55] ICRP, Publication 26 (1977), para. 100.
[56] ICRP, Publication 26 (1977), para. 96.
[57] ICRP, Publication 26, para. 118. It is recalled that the same assumption is adopted in Publication 9 as a basis for deriving the dose limit for public exposure. See Chapter 2.1.1.1.

The ICRP itself clearly admits that it is "will not necessarily be suitable, and may often be inappropriate" for the authorities to introduce the ICRP recommendations into the country as they are.[58] In other words, the authorities are fully allowed to adopt more stringent dose limits than the values presented by the ICRP in Publication 26.

2.1.2.2 Reference Levels for Interventions in Abnormal Situations

In abnormal situations, including accidents,[59] exposures are accidental and thus the source is out of control. In this situation, the ICRP recommends that the authorities limit such accidental exposures through "remedial actions" or "countermeasures" [60] taken as "intervention," [61] not dose limits that are applicable only to normal conditions in which the source of exposure is under control. Thus, it is ideal that the authorities determine in advance the dose levels at which intervention (i.e. implementation of remedial actions) should be considered in the event of an emergency (i.e. intervention level).

In this regard, however, the ICRP shows reluctance to recommend intervention levels above which interventions will be always required. The ICRP also considers that it is "not possible" for the authorities to set out intervention levels that are generally applicable.[62] The ICRP refers to the following two reasons for being cautious. Firstly, the situations where intervention should be considered can be various.[63] Secondly, the implementation of remedial actions as intervention normally imposes a significant burden on individuals and society. According to the ICRP, any countermeasures taken as intervention "carry some detriment to the people concerned, whether it is a risk to health or some social disruption."[64]

Instead of establishing such levels, the ICRP suggests that a decision to take countermeasures should be made on a case-by-case basis, taking into account the balance between the detriment caused by the measures and the reduction in exposure achieved by the measures.[65] In other words, the ICRP notes that the

[58] ICRP, Publication 26 (1977), para. 5.
[59] The ICRP does not define the phrase "abnormal situation" often referred to in Publication 26. But it appears that this is considered to be equivalent to the condition of exposure from uncontrolled sources in Publication 9. It is true that the ICRP emphasizes in Publication 26 that its "recommendations deal quite differently with two distinct conditions of exposure," in accordance with Publication 9. ICRP, Publication 26 (1977), para. 81. Nevertheless, it is noted that its recommendations in Publication 26 are not necessarily made based on this distinction in conditions of exposure.
[60] It is noted that the terms "remedial actions" and "countermeasures" are used interchangeably in Publication 26. This is evident especially in paragraph 134 of Publication 26.
[61] ICRP, Publication 26 (1977), para. 190.
[62] ICRP, Publication 26 (1977), para. 242.
[63] ICRP, Publication 26 (1977), paras. 133.
[64] ICRP, Publication 26 (1977), paras. 133, 152. 242.
[65] ICRP, Publication 26 (1977), para. 242.

form of intervention should be optimized.[66]

On the other hand, the ICRP recognizes that it is possible and useful to establish levels below which intervention is unlikely to be required or appropriate in advance as part of an emergency plan.[67] Such levels are termed "intervention exemption levels" in the subsequent recommendations. However, it does not make any quantitative recommendations for this type of level in Publication 26.

It should be noted that both the former (i.e. intervention level) and the latter (i.e. intervention exemption level) are characterized by the ICRP as one of the "reference levels," which are only intended to serve as "guidance in making decisions" as to the introduction of remedial actions. Thus, these levels should not be applied "automatically."[68] It means that, even if the existing dose is above the former level (if any), the authorities are still expected to reassess whether to take remedial actions "in the light of all the available information at the time of intervention."

2.2 Radiological Protection and International Trade: ICRP's Focus on the Exporting Country's Interests

Once radioactive materials are deposited in the soil as a result of a nuclear accident, there is a possibility that these materials are contained in the agricultural products produced in this area not only right after the accident but also for a long period of time. It was in Publication 40 (1984) when the need to restrict the distribution of foodstuffs containing radioactive materials released by the accident was explicitly recognized.[69] As a result of distribution restrictions, food products produced in the area affected by the accident cannot be placed on both the domestic and foreign markets.

Authorities may decide to discontinue such distribution restrictions at some stage, taking into account societal and economic factors of the country.[70] As a result of

[66] ICRP, Publication 26 (1977), para. 157. This is called "the principle of optimization of protection" in subsequent recommendations, but this designation is not yet in use at the time of Publication 26. As noted at the beginning of this section, a system of dose limitation recommended by the ICRP in Publication 26, including optimization, does not apply to the condition where the source of exposure is not under control. Nevertheless, it is explained that the methodology "optimization" can be also used as an "aid" for decision-making in such condition. ICRP, Publication 40 (1984), para. 9.
[67] ICRP, Publication 26 (1977), paras. 133, 152, 242.
[68] ICRP, Publication 26 (1977), para. 243. The term "reference levels" used in Publication 26 appears to correspond to "action levels" in Publication 9 (1965).
[69] ICRP, Protection of the Public in the Event of Major Radiation Accidents: Principles for Planning. ICRP Publication 40. Ann. ICRP 14 (2) (1984).
[70] For example, assume that the authorities decide to permit residents to return to the area affected by the accident on the grounds that the radiation dose has decreased over time in the area. In this case, they may also allow the production and distribution of food products

discontinuing the distribution restrictions, such food products will be firstly placed on the domestic market, and then they could be further distributed to foreign markets. Importantly, due to the globalization of commodity markets and food chains, the ICRP recommends that the authorities and international organizations establish a radiological standard that allows for the distribution of commodities to the markets.

In this case, other countries will be faced with the importation of food products produced in the areas affected by the accident. Then, the question occurs on what rational basis they should accept such food products. Although the ICRP was also aware of this question, it appears to have presented the rationales only in an abstract and undeveloped manner in its reports, each of which will be examined in this section. To this extent, one might consider that the ICRP focuses on the export of food products from the country where the accident occurred in terms of radiological protection, while not paying attention to the interests of the country importing such food products.

2.2.1 ICRP Publication 40 (1984)

In Publications 9 and 26, the ICRP recommendations state that the exposure can be limited in amount only by remedial actions taken as intervention in the condition where the source of exposure is not under control (i.e. abnormal situation). While recommending a system of dose limitation that is applicable to the condition in which the source of exposure is under control, however, the ICRP recommendations regarding intervention are limited to the general conditions under which intervention can be permitted.

On the other hand, in Publication 40 (1984), the ICRP aims to provide "further guidance" on the application of radiation protection principles in planning interventions to protect members of the public in the event of an accident.[71] The ICRP itself characterizes Publication 40 as the "first guidance" setting out principles for the authorities to plan "countermeasures"[72] in the event of an accident.[73]

The focus of Publication 40 is explained to be on "short- and medium-term

produced in the area for the purpose of giving the returned residents a means of livelihood.

[71] ICRP, Protection of the Public in the Event of Major Radiation Accidents: Principles for Planning. ICRP Publication 40. Ann. ICRP 14 (2) (1984), para. 2.

[72] Although the terms "remedial actions" and "countermeasure" are used interchangeably in Publication 26, the term "countermeasures" is used predominantly in place of "remedial actions" in Publication 40.

[73] ICRP, Application of the Commission's Recommendations to the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or a Radiation Emergency. ICRP Publication 111. Ann. ICRP 39 (3) (2009), para. 3.

actions"[74] to be taken after an accident, although there are some references to the recovery phase in which a decision is made concerning the return to normal living conditions. This is significantly different from the subsequent recommendations made by the ICRP, for example, in Publication 63 (1993) that primarily cover "long-term actions" after an accident.[75] Moreover, as will be explained later, the ICRP primarily deals with a situation where the source of exposure is not under control in Publication 40.

2.2.1.1 Dividing an Accident into Sequential Time Phrases

As has been confirmed in the previous recommendations, the ICRP also notes in Publication 40 that exposure cannot be reduced through dose limits in conditions in which the source of exposure is not under control, like emergency situations following an accident. Rather, the ICRP notes that "intervention" is used to restrict the exposure of the public.[76] In order to develop the radiological protection principles for planning interventions, the ICRP divides sequential time phrases of an accident as follows:

> (i) Early phase: a phase during which there is a threat of a serious release of radioactive materials, and the first few hours after the commencement of that release[77]
> (ii) Intermediate phase: a phase ranging from the first few hours to a few days after the accident[78]
> (iii) Recovery phase: a phase in which decisions are made concerning the return to normal living conditions, and which may extend over a prolonged period[79]

The main characteristic of the time division above is that the source of exposure is not under control in both the (i) early and (ii) intermediate phases.[80] On the other hand, although not explicitly described in the text, the source of exposure is, by definition, supposed to be under control in the (iii) recovery phase.[81]

Based on these time categories, the ICRP notes that countermeasures to be taken

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[74] ICRP, Publication 111 (2009), para. 3. See also ICRP Publication 60 (1991), para. 223 (noting that Publication 40 "was confined to short- and medium-term action.").
[75] See Chapter 2.2.3.
[76] ICRP, Publication 40 (1984), paras. 1, 9.
[77] ICRP, Publication 40 (1984), para. 15.
[78] ICRP, Publication 40 (1984), para. 17.
[79] ICRP, Publication 40 (1984), para. 19.
[80] ICRP, Publication 40 (1984), para. 9. The ICRP also notes that "the period of *uncontrolled* release of radioactive material could extent over many days" in the (ii) intermediate phase. ICRP, Publication 40 (1984), para. 17 (Italic Added).
[81] This is so, because it is unlikely that a decision is made regarding the return to normal living (e.g. permission to return evacuees) when the source is still not under control.

as interventions may differ depending on the major exposure pathways in each phase. It is noted that the main exposure pathway during the (ii) intermediate and (iii) recovery phases includes "internal exposure from ingestion of contaminated foodstuffs or agricultural products derived from contaminated areas."[82] Thus, the ICRP recommends that countermeasures intended to reduce the exposure of the public (i.e. control of foodstuffs and water produced in contaminated areas) be taken in these phases.[83]

On the other hand, during the period immediately after an accident, the early phase, internal exposure through ingestion of contaminated foodstuffs is not considered as the major exposure pathway. Countermeasures to be taken during this phase mainly include sheltering and evacuation.[84]

Since the focus of this dissertation is on international trade in foodstuffs produced in areas contaminated due to an accident, the following will overview the ICRP recommendations regarding the principles for planning countermeasures on foodstuffs in the intermediate and recovery phases.

2.2.1.2 Action Levels for Introducing and Exempting Interventions

In Publication 40, the ICRP recommends that the regulatory authorities establish action levels in advance as part of an emergency plan for the consideration of taking countermeasures.[85] Action levels are considered to take two forms; that is first, action levels above which interventions should almost certainly be taken (i.e. upper dose level), and second, action levels below which intervention is not warranted (i.e. lower dose level).[86] While the former is also termed "intervention level" in Publication 40, the latter is the same concept as the one generally called "intervention exemption level." While this term is not yet used in Publication 40, the term "intervention exception level" is used below for convenience.[87]

As a reference, the ICRP recommends the "projected dose" of 50 mSv/year as an appropriate intervention level, and that of 5 mSv/year as intervention exemption level regarding control of distribution and consumption of foodstuffs and water

[82] ICRP, Publication 40 (1984), paras. 17, 19.
[83] ICRP, Publication 40 (1984), paras. 30 (Table 1), B14, B23.
[84] ICRP, Publication 40 (1984), paras. 30, B1, C3.
[85] ICRP, Publication 40 (1984), paras. 3. In the ICRP, the terms "action level," "intervention level," and "reference level" have often been used interchangeably. To put it in perspective, the ICRP notes in Publication 60 (1990) that levels of dose that call for the initiation of a defined course of action are called "action or investigation levels, or, in more general cases, reference levels." ICRP, Publication 60 (1990), para. 125.
[86] ICRP, Publication 40 (1984), para. 34.
[87] To the present author's knowledge, it is Publication 60 (1990) where the term "intervention exemption level" is firstly used. See Chapter 2.2.2.3.

during the (ii) intermediate phase.[88]

The unit "projected dose" means the overall dose that would be incurred as a result of the emergency exposure situation if no protective measures were taken.[89] Therefore, for example, if the annual dose that would be incurred by members of the public without any control of food and water is estimated to exceed 50 mSv in the intermediate phase, countermeasures (i.e. restrictions on the production or the distribution of foodstuffs produced in contaminated areas) should almost certainly be taken. Yet, control of food and water is not justified if the annual dose that would be incurred by members of the public without such control is estimated to remain below 5 mSv.

The ICRP itself admits that the recommended action levels can be flexible depending on the situation. For example, "when alternative supplies are not available," the intervention exemption level (i.e. projected dose of 5 mSv/year) can be set out higher than the projected dose of 5 mSv/year.[90] In this case, if the authorities adopt excessively strict criteria for food contamination, foods failing to meet the criteria will be excluded from the market, and as a result, residents may be exposed to the risk of "food shortage" other than food contamination. Thus, in this case, the authorities are required to ensure the production and distribution of such foodstuffs by relaxing the criteria for food contamination.

So far, the ICRP recommendations regarding the action levels for intervention taken in the intermediate phase have been reviewed in Publication 40. However, while control of foodstuffs and water is also considered as one of the countermeasures to be taken in the recovery phase, the ICRP does not provide any quantitative dose levels for such interventions in Publication 40.[91]

2.2.1.3 Numerical Basis for Deriving Action Levels

One might wonder on what grounds the ICRP derives the projected dose of 5 mSv/year as a lower dose level, below of which control of foodstuffs and water produced in contaminated areas is not warranted (i.e. lower dose level).

In this regard, the ICRP simply notes that interventions "would not appear to be warranted at projected doses…that are below the annual *dose limits* for members

[88] ICRP, Publication 40 (1984), para. C9. The contrast should be emphasized with Publications 9 and 26 where no action levels were quantitatively presented by the ICRP.
[89] ICRP, Publication 103 (2007), para. 276. See also ICRP, Publication 109 (2009), para. 23 (noting that "[t]he projected dose is the individual effective (or equivalent) dose that is expected to occur as a result of an emergency exposure situation if no protective measures are employed.").
[90] ICRP, Publication 40 (1984), para. C6.
[91] ICRP, Publication 40 (1984), paras. 37, C1.

of the public."[92] Thus, based on its recommendation for a dose limit of 5 mSv/year for public exposure in Publication 26 (1977),[93] the ICRP presents the projected dose of 5 mSv/year as a lower dose level in Publication 40.

One might also wonder on what grounds the ICRP derives the projected dose of 50 mSv/year as an upper dose level, above which control of locally produced foodstuffs and water is almost certainly justified (i.e. intervention level). Firstly, the ICRP notes that control of foodstuffs and water produced in contaminated areas may be appropriate in the intermediate phase, "if the projected dose within the first year would otherwise exceed the *annual dose limit* for members of the public."[94] Secondly, the ICRP also notes that the upper level of the dose should be set "an order of magnitude higher" than the annual dose limit for members of the public.[95] Then, based on its recommendation for a dose limit of 5 mSv/year for public exposure in Publication 26, the ICRP appears to derive the intervention level by increasing the annual dose limit by 10 times.

In light of the above, it is fair to note that the annual dose limits for members of the public (i.e. public exposure), which are supposed to apply only in a controlled exposure situation, also serve as a benchmark for setting intervention exemption levels applicable in an uncontrolled situation. In this regard, the ICRP also notes that the principles in the system of dose limitation "can form the basis for planning intervention."[96]

2.2.1.4 Codex's Guideline Levels for Foodstuffs Based on ICRP Recommendations

In Publication 40, aside from the lower and upper dose levels examined above, the ICRP is clearly aware that the authorities need to establish in advance "derived intervention levels," such as concentration levels of radionuclides in foodstuffs, expressed in terms of "Bq/kg."[97]

Since the *Chernobyl* accident occurred in April 1986, a number of countries have banned food imports from the regions affected by the accident for a long period of time. In 1989, Codex adopted the "Guideline Levels" (GLs) for radionuclides in foodstuffs to be traded internationally only for "one year following a nuclear accident."[98] For example, the GLs were set as 1,000 Bq/kg for caesium-134 in

[92] ICRP Publication 40 (1984), para. C2 (Italic Added).
[93] See Chapter 2.1.2.1.
[94] ICRP, Publication 40 (1984), para. C6 (Italic Added).
[95] ICRP, Publication 40 (1984), paras. C6, C8.
[96] ICRP, Publication 40 (1984), para. 9.
[97] ICRP, Publication 40 (1984), para. 36.
[98] The GLs were set only for six types of radionuclides in food, covering caesium-134 (Cs-134), caesium-137 (Cs-137), iodine-131 (I-131), strontium-90 (Sr-90), plutonium-239 (PU-239),

general food, excluding milk and infant food, and thus foodstuffs below this level are considered to be safe for consumption. It is important to note that the Codex GLs in 1989 were derived from the lower dose level (i.e. projected dose of 5 mSv/year) presented by the ICRP in Publication 40.[99]

In this regard, the lower dose level presented by the ICRP is an threshold level, below which intervention especially for contaminated foodstuffs and water is not warranted in the intermediate phase. This phase is supposed to range from the first few hours to a few days after the accident. Therefore, given the limited nature of the lower dose level (i.e. intervention exemption level) that the 1989 GLs were based on, it was appropriate for the Codex to originally limit the scope of application of the GLs to one year following an accident.

Later on, in March 1991, the Codex agreed to extend the applicability of the GLs on a "permanent basis," covering not only an emergency situation, but also a long-term exposure situation.[100] In view of the nature of the lower dose level presented by the ICRP in Publication 40, one might wonder if it is appropriate to extend the period of application of the GLs without changing the rationale underlying the GLs.

2.2.2 ICRP Publication 60 (1991)

A system of radiological protection recommended by the ICRP in Publication 60 (1991) is based on the binary categorization of human activities into (i) "practices" that increase the overall exposure to radiation, and (ii) "interventions" that decrease the overall exposure by removing existing sources.[101] It is noted that this distinction remains central to a system of radiological protection recommended by the ICRP in all three reports covered in this Chapter (i.e. Publications 60, 63, and 82). The ICRP also expressly states that this report is intended to supersede the previous ones, including, for example, Publication 9 (1966) and Publication 26 (1977).[102]

One the one hand, for example, the use of radiation (e.g. radiography, sterilization of crops) and the installation of nuclear power plants can be considered as "practices". Although such human activities certainly cause additional doses, they are characterized as "conscious decisions" made by

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and americium-241 (Am-241).

[99] As to its negotiation history, applicable scope, and scientific basis of the 1989 GLs adopted by the Codex, see Chapter 3.1.1.

[100] Codex Alimentarius Commission, Report of the 19th Session of the Codex Alimentarius Commission, ALINORM 91/40, para. 221.

[101] ICRP, Publication 60 (1991), para. 106.

[102] ICRP, Publication 82 (1999), footnote 14.

individual or the authorities to obtain medical or social benefit. In this way, practices represent new activities based on deliberate choice.[103]

Interventions can be an issue, for example, when massive radioactive materials are released into the air due to an accident at a nuclear power plant. In this case, the sources of exposure, the exposure pathways, and the exposed individuals are already in place in the environment. Therefore, the national authorities can only reduce the overall exposure by modifying the network of pathways from existing sources to human (e.g. evacuation, restrictions on the placement of contaminated foodstuffs on the market). Importantly, unlike practices, this is not a matter of deliberate choice.[104]

The following will provide an overview of the recommendations made by the ICRP in Publication 60, especially on the timing and criteria for introducing interventions to protect the public in the event of an accident, as well as for exempting the remedial actions once introduced.

2.2.2.1 Radiological Protection for Practices

The overall exposure of individuals increases by the planned use of radiation (e.g. nuclear power generation, X-ray diagnostics).[105] In the ICRP's system of radiological protection, such human activities are termed "practices". According to the ICRP, the principles of this system; that is (a) justification of practice, (b) optimization of protection, and (c) dose limits, are applicable to proposed practices.[106] Therefore, the introduction of practices should not be justified unless it turns out that the benefit outweighs the detriment caused by these practices. Even if so, such practices should also be designed in a way that keeps the detriment associated with such activities as low as reasonably achievable, in light of economic and social factors.[107]

However, the ICRP recognizes that the application of the principle of "optimization of protection" might lead to an unequal outcome that contributes to the benefits of some groups or individuals. For example, in general, groups or populations that benefit from nuclear power generation are usually broader than those who potentially incur detriments from it (e.g. people living near the plant). Thus, even if small groups are exposed to extremely high levels of radiation, such practices in favor of large groups may still be adopted as a result of the optimization process. Therefore, in order to avoid such "inequality", the ICRP proposes to incorporate

[103] ICRP, Publication 82 (1999), paras. 19, D25.
[104] See e.g. ICRP, Publication 82 (1999), para. D25.
[105] ICRP, Publication 60 (1991), para. 106.
[106] ICRP, Publication 60 (1991), para. 112. See also Chapter 2.1.2.1.1.
[107] ICRP, Publication 60 (1991), paras. 115-120.

"dose limits" into the process of optimization.[108]

As has been confirmed by the ICRP,[109] dose limits are intended to represent the levels of risk resulting from the practices that the authorities deem acceptable in light of social and economic factors.[110] In other words, dose limits are considered to reflect the dose level beyond which society would not accept. Thus, the authorities are expected to optimize its plan to introduce new sources in a manner that the annual dose added by the practices does not exceed the established limits. Put it differently, no practice should be introduced if the established dose limits are exceeded.

As noted by the ICRP, dose limits and thresholds are often erroneously regarded as drawing a boundary between "safe" and "dangerous".[111] For example, one might consider that the exposure above the dose limits is dangerous, while the exposure below the limits is safe. Yet, this is a misunderstanding. As explained before,[112] the ICRP assumes that there is no threshold for stochastic effects, and thus that the radiation risk cannot be zero no matter how small the exposure dose is. Rather, dose limits only represent the level of risk arising from the exposure that the authorities consider acceptable. Thus, for example, even if the exposure dose is below the dose limit, it does not mean that it is safe for the human body. In this case, certain risks are assumed to remain.

In Publication 60, the ICRP recommends the effective dose of "1 mSv/year" as a dose limit for public exposure.[113] It means that this value represents the level of risk that, the ICRP considers, is acceptable to the authorities regarding stochastic effect of radiation. The ICRP derives this value from the rough calculation as follows.[114]

Firstly, there is no significant difference in mortality rate by age group when comparing populations exposed continuously to 5 mSv/year with other

[108] ICRP, Publication 60 (1991), para. 121.
[109] See Chapters 2.1.1.1, 2.1.2.1.1.
[110] ICRP, Publication 60 (1991), para. 123.
[111] ICRP, Publication 60 (1991), para. 124. The ICRP also sets dose limits to prevent the occurrence of deterministic effects (i.e. tissue reactions) at values so that the threshold dose would not be exceeded. To this extent, the dose limits recommended by the ICRP represent the boundary between safety (below the threshold) and danger (above the threshold). For example, the public dose limit for skin is set as the equivalent dose of 50 mSv/year. ICRP Publication 26, paras. 10, 103, 243.
[112] See Chapter 2.1.1.1.
[113] ICRP, Publication 60 (1991), para. 191. Public exposure includes all exposures except occupational exposure (i.e. exposure of people at work) and medical exposure (i.e. exposure of people as their medical diagnosis or treatment). ICRP, Publication 60 (1991), para. 140.
[114] The ICRP also notes that a higher effective dose than 1 mSv/year can still be acceptable in special circumstances, "provided that the average over 5 years does not exceed 1 mSv per year." ICRP, Publication 60 (1991), para. 192.

populations. In other words, this suggests that adverse health effects can be ignored as such doses. Secondly, the annual effective dose from natural sources is around 1 mSv. Even in areas where the dose is relatively high, it is estimated to be at most twice that level. In other words, the regional difference in exposure dose from natural sources (except radon) is about 1 mSv/year. When we change places of residence, we hardly notice the increase of natural sources at the new location. This means that, according to the ICRP, an additional exposure of about 1 mSv/year can be considered generally acceptable.[115]

In sum, when introducing human activities that increase the radiation exposure, the ICRP recommends that the regulatory authorities examine whether proposed practices are justified, and the protection achieved by them is optimized. In the process of optimization, it also recommends that the effective dose added as a result of introducing the practices does not exceed 1 mSv/year for public exposure.

2.2.2.2 Radiological Protection in Emergency Situations through Intervention

According to the ICRP, when the source of exposure and the exposure pathways are already present in the environment as a result of, for example, a nuclear accident, "the only available action is some form of intervention".[116] The overall exposure in such an accident or emergency situation can be reduced by removing the existing sources (e.g. decontamination), modifying the network of pathways from existing sources to human (e.g. restrictions on the placement of contaminated foodstuffs on the market), or reducing the number of exposed individuals (e.g. relocation).[117]

In Publication 60, the ICRP recognizes two situations where "remedial actions"[118] taken as intervention may be needed; that is (i) long-standing exposure situations, and (ii) accident and emergency situations.[119] The former situation includes the exposure from radon in dwellings, and long-lived radioactive residues from previous events dispersed in agricultural areas.[120] As to intervention for the public after an accident, the ICRP basically reiterates the outline of its previous recommendations, and notes that it is in the middle of drafting an additional

[115] ICRP, Publication 60 (1991), para. 191.
[116] ICRP, Publication 60 (1991), paras. 111, 130. The ICPR also notes that "[d]oses due to major accidents are not subject to the dose limits because they can be dealt with only by intervention." ICRP, Publication 60 (1991), para. 192.
[117] ICRP, Publication 60 (1991), para. 106.
[118] The terms "remedial actions", "countermeasures" and "protective actions" are used interchangeably in Publication 60.
[119] ICRP, Publication 60 (1991), para. 215.
[120] ICRP, Publication 60 (1991), para. 219.

report that covers not only short- and medium-term actions, which are addressed in Publication 40 (1984)[121], but also long-term measures after the accident.[122] As explained below, it is fair to note that the ICRP fails to make detailed recommendations on interventions in the event of an accident or emergency in Publication 60.

The ICRP confirms that the general principles for the system of radiological protection for practices also apply in planning for an intervention program. It is recalled that they consist of (a) justification of intervention, and (ii) optimization of protection.[123] Thus, it follows that the authorities are recommended to examine whether the proposed intervention is justified, and its form, scale, and duration is optimized in a manner that maximizes the net benefit.[124] In this case, however, dose limits do not apply, that are intended to be used only for controlling practices.[125]

Furthermore, the ICRP recommends that the regulatory authorities establish intervention levels, above which some remedial actions should be considered,[126] for emergency situations.[127] According to the ICRP, intervention levels are expressed in terms of "averted dose", which refers to the dose averted as a result of implementing the proposed intervention.[128] In other words, the ICRP considers that the benefit derived from a particular protective action should be judged on

[121] See Chapter 2.2.1.
[122] ICRP, Publication 60 (1991), para. 223. Long-term actions after an accident are addressed in Publication 82 (1999), which will be examined later in this Chapter. See Chapter 2.2.4.
[123] The first principle (a) briefly means that the proposed intervention should do more good than harm. To be more specific, this principle refers to a process of deciding that the reduction in the dose likely to be achieved should be enough to justify the harm and costs, including monetary and social costs, caused by implementing the proposed intervention. The second principle (b) further represents a process of deciding that the form, scale, and duration of the proposed intervention are optimized, so as to maximize the net benefit. ICRP, Publication 60 (1991), paras. 113, 212.
[124] ICRP, Publication 60 (1991), para. 210. For example, the authorities might decide to restrict the placement of foodstuffs produced in contaminated areas on the domestic market in order to avoid internal exposure through ingestion of such foods. Nevertheless, this intervention might not be justified if, for example, no other alternative foods are available. In this case, food shortages may cause more serious problems than the reduction in dose exposure. Moreover, even if this restriction on foodstuffs is estimated to bring more benefits than detriments and costs, this proposed restriction should not be excessive. Instead, it should be designed in a way of maximizing the net benefit by, for example, limiting the scope of distribution restrictions.
[125] ICRP, Publication 60 (1991), para. 113. For example, it might happen that the existing dose is already higher than dose limits when the authorities make a decision on intervention. In this case, dose limits may be useless to decrease the existing exposure. According to the ICRP, the use of dose limits in such a situation might even conflict with the principle of justification. ICRP, Publication 60 (1991), para. 131. On the other hand, the ICRP recognizes a circumstance where dose limits can be relevant for deciding whether the proposed intervention is necessary. According to the ICRP, some interventions will be "almost mandatory" when the dose is close to the level at which serious deterministic effects appear. ICRP Publication 60 (1991), para. 131.
[126] As to the definition of intervention levels, see ICRP, Publication 60 (1991), para. 257.
[127] ICRP, Publication 60 (1991), paras. 125, 221.
[128] ICRP, Publication 60 (1991), para. 283.

the basis of the reduction in dose achieved by that action.[129] For example, if it is estimated that the restriction on foodstuffs will make it possible to avert more doses than the established level, the authorities are suggested to take this remedial action. In this case, since intervention levels are considered as "guides to action", not as limits,[130] the authorities are not obliged to take this action.

However, in Publication 60, the ICRP does not recommend any specific values for reference levels to be set by the authorities, above which some remedial actions should be considered, in emergency situations. [131] A more detailed recommendation on this point is made in Publication 63 (1992), which will be examined in the next section.

2.2.2.3 Intervention Exemption Levels for International Trade in Foodstuffs

Aside from intervention levels, the ICRP also recognizes the situation where intervention should be discontinued or exempted, especially in relation to international trade in foodstuffs. Publication 60 is the first time for the ICRP to make recommendations on "intervention exemption levels" in an explicit form. It is recalled that the ICRP already recognized a similar concept with a different term (i.e. lower dose level) in Publication 40.[132]

2.2.2.3.1 Reference Levels for Exempting Intervention

As noted before, in an emergency situation, the authorities might decide to restrict the placement of foodstuffs produced in areas affected by a nuclear accident on other domestic markets. As a result, such foodstuffs are prevented from being distributed to unaffected domestic markets, as well as from being exported to foreign markets similarly unaffected. In other words, this indicates that restrictions on foodstuffs taken as intervention within the country where an accident occurred (i.e. accident country) may also constitute export restrictions at an international level. In this way, radiological protection, which is primarily addressed within a country or region where an accident occurred, will also be relevant to international trade.

Indeed, in Publication 60, the ICRP fails to indicate the specific circumstance where exemption from intervention can be an issue in relation to international trade. However, the ICRP probably has the following in mind. Even if the

[129] ICRP, Publication 60 (1991), para. 222.
[130] ICRP, Publication 60 (1991), para. 283.
[131] It is recalled that the ICRP made more detailed recommendations on the reference (action) levels regarding control of distribution and consumption of foodstuffs and water in emergency situations in Publication 40 (1984). See Chapter 2.2.1.2.
[132] See Chapter 2.2.1.2.

restrictions mentioned above are once implemented, the exposure situation may improve enough to consider the resumption of normal living conditions in contaminated areas. In that case, the authorities may decide to discontinue or exempt such intervention on the ground that "the source gives rise to small individual doses".[133] As a result, they will allow the distribution of foodstuffs produced in contaminated areas to other unaffected markets, including foreign ones.

In order to avoid trade restrictions that are no longer needed, the ICRP recommends that the authorities establish reference levels, below which intervention, such as restrictions on foodstuffs, should be exempted. Such levels are explicitly called "intervention exemption level" for the first time in Publication 60, specifically in the context of international trade. According to the ICRP, any trade restrictions on foodstuffs below this level should be regarded as artificial barriers to trade, and thus exports of such foodstuffs from the accident country should be permitted.[134] However, in Publication 60, the ICRP does not present any numerical values for such levels.[135]

2.2.2.3.2 Analysis

It is worth commenting on the following characteristics of the notion of "intervention exemption level" addressed by the ICRP in Publication 60. It appears that much remains unclear about this concept, at least at the time of adopting Publication 60.[136]

In general, the regulatory authorities are entitled to set out their own level of protection, or its acceptable level of risk, at their discretion, taking into account social and economic conditions prevailing within the country. In a system of radiological protection by the ICRP, it is recalled that the proposed intervention needs to be justified, and the protection achieved through the intervention needs to be optimized.[137] Therefore, a decision by the authorities to exempt interventions is also supposed to be made in accordance with these principles.

For example, if a major agricultural production area is contaminated by an accident, the authorities may set a relatively moderate level of contamination in foodstuffs to ensure domestic food supplies. Another country that has been economically dependent on food exports may set relatively modest levels for

[133] ICRP, Publication 60 (1991), para. 287.
[134] ICRP, Publication 60 (1991), para. 284.
[135] ICRP, Publication 60 (1991), para. 288.
[136] The ICRP further elaborates this concept in Publication 82 (1999), specifically in the context of prolonged exposure situation. See Chapter 2.2.4.3.
[137] ICRP, Publication 60 (1991), para. 113.

permitting the shipment and distribution of foods produced in its affected areas to foreign markets. When permitting the return of evacuees, the authorities may also allow them to engage in the production and distribution of agricultural products in view of the economic recovery of the region. Therefore, it is important to note that, when recognizing the necessity to exempt interventions (e.g. restrictions on foodstuffs), it means that the ICRP also recognizes the necessity to export foodstuffs produced in contaminated areas to both domestic and foreign markets. Put differently, the ICRP appears to take it for granted that importing countries or consumers in foreign markets will accept such foodstuffs.

2.2.3 ICRP Publication 63 (1992)

In Publication 63 (1992), the ICRP aimed to update and extend its previous reports, including Publication 40 (1984) which set out the principles for planning intervention, and then to provide further guidance, including quantitative one, for introducing intervention in "radiological emergencies"[138] to protect the public.[139] It is recalled that, in Publication 40, the ICRP sets out the principles applying to intervention taken after an accident "over short times".[140] In Publication 63, the ICRP aims to cover "protective actions"[141] adopted "over protracted timescales lasting perhaps years" after an accident.[142]

In subsequent reports after Publication 63, the ICRP makes recommendations for planning interventions in emergency situations, for example, in Publication 86 (2000),[143] Publication 96 (2005),[144] Publication 97 (2005)[145], Publication 98 (2005)[146] and 109 (2009). However, since the focus of this thesis is on international trade in foodstuffs produced in contaminated areas in a rehabilitation situation following an emergency situation, we will not examine in detail these reports addressing the emergency situation.

Although Publication 63 also deals with an emergency situation after an accident,

[138] The term "radiological emergency" widely used in Publication 63 is almost synonymous with the term "emergency situations" commonly used in ICRP.
[139] ICRP, Publication 63 (1992), para. 3.
[140] See Chapter 2.2.1.
[141] Unlike the previous reports where the terms "remedial actions" and "countermeasures" are dominantly used, the ICRP exclusively uses the term "protective actions" in Publication 63.
[142] ICRP, Publication 63 (1992), para. 3.
[143] ICRP, Prevention of Accidents to Patients Undergoing Radiation Therapy. ICRP Publication 86. Ann. ICRP 30 (3) (2000).
[144] ICRP, Protecting People against Radiation Exposure in the Event of a Radiological Attack. ICRP Publication 96. Ann. ICRP 35 (1) (2005).
[145] ICRP, Prevention of high-dose-rate brachytherapy accidents. ICRP Publication 97. Ann. ICRP 35 (2) (2005).
[146] ICRP, Radiation safety aspects of brachytherapy for prostate cancer using permanently implanted sources. ICRP Publication 98. Ann. ICRP 35 (3) (2005).

it contains detailed recommendations and guidance for the authorities on the control of foodstuffs and water in such a situation, including foodstuffs traded internationally. Thus, the following will review the ICRP recommendations in this report with a focus on this specific issue.

2.2.3.1 Control of Foodstuffs in an Emergency Situation

In Publication 63, the ICRP recognizes the following time stages in radiological emergencies for the purpose of planning interventions; that is (i) a pre-release stage,[147] (ii) a release stage, and (iii) a post-release stage. In particular, according to the ICRP, the (iii) post-release stage may last "over a prolonged period of months or years", during which decisions will be made concerning the return of evacuees to normal living conditions.[148] Thus, it is noted that this stage includes a "rehabilitation phase", which is usually trigged by the authorities making a decision to return evacuees. To this extent, the scope of Publication 63 is clearly different from Publication 40, which focuses on short- and medium-term actions following an accident.

During the (ii) release stage, and in the (iii) post-release stage, radioactive materials might be accidentally released into the environment, deposited on the ground, and then transferred to foodstuffs and drinking water. Thus, ingestion of contaminated foodstuffs and water is regarded as one of the principal exposure pathways in an emergency situation.[149] Especially, protective actions taken for foodstuffs containing long-lived radionuclides in the (iii) post-release stage may be maintained "for considerable periods of time".[150]

According to the ICRP, protective actions taken during these stages to protect the public from ingestion of contaminated foodstuffs can be divided into the following types.[151]

- directly restricting the distribution and consumption of contaminated foodstuffs.
- limiting the transfer of radionuclides into the food-chain from contaminated air, soil and water.

While recognizing the need to take protective actions over the long-term after an accident, especially in the (iii) post-release stage, the ICRP itself admits in its

[147] It covers a period of time from when potential or actual accidental exposure is recognized, to the time when significant amounts of radioactive material are released. ICRP, Publication 63 (1992), para. 47.
[148] ICRP, Publication 63 (1992), para. 49.
[149] ICRP, Publication 63 (1992), paras. 43, 82.
[150] ICRP, Publication 63 (1992), para. 87.
[151] ICRP, Publication 63 (1992), paras. 82, 85-86.

subsequent report that the recommendations in Publication 63 deals with the "early and intermediate stages of intervention" after the accident.[152] Thus, it is Publication 82 (1999) where the ICRP makes detailed recommendations on intervention in a prolonged exposure situation after an accident.[153]

2.2.3.2 Intervention Levels for the Control of Foodstuffs

As repeatedly confirmed by the ICRP,[154] dose limits cannot be an effective tool to reduce exposure in emergency situations. They are intended to be used for controlling "practices" that deliberately increase the exposure. Rather, in a radiological emergency, the authorities should be provided with intervention levels as a reference for taking protective actions, including the control of foodstuffs.[155] Given its view that the principles of its system of radiological protection for intervention apply to emergency situations,[156] the ICRP notes that intervention levels should be established based on a process of "justification of the protective action" and "optimisation of protection".[157]

As intervention levels, above which intervention is almost always justified,[158] the ICRP recommends an averted effective dose of 10 mSv/year for any single foodstuff.[159] In this regard, the term "averted effective dose" refers to the amount of dose saved by implementing a protective action.[160] Thus, according to this recommendation, the control of a single foodstuff, such as eliminating foodstuffs produced in contaminated areas from the market, will be almost always justified in an emergency situation, provided that the effective dose averted by implementing such control is estimated to exceed 10 mSv/year. However, it is not clearly explained in Publication 63 on what grounds the specific value of 10 mSv/year is derived. It is also not clear from the report whether the ICRP considers that this intervention level applies to foodstuffs produced during a long-term exposure situation.

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[152] ICRP, Publication 82 (1999), para. 116.
[153] See Chapter 2.2.4.
[154] See e.g. Chapters 2.2.1.1, 2.2.2.2.
[155] ICRP, Publication 63 (1992), paras. 1, 21.
[156] It has been long confirmed by the ICRP that the principles of its system of radiological protection for intervention consist of (i) the justification of intervention, and (ii) the optimisation of protection achieved by the intervention.
[157] ICRP, Publication 63 (1992), paras. 22, 54.
[158] ICRP, Publication 63 (1992), para. 18.
[159] ICRP, Publication 63 (1992), paras. 89, 119. It is recalled that, in Publication 40, the ICRP recommends a "projected dose" of 50mSv/year as a reference level (i.e. upper dose level), above which intervention should almost certainly be taken, especially for the control of foodstuffs and water in the intermediate phase after an accident. Later on, in Publication 60, the ICRP makes no quantitative recommendations for intervention in an emergency situation. See Chapters 2.2.1.2, 2.2.2.2.
[160] ICRP, Publication 63 (1992), paras. 10, 54.

The ICRP notes that this intervention level is subject to certain modification.[161] For example, if alternative food supplies are not readily available, the control of foodstuffs may be justified only if the "projected dose" is estimated much higher than 10 mSv/year. In this case, according to the ICRP, interventions may be justified only if the level of exposure though ingestion of foodstuffs without taking any protective actions is estimated to be much higher than 10 mSv/year.[162]

Furthermore, the ICRP emphasizes the necessity to establish intervention levels in terms of quantities, instead of averted dose, for enabling decisions to be made quickly in an emergency situation, as well as for being easily and directly measured.[163] According to the ICRP, the "activity concentration" of radionuclides, which generally means the amount of radioactivity in materials, in foodstuffs is the most convenient form of implementing protective actions in an emergency situation.[164]

The ICRP recommends the activity concentration levels in foodstuff based on the intervention level for the control of a single foodstuff (i.e. averted dose of 10 mSv/year). Such levels range from 1,000-10,000 Bq/kg for radionuclides with low values of dose (most beta and gamma emitters), and from 10-100 Bq/kg for radionuclides with high values of dose (alpha emitters).[165] For example, if cesium-134 (beta emitter) contained in a single foodstuff exceeds 10,000 Bq/kg, it means that restrictions on placing this foodstuff on the domestic market will be almost always justified. Moreover, the ICRP also acknowledges that much higher levels would be adopted especially when alternative foods are not readily available.[166]

On the other hand, it is not clear whether the ICRP also considers that intervention will not be justified if the activity concentration level in foodstuffs is below the established level.[167] In other words, the ICRP is primarily concerned with the introduction of intervention in an emergency situation, not its discontinuance or exemption, in Publication 63. The reference levels, below which intervention is not warranted, tend to be an issue in a long-term exposure situation (i.e. rehabilitation phase), and are addressed in Publication 82 (1999).

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[161] A similar consideration is found in Publication 40. See Chapter 2.2.1.2.
[162] ICRP, Publication 63 (1992), para. 89.
[163] ICRP, Publication 63 (1992), para. 13. Such levels are called "operational intervention levels" in Publication 63. It is recalled that, in Publication 60, the ICRP is also aware of the necessity to establish derived intervention levels in quantities on the ground that "the dose that will be averted cannot easily be estimated in the period immediately after an accident". ICRP, Publication 60 (1991), para. 143.
[164] ICRP, Publication 63 (1992), paras. 15-16, 21, para. B2.
[165] ICRP, Publication 63 (1992), paras. 90, 119.
[166] ICRP, Publication 63 (1992), para. 90.
[167] ICRP, Publication 63 (1992), para. 14.

Lastly, it is again recalled that the levels of activity concentration in foodstuffs presented by the ICRP in Publication 63 are only reference for the authorities. As confirmed before, the ICRP only hopes that the regulatory authorities designed its regulatory structure on radiological protection in a manner that is "broadly consistent with the guidance" in its report.[168] In other words, the ICRP expects that "the report will be of help to management bodies with responsibilities for radiological protection".[169] Therefore, in Publication 63, the ICRP intends to provide guidance for the authorities willing to establish intervention levels in terms of activity concentration for the control of contaminated foodstuffs in an emergency situation.

2.2.3.3 Rationales for Importing Countries to Accept Contaminated Foodstuffs in the Post-release Stage

After an accident, the authorities might decide to restrict the distribution of foodstuffs produced in contaminated areas within the domestic market. Especially, protective actions taken for the control of foodstuffs containing long-lived radionuclides might remain in force "for considerable periods of time".[170] Nevertheless, as the exposure situation settles down, at some point, they might make a decision to discontinue or relax such a protective action in light of its social and economic factors.[171] As a result, they will allow the distribution of some foodstuffs produced in contaminated areas to other unaffected markets. In this case, the ICRP recommends that the authorities make such a decision in accordance with the principles of its system of radiological protection.

In this regard, once such foodstuffs are allowed to be placed in the domestic market, they become visually indistinguishable from other normal foodstuffs. This makes control difficult. Furthermore, such foodstuffs may be exported in some form to foreign markets. To this extent, a decision made by the authorities to discontinue the control of foodstuffs once introduced following an accident is closely linked to the interests of importing countries. For example, countries with a high awareness of food safety may not allow imports of foodstuffs produced on a more moderate basis than their own. However, a decision made by the authorities to discontinue the control of foodstuffs in terms of radiological protection is basically made without regard to such interests of importing countries.

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[168] ICRP, Publication 60 (1991), para. 10.
[169] ICRP, Publication 60 (1991), para. 10.
[170] ICRP, Publication 63 (1992), para. 87.
[171] For example, when permitting the return of evacuees, the authorities may set a relatively moderate level of activity concentration in foodstuffs, so as to allow them to engage in the production and distribution of agricultural products in view of the economic recovery of the region.

As noted before,[172] it is widely accepted that importing countries have the discretion to determine the acceptable level of health risks arising from ingestion of contaminated foodstuffs in light of its policy considerations. Nevertheless, the ICRP notes that "there are advantages" for importing countries to adopt the same criteria as the exporting country, even if cases where there are good scientific reasons for not doing so. Otherwise, according to the ICRP, "[c]onfidence in authorities responsible for protecting the public is lost".[173] According to the ICRP, this is how "difficulties in international trade in foods" can be avoided.[174] Put it differently, the ICRP presents the rationales for importing countries to accept foodstuffs produced in contaminated areas within the accident (i.e. exporting) country; that is "advantages" and "confidence" for them. One might consider these rationales as abstract or undeveloped.

The ICRP also refers to the guideline levels (i.e. GLs) of radionuclides in foodstuffs to be traded internationally adopted by the Codex in 1989,[175] as an example where difficulties in international trade in foodstuffs can be avoided. In 1991, the Codex agreed to extend the applicability of the GLs on a permanent basis, also covering a long-term exposure situation.[176] Assuming that foodstuffs with radionuclide levels below the GLs are considered as "safe for human consumption", the Codex requires both (i) exporting countries not to allow exports of foodstuffs failing to meet the GLs, as well as (ii) importing countries to accept imports of foodstuffs meeting the GLs. To this extent, as noted by the ICRP, difficulties in international food trade can be avoided through the adoption of the same criteria (i.e. Codex GLs) by both exporting and importing countries.

In the WTO, importing Members are entitled to deviate from the Codex GLs by adopting a higher level of protection than that assumed by the Codex GLs, provided that certain conditions set out in the SPS Agreement are met.[177] If the ICRP takes it for granted that importing countries adopt the same level of protection as exporting countries, it might mean that there is a fundamental conflict between the international trade system centered on the WTO and the system of radiological protection recommended by the ICRP.

2.2.4 ICRP Publication 82 (1999)

In Publication 82 (1999), the ICRP intends to provide guidance to the authorities

[172] See Chapter 2.2.2.3.
[173] ICRP, Publication 63 (1992), para. 91.
[174] ICRP, Publication 63 (1992), para. 91.
[175] See Chapter 3.1.1.
[176] Codex (Report of the 19th Session of the Codex Alimentarius Commission), ALINORM 91/40, para. 221.
[177] See Chapter 3.2.1.

responsible for radiological protection on how to apply its system of radiological protection to the situations where members of the public are subject to prolonged exposure (i.e. prolonged exposure situation).[178] Contrary to Publication 63 (1992) primarily dealing with the "early and intermediate stages" of intervention after an accident, the ICRP explicitly excludes the recommendations for intervention in emergency situations after an accident from its scope in Publication 82.[179]

Prolonged exposure can be caused by long-lived "radioactive residues" that might be present in "commodities" (e.g. building materials and foodstuffs)[180] due to an accident. In other words, such commodities containing radioactive materials can serve as a main source of prolonged exposure. Therefore, the restrictions on commodities that are produced in areas affected by the accident (e.g. distribution ban on foodstuffs) can be one of the "protective actions"[181] to be taken by the authorities in prolonged exposure situations.

As the exposure situation improves over time, however, such protective actions may no longer be needed, or may become excessive. Whether or not to discontinue the protective actions taken so far can be important, especially when the authorities make a decision to return evacuees to normal living (because of the need to ensure the livelihoods of residents after their return).[182] In this case, it must be emphasized that allowing the distribution of foodstuffs produced in contaminated areas is closely related to the interests of other countries to which contaminated foodstuffs might be exported. In Publication 82, the ICRP attempts to develop rationales for importing countries to accept contaminated foodstuffs at the same level as that of exporting (accident) country permitting the distribution of such foodstuffs to the market.

2.2.4.1 Control of Prolonged Exposure Attributable to Long-lived Radioactive Residues

The ICRP firstly defines the scope of "prolonged exposure situations" covered by Publication 82. Such situations refer to the exposures that are adventitiously and persistently incurred by members of the public over long period of time (e.g.

[178] ICRP, Protection of the public in situations of prolonged radiation exposure. ICRP Publication 82. Ann. ICRP 29 (1–2) (1999), para. 13.
[179] ICRP, Publication 82 (1999), paras. 115-116.
[180] The term "commodity" used in this publication refers to ones "that can generally be used or consumed by the public". ICRP, Publication 82 (1999), fn. 11.
[181] In Publication 82, the term "protective actions" is used to mean "suitable steps taken to avert doses through intervention". ICRP, Publication 82 (1999), fn. 10.
[182] For example, the ICRP notes that, in order to return evacuees to "normal living conditions", the authorities may need to discontinue some protective actions at some stage in spite of the presence of radioactive residues. ICRP, Publication 82 (1999), para. 115.

"around a decade or more").[183] Prolonged exposures can be caused by either "natural sources" (e.g. cosmic radiation)[184] or "artificial sources", especially long-lived "radioactive residues" (see below) remained in the environment as a result of past human activities, such as an accident.[185]

The ICRP defines "radioactive residues" to specifically mean "radioactive materials that have remained in the environment from early operations (including past practices) and from accidents".[186] According to the ICRP, it is acknowledged that such radioactive residues are a "common cause of prolonged exposure".[187]

Importantly, radioactive materials may be contained in commodities, such as building materials and foodstuffs. They may be artificially incorporated into commodities as a result of the operation of regulated activities (i.e. practices). On the other hand, they may also be contained in commodities that are produced in an area where radioactive residues remain due to unregulated events, such as a nuclear accident. This is how commodities containing radioactive materials can be a source of prolonged exposure.[188]

The actions taken to control exposures attributable to radioactive residues may differ depending on whether they are caused by "practices" or other events not regulated as practices. Firstly, radioactive residues may result from the termination of regulated activities (i.e. practices). For example, they might remain at and around the site of a nuclear installation that has already been decommissioned.[189] In this case, it is proposed that dose limits be used to reduce the exposure. Secondly, radioactive residues may also remain in the environment as a result of past activities and events that not regulated as practices at that time. For example, they might remain on the ground as a result of an accident at a nuclear power plant that released radioactive materials into the environment. In this case, exposure should be reduced through protective actions taken in the process of intervention.[190]

Lastly, according to the ICRP, almost all prolonged exposures attributable to radioactive residues, whether they result from practices or unregulated events, are considered as "controllable" in that such exposures can be effectively restricted by protective measures. On the other hand, prolonged exposures that

[183] ICRP, Publication 82 (1999), para. 1.
[184] They are normally termed "naturally occurring radioactive materials (NORMs)". ICRP, Publication 82 (1999), fn. 3.
[185] ICRP, Publication 82 (1999), paras. 2, 9.
[186] ICRP, Publication 82 (1999), para. 2, fn. 4.
[187] ICRP, Publication 82 (1999), para. (b).
[188] ICRP, Publication 82 (1999), paras. 10, 123-124, 128.
[189] ICRP, Publication 82 (1999), paras. (c), (t), 20.
[190] ICRP, Publication 82 (1999), paras. (c), (u).

are not controllable (e.g. exposure to cosmic radiation) are supposed to fall outside the scope of regulations on radiological protection.[191]

2.2.4.2 Reference Levels for Interventions in Prolonged Exposure Situations

Long-lived radioactive residues may be present in the environment due to past human activities and events that are not regulated as practices (e.g. nuclear accident, nuclear weapons testing). Given that those residues already exist in human habitats, the exposure can be effectively reduced through the application of the system of radiological protection for "intervention".[192] As has been confirmed by the ICRP, the general principles of its system of radiological protection for intervention, which consist of (i) the justification of intervention, and (ii) the optimization of the protective actions,[193] are also applicable to prolonged exposure situations.[194]

In this regard, the ICRP recommends that the authorities establish reference levels so as to facilitate decision-making as to whether or not to intervene, and if so, what form and duration, in prolonged exposure situations.[195] The term "reference level" is defined as "values of measured quantities above which some specified action or decision should be taken".[196] Thus, the following will overview how the prolonged exposure can be reduced through protective actions taken in a process of intervention in accordance with the reference levels.

Firstly, the ICRP suggests that the national authorities and relevant international organizations establish *specific* reference levels for intervention in "particular" prolonged exposure situations in terms of averted dose.[197] This type of reference level is useful when there are dominant components constituting the "existing annual dose", which refers to the sum of the annual doses incurred by an individual from all relevant sources, whether natural or artificial, in human

[191] ICRP, Publication 82 (1999), paras. 8, 19. See also ICRP, Publication 60 (1991), para. 291 (noting that "[s]ources that are essentially uncontrollable…can best be dealt with by the process of exclusion from the scope of the regulatory instruments".).
[192] ICRP, Publication 82 (1999), paras. (c), 20. Long-lived radioactive residues may remain in the environment as a result of the operation of "practices". For example, they can be detected on and around nuclear facilities after their decommissioning. Since exposure can be reasonably expected to occur in this case, it should be reduced through the system of radiological protection for practice.
[193] As to the general principles of the ICRP's system of radiological protection for intervention, see ICRP, Publication 60 (1991), para. 113. See also Chapter 2.2.2.2.
[194] ICRP, Publication 82 (1999), para. (m).
[195] ICRP, Publication 82 (1999), paras. 5, 49.
[196] ICRP, Publication 82 (1999), para. 49, fn. 32. See also ICRP, Publication 60 (1991), para. 257.
[197] ICRP, Publication 82 (1999), paras. (p), 65-66.

habitats.[198] Thus, if the dose that can be averted by implementing a specific protective action is estimated to exceed the established intervention level, it follows that such specific protective action should be taken. However, in Publication 82, the ICRP does not make any quantitative recommendations for such reference levels.[199]

Secondly, aside from *specific* reference levels applying to a particular prolonged exposure situation, in Publication 82, the ICRP also recommends that the authorities use generic reference levels, especially when there are no dominant components constituting the existing annual dose.[200] This type of reference level is useful for the authorities to recognize the extreme cases of prolonged exposure situations; that is (i) where the annual dose is low enough to make intervention unlikely to be justifiable, and (ii) where the annual dose is high enough to justify intervention in almost any circumstances.[201] In other words, the *generic* reference level only aims to provide rough boundaries as to whether intervention may be justified or not, and thus should not be considered as representing "acceptable levels" of risks.[202]

In Publication 82, the ICRP recommends that, in prolonged exposure situations, intervention will be almost always justified if the existing annual dose rises "towards 100 mSv".[203] This value can be derived as follows. It is recalled that generic reference level for intervention is useful to recognize the situation where the annual dose is high enough to justify intervention in almost any circumstances. In this regard, no one will doubt the necessity of intervention if the existing annual dose approaches the threshold for deterministic effects (i.e. around 100 mSv/year), or if it brings about a high risk of stochastic effects. This is how the ICRP recommends the existing annual dose rising "towards 100 mSv" as the upper generic reference level.[204]

2.2.4.3 Intervention Exemption and International Trade in Foodstuffs

[198] Existing annual dose covers (i) the dose from natural radiation sources, (ii) the doses caused by long-lived radionuclides released from practices, and (iii) the doses caused by long-lived radioactive residues from previous human activities and from long standing accidental contamination of the environment. ICRP, Publication 82 (1999), para. B14.
[199] This is not the first time for the ICRP to recommend the establishment of reference levels for intervention in terms of averted dose. In the past, the ICRP recommended some specific reference levels for intervention regarding a dominant single component. For example, in Publication 63 (1992), the ICRP recommended that intervention for a single foodstuff be almost always justified at an averted dose of 10 mSv/year in emergency situations. See Chapter 2.2.3.2.
[200] ICRP, Publication 82 (1999), para. 80.
[201] ICRP, Publication 82 (1999), paras. 50, 71.
[202] ICRP, Publication 82 (1999), para. 84.
[203] ICRP, Publication 82 (1999), paras. (r), 79. It is recalled that *specific* reference levels are expressed in terms of annual averted dose.
[204] ICRP, Publication 82 (1999), para. 78.

After an accident, the authorities are likely to restrict the placement of foodstuffs produced in the areas affected by radioactive materials released due to an accident on the market. Such restrictions may be maintained for a prolonged time, given the fact that some radioactive materials tend to remain in the environment long after the accident.[205] As a result, radioactive residues may also be incorporated into foodstuffs produced in such an environment, which is considered as the main cause of prolonged exposure.

However, protective actions taken by the authorities as intervention after an accident inherently constrain the normal living conditions of people. For example, the restrictions on the distribution of foodstuffs from areas affected by the accident will cause serious damage on the local economy. In some cases (e.g. prolonged evacuation, permanent relocation), protective actions could be even "[d]isruptive".[206] Thus, if the overall exposure decreases over time, the authorities might consider that the protective actions being implemented are disproportionate, and thus need to be discontinued or exempted.

As explained before,[207] in Publication 60 (1991), the ICRP was aware of the necessity for reference levels below which intervention should be exempted (i.e. intervention exemption level) in relation to international trade. According to the ICRP, any trade restriction on foodstuff should be regarded as artificial barriers to trade when the activity concentration of radionuclide in this foodstuff is below this level. In this report, however, the ICRP failed to indicate the specific circumstances in which such intervention exemption is practically required.

In Publication 82, the ICRP attempts to provide the rationales for the authorities to consider the exemption or discontinuation of protective actions, especially the restrictions on the placement of contaminated commodities (e.g. foodstuffs) on the market, in a prolonged exposure situation.

2.2.4.3.1 Necessity to Exempt Interventions for Commodities

In Publication 82, the ICRP explains the necessity to consider the exemption or discontinuation of protective actions imposed on commodities (e.g. foodstuffs) in a prolonged exposure situation on the following grounds.

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[205] According to the ICRP, of the approximately 2000 radionuclides currently identified, approximately one hundred have "half-life" long enough to cause prolonged exposure (i.e. about 10 years or more). ICRP, Publication 82 (1999), para. A1. The term "half-life" of radionuclides refers to the time required for half the original nuclides to decay. Law, Jonathan (eds), *A Dictionary of Science*, 7th edn (Oxford University Press, Oxford: 2017) 252.

[206] ICRP, Publication 82 (1999), para. 115. The ICRP also notes that prolonged evacuation and permanent relocation "have sometimes been found to be highly traumatic". ICRP, Publication 60 (1991), para. 213.

[207] See Chapter 2.2.2.3.

Firstly, the ICRP refers to the "globalisation of markets" as a reason for the authorities to consider the discontinuation of the restrictions on commodities in a prolonged exposure situation.[208] For example, when a protective action takes a form of restricting the placement of contaminated commodities on the market, it is recalled that they may also act as restrictions on international trade in those commodities.[209] Therefore, in order to respond to the demand for globalization of commodity markets, the ICRP recommends that the authorities establish in advance reference levels below which such restrictions should be exempted or discontinued.[210]

Secondly, the restrictions on the placement of commodities, especially foodstuffs, on the market can be serious economic constraint for local residents engaging in agricultural production, especially when the authorities decide to return evacuees to the "normal" living conditions.[211] If they cannot engage in agriculture as before even after they return home, or in other words, if the distribution of agricultural products produced there is not yet permitted, they will immediately face economic difficulties. Therefore, in light of these social and economic reasons, the authorities might consider the exemption or discontinuation of such restrictions imposed on foodstuffs.[212]

In Publication 82, the ICRP recommends a reference level for intervention exemption of "around 1 mSv" for a dominant type of commodity in terms of "additional annual dose".[213] Therefore, if the annual dose added as a result of exempting interventions is estimated to be below around 1 mSv, it means that the discontinuation of such restrictions should be considered.[214] Then, after consideration, the authorities may eventually decide to lift such restrictions on imposed commodities, while they are not precluded from reaching a decision not to exempt such restrictions in light of other social and economic factors. It is

[208] ICRP, Publication 82 (1999), paras. (x), 124.
[209] If the distribution of foodstuffs is restricted on the ground that they fail to meet certain radiological criteria, these foodstuffs cannot be exported to foreign markets.
[210] ICRP, Publication 82 (1999), para. 51.
[211] ICRP, Publication 82 (1999), paras. (w), 115.
[212] For example, the authorities might decide to relax the radiological criteria in foodstuffs on which the distribution restrictions are based, with a view to supporting rehabilitation in areas affected by the accident.
[213] ICRP, Publication 82 (1999), paras. (y), 126, 132 (Table 1).
[214] One might wonder why the unit of "additional annual dose" is used here. In this regard, the discontinuation of protective actions adopted after an accident can be functionally equated with "practices" in that both of them cause the increase of radiation exposure to people. According to the ICRP, a situation in which protective actions are discontinued "could conceptually be considered 'normal' again". ICRP, Publication 82 (1999), para. 118. Lifting restrictions on foodstuffs produced in an area affected by the accident will inevitably increase the dose exposed through ingestion of such foodstuffs. This is why the ICRP recommends the intervention exemption level in terms of additional annual dose, which is normally used to express the dose added as a result of practices. ICRP, Publication 82 (1999), para. (f).

recalled that the ICRP only recommends that the authorities establish "reference levels".[215]

Furthermore, the ICRP recommends that such reference levels be established in a standardized manner,[216] specifically in terms of the activity concentrations of radionuclides in commodities (i.e. Bq/kg). In this regard, it is recalled that the Codex adopted the Guideline Levels (GLs) for activity concentration in foodstuffs to be traded internationally in 1989 on the basis of the recommendation by the ICRP in Publication 40 (1984).[217] In 2006, the Codex further revised the 1989 GLs based on the intervention exemption level of "around 1 mSv/year" recommended by the ICRP in Publication 82.[218] Since the Codex assumes that foodstuff with lower activity concentration than the GLs are considered to be safe for human consumption, the authorities are encouraged to exempt the restrictions on the placement of such foodstuffs on the market, and then allow them to be in the market, whether domestic and foreign. To this extent, the Codex GLs can be descried as "de facto generic intervention exemption levels" for foodstuffs.[219]

In sum, in Publication 82, the ICRP presents the rationales for the authorities to consider the exemption or discontinuation of protective actions, especially the restrictions on the placement of contaminated commodities, in a prolonged exposure situation; that is (i) the demand for the globalization of commodity markets, and (ii) the economic and social needs to support the areas affected by the accident. In other words, in Publication 82, the ICRP appears to express its understanding that the contaminated foodstuffs should be acceptable for being traded internationally, as long as the annual dose added from ingestion of such foodstuffs remains below "around 1 mSv". Yet, this understanding might overlook the fact that some importing countries adopting higher levels of protection may not accept such contaminated foodstuffs. This is an issue of "market acceptance", which will be addressed later.

2.2.4.3.2 Basis for "around 1 mSv"

First of all, it is recalled that the ICRP presents the existing annual dose "approaching about 10 mSv" as the *generic* reference levels below which intervention is not likely to be justified.[220] It stresses that the use of generic

[215] It is recalled that reference levels used by the ICRP generally mean "values of measured quantities above which some specified action or decision should be taken". ICRP, Publication 60 (1991), para. 257. See also ICRP, Publication 82 (1999), para. 49, fn. 32.
[216] ICRP, Publication 82 (1999), paras. (x), 124.
[217] See Chapter 2.2.1.4.
[218] See Chapter 3.1.2.4.
[219] ICRP, Publication 82 (1999), para. 129.
[220] Despite the suggested use of the *generic* reference levels, the ICRP clearly puts a priority on the full use of *specific* reference levels, especially when there is a dominant component of the

reference level is useful especially when there are "no" dominant components constituting the existing annual dose.[221] For example, if the sum of the doses caused by all the sources of prolonged exposure in a human habitat is lower than this level, it is suggested that interventions are no longer justified.[222] The ICRP appears to derive this value from the fact that large populations have lived for years in areas of the world where the natural existing dose is up to about 10 mSv/year.[223]

As explained before, in Publication 82, the ICRP recommends a reference level for intervention exemption of "around 1 mSv" for a dominant type of commodity in terms of additional annual dose. This value appears to be derived from the following assumptions.

Firstly, it is estimated that the global average of the existing natural dose (i.e. dose from natural background exposure) is "around 2.4 mSv/year", and that the majority of the world's population is exposed to it below this level.[224] Secondly, the ICRP continues to recommend a dose limit of "1 mSv/year" for the public exposure from all regulated practices.[225] Thirdly, it is unlikely that several types of commodities become sources of prolonged exposure situations at the same time. In light of these assumptions, the ICRP explains the calculation method of "around 1 mSv/year" as follows:

> Natural background exposure causes annual doses of at least a few milli-sieverts per annum and, taking account of possible annual doses from authorized practices, this leaves an upper bound of the order of a few millisieverts per annum for the annual doses from all commodities to be exempted from intervention.[226]

In sum, the intervention exemption level recommended by the ICRP appears to be roughly calculated by subtracting the sum of 2.4 mSv/year and 1 mSv/year from the generic reference level for intervention exemption (i.e. about 10 mSv/year).

The ICRP also admits the possibility that this level might be amended, especially when the commodity at issue cannot be replaced and is essential for normal

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existing annual dose. Thus, even if the existing annual dose is lower than 10 mSv, intervention to reduce the dominant component may still be justified depending on the amount of annual dose saved by implementing protective actions. ICRP, Publication 82 (1999), paras. (r), 79, 83, 125.

[221] ICRP, Publication 82 (1999), para. 80.

[222] ICRP, Publication 82 (1999), paras. (q)-(r), 72-73, 75.

[223] The ICRP notes that "levels up to 10 mSv per annum are relatively rare in global terms." ICRP, Publication 82, para. A10.

[224] ICRP, Publication 82 (1999), paras. 76, A10.

[225] ICRP, Publication 82 (1999), paras. (l), 43.

[226] ICRP, Publication 82 (1999), para. 125.

living.[227] In that case, the intervention exemption level for such commodity (i.e. annual dose added as a result of accepting such commodity) can be set higher than around 1 mSv.

2.2.4.3.3 An Issue of "Market Acceptance"

Even when the authorities decide to discontinue the restrictions on the distribution of contaminated produced in contaminated areas, long-lived radioactive residues are often present in the environment. In this case, such foodstuffs could also contain radioactive substances.[228] It means that the decision by the authorities to exempt intervention might result in the distribution of contaminated foodstuffs to consumers living in areas not affected by the accident, whether domestic or foreign markets.

The question is when, in spite of the existence of long-lived radioactive residues in the environment, the authorities are entitled to treat a prolonged exposure situation as "normal". To be more specific, the question is under what conditions the restrictions on the distribution of contaminated foodstuffs can be exempted or discontinued in a prolonged exposure situation.[229] As rightly recognized by the ICRP, an issue of "market acceptance" could arise in both (i) domestic and (ii) foreign markets.

On the one hand, assume that the areas affected by the nuclear accident re originally major agricultural areas in the country. In this case, the authorities might decide to allow the distribution of foodstuffs produced in these areas with relatively high level of activity concentration to (i) domestic markets, so as to promote the reconstruction of the agricultural sector in the areas. Such a decision is often made in a set to allow evacuees to return to this area. As noted above, however, this decision might increase the possibility that consumers in other areas not affected by the accident are more exposed to the dose through ingestion of such foodstuffs. Therefore, it might occur that consumers in non-affected areas refuse to accept such foodstuffs produced in contaminated areas within the same country. This is called an issue of "market acceptance".

In this context, the ICRP suggests that the generic reference level for intervention exemption (i.e. existing annual dose of about 10 mSv) might provide a basis for the decision to discontinue the restrictions on foodstuffs.[230] Thus, if the sum of the annual doses incurred by an individual from all relevant sources in human habitats is below about 10 mSv, the authorities might decide to discontinue such

[227] ICRP, Publication 82 (1999), para. 127.
[228] ICRP, Publication 82 (1999), para. 128.
[229] ICRP, Publication 82 (1999), paras. 117.
[230] ICRP, Publication 82 (1999), paras. 122.

restrictions. In addition, the ICRP also emphasizes that it is important to get "stakeholders", such as agricultural producers, and consumers, involved in the domestic policy-making process so as to reach an agreement regarding the placement of foodstuffs produced in the contaminated areas on the domestic market.[231] In this case, for example, domestic consumers may accept certain levels of activity concentration in foodstuffs produced in the affected areas of the same country for humanitarian purposes in order to assist in the reconstruction of the areas.[232]

The issue of acceptance in (ii) foreign markets entails a more serious conflict among stakeholders than in domestic markets. As noted before, the decision by the authorities to discontinue or exempt the restrictions on the distribution of foodstuffs produced in contaminated areas might result in allowing such foodstuffs to be exported to foreign markets. Thus, an issue of market acceptance may also arise in importing countries. The ICRP clearly recognizes this issue when it states that "issues of market acceptance could arise, particularly if there are transboundary movements of the commodities".[233]

In contrast to the issue of acceptance in domestic markets, however, whether to discontinue the restrictions on the distribution of foodstuffs produced in contaminated areas is exclusively decided through the domestic policy-making process where foreign consumers are not usually involved. In addition, importing countries are not affected by the accident, nor are responsible for it. Therefore, foreign consumers have far less incentives to accept foodstuffs produced in contaminated areas than domestic consumers. In light of the above, it is understandable that foreign consumers do not accept such foodstuffs, and rather hope to apply the stricter radiological criteria to imported foodstuffs than that adopted in the exporting (i.e. accident) country.

It appears, however, that the ICRP understands that the level of dose accepted in the accident country added from ingestion of contaminated foodstuffs should also be accepted in other non-affected area, including importing countries.[234] To this extent, it is fair to note that the ICRP takes a position of limiting the discretion of importing countries to set their acceptable levels of health risk through ingestion

[231] ICRP, Publication 82 (1999), paras. 122. This is the first time for the ICRP to introduce the concept of "stakeholders" in the context of radiological protection. See e.g. ICRP, Publication 111 (2009), para. (b).
[232] Given the possibility of importing agricultural products, it is unlikely that domestic consumers would agree to accept foodstuffs produced in these areas on the grounds of food security.
[233] ICRP, Publication 82 (1999), para. 128.
[234] ICRP, Publication 82 (1999), para. 130.

of contaminated foodstuffs. As noted before,[235] it is clearly confirmed in the WTO that it is up to an importing country to determine its level of protection, or in other words, how much risk it accepts. However, the ICRP fails to develop rationales for importing countries to accept contaminated foodstuffs at the same level as that of exporting (accident) country in Publication 82.

2.3 Radiological Protection and International Trade: ICRP's Shift towards the Importing Country's Interests?

As explained in the previous sections, the ICRP has been aware of the linkage between radiological protection and international trade in commodities (e.g., foodstuffs) in Publications 60 (1991), 63 (1992) and 82 (1999). After an accident, the authorities often restrict the placement of foodstuffs produced in the affected areas on the market. However, as the exposure situation improves, the authorities might consider the discontinuation or exemption of such restrictions, taking into account their own economic and social circumstances. Once such restrictions are discontinued, foodstuffs produced in the affected areas will be placed on the domestic market, and then such foodstuffs could be further distributed to international or foreign markets.

In this regard, the ICRP has recognized the necessity to consider the discontinuation of the restrictions on the distribution of contaminated foodstuffs (i.e., intervention exemption) especially in a rehabilitation phase. However, it must be emphasized that the decision to discontinue the distribution restrictions on foodstuffs, which is made from the perspective of radiological protection, can have a significant impact on the interests of other countries. However, it appears that the ICRP had not paid sufficient attention to the rationale on which other countries should accept such foodstuffs imported from the country where the accident occurred. Instead, the ICRP appears to have taken the position that other countries should be able to live with it because the level of exposure from ingesting such foodstuffs will not exceed that level in the country where the accident occurred.

In Publication 111 (2009), which is fully based on the recent recommendations in Publication 103 (2007), the ICRP attempts to provide the rationales for foodstuffs produced in the affected areas in a rehabilitation phase to be traded internationally, and to be accepted in other countries, in accordance with the principle of optimization of protection, which is one of the fundamental principles of the ICRP's system of radiological protection. In other words, the ICRP has expanded this principle, which originally applies in relation to radiological

[235] See Chapter 2.2.3.3.

protection within the country where the accident occurred, as a basis for other countries to accept foodstuffs produced in the affected areas during the rehabilitation phase.[236]

2.3.1 ICRP Publication 103 (2007)

It is recalled that the system of radiological protection recommended by the ICRP in Publication 60 (1991) adopted the "process-based" protection approach, which is centered on the distinction of human activities (i) that increase the overall exposure (i.e. practices), and (ii) that decrease the overall exposure (i.e. interventions).[237] Since then, the ICRP has made recommendations based entirely on this conceptual distinction, for example, in Publication 63 (1992) and Publication 82 (1999). According to the ICRP, however, this distinction has seen "artificial" and not been clearly understood even in the radiological protection community.[238]

In response to this reflection, in Publication 103 (2007), the ICRP abandons this distinction,[239] and instead recommends an elaborated system of radiological protection centered on differences in the characteristics of exposure situations. To

[236] It should be added that there is a report that is currently undergoing an adoption process in the ICRP. Once adopted, this is going to supersede the previous reports, including, for example, Publication 40 (1984), Publication 63 (1992), Publication 82 (1999), and Publication 111 (2009). ICRP, Radiological protection of people and the environment in the event of a large nuclear accident: update of ICRP Publications 109 and 111. ICRP Publication 1XX. Amn. ICRP 4X(X), para. 9. At the time of writing, however, it has not yet been adopted.

[237] ICRP, Publication 103 (2007), paras. (c), 173. See Chapter 2.2.2.

[238] ICRP, Publication 103 (2007), para. (m). Elsewhere, the ICRP also admits that this distinction causes difficulties and is seen as "artificial". ICRP, Radiological protection in medicine. ICRP Publication 105. Ann. ICRP 37(6) (2007), para. 54. For example, at the *Fukushima Daiichi Nuclear Power Plant*, seawater has been injected constantly since the accident to cool the nuclear fuel that melted and remained in the reactor containment vessel, because of the core meltdown caused by the *Fukushima* accident. As a result, seawater will come into contact with nuclear fuel and produce contaminated water with high levels of radioactivity. Until now, contaminated water has been pumped up, cleaned up, and stored in a water storage tank after radioactive materials are removed by purification (only tritium is difficult to remove with the current technology). However, the amount of contaminated water has continued to increase since then, and the tanks will soon reach their storage limit. Therefore, the release of contaminated water into the ocean is currently under consideration by the government. On the one hand, such an activity is considered as an "action" in the sense that it increases the source of radiation. On the other hand, it is undisputed that the activity of cooling melted nuclear fuel is to reduce exposure, and that it constitutes an "intervention". And since the ocean release of the polluted water is part of this intervention, it can be also considered as "intervention" in that sense. As such, it may be difficult to distinguish human activities as "acts" or "interventions". In contrast, in Publication 103, the release of contaminated water into the ocean is considered as a protective measure in an existing exposure situation.

[239] Nevertheless, it does not mean that these terms are no longer used. As admitted by the ICRP, these terms have been widely used in this field. Rather, the term "practices" continues to be used to describe human activities that increase exposure to radiation. Likewise, the term "interventions" is used to generally describe "protective actions" that reduce exposure. ICRP, Publication 103 (2007), paras. 48-50.

this extent, the recommendations in Publication 103 are intended to "formally replace" the previous ones issued in Publication 60.[240] According to the ICRP, exposure situations can be classified as follows:[241]

> (i) Planned exposure situation: situations involving the planned introduction and operation of sources, including situations that would have been categorized as "practice" before.
> (ii) Emergency exposure situation: unexpected situations that may occur during the operation of a planned situation, or from a malicious act, requiring urgent attention.
> (iii) Existing exposure situation: situations that already exist when a decision on control has to be taken.

Unlike in the previous system where different principles were applied to practices and interventions,[242] the ICRP confirms in Publication 103 that one set of fundamental principles of its radiological protection system, which consist of (i) justification, (ii) optimization of protection, apply to all of these exposure situations.[243]

2.3.1.1 Rehabilitation Phase as an Existing Exposure Situation

The focus of this thesis is on how international trade in foodstuffs produced in areas contaminated as a result of a nuclear accident should be disciplined during a rehabilitation or recovery phase after the return of evacuees. Importantly, such post-accident recovery phase is categorized into an "existing exposure situation", pursuant to the ICRP classification mentioned above.[244] Existing exposure situations are mainly due to the following types of exposures.[245]

- Exposures caused by radon in dwellings.
- Exposures caused by naturally occurring radioactive material (i.e. NORM).[246]
- Exposures caused by radioactive residues that are released into the environment as a result of emergencies (e.g. accident).

All of these can be attributed to existing exposure situations, but unlike the first

[240] ICRP, Publication 103 (2007), para. (a).
[241] ICRP, Publication 103 (2007), paras. (n), 176.
[242] See Chapter 2.2.2.1 and 2.2.2.2.
[243] ICRP, Publication 103 (2007), para. 47. However, as in the past, the ICRP radiological protection system does not cover uncontrolled exposure situations (e.g. exposure to potassium-40 incorporated into the human body). ICRP, Publication 103 (2007), para. 53. Potassium-40 is inevitably present in foods of all plant and animal origin.
[244] See Chapter 2.3.2.
[245] ICRP, Publication 103 (2007), para. 284.
[246] Even now, radionuclides introduced to the Earth from space during the Earth's formation process still remain in soil and rocks.

two, the third one has the following characteristics. Firstly, whereas the first two are naturally occurring exposures, the third one is a "man-made" exposure situation. The third one often takes a long-term exposure situation especially resulting from emergencies. Secondly, the third one occurs in succession of, or as an extension of, an emergency exposure situation following an accident, while such a transition of exposure situation does not occur in the first two. Thirdly, the third is tied to a specific period of "post-accident recovery phase", but no such connection exists for the first two.

Since the purpose and characteristics of protective actions differs between an emergency exposure situation and an existing exposure situation, the question arises as to when the emergency exposure situation after the accident will shift to the existing exposure situation, or rehabilitation phase. The immediate aftermath of a major nuclear accident will be classified as an "emergency exposure situation" under the ICRP's system of radiological protection. However, once such emergencies begin to stabilize with the implementation of immediate remedial actions, radiation doses might be progressively reduced to a degree sufficient to allow for normal life. In that case, the authorities might decide to allow evacuees to come back and live permanently in the areas affected by the accident. In this case, it is explained that the emergency exposure situation evolves to an "existing exposure situation".[247]

2.3.1.2 Radiological Protection in an Existing Exposure Situation

The following will provide an overview of how (a) the principle of justification and (b) the principle of optimization of protection are applied when making decisions on radiological protection in an existing exposure situation.[248] Such decisions are specifically about (i) whether to introduce, maintain, or discontinue protective measures reducing the doses is *justified*, and (ii) if so, how the reduction of the doses should be *optimized*.[249]

It should be also noted that these two principles are both "source-related".[250] For example, the residents of an area affected by a nuclear accident may be simultaneously exposed to multiple sources, such as natural sources (e.g. radon in the atmosphere) that have existed independently of the accident, in addition to

[247] The ICRP notes that an existing exposure situation following an emergency exposure situation can be characterized by "the need for a population to continue living in an area with known or assessable level of exposure". ICRP, Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations: Publication 109 (2009), para. 114.
[248] The ICRP confirms that these two principles are applicable in all exposure situations. ICRP, Publication 103 (2007), para. 203.
[249] ICRP, Publication 104 (2007), para. 113.
[250] ICRP, Publication 103 (2007), para. 203.

sources caused by the accident (e.g. cesium released into the soil by the accident).[251] Nevertheless, given the assumption that there is generally a dominant source, the ICRP recommends that each source be treated on its own for the purpose of radiological protection.[252] For example, exposure from radon would not be taken into account in deciding whether to carry out decontamination work for cesium is justified or optimized. In other words, the authorities are not allowed to use the continued presence of radon in the atmosphere as a basis for not justifying or optimizing decontamination work for cesium.[253]

2.3.1.2.1 Principle of Justification

Unlike in a planned exposure situation, the decision made by the authorities in an existing exposure situation would be whether or not to take protection strategies in order "to avert further exposure".[254] It is widely known, however, that "[a]ny decision taken to reduce doses…always have some disadvantages".[255] Therefore, the ICRP makes a general recommendation that such protective actions be justified in that they "do more good than harm".[256] To be more specific, when taking protective actions, this principle requires that they "should achieve sufficient individual or societal benefit to offset the detriment it causes".[257] In other words, the application of the justification principle is to exclude exposure situations that are uncontrollable or unfamiliar to regulation.[258]

Importantly, the considerations herein are not limited to those associating with the radiation. The detriment caused by implementing protective actions might include "various economic, political, environmental, social, and psychological consequences".[259] Thus, the ICRP admits that the process of justification "goes far beyond the scope of radiological protection".[260] Since the application of the justification principle is beyond the responsibility of the radiological protection authorities, the ICRP dares to make only a simple recommendation on this principle that "the net benefit be positive".[261]

Furthermore, even if there is a net benefit for each individual protective action,

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[251] The ICRP notes that "if they [radioactive substances] are already dispersed in the environment, the portion of them to which people are exposed may be considered a source." ICRP, Publication 103 (2007), para. 174.
[252] ICRP, Publication 103 (2007), para. 172. See also ICRP, Publication 60 (1991), para. 103.
[253] ICRP, Publication 103 (2007), paras. 197, 199.
[254] ICRP, Publication 103 (2007), para. 207. On the other hand, in a planned exposure situation, the decision made by the authorities would be whether or not to introduce new activities.
[255] ICRP, Publication 103 (2007), para. 207.
[256] ICRP, Publication 103 (2007), paras. 203, 207.
[257] ICRP, Publication 103 (2007), para. 203.
[258] ICRP, Publication 104 (2007), para. 11.
[259] ICRP, Publication 111 (2009), para. 27.
[260] ICRP, Publication 103 (2007), para. 205.
[261] ICRP, Publication 103 (2007), para. 205.

those actions cannot be justified unless the overall benefit of the protection strategies, which are composed of those protective actions, is also positive.[262]

As noted before, it is recalled that the principle of justification is a "source-related" principle. The question of whether the protective actions at issue are justified should be examined in relation to the specific (dominant) source, which needs to be distinguished from other sources to which people are exposed.

2.3.1.2.2 Principle of Optimization of Protection

The ICRP further recommends that, even if protective actions are justified, such measures should be taken in a way that maximizes "the margin of benefit over harm". In short, the authorities are recommended to take the "best" protective actions. However, that does not necessarily mean minimizing the dose.[263] Rather, optimization is about reducing exposure "as low as reasonably achievable" (i.e. ALARA), taking into account social and economic factors.[264] For example, when deciding whether or not to allow the return of evacuees from the area surrounding the nuclear accident, the best decision, if the focus is on radiation dose alone, would be "not to allow them to return until the radiation dose is as low as possible". However, the evacuation will result in mental and physical distress for the population.[265] Given these realities, a decision not to allow evacuees to return based on radiation dose alone may be contrary to the principle of optimization. In this case, such a decision may not be said to have taken into account economic and social factors.

The following will provide an overview of how the principle of optimization of protection applies when the authorities plan and implement protective actions, especially in an existing exposure situation.

The ICRP recommends that the authorities use "reference levels" in conjunction with implementing the optimization process in an existing exposure situation.[266] The ICRP recommends that the authorities set reference levels at the end of an emergency exposure situation,[267] and then optimize protective actions so that the "residual dose", which is the dose that would result after protection strategy

[262] ICRP, Publication 109 (2009), para. 34.
[263] The ICRP notes that "the best option is not necessarily the one with the lowest dose." ICRP, Publication 103 (2007), para. 219.
[264] To be more specific, the principle of optimization is defined as a process "to keep the likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses as low as reasonably achievable, taking into account economic and societal factors". ICRP, Publication 103 (2007), paras. (o), 203, 212.
[265] See Chapter 2.3.2.1.
[266] ICRP, Publication 103 (2007), paras. 216. See also ICRP, Publication 104 (2007), para. 115.
[267] ICRP, Publication 111 (2009), para. 46.

has been fully implemented,[268] is estimated not to exceed those levels.[269] Therefore, a plan to take protective actions resulting in the doses higher than the reference levels should be considered as "inappropriate", and thus should be rejected.[270] The ICRP recommends that, when setting reference levels for existing exposure situations, the authorities determine the annual residual dose within a band of "1 mSv to 20 mSv band".[271]

The reference level also works retrospectively. For example, it may be the case that the residual dose may exceed the reference level when protective actions, which were estimated to be below the reference level in the planning stage, are actually implemented. This will become apparent when assessing the "effectiveness" of such protective actions after they are implemented. In this case, the ICRP recommends that the authorities should give priority to reducing the highest exposures to below reference levels in order to protect the people with such exposures.[272] To this extent, the ICRP notes that "[t]he reference level may then assume a different function as a benchmark against which protection options can be judged retrospectively."[273]

Furthermore, even if the implementation of protective actions results in a residual dose below the reference level, that is not the end of the authorities' work. The authorities are recommended to consider on an ongoing basis whether current protection is being optimized, or whether further protective actions are required.[274] As noted by the ICRP, past experience has shown that the authorities often end up setting reference levels at or close to 1 mSv/year. This reflects the hope of the public that the dose should be reduced to the dose limit for public exposure in a planned exposure situation, or to levels that are close to "normal" situations.[275]

In sum, reference levels are used by the authorities to assist in ensuring that all exposures are reduced to as low as reasonably achievable, taking into account economic and social factors. Thus, the ICRP describes reference levels as "key parts" in the optimization process.[276] Importantly, as explained above,

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[268] As to the definition of residual dose, see ICRP, Publication 103 (2007), at 32.
[269] ICRP, Publication 103 (2007), paras. (t), 234.
[270] ICRP, Publication 111 (2009), paras. (p), 43, 234. Elsewhere, the ICRP well summarizes this understanding by noting "[a] protection strategy that does not reduce residual doses to below the reference levels should be rejected at the planning stage". ICRP, Publication 104 (2007), para. 106.
[271] ICRP, Publication 103 (2007), paras. 287, 300 (Table 8).
[272] ICRP, Publication 103 (2007), para. 235. See also ICRP, Publication 111 (2009), para. 39.
[273] ICRP, Publication 103 (2007), para. 286.
[274] ICRP, Publication 103 (2007), para. 286.
[275] ICRP, Publication 103 (2007), para. 288. See also ICRP, Publication 111 (2009), paras. (o), (bb), 50.
[276] ICRP, Publication 103 (2007), paras. 198, 225.

optimization of protection can be characterized as an "ongoing, interactive process", through which the authorities achieve the best level of protection.[277] In other words, according to the ICRP, optimization can be considered as a sort of "frame of mind" that constantly checks if the best option is being taken.[278]

Lastly, it is worth noting that in Publication 103, the ICRP expresses "for the first time" the need to take into account the perspectives and concerns of stakeholders when optimizing protective actions.[279] To be more specific, the ICRP notes that the authorities should establish their own reference levels "taking into account the prevailing economic and societal circumstances".[280] In this case, the ICRP acknowledges that relevant stakeholders, aside from radiological protection specialists, should involve in the decision-making process of establishing reference levels.[281] Elsewhere, the ICRP clearly notes that the process of setting reference levels should be carefully balanced with proper consideration of the views of stakeholders.[282]

2.3.2 ICRP Publication 111 (2009)

When a nuclear accident or a radiological emergency occurs, urgent protective actions are needed to avoid or reduce undesirable health consequences of the radiation. This unexpected situation is classified by the ICRP as an "emergency exposure situation".[283] As has been pointed out by the ICRP in previous reports, restrictions on the consumption of contaminated foodstuffs are one of the protective actions implemented in an emergency exposure situation.[284] For example, the authorities are likely to severely restrict the intake and distribution of green vegetables grown in the open.[285]

Once the situation is under control, the authorities might be required to decide whether or not to allow evacuees to come back and live permanently in the areas that are still contaminated due to the accident. According to the ICRP, the timing of the evacuees being allowed to return by the authorities suggests that the

[277] ICRP, Publication 103 (2007), para. 214.
[278] ICRP, Publication 103 (2007), para. 217.
[279] ICRP, Publication 103 (2007), at 4 (Editorial). However, it is noted that the reference to stakeholders has already been made in Publication 82. See Chapter 2.2.4.3.3.
[280] ICRP, Publication 103 (2007), para. 295.
[281] ICRP, Publication 103 (2007), para. 224.
[282] ICRP, Publication 111 (2009), para. 49.
[283] ICRP, Publication 111 (2009), para. 1.
[284] It is Publication 40 (1984) where explicit reference is made to restrictions on the distribution of foodstuffs as a protective action taken in an emergency situation within an accident country. See Chapter 2.2.1.1.
[285] ICRP, Publication 109 (2009), para. 68. This is because the radioactive materials released by the accident are more likely to be deposited on the leaves of vegetables grown in open fields than those grown in houses.

emergency situation after the accident ends, and shifts to a "rehabilitation" phase, in which people live and work in contaminated areas.[286] Such a situation is specifically termed a "post-accident rehabilitation situation" in Publication 111 (2009).

Thus, in this report, the ICRP intends to provide guidance on the application of its system of radiological protection to people living in areas contaminated as a result of a nuclear accident. To be more specific, it addresses "protection strategies"[287] to be taken by the authorities during a rehabilitation period, in which people are allowed to live in contaminated areas, after an earlier emergency exposure situation.[288] On the other hand, Publication 111 does not deal with an emergency exposure situation, which is further addressed by Publication 63 (1992)[289] and Publication 109 (2009).

2.3.2.1 Radiological Protection in a Rehabilitation Phase following an Emergencies

When radioactive materials are released into the atmosphere due to a major accident, the residents around the accident site may be forced to evacuate to a non-affected area to avoid radiation exposure. However, once the emergency exposure situation is under control, the authorities might decide at some point whether or not to permit evacuees displaced by the accident to return.

This situation in which evacuees return to the contaminated area from the evacuation site and start living there is generally referred to as the "recovery period". And according to the ICRP classification, such a situation falls under the category of "existing exposure situation".[290] In this regard, the ICRP clearly notes that "[l]iving or working in a contaminated area is considered as an existing exposure situation."[291] Thus, Publication 111 is considered as the first report that elaborates on radiological protection in an existing exposure situation since Publication 103 (2007) in which the distinction based on exposure situations was introduced for the first time.[292]

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[286] ICRP, Publication 111 (2009), paras. (d), 8.
[287] The term "protection strategies" used in Publication 111 are composed of "a series of protective actions directed at the relevant pathways". ICRP, Publication 111 (2009), para. (h).
[288] ICRP, Publication 111 (2009), at 3 (Editorial).
[289] See Chapter 2.2.3.
[290] ICRP, Publication 111 (2009), paras. (a), 2. It is recalled that an "existing exposure situation" is defined as situations that already exist when a decision on control has to be taken. Given that a rehabilitation phase refers to a situation, after an emergency exposure situation, where people are permitted to live and work in contaminated areas, it is undisputed by definition that the exposure situation already exists when the authorities make a decision to take protective actions during a rehabilitation period.
[291] ICRP, Publication 111 (2009), para. 24.
[292] ICRP, Publication 111 (2009), para. (b).

As confirmed in Publication 103, the fundamental principles of radiological protection recommended by the ICRP, that is (a) the principle of justification, and (b) the principle of optimization of protection, apply in an existing exposure situation.[293] In relation to a rehabilitation phase, these principles are firstly applied by the authorities in making a decision whether or not to allow evacuees to return and live in contaminated areas.[294]

2.3.2.1.1 Principle of Justification

The principle of justification, in short, requires protective actions taken by the authorities to do "more good than harm". Obviously, allowing evacuees to return and live in the contaminated areas means increasing their exposure. Therefore, if the goal is only to reduce accidental radiation exposure, such a decision would be inappropriate.[295] However, as noted by the ICRP, past history indicates that "neither nations nor individuals are very willing to leave affected areas".[296] In fact, it is already clear that evacuation will place on economic, physical and mental burden on the residents.

For example, as a result of the *Fukushima* accident in Japan, around 470,000 people living in the vicinity of the Fukushima Daiichi Nuclear Power Plant have been forced to abandon their homeland and evacuate to other areas not affected by the accident.[297] In some municipalities, the number of people who died in evacuation centers exceeds the number of people who died due to the tsunami itself.[298] This fact shows how evacuation, while being excellent in terms of avoiding exposure, can be burdensome for evacuees.[299]

Thus, viewed differently, allowing evacuees to return and live in the contaminated

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[293] The explanation of these principles will not be repeated here. As to a more detailed explanation of these principles, see Chapter 2.3.1.

[294] ICRP, Publication 111 (2009), paras. (i), 26. In addition, in an existing exposure situation, the authorities might also have to decide whether to continue or discontinue protective actions implemented during an emergency exposure situation, or to take new protective actions. ICRP, Publication 111 (2009), para. 31. In such cases, these principles also apply.

[295] Put it differently, in this case, evacuation from the area where the accident occurred would be the most efficient.

[296] ICRP, Publication 111 (2009), paras. (j), 29.

[297] Reconstruction Agency, Japan, *Great East Japan Earthquake*, available at <https://www.reconstruction.go.jp/english/topics/GEJE/index.html>, last visited 15 May 2020.

[298] As of 30 September 2019, in *Fukushima* Prefecture, the number of people who died tsunami itself was 1,613, compared to 2,286 due to diseases caused by the physical burden of living in evacuation centers. Reconstruction Agency, Japan, *Number of earthquake related deaths in the Great East Japan Earthquake (Result of a survey as of 30 September 2019)*, available at <https://www.reconstruction.go.jp/topics/main-cat2/sub-cat2-6/20191227_kanrenshi.pdf>, last visited 15 May 2020 (only in Japanese).

[299] The ICRP also notes that "most inhabitants generally prefer to stay in their homes rather than to be relocated (voluntarily or not) to non-contaminated areas". ICRP, Publication 111 (2009), para. 48.

areas will relieve them of such burdens, although their exposure will increase.

In light of the above, the ICRP notes that, when deciding whether a proposed protective action is justified, the authorities have to take into account not only the extent to which exposure is reduced or avoided, but also its economic, political, environmental, social and psychological effects "beyond the scope of radiological protection".[300] After a comprehensive analysis, such a decision will be justified if the economic and social benefits of allowing the evacuees to return outweigh the increased exposure.

Nevertheless, the ICRP notes that, unless the adverse effects caused by radiation exposure are excessive, the authorities should "aim to rehabilitate these [contaminated] areas wherever possible to allow further human activities".[301] In other words, given the significant impacts of the evacuation, the ICRP appears to suggest that the authorities should allow evacuees to return as much as possible.

2.3.2.1.2 Principle of Optimization

The principle of optimization, in short, requires the authorities to choose protective actions that maximize "the margin of benefit over harm". Put it differently, optimization is about reducing exposure "as low as reasonably achievable", taking into account social and economic factors.

There is no doubt that permitting evacuees to return to and live in the contaminated areas means increasing the exposure of people living there. The main exposure pathways in a rehabilitation phase is either (i) external exposure from deposited radionuclides, or (ii) internal exposure due to the ingestion or inhalation of radionuclides.[302] According to the ICRP, the predominant pathway for people living there is the ingestion of contaminated foodstuffs, such as vegetables, milk, meat and fish.[303]

Therefore, the question as to what "form, scale, and duration"[304] evacuees are permitted to return to and live in the contaminated areas is closely related to how the consumption of contaminated foodstuffs by residents are regulated in those areas. In other words, permission to return to and live in such areas would not be considered "optimized" if the consumption of contaminated foodstuffs were not properly regulated there.

In this regard, the most effective way to reduce exposure from the ingestion of

[300] ICRP, Publication 111 (2009), para. 27.
[301] ICRP, Publication 111 (2009), para. 29.
[302] ICRP, Publication 111 (2009), para. 14.
[303] ICRP, Publication 111 (2009), para. 35.
[304] ICRP, Publication 111 (2009), para. 38.

contaminated foodstuffs would be to ban the production of agricultural products and other foodstuffs in the contaminated areas. As one can easily imagine, however, such protective action will result in depriving people living in such areas of livelihoods, and then undermine "the sustainable development of the contaminated areas".[305]

The next section will consider the restriction on the placement of contaminated foodstuffs on the market as a means to regulate the consumption of such foodstuffs by residents, which is the dominant exposure pathway in an existing exposure situation (i.e. rehabilitation period).

2.3.2.2 Optimizing Protection Strategies: Restrictions on the Placement of Contaminated Foodstuffs on the Market

The ICRP recommends that protection strategies for foodstuffs produced in contaminated areas during a rehabilitation period (i.e. existing exposure situation) should be planned and implemented in view of the principle of optimization of protection. To be more specific, the authorities are required to choose strategies that reduce exposure from the ingestion of foodstuffs produced in contaminated areas in a rehabilitation phase "as low as reasonably achievable, taking into account social and economic factors.[306]

In particular, the question is how to optimize protective measures by reconciling the demands of securing the livelihoods (e.g. agriculture, fisheries) of local residents who have returned from evacuation sites on the one hand, and ensuring food safety (i.e. avoidance of exposure through food intake) for consumers on the other. Such reconciliation is an inherent phenomenon that arises from the decision by the authorities to let people live in contaminated areas, and is a "specialty" of the existing exposure situation after the accident (i.e. rehabilitation period).[307]

2.3.2.2.1 Reconciliation of Interests between People Living inside and outside the Contaminated Areas

As a protective action taken in an existing exposure situation after an accident (i.e. rehabilitation period), the authorities may have to decide whether or not to allow the distribution of agricultural products or foodstuffs produced in the contaminated areas to the market. In doing so, the authorities are required to optimize such an action in a way that reconciles, on the one hand, the interests of producers in contaminated areas who are also returnees from evacuation sites, and, on the other hand, the interests of consumers living outside the

[305] ICRP, Publication 111 (2009), para. (y).
[306] ICRP, Publication 111 (2009), para. 83.
[307] ICRP, Publication 111 (2009), para. 35.

contaminated areas.[308]

On the one hand, it is easy to imagine that people living outside the contaminated areas would react negatively to the distribution of agricultural products or foodstuffs produced in the contaminated areas, albeit in the same country, into the market, due to concerns about adverse health effects.[309] Thus, the question of whether or not consumers will accept foodstuffs is called "issues of market acceptance".[310] This problem is likely to be more acute in markets where consumer groups are more influential.

On the other hand, there may be a need in the country where the accident occurred to place agricultural products and foodstuffs produced in contaminated areas on the market.[311] Firstly, if, for example, the area affected by the nuclear accident is traditionally a major agricultural production area, less stringent contamination criteria may be adopted to ensure food for consumers. Secondly, in allowing people displaced by the nuclear accident to return home, the authorities may also adopt less stringent criteria to ensure their means of livelihood and maintain their standard of living.[312] More interestingly, the ICRP notes that the production of foodstuffs in contaminated areas and the distribution of such foodstuffs to the market may be required on the ground that they are "deeply embedded in traditions".[313]

The process of reconciling the interests of the people living inside and outside contaminated areas within the same country is ultimately a question of social value judgements about what extent the contaminated areas should be included in the economy of the country. To be more specific, it relates to a judgmental decision as to whether "individual preferences of the consumers should outweigh the need to maintain agricultural production, rehabilitation of rural areas, and a decent living for the affected local community."[314]

In order for the authorities to make such value judgments, the ICRP recognizes the need for "[a] thorough debate at national level", and then recommends that such decision be made through an involvement of relevant stakeholders (such as authorities, farmers, food industry, food distribution, consumer NGOs) and

[308] ICRP, Publication 111 (2009), paras. (y), 82.
[309] The ICRP rightly describe the perception of consumers from non-affected areas as "generally expect[ing] uncontaminated foodstuffs to be placed on the market". ICRP, Publication 111 (2009), para. 88.
[310] ICRP, Publication 111 (2009), paras. (y), 82.
[311] ICRP, Publication 111 (2009), para. 83.
[312] See e.g. Chapter 2.2.2.3.2.
[313] ICRP, Publication 111 (2009), para. 86.
[314] ICRP, Publication 111 (2009), paras. 82, 84.

representatives of the public.[315] Moreover, in order to enable various stakeholders to be involved in policy-making, the ICRP points out that it is necessary to ensure that relevant information (e.g. data, parameters, values) are made publically available.[316]

While acknowledging that how to reconcile such domestic interests is left to the judgmental or policy decision of each country, the ICRP nevertheless seems to take a certain position on this issue. According to the ICRP, the decision to allow people to live in contaminated areas "supposes that an economic activity is maintained on the spot with local production and trade of goods including foodstuffs"[317] It can be read from this text that ICRP's position is that consumers in non-affected areas of the country should accept foodstuffs and agricultural products produced in contaminated areas in order to sustain economic activity in those areas. So where does such a sort of "obligation" arise? According to the ICRP, it comes from the idea of "solidarity in sharing some disadvantages of the situation between local and non-local populations".[318] Again, as mentioned above, in this case, it will be necessary to reach a consensus through national debates involving producers living in the contaminated area, and consumers living outside it.

2.3.2.2.2 Reconciliation of Interests between People in the Contaminated Areas and International Population

As explained above, when making a decision whether or not to allow the distribution of foodstuffs produced in contaminated areas to the market in a rehabilitation phase, the authorities need to optimize it in a way that reconciles the interests of producers living in contaminated areas with the interests of consumers living outside the contaminated areas. What is envisaged here is the reconciliation of interests among stakeholders within the country where the accident occurred. Therefore, the ICRP explains that consumers outside the contaminated areas have a sort of obligation to accept foodstuffs produced in the contaminated areas on the basis of the concept of "solidarity" shared between residents inside and outside the contaminated areas.

In this regard, the ICRP further notes as follows:

> Optimisation strategies should balance the need to protect people against radioactivity and the need for the local economy to exist and to be

[315] ICRP, Publication 111 (2009), para. 84.
[316] ICRP, Publication 111 (2009), para. 33.
[317] ICRP, Publication 111 (2009), para. 35.
[318] ICRP, Publication 111 (2009), para. 35.

integrated in the global market [.][319]

Importantly, in the quote above, the ICRP notes that the "need for the local economy…to be integrated in the global market" should be taken into account in the optimization process. In this regard, the integration of the local economy in the contaminated areas into the global market seems to mean that foodstuffs produced in such areas are accepted by foreign markets or consumers. In other words, the ICRP seems to consider that, in order to ensure the sustainable economic development of the contaminated area, not only domestic consumers outside the contaminated area but also foreign consumers have a kind of obligation to accept foodstuffs produced in the contaminated area of the country where the accident occurred.

However, as with domestic consumers from non-affected areas, consumers in foreign markets generally expect uncontaminated foodstuffs to be placed in their own markets. In other words, as is the case of domestic markets, the issue of acceptance in the foreign markets will also arise. To this extent, as clearly recognized by the ICRP, the authorities need to optimize protective actions by reconciling the interests of "local population (i.e. domestic farmers)" in economic development with the interests of "international population (i.e. foreign consumers)" in food safety.[320] However, such "transboundary" reconciliation is generally more difficult to achieve than that among stakeholders within an accident country.

As explained earlier, in reconciling the interests of people living inside and outside the contaminated areas within an accident country, the ICRP recommends that a decision as to whether or not to place contaminated foodstuffs on the market be made through debate at national level among relevant stakeholders, including producers and consumers.[321] The ICRP further suggests that domestic consumers living in non-affected areas should accept foodstuffs produced in contaminated areas on the basis of the idea of "solidarity" shared between two groups.

In this regard, the ICRP appears to believe that the logic described above also applies in the context of transboundary reconciliation. The ICRP expects "international population" (i.e. foreign consumers) to accept foodstuffs produced in contaminated areas in the accident country on the basis of the idea "solidarity" that is supposed to be shared with local population (e.g. producers).[322] To this

[319] ICRP, Publication 111 (2009), para. 35 (Underline Added).
[320] ICRP, Publication 111 (2009), para. 35.
[321] Chapter 2.3.2.2.1.
[322] ICRP, Publication 111 (2009), para. 35.

extent, the ICRP appears to believe that an issue of "market acceptance" occurring in both domestic and foreign markets with respect to foodstuffs produced in the contaminated areas can be solved in a parallel manner.

The transboundary reconciliation based on "solidarity" explained above appears to have the following problems.

Firstly, unlike domestic consumers from non-affected areas, consumers in foreign markets are not entitled to involve the decision-making process as a stakeholder as to whether or not to allow the placement of foodstuffs produced in contaminated areas on the market.[323] Therefore, unless there is a system for building and sharing the notion "solidarity" with international populations, it would be difficult to resolve an issue of acceptance in foreign markets on the basis of solidarity.[324]

Secondly, even if a nuclear accident occurs within an exporting country, it should be emphasized that the importing country that is not affected by the accident is basically in a "planned exposure situation". As recognized by the ICRP, "[t]rade is a human activity that may involve radiation exposure and lead to increased exposure" from the perspective of importing countries, and thus notes that international trade "fits the usual regulatory definition of a planned exposure situation".[325]

Importantly, the fact that the importing country is in a planned exposure situation means that it has "the ability to choose a priori whether to accept a beneficial practice and its consequent exposures".[326] And, in this situation, the importing country is in a position to decide or plan in advance how much exposure it will accept from the import of contaminated foodstuffs. Therefore, the idea explained above that foreign consumers have a kind of obligation to accept foodstuffs produced in contaminated areas due to "solidarity" might be inherently inconsistent with the ability or authority that the importing country is supposed to have in a planned exposure situation to set the acceptable level of health risk through contaminated foodstuffs.

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[323] Elsewhere, the ICRP recognizes the need for a thorough debate at national level as "to achieve a certain degree of solidarity *within the country*", which does not appear to cover *transboundary* solidarity with international population. ICRP, Publication 111 (2009), para. 84 (Italic Added).

[324] In the first place, consumers in foreign markets have no responsibility for the nuclear accident in another country, and thus have less moral incentive to accept food produced in areas contaminated by the accident than consumers in the country of the accident.

[325] ICRP, Publication 104 (2007), para. 179. In other words, international trade can be characterized as "practice" within the meaning of the ICRP's previous recommendations, which refer to human activities that increase the overall exposure to radiation.

[326] ICRP, Publication 104 (2007), para. 30.

2.3.2.2.3 Placement of Contaminated Foodstuffs on the Market in Accordance with the Codex Guideline Levels

As will be examined in more detail in Chapter 3, the Codex adopted the guideline levels (GLs) for radionuclides in foodstuffs to be traded internationally in 1989, and further revised them in 2006. According to the Codex, foodstuffs are considered to be safe for human consumption if its activity concentration level of radionuclides is below the Codex GLs, which are expressed in term of Bq/kg. Therefore, the Codex requests exporting countries to ensure that foodstuffs produced in contaminated areas do not exceed the GLs at the time of export, as well as importing countries to accept such foodstuffs meeting such levels.[327]

If and when the GLs are exceeded, the Codex notes that "governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction".[328] Thus, for example, an importing country may restrict the importation of such foodstuffs, while it may also accept and allow such foodstuffs to be placed within its territory if it sets a lower level of protection than the Codex GLs.[329] Moreover, although an exporting country cannot export such foodstuffs, it is still entitled to place them on the market within its territory or jurisdiction as a policy decision.

However, it appears that the ICRP strongly expects the exporting country, which is also the accidental country, to follow the Codex GLs. Given its concern that "once food is placed on the market, it is very difficult to manage doses",[330] the ICRP appears to suggest that foodstuffs produced in contaminated areas can be placed on the market only when the GLs are not exceeded.[331] Put it differently, contrary to Codex's position above, the ICRP seems to argue that the exporting country should be more cautious about placing foodstuffs exceeding the Codex GLs on the market. In this regard, the ICRP notes that the placement of foodstuffs exceeding the Codex GLs on the market might lead to an "unethical" situation.[332]

Furthermore, the ICRP notes that, when implementing protective actions, they

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[327] It is noted that Codex recommendations are not legally binding.
[328] See e.g. Codex Alimentarius Commission, Report of the 18th Session of the Codex Alimentarius Commission, ALINORM 89/40 (1989), para. 101.
[329] For example, a country may decide to accept the importation of foodstuffs that lack sustainability (i.e. foodstuffs that cannot be substituted by other similar products) even if its activity concentration level of radionuclide exceeds the GLs. In practice, however, few foodstuffs lack substitutability.
[330] ICRP, Publication 111 (2009), para. 89.
[331] The ICRP notes that "[t]he placement of contaminated foodstuffs on the market may be governed by the Codex guideline levels for use in international trade". ICRP, Publication 111 (2009), para. 89.
[332] As an example, the ICRP notes that foodstuffs above the Codex GLs might be used as humanitarian aid. ICRP, Publication 111 (2009), para. 89.

need to be optimized, taking into account "international recommendations (e.g. on trade of foodstuffs)",[333] which obviously include the Codex GLs. It means that the authorities are required to make a decision whether or not allow to place foodstuffs produced in contaminated areas on the market is made, in light of the Codex GLs. It suggests that, according to the ICRP, a decision by the authorities to allow the placement of foodstuffs exceeding the Codex GLs on the market might not be considered as "optimized".

On the other hand, even if foodstuffs produced in contaminated areas exceed the Codex GLs, the ICRP recognizes that there could be a way to place such foodstuffs on the market without causing the "immoral" situation described above.[334] However, the ICRP only notes that "the management of market mechanisms is beyond the scope of the Commission's recommendations",[335] and does not present any specific proposals.

Conclusion

It is recalled that radiological protection aims to protect people from harmful effects (e.g. stochastic effects) of ionizing radiation. Thus, one might consider that the idea of radiological protection tends to justify the imposition of import restrictions on food products originating in the areas affected by the nuclear accident. However, this is not the case at least in the system of radiological protection recommended by the ICRP.

It is noted that the relationship between radiological protection and international trade becomes an issue not in the emergency situation right after the nuclear accident, but rather in the "rehabilitation period" after the accident is settled. This period can be described as a situation in which the source of exposure is once again controllable and the residents have returned, but the low level of exposure still continues for an extended period of time due to the radioactive residues released by the accident.

If the "optimization principle", which is the main principle forming the ICRP's system of radiological protection, is followed in such a long-term exposure situation, the authorities may decide to allow the evacuated residents to return, while at the same time permitting the resumption of production in the area, and the distribution of food products (e.g. agricultural products) produced there in order to provide the returned residents with a means of livelihood.

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[333] ICRP, Publication 111 (2009), para. 35.
[334] For example, as pointed out by the ICRP itself, the authorities might require such foodstuffs to be labeled with a place of origin. ICRP, Publication 111 (2009), para. 90.
[335] ICRP, Publication 111 (2009), para. 90.

Yet, it is easy to imagine that consumers in areas not affected by the accident (including foreign markets) may not want to consume such food products. Thus, the ICRP relies on the concept of "solidarity" and expect consumers in foreign markets, not to mention other unaffected areas of the country where the accident occurred, to accept such products. According to the ICRP, since it is unlikely that importing countries will be exposed to the same level of radiation as the country in which the accident occurred, it should not be a problem for them to accept foodstuffs that are once allowed to be placed on the market by the authorities of the exporting (i.e. accident) country.

However, it will be seen that the ICRP's view above appears to be contrary to that of the SPS Agreement, where, in principle, importing Members have the discretion to determine, based on policy considerations, the level of health risks they can accept arising through ingestion of contaminated foodstuffs. For example, the Appellate Body found that "[t]he determination of the appropriate level of protection…is a *prerogative* of the Member concerned".[336]

In light of the above, one might consider that, in the ICRP's system of radiological protection, importing countries are deprived of their discretion to determine the level of radiological protection, and thus that there exists a conflict between ICRP's system of radiological protection and the WTO regime. In other words, the ICRP appears to be of the view that the need for the exporting country to export contaminated foodstuff in a radiological protection system should prevail over the prerogative of importing countries confirmed in international trade regime.

[336] See e.g. Appellate Body Report, *Australia – Salmon*, para. 199 (Italic Original).

Chapter 3

Disciplines on International Trade in Foodstuffs by the Codex Alimentarius Commission

Introduction

The nuclear power plant accident in *Fukushima* has brought attention to the regulation of international trade on foodstuffs contaminated with radionuclides released into the environment. It is not disputed that radiation might adversely affect the human body.[1]

Right after the *Chernobyl* accident occurred in April 1986 in northern Ukraine near the Belarusian border,[2] many countries set their own levels of radionuclide activity (or radioactivity) concentration in food, restricting the imports of food products from areas affected by the accident. In response to this, the relevant international organizations initiated the process to regulate international trade on foodstuffs contaminated with radionuclides following a nuclear accident. In 1989, the Joint FAO/WHO Codex Alimentarius Commission adopted the "Guideline Levels" (GLs) for radionuclides in food traded internationally. In 2006, the GLs were further revised and included in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).[3]

On March 11, 2011, when a large earthquake with a magnitude of 9.0 occurred off the coast of the *Tohoku* region of Japan, a large tsunami that occurred immediately after the earthquake struck the Fukushima Daiichi Nuclear Power Plant, which was located on the coast of *Fukushima* Prefecture. As a result, radioactive material in the nuclear reactor diffused into the atmosphere and deposited the ground and sea.[4] Unlike after the *Chernobyl* accident, the GLs

[1] See Chapter 1.1.4.
[2] For the detailed explanation of the *Chernobyl* accident, see UNSCEAR, *Sources and Effects of Ionizing Radiation: UNSCEAR 2008 Report to the General Assembly with Scientific Annexes, Volumes II, Scientific Annexes C, D and E* (United Nationals Publication, New York: 2011), available at <https://www.unscear.org/docs/reports/2008/11-80076_Report_2008_Annex_D.pdf>, last visited 30 April 2020.
[3] Codex Alimentarius Commission, *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (1995).
[4] For the details and impact of the accident, see Chapter 1.2.

revised by the Codex Alimentarius Commission in 2006 existed when the *Fukushima* accident occurred. Nevertheless, immediately after the accident, around 80 countries imposed some import bans or restrictions on Japanese food products, particularly agricultural and fishery products produced in and around the *Fukushima* Prefecture. Whereas most countries have withdrawn their import restrictions to date, there are some countries still maintaining the import ban as of April 2020.[5] This fact might cast doubt on the effectiveness of the 2006 GLs.

In May 2015, Japan requested consultations with Korea in accordance with the WTO dispute settlement procedures, claiming that, among others, Korea's import ban on the 28 fishery products from 8 prefectures, including *Fukushima* and other surrounding prefectures, was inconsistent with the SPS Agreement (i.e. *Korea - Radionuclides*). The Panel and the Appellate Body Reports were adopted by the WTO Dispute Settlement Body in April 2019.[6] Importantly, among others,[7] Japan did not claim that Korea's measure was not based on the GLs in 2006 as relevant international standards, pursuant to Article 3 of the SPS Agreement. It implies that Japan acknowledged a wide range of discretion given to Korea under the GSCTFF, and the compatibility of Korea's blanket import ban with this provision.

These elements explained above may raise questions regarding the discipline and scope of the Codex GLs, and, most importantly, its role and effectiveness. Based on this concern, this chapter will show a long-term attempt by relevant international organizations to regulate international trade on foodstuffs contaminated with radionuclides following a nuclear accident by setting GLs in foods (Chapter 3.1). Then it will further examine how the regulation of such international trade is enforced through the WTO (Chapter 3.2).

3.1 Guideline Levels for Radionuclides in Food for International Trade

Until the *Chernobyl* accident occurred in April 1986, little necessity had been recognized to regulate international trade on foods accidentally contaminated with radionuclides. In response to the accident, many countries set their own levels of radionuclide activity concentration in food, restricting imports of food

[5] See Introduction of the dissertation.
[6] WTO, Minutes of Meeting Held in the Centre William Rappard on 26 April 2019, WT/DSB/M/428, 25 June 2019, para. 9.27.
[7] As to an article analyzing the various issues in this dispute, for example, see Cai, Yan, and Kim, Eunmi, 'Sustainable Development in World Trade Law: Application of the Precautionary Principle in Korea – Radionuclides' (2019) 11(7) *Sustainability* 1; Taro Hamada and Yoshimichi Ishikawa, 'Are Korea's Import Bans on Japanese Foods Based on Scientific Principles? Comments on Report of the Panel and the Appellate Body on Korean Import Bans and Testing and Certification Requirements for Radionuclides (WT/DS495)' (2020) 11 (1) *European Journal of Risk Regulation* 155.

products, especially dairy products, from areas affected by the accident. As a result, it is reported that, for example, such levels for caesium-134 in milk ranged from 50 to 4,600 Bq/l, depending on the countries.[8] In addition, many countries required "lot-by-lot certification" in order to prevent contaminated foods from being imported.[9]

This section will provide an overview of a long-term attempt of the relevant international organizations, in response to diffusion of import restrictions after the *Chernobyl* accident, to regulate international trade on foodstuffs contaminated with radionuclides following a nuclear accident. It will also demonstrate that the GLs adopted in 1989 and later revised in 2006 by the Codex Alimentarius Commission were heavily based on the recommendations by the ICRP.

3.1.1 Establishment of GLs in 1989

In July 1989, the Codex Alimentarius Commission, a joint commission of the FAO and the WHO established in 1963,[10] adopted the GLs for radionuclide activity concentration in food for use in international trade. Since the GLs in 1989 were set based on the recommendation by the ICRP in Publication 40 (1984),[11] the applicable scope and contents of the GLs were largely determined in accordance with the views of the ICRP.

3.1.1.1 Negotiation History

In November 1986, seven months after the accident, the Council of the FAO referred to the necessity to establish "internationally-agreed standards regarding the radio-nuclide contamination of food".[12] According to the Council of the FAO, the absence of such standards led to a barrier to agricultural trade. Thus, FAO Director-General called on the Secretariat to establish levels of radionuclide contained in foods for use in international trade, in collaboration with the WHO and the IAEA,[13] which could be accepted by the Codex Alimentarius Commission.

In December 1986, the FAO Expert Consultation on Recommended Limits for

[8] See Introduction. 1. See also Winteringham, F P W, Radioactive Fallout in Food and Agriculture, IAEA-TECDOC-494 (1989) 64. As a literature showing action levels applied by different countries after the Chernobyl accident, see e.g. Baratta, Edmond J, 'Manual of Food Quality Control, 16. Radionuclides in Food', FAO Food and Nutrition Paper 14/16 (1994).
[9] Codex Alimentarius Commission, Report of the 17th Session of the Codex Alimentarius Commission, ALINORM 87/39 (1987), para. 35.
[10] For a detailed description of the Codex's procedures for establishing international food standards (i.e. Codex Standard), see Nakagawa, Junji, *International Harmonization of Economic Regulation* (Translated by Jonathan Bloch and Tara Cannon) (Oxford University Press, Oxford: 2011) 127-132.
[11] ICRP, Protection of the Public in the Event of Major Radiation Accidents: Principles for Planning. ICRP Publication 40. Ann. ICRP 14 (2) (1984)
[12] FAO, Report of the Council of FAO, 90th Session, CL 90/REP (1986), para. 28.
[13] Codex Alimentarius Commission (17th Session), para. 34.

Radionuclide Contamination of Foods prepared a report proposing the adoption of the Interim International Radionuclide Action Levels for Foods (IRALFs), below which no interventions (e.g. import restrictions) are warranted. Importantly, they were essentially based on the recommendations by the ICRP in Publication (1984).[14] In Publication 40, the ICRP set a lower level of dose below which intervention is not warranted.[15] This might be also called "non-intervention" level. As a level for the control of foodstuffs in the first year after a nuclear accident, the ICRP recommended a projected dose[16] of 5 mSv/year for the whole body, and 50 mSv/year for individual organs (e.g. thyroid, bone surface).[17] Then, the FAO Expert Consultation recommended 350 Bq/kg of caesium-134 (Cs-134) for whole body based on a reference level of 5 mSv/year, and 400 Bq/kg of iodine-131 (I-131) for thyroid based on a reference level of 50 mSv/year, with respect to general food (except infant food) in the first year.

In March 1987, the report of the FAO Expert Consultation was reviewed by the Codex Committee on Food Additives and Contaminants (CCFAC), which agreed to forward it to the Commission for consideration.[18] However, while emphasizing that WHO regarded the FAO report as offering "no unacceptable risk to health", the Commission also "expressed disappointment" that there had been no joint FAO/WHO proposal for this issue.[19] In addition, the WHO suggested postponing the Commission's review of the FAO Expert Consultation report until the WHO would complete its work to establish derived intervention levels of radionuclides contained in food.[20] Thus, the Codex Alimentarius Commission decided not to adopt the FAO guidelines, and agreed that they would be submitted to the Commission only for information and reference purposes. Instead, the Commission called for speedy action in arriving at a joint FAO/WHO proposal for levels of radionuclide contamination in food for international trade.[21]

In July 1988, almost a year after the Commission's call, a joint paper prepared by FAO, WHO and IAEA was submitted to the Codex Executive Committee (CCEXEC).

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[14] See e.g. Lupien, J R and Randell, A W, 'FAO Recommended Limits for Radionuclide Contamination of Food', in J H Harley et al (eds), *Radionuclides in the Food Chain* (Springer, New York: 1988) 389, 395.
[15] ICRP, Publication 40, para. 34.
[16] ICRP, Publication 40, para. 35. It refers to the overall dose that would be incurred as a result of the emergency exposure situation if no protective measures were taken. ICRP, The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37(2-4) (2007), para. 276.
[17] ICRP, Publication 40, para. C9.
[18] Codex Alimentarius Commission, Report of the 19th Session of the Codex Committee on Food Additives, ALINORM 87/12A (1987), para. 100.
[19] Codex Alimentarius Commission (17th Session), para. 53.
[20] Indeed, the WHO adopted guideline levels in 1988. WHO, Derived Intervention Levels for Radionuclides in Food: Guidelines for application after widespread radioactive contamination resulting from a major radiation accident (1988).
[21] Codex Alimentarius Commission (17th Session), para. 34.

Like other organizations, WHO and FAO also assumed 5 mSv as a reference level of dose, and derived levels of radionuclides contained in food for international trade, below which no restrictions need to be taken, from conservative assumptions that 550 kg of annual food consumption is all contaminated. As a result, they recommended 1,000 Bq/kg for all radionuclides except actinides and strontium-90.[22] In response to comments from members, the CCEXEC requested FAO and WHO to revise the paper, and decided to forward this matter to the CCFAC for consideration before being sent to the Commission.[23]

In March 1989, the CCFAC agreed to amend the revised proposal, and forward it to the Commission.[24] Then, at the 18th Session held in July 1989, the Codex Alimentarius Commission adopted the guideline levels for radionuclides in food to be traded internationally.[25] They are described as "GLs in 1989" in this article.[26]

3.1.1.2 Scope and Content

Firstly, the GLs were set only for six types of radionuclides in food, covering caesium-134 (Cs-134), caesium-137 (Cs-137), iodine-131 (I-131), strontium-90 (Sr-90), plutonium-239 (PU-239), and americium-241 (Am-241). For example, the GLs was set as 1,000 Bq/kg for caesium-134 in general food, excluding milk and infant food (see, Table 4).

Table 4 Codex Guideline Levels in 1989 (Bq/kg)

Radio-nuclides	General Foods	Radio-nuclides	Infant Foods
Am-241 Pu-239	10	Am-241 Pu-239	1
Sr-90	100	I-131 Sr-90	100
I-131 Cs-134 Cs-137	1,000	Cs-134 Cs-137	1,000

The definition of GLs, which was proposed by the Secretariat and then adopted by

[22] Codex Alimentarius Commission, Proposals for Action by the Commission in Relation to Radionuclide Contamination of Foods, CX/EXEC 88/35/4 (1988), paras. 16-22.
[23] Codex Alimentarius Commission, Report of the 35th Session of the Executive Committee of the Codex Alimentarius Commission, ALINORM 89/3 (1989), para. 19.
[24] Codex Alimentarius Commission, Report of the 21st Session of the Codex Committee on Food Additives and Contaminants, ALINORM 89/12A (1989), para. 37.
[25] Codex Alimentarius Commission (18th Session), para. 102.
[26] Codex Alimentarius Commission, Codex Guideline Levels for Radionuclides in Foods foll owing Accidental Nuclear Contamination for Use in international Trade, CAC/GL 5-1989 (1 989), available at <http://www.criirad.org/actualites/dossiers2005/menacesradioactivesaliments/codexanglais1989.pdf>, last visited 3 October 2019.

the Codex Alimentarius Commission in 1989, read as follows:

> Guideline Levels are intended for use in regulating foods moving in international trade. When the Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction.[27]

As explained later,[28] the GLs were calculated (based on the recommendation by the ICRP in Publication 40 (1984)) in a way that no individual receives a dose level of 5 mSv/year through ingestion of imported foods contaminated with radionuclides at a lower level than the GLs. Put simply, the GLs were derived by regarding this level as its ALOP. Therefore, although there was no clear description in the definition above, the Commission clearly assumed that food contaminated with radionuclides lower than the GLs were safe for human consumption.[29]

On the other hand, even if figures above the GLs are detected in food, it does not automatically mean that governments should immediately prohibit the importation of the food. Instead, in this case, "governments should decide whether, and under what circumstances, the food should be distributed within their territory or jurisdiction".[30] In this regard, it is recalled that, as will be later explained, the GLs were derived based on a non-intervention level of 5 mSv/year for whole body, below which intervention is not justified. It does not necessarily mean, however, that interventions are justified above this level. Thus, governments are given a wide range of discretion in the policies to be taken when contamination levels in food exceed the GLs. This approach was explicitly carried over to the GSCTFF in 2006.

Secondly, the GLs were designed to be applicable only for "one year following a nuclear accident".[31] In other words, the GLs were originally considered to regulate international trade on foods in radiological emergency situations.[32] Specifically, the CCFAC confirmed, during the drafting process, that the recommended levels only be applied to a nuclear accident situation "declared

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[27] Codex Alimentarius Commission (18th Session), para. 101.
[28] See Chapter 3.1.1.3.
[29] A sentence confirming the safety of consumption of food below the GL was explicitly inserted in the GSCTFF in 2006. See Chapter 3.1.2.2.
[30] Codex Alimentarius Commission (18th Session), para. 101.
[31] Contrary to this, as explained in Chapter 3.1.1.1, the IRALFs recommended by FAO, which served as the basis for the GLs in 1989, dealt with not only the first year but also "following years" after a nuclear accident.
[32] It is worth noting that the FAO/WHO joint proposal, which served as the basis for the GLs in 1989, did not made a reference to the applicable scope. Thus, in the subsequent negotiation process, it was clearly agreed that "[i]n accordance with the recommendations of the ICRP", they applied only to one year after a nuclear accident. Codex Alimentarius Commission (21st Session of CCFAC), para. 29.

under the notification Conventions of IAEA".[33] It should be also recalled that the 1989 GLs were derived based on the recommendations by the ICRP in Publication 40 (1984), specifically dealing with interventions for protecting the public in the event of a nuclear accident.[34] In March 1991, however, the Codex agreed to extend the applicability of the GLs on a permanent basis, covering not only an emergency situation, but also a long-term exposure situation.[35]

Thirdly, the fact that GLs applied only to food contamination after a nuclear accident means that they excluded from its scope "naturally occurring radionuclides" contained in foods as a result of plant and animal growth. The main radionuclide contained in almost all foods is potassium; 0.01% of which is radioactive (K-40). Radioactive potassium releases beta and gamma radiation, which leads to internal exposure through food intake. Nevertheless, they are outside the scope of GLs.

3.1.1.3 Basis for Deriving GLs

Firstly, the 1989 GLs were derived from a reference level of dose (i.e. 5 mSv/year) based on the recommendation by the ICRP in Publication 40 (1984). As explained before, in this publication, the ICRP set a lower level of dose below which intervention is not warranted. As a level for the control of foodstuffs in the first year after a nuclear accident, the ICRP recommended a projected dose of 5 mSv/year for whole body.[36] Based on the meaning of "projected dose,"[37] it follows that if the overall dose that would be incurred when no protective measures were taken is below 5 mSv/year for whole body, interventions are not justified.

Next, the GLs were established in a way that no individual annually receives a dose level higher than a reference level (i.e. 5 mSv) through intake of imported goods contaminated with radionuclides at a lower level than the GLs.[38] In other words, the GLs can be said to have been derived by regarding this non-intervention level of 5 mSv/year as an acceptable level of protection (ALOP) or acceptable level of risk.

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[33] Codex Alimentarius Commission (21st Session of CCFAC), para. 35. Apparently, the CCFAC referred to the Convention on Early Notification of a Nuclear Accident adopted after the *Chernobyl* accident. See IAEA, Convention on Early Notification of a Nuclear Accident, 26 September 1986, 1439 UNTS 275.
[34] ICRP, Publication 40, paras. 1-2.
[35] Codex Alimentarius Commission, Report of the 19th Session of the Codex Alimentarius Commission, ALINORM 91/40 (1991), para. 221.
[36] ICRP, Publication 40, para. C9.
[37] ICRP, Publication 103, para. 276.
[38] For example, when an adult ingests 550 kg/year of food contaminated with 1,000 Bq/kg (caesium-134), it means that he or she will be exposed to below 5 mSv/year through ingestion of food products.

During the negotiation process, some delegations (e.g. India) expressed their concerns that 5 mSv, as a reference level of dose, was too high and rather suggested the use of 1 mSv for deriving levels of radionuclide activity concentration in food.[39] In this regard, the Commission noted that, due to the conservative assumptions explained above, it is most unlikely that a dose to an individual from food ingestion will be "greater than a small fraction of 1 mSv".[40] In other words, while adopting 5 mSv/year as the reference level of dose, the Commission recognized that this level would be unlikely to be exceeded.

Secondly, the GLs were calculated based on the "extremely conservative assumptions"; that (1) an adult annually consumes 550 kg of food, (2) all food consumed are imported, and imported foods are all contaminated, and (3) each of the three radionuclide groups is treated independently.[41] The second assumption (i.e. 100% of contamination rate) seems to reflect the reality that it is difficult to immediately replace foods that have been imported from contaminated regions with the ones from regions not affected by the accident.[42]

As the third assumption above (i.e. contribution rate), the GLs were set assuming that each of the three radionuclide groups in Table 1 is treated independently.[43] Depending on the circumstances of the nuclear accident, food products are usually contaminated with multiple radionuclides. According to the GLs in 1989, however, even if the particular land where the food is produced is contaminated with caesium-134 (90% contribution) and strontium-90 (10% contribution), each of which is categorized into different groups (see Table 1), following a nuclear accident, and food intake of caesium-134 and strontium-90 would be examined separately. As a result, even if each value does not exceed a reference level of 5 mSv/year, the total of these values might exceed the reference level. Nevertheless, the Codex did not take contribution rate into account when deriving the GLs on the ground that "the proposed levels have extensive conservative assumptions built-in".[44]

Thirdly, the concept of the "dose per unit intake (DPUI)" factor referred to in the 1989 GLs need to be explained. When radioactive materials are ingested into the body, it is not easy to calculate the internal dose to tissues and organs. Thus, it is

[39] Codex Alimentarius Commission (18th Session), paras. 92-94.
[40] Codex Alimentarius Commission (GLs in 1989), at 3.
[41] Codex Alimentarius Commission (GLs in 1989), at 3, Appendix.
[42] This view was later articulated in the revised GLs adopted by the Commission in 2006.
[43] On the other hand, different radionuclides with the same group will be added together. For example, if both caesium-134 and caesium-137 are contained in food, the question is whether the summed activity concentrations of these radionuclides in the food exceed the GL (i.e. 1,000 Bq/kg). See Codex Alimentarius Commission (GLs in 1989), at 1.
[44] Codex Alimentarius Commission (GLs in 1989), at 1. This was already pointed out by Malaysia during the GL negotiation process. Codex Alimentarius Commission (21st Session of CCFAC), para. 36.

useful to determine, in advance, the relationship between the amount of radioactive materials ingested and the dose level received by tissues or organs as a coefficient. With this coefficient, it is possible to calculate the internal dose corresponding to the amount of radioactive materials in foods. The coefficient representing this relationship is called the "effective dose coefficients", which is expressed by Sv/Bq.

In this regard, the Codex divided effective dose coefficients, or DPUI factors, into three categories for the purpose of convenience. For example, a dose per unit intake factor for caesium-134 and caesium-137 was set at 10^{-8}, so that the internal dose of the public from annual consumption of imported foods contaminated with 1,000 Bq/kg of caesium-137 is estimated from the following formula; 1,000 Bq/kg×550kg×10^{-8} Sv/Bq×1.0. However, it is not clear where DPUI factors that the Codex conveniently relied on in deriving the GLs are from.

3.1.2 Revision of GLs in 2006

The momentum for revising the 1989 GLs increased mainly for the following reasons. First, while the 1989 GLs were derived based on a reference level of 5 mSv/year, the ICRP recommended a reference level for intervention exemption of "around 1 mSv/year" for the public dose in Publication 82 (1999).[45] It is recalled that, during negotiations on the 1989 GLs, some delegations argued that a reference level for deriving GLs should be 1 mSv/year. Second, as expressed by the United Nation (UN) in January 2000, almost 13 years after the accident, the disaster at the *Chernobyl* nuclear power plant caused "the long-term nature of the consequences". [46] In other words, the *Chernobyl* accident highlighted the necessity to revise the 1989 GLs and expand the applicability of the GLs to long-term exposure situations.

3.1.2.1 Negotiation History

It was the IAEA which took the initiative of revising the GLs in 1989 in order to address prolonged exposure situations. The concern expressed by the UN above was shared by the IAEA, which had not succeeded in setting any radiological criteria for long-lived radionuclides in commodities. Thus, in September 2000, the IAEA adopted a resolution requesting the Secretariat "to develop…radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs".[47]

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[45] ICRP, Protection of the public in situations of prolonged radiation exposure. ICRP Publication 82. Ann. ICRP 29 (1–2) (1999), para. (y).

[46] UN, Strengthening of international cooperation and coordination of efforts to study, mitigate and minimize the consequences of the Chernobyl disaster, UNGA 165, A/RES/54/97, 28 January 2000.

[47] IAEA, Radiological Criteria for Long-Lived Radionuclides in Commodities (especially

In response to this resolution, the IAEA began its work to develop its Safety Guide but faced a number of issues in the process. According to the IAEA, first, the GLs in 1989 were not designed in a clear manner to apply to longer-term situations after a nuclear accident. Second, the GLs in 1989 only covered a limited number of radionuclides. Therefore, in April 2002, the IAEA requested the Codex Alimentarius Commission to consider the establishment of criteria for radionuclides in foods "for long-term use", and to extend the applicable scope of the GLs 1989 to other radionuclides.[48] In May 2002, however, the Executive Committee of the Codex Alimentarius Commission (CCEXEC) decided against these proposed elaborations at this stage, and referred to the CCFAC for further consideration in collaboration with the IAEA.[49]

The IAEA submitted proposals to the CCFAC for deriving GLs for radionuclides in foods for long-term situations.[50] In March 2003, while agreeing with the proposals by the IAEA, the CCFAC requested it to prepare a revised version of the GLs in 1989 based on this proposal with Finland for consideration at Step 3 of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (Procedure).[51] The Commission also approved this CCFAC's new work.[52]

In March 2004, the IAEA presented the revised proposal, entitled "Proposed Draft Revised Guideline Levels for Radionuclides in Foods for Use in International Trade", to the CCFAC.[53] Since the contents of the revised GLs proposed by IAEA in 2004 and the revised GLs adopted by the Commission in 2006 are almost the same,[54] the explanation of the former will be given later together with the latter. However, it is sufficient, here, to point out the fact that the 2006 GLs by Codex were originally drafted by IAEA. Then, the CCFAC agreed on the revised GLs proposed by the IAEA and decided to forward it to the Commission for preliminary adoption at Step 5 of the Procedure.[55] In July 2004, the Commission adopted the proposal

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foodstuffs and wood), Resolution adopted on 22 September 2000, GC(44)/RES/15 (2000).

[48] Codex Alimentarius Commission, "Consideration of New Work Proposals at Step 1 of the Procedure", Executive Committee of the Codex Alimentarius Commission, 50th Session, CX/EXEC 02/50/7 (2002), ANNEX 1.

[49] Codex Alimentarius Commission, Report of the 50th Session of the Executive Committee of the Codex Alimentarius Commission, ALINORM 03/3A (2002), para. 67.

[50] Codex Alimentarius Commission, Consideration of a Revision or Amendments to the Guideline Levels for Radionuclides in Foods following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989), including Guideline Levels for Radionuclides for Long-Term Use, CX/FAC 03/13 (2003), Annex II.

[51] Codex Alimentarius Commission, Report of the 35th Session of the Codex Committee on Food Additives and Contaminants, ALINORM 03/12A (2003), paras. 83-84.

[52] Codex Alimentarius Commission, Report of the 26th Session of the Codex Alimentarius Commission, ALINORM 03/41 (2003), Appendix VIII.

[53] Codex Alimentarius Commission, Report of the 36th Session of the Codex Committee on Food Additives and Contaminants, ALINORM 04/27/12 (2004), Appendix XXII.

[54] As will be explained later, the IAEA proposal included two major faults.

[55] Codex Alimentarius Commission (36th Session of the CCFAC), para. 204.

at Step 5, and advanced it to Step 6.[56]

In July 2005, however, the CCFAC agreed to return the revised draft discussed at Step 7 to Step 2 for further revision, comments at Step 3 and consideration at its next Session, mainly due to the objections raised by the European Community (EC); that is the revised draft by the IAEA failed (i) to clarify that the GLs applied only in situations relating to a nuclear or radiological emergency, and (ii) to distinguish between the GLs for general and infant food.[57]

In April 2006, the *ad hoc* Working Group led by the EC and IAEA presented the revised draft to the CCFAC,[58] which agreed to forward the revised GLs to the Commission for adoption at Step 5/8,[59] and inclusion in the GSCTFF.[60] In July 2006, the Commission adopted the revision of the GLs as proposed at Step 5/8,[61] while revoking the 1989 GLs.

3.1.2.2 Scope and Content

First, contrary to the GLs in 1989 recommending the GLs only for six kinds of radionuclides, the GLs in 2006 cover only 20 kinds of radionuclides (i) that are "important for uptake into the food chain", (ii) are "usually contained in nuclear installations…in large enough quantities to be significant potential contributors to levels in foods", and (iii) that "could be accidentally released into the environment from typical installations"[62] (see Table 5).

Table 5 Revised Codex Guideline Levels in 2006 (Bq/kg)

Radionuclides	Infant Foods	Other Foods
Pu-238, Pu-239, Pu-240, Am-241	1	10
Sr-90, Ru-106, I-129, I-131, U-235	100	100
S-35, Co-60, Sr-89, Ru-103, Cs-134 Cs-137, Ce-144, Ir-192	1,000	1,000
H-3, C-14, Tc-99	1,000	10,000

[56] Codex Alimentarius Commission, Report of the 27th Session of the Codex Alimentarius Commission, ALINORM 04/27/41 (2004), para. 71, Appendix IV.
[57] Codex Alimentarius Commission, Report of the 37th Session of the Codex Committee on Food Additives and Contaminants, ALINORM 05/28/12 (2005), paras. 208-215.
[58] Codex Alimentarius Commission, Report of the 38th Session of the Codex Committee on Food Additives and Contaminants, ALINORM 06/29/12 (2006), Appendix XXXI.
[59] It refers to a procedure in the Codex for adopting the text at Step 8 with Steps 6 and 7 omitted.
[60] Codex Alimentarius Commission (38th Session), paras. 195-198.
[61] Codex Alimentarius Commission, Report of the 29th Session of the Codex Alimentarius Commission, ALINORM 06/29/41 (2006), para. 65.
[62] It follows by definition that radionuclides of natural origin contained in foodstuffs were excluded from its scope.

Secondly, the meaning of GL was further clarified. In 1995, the GSCTFF had already set a general definition for a GL, which refers to "the maximum level of a substance in a food or feed commodity which is recommended by the Codex Alimentarius Commission to be *acceptable* for commodities moving in international trade."[63] Moreover, when the revised GLs were adopted and included into the GSCTFF in 2006, the definition of a GL in the GSCTFF read as follows:

> …when radionuclide levels in food do not exceed the corresponding Guideline Levels, the food should be considered as safe for human consumption. When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.[64]

As later explained,[65] the GLs were revised based on intervention exemption level recommended by the ICRP in Publication 82 (1999) in a way that no individual receives a dose level of around 1 mSv/year through ingestion of imported foods contaminated with radionuclides at a lower level than the GLs. Put simply, the 2006 GLs were derived by regarding this level as its ALOP. It follows that food contaminated with radionuclide below the GLs should be regarded as "*safe* for human consumption".[66]

On the other hand, like the 1989 GLs, even if the GLs are exceeded in food, "national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction". In this regard, it is recalled that, as later explained,[67] the GLs were derived based on the intervention exemption level of around 1 mSv/year, below which intervention is not justified. It does not necessarily mean, however, that interventions are justified above this level. Therefore, governments are still given, under the GSCTFF, a wide range of discretion in the policies to be taken when contamination levels in food exceed the GLs. In other words, the GSCTFF international standards provide nothing about how to treat food contaminated with radionuclides at a higher level than the GLs . This fact makes it difficult to challenge import restrictions on contaminated food under Article 3.1 of the SPS Agreement.

Thirdly, right after the *Chernobyl* accident, the GLs in 1989 were established for regulating international trade in foods accidentally contaminated with

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[63] Codex Alimentarius Commission (CODEX STAN 193-1995), fn. 1 (Italic Added).
[64] Codex Alimentarius Commission (CODEX STAN 193-1995), fn. 1.
[65] See Chapter 3.1.2.4.
[66] The identical phrase already appeared in the proposal by the IAEA in 2004. Codex Alimentarius Commission (36th Session of the CCFAC), Appendix XXII (Italic Added).
[67] See Chapter 3.1.2.4.

radionuclides as a result of a nuclear accident. As noted before, however, the revised GLs proposed by the IAEA in 2004 failed to clarify this original position of the GLs.[68] Then, in response to the EC's comments, the *ad hoc* Working Group led by the EC and IAEA further presented the revised proposal, newly adding a phrase confirming that the GLs apply to radionuclides in foods "which have been contaminated following a nuclear or radiological emergency", including both accidents and malevolent actions (e.g. terror).[69]

Finally, as explained at the beginning of this section, negotiations to revise the GLs were originally initiated to deal with long-term exposure. Thus, it is assumed that the revised GLs apply to radionuclides in foods in both one-year exposure situation (i.e. during the first year after a major radionuclide release into the environment) and prolonged exposure situation (i.e. beyond the first year).[70] As noted in the GSCTFF, the fraction of contaminated food in the market, which is one of the elements assumed in deriving the GLs, will decrease in the long term "by a factor of a hundred or more".[71] This leads to a gradual decrease in exposure dosage through the ingestion of contaminated food in prolonged exposure situation.

3.1.2.3 Basis for Deriving GLs

The scientific basis for deriving the revised GLs, which is described in Annex 1 of the GSCTFF for radionuclides, is basically the same as that for the GLs in 1989 with a few amendments.

First, while the 1989 GLs were derived from a reference level of dosage (i.e. 5 mSv/year), the revised GLs were derived in a way that no individual receives a dose level of "around 1 mSv/year" through ingestion of imported foods contaminated with radionuclides at a lower level than the GLs. Put differently, the 2006 GLs were derived by regarding this level as its ALOP. However, it is not clear why this dose level was chosen as an ALOP for the 2006 GLs. The only thing that can be said is that the 2006 GLs embodied the concept of "intervention exemption level", which was recommended by the ICRP in Publication 82 (1999) as "around 1 mSv/year".

Secondly, the GLs were calculated under conservative assumptions as follows: that is (1) an adult annually consumes 550 kg of food (200kg for infants), (ii) imported foods account for 10% of the total, and (iii) imported foods are all contaminated. On the one hand, while the 1989 GLs were calculated on the

[68] See Chapter 3.1.2.1.
[69] Codex Alimentarius Commission (38th Session), Appendix XXXI; Codex Alimentarius Commission (CODEX STAN 193-1995), at 50.
[70] See e.g. ICRP, Publication 82, para. (a).
[71] Codex Alimentarius Commission (CODEX STAN 193-1995), at 60.

assumption that all foods consumed were imported ones, the revised GLs assumes that the ratio of imported foods to the total produced and imported foods in the country, which is called the "import/production factor (IPF)", is 0.1. On the other hand, the assumed contamination rate, which is the same as that of the 1989 GLs, reflects the reality that it is difficult to immediately replace foods that have been imported from contaminated regions with ones from regions unaffected by the accident.

Third, like the 1989 GLs, the revised GLs were set assuming that each of the radionuclide groups in Table 2 is treated independently.[72]

Fourthly, as explained in the context of the 1989 GLs, the effective dose coefficients are indispensable for calculating the level of internal dose through intake of foods contaminated with radionuclides. Although it was not clear where they were from in calculating the 1989 GLs, the IAEA firstly clarified in its revised proposal that they were based on the ones presented by the IAEA and so on in 1996.[73] Later on, the Codex Alimentarius Commission also clarified this in the 2006 GLs. For example, based on the assumptions above, the annual dose that the public receives from intake of imported foods contaminated with 1,000 Bq/kg of caesium-137 can be derived from the following formula; 1,000 Bq/kg×550kg×dose coefficient (i.e. 1.3 10^{-5}mSv/Bq)×contamination rate (0.1)=0.7 mSv.[74]

Since the GLs in 2006 were derived from a reference level for intervention exemption of "around 1 mSv/year" as an ALOP, which is about five times more stringent than that in the 1989 GLs, one might consider that the revised GLs should also maintain more stringent values. When comparing both values, however, it turns out that they are almost identical (see Table 1 and 2).

The reason for this result is that GLs are derived from a dose criterion or an ALOP, as well as other assumptions. Even if a radiological criterion or an ALOP itself is set as a more stringent value, difference in derived GLs may still be minor, depending on other assumptions. When revising the GLs in 2006, a more realistic assumption was taken that only 10% of major food ingested worldwide is imported, while it was assumed in 1989 that 100% of major foods consumed were imported. On the other hand, both assumed that all imported foods were contaminated. As a result, the contamination fraction was estimated as 0.1 for

[72] As to the details, see Chapter 3.1.1.3.
[73] FAO, IAEA, ILO, Nuclear Energy Agency of the OECD, Pan American Health Organization, WHO, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115 (1996) 166-201. Codex Alimentarius Commission (36th Session of the CCFAC), Appendix XXII.
[74] Codex Alimentarius Commission (CODEX STAN 193-1995), at 51.

deriving the 2006 GLs, while it was set as 1.0 for deriving the 1989 GLs. GLs for radionuclides are set in a way that no individual annually receives a dose level higher than a reference level through intake of imported foods, and the contamination fraction also affects this calculation.[75]

Therefore, even if a dose criterion or an ALOP is more stringent than that in the 1989 GLs, the derived GLs in 2006 are less stringent mainly due to the different contamination rates, which is set at one tenth compared to the one in the 1989 GLs.

3.1.2.4 Intervention Exemption Level

It is explained that the revised GLs in 2006 for radionuclides in food were derived from an intervention exemption level of "around 1 mSv/year" recommended by the ICRP in Publication 82 (1999). To be more specific, the 2006 GLs were calculated in a way that no individual receives a dose level higher than around 1mSv/year from ingestion of imported foods contaminated with radionuclides at a lower level than the GLs. In other words, when deriving the 2006 GLs, a reference was made to the intervention exemption level recommended by the ICRP only for adopting "around 5 mSv/year" as its ALOP. Nevertheless, it is fruitful to overview the development of the concept of intervention exemption level in the ICRP and clarify its role and meaning.

3.1.2.4.1 Reference Levels

The ICRP had recognized the notion "reference levels" to widely mean the levels "above which some specified action or decision should be taken".[76] In Publication 82 (1999), the ICRP further introduced the distinction between "generic reference levels" and "specific reference levels" particularly for "interventions" in prolonged exposure situations.

In its publication in 1991, the ICRP recommended a system of radiological protection which is structured based on the distinction of human activities between "practice" and "intervention". The former refers to activities that increase the overall radiation exposure (e.g. new establishment of nuclear power plant), while the latter refers to activities that reduce the overall exposure. To be more specific, intervention refers to protective actions, such as removing existing sources, modifying pathways, or reducing the number of exposed individuals (e.g.

[75] It is recalled that the amount of internal dose from intake of imported products can be estimated by "annual food consumption (550 kg) × contamination level of food (Bq/kg) × fraction of imported products (10%) × contamination rate (100%) × effective dose coefficient".
[76] ICRP, 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21 (1–3) (1991), para. 257.

decontamination, food shipment restriction).[77] It should be noted that, unlike "practice" that deals with the introduction of new sources, "intervention" deals with situations where "the sources of exposure and the exposure pathways are already present",[78] especially in emergency situations and prolonged exposure situations.

The ICRP quantitatively recommended generic reference levels, (i) toward which interventions are almost always justified in prolonged exposure situations (i.e. around 100 mSv/year). The ICRP also recommended levels (ii) below which interventions are not likely to be justified (and above which it may be necessary) in prolonged exposure situations (i.e. around 10 mSv/year).[79] According to the ICRP, generic reference levels are useful when there are no dominant components constituting the existing dose.[80] Therefore, they are normally expressed in the form of existing annual dose, which refers to the sum of doses caused by all sources of prolonged exposure in a given location.[81]

As to the generic reference level below which intervention is not justified (and above which it may be necessary), the question is on *what* grounds this "around 10 mSv/year" was derived. In this regard, the ICRP derived it from the fact that large populations live for years in areas of the world where the natural existing dose is up to around 10 mSv/year.[82] Nevertheless, the ICRP emphasized that generic reference levels provided only "broad boundaries" for making decisions regarding interventions in prolonged exposure situations, and thus they should not be considered as reflecting "acceptable levels" of any kind.[83]

Furthermore, the ICRP also encouraged national authorities and international organizations to pre-determine "specific reference levels", which are applicable only to particular prolonged exposure situations, especially when there are dominant components constituting the existing dose.[84] In the past, the ICRP had already recommended a few specific reference levels for intervention for a dominant single component. For example, in relation to foodstuffs, the ICRP recommended that intervention for a single foodstuff will be almost always justified above an averted dose of 10 mSv/year in Publication 63 (1992).[85] In

[77] ICRP, Publication 60, para. 106.
[78] The ICRP notes that "[a]ccidents, once they have occurred, give rise to situations in which the only available action is some form of intervention." ICRP, Publication 60, para. 111.
[79] ICRP, Publication 82, paras. 79, 83.
[80] ICRP, Publication 82, para. 80.
[81] ICRP, Publication 82, paras. (f), 132.
[82] According to the ICRP, "levels up to 10 mSv per annum are relatively rare in global terms." ICRP, Publication 82, para. A10.
[83] ICRP, Publication 82, para. 84.
[84] ICRP, Publication 82, para. 73.
[85] ICRP, Principles for intervention for protection of the public in a radiological emergency. ICRP Publication 63. Ann. ICRP 22 (4) (1992), paras. 89, 119, B7.

other words, protective measures (e.g. food shipment restrictions) for single foodstuff will be almost always justified if the effective dose averted by this protective measure exceeds 10 mSv/year. Such intervention levels, as well as intervention exemption levels explained below, are both specific reference levels.[86]

3.1.2.4.2 Intervention Exemption Level

Aside from intervention levels, the ICRP also recognized the need to set levels "below which intervention is almost always unnecessary" in the context of international trade in foodstuffs, due to the contemporary demand for promoting "the globalization of markets".[87] According to the ICRP, interventions should be exempted in case that the internal dose, through intake of imported foods, remains small.[88] Such levels are called *intervention exemption levels*.

Contrary to intervention levels applicable in emergency situations after a nuclear accident, intervention exemption levels are applicable in prolonged exposure situations, which specifically refer to the exposure "adventitiously and persistently incurred by the public over long periods of time".[89] A prolonged exposure situation is typically caused either by "natural" sources (e.g. cosmic radiation) or "artificial" sources (e.g. radioactive materials dispersed in areas as a result of nuclear accidents).[90]

In the context of international trade, intervention exemption levels refer to the levels below which international trade in foodstuffs are "freely permitted", and therefore any interventions, or trade restrictions in this context, should be regarded as "artificial barriers to trade".[91] In 1999, the ICRP quantitatively recommended the additional annual dose[92] of "around 1 mSv" as the intervention exemption level for a dominant type of commodity.[93] Therefore, pursuant to the definition of intervention exemption level, if the additional exposure dose through ingestion of food products remains below or "around 1 mSv/year", intervention in

[86] ICRP, Publication 82, para. 65.
[87] ICRP, Publication 82, para. (x).
[88] ICRP, Publication 60, para. 287. To be more specific, the ICRP noted that intervention or regulatory control should be exempted when "the source gives rise to small individual doses and small collective doses".
[89] ICRP, Publication 82, paras. (a), 68.
[90] ICRP Publication 82, para. (b).
[91] The ICRP noted that "[t]o avoid unnecessary restrictions in international trade, especially in foodstuffs, it may be necessary, in this context, to apply derived intervention levels in a different way. They could then indicate a line of demarcation between freely permitted exports or imports and those that should be the subject of special decisions. Any restrictions applied to goods below the intervention levels, better called intervention exemption levels for this purpose, should be regarded as artificial barriers to trade." ICPR, Publication 60, para. 284.
[92] The additional annual dose refers to "[t]he annual dose that is added to the existing annual dose as a result of a practice". ICRP Publication 82, para. (f).
[93] ICRP, Publication 82, paras. (y), 126.

the form of import restrictions should be regarded as unnecessary, and thus should be exempted.[94]

In 1999, even before the IAEA adopted a resolution for revising the GLs in September 2000,[95] the ICRP already called on states and international organizations to derive generic intervention exemption levels of radionuclide activity concentration in some products based on the recommended intervention exemption level.[96] In 2006, the Codex adopted the revised GLs, and then they should be characterized as an articulation of generic intervention exemption levels.[97] It follows that foods contaminated with radionuclides lower than the GLs, which are derived from the intervention exemption level, should not be subject to any interventions or trade restrictions, and thus "are acceptable without restriction for international trade".[98]

Later, however, it is worth noting that the ICRP itself found the concept of intervention exemption level unnecessary. According to the ICRP, international trade continues without regulatory intervention, and thus the concept of intervention exemption is a "double negative" in that it exempts intervention into international trade. Instead, the ICRP showed its preference over the simple expression, such as "radiological criteria for no action" or "radiological criteria in commodities".[99]

3.1.2.4.3 Basis for "around 1 mSv/year"

The question is on what grounds the ICRP derived an intervention exemption level of "around 1 mSv" for food commodities. Although it is not clearly explained in Publication 82 (1999), it appears that the ICRP roughly derived this specific value by subtracting (i) the annual dose from natural background exposure (i.e. 2.4 mSv), and (ii) the sum of the prolonged exposures from authorized practices (i.e. 1 mSv) from (iii) generic reference levels under which intervention is not likely to be justified (i.e. 10 mSv/year).[100]

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[94] On the other hand, it should be recalled that interventions or trade restrictions are not automatically justified even when the intervention exemption level is exceeded. As explained before, intervention is almost always justified only when the averted dose exceeds 10 mSv/year, which is different from the intervention exemption level. The ICRP noted that "[t]rade in materials above an intervention exemption level should not automatically be prohibited". ICRP, Publication 60, para. 284.
[95] Chapter 3.1.2.1.
[96] ICRP Publication 82, paras. (s), (z), 96, 126.
[97] Although the concept of intervention exemption level was not explicitly recognized before 1990, the ICRP regards the 1989 CODEX GLs as *de facto* generic intervention exemption levels for radionuclides in foodstuffs. ICRP Publication 82, paras. (aa), 129.
[98] ICRP, Publication 63, para. 92.
[99] ICRP, Scope of radiological protection control measures. ICRP Publication 104. Ann. ICRP 37 (5) (2007), paras. 178-179.
[100] ICRP Publication 82, para. 125.

It is estimated that the global average of the existing natural dose (i.e. annual dose from natural background exposure) is around 2.4 mSv/year, and the majority of the world's population is exposed to it even below this level.[101] In addition, the ICRP had once recommend that a dose limit for the public from practices, human activities that increase exposures, be set as aggregated additional dose from all practices of "1 mSv/year".[102] In light of the above, the ICRP explained the calculation method of "around 1 mSv/year" as follows:

> Natural background exposure causes annual doses of at least a few milli-sieverts per annum and, taking account of possible annual doses from authorized practices, this leaves an upper bound of the order of a few millisieverts per annum for the annual doses from all commodities to be exempted from intervention.[103]

In sum, according to the ICRP, intervention is not likely to be justified below a generic reference level of "about 10 mSv/year" in prolonged exposure situations, while the global average of the existing natural dose is "around 2.4 mSv/year", and the additional dose from all practices that is acceptable in planned exposure situations is "1 mSv/year". Thus, it appears that an intervention exemption level for commodities was roughly calculated to be around 1 mSv as the additional annual dose from the equation 10 – (2.4 + 1).

3.2 Codex GLs as International Standards in the SPS Agreement

The previous section overviewed a long-term attempt by relevant international organizations to regulate international trade on foodstuffs contaminated with radionuclides, following a nuclear accident, by setting GLs in foods. This section will further examine how the regulation of such international trade is enforced through the WTO.

The Codex GLs can be relevant to the WTO, especially in relation to Article 3 of the SPS Agreement. Article 3.1 of the SPS Agreement obliges WTO Members to base their SPS measures on "international standards, guidelines or recommendations", where they exist.[104] Pursuant to the jurisprudence,[105] the GSCTFF dealing with

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[101] ICRP Publication 82, paras. 76, A10.
[102] ICRP Publication 82, paras. (l), 43.
[103] ICRP Publication 82, para. 125.
[104] Article 3.1 of the SPS Agreement reads that "[t]o harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3."
[105] For example, the panel in *EC – Hormones* readily concluded that the Codex standards for the five hormones at issue were international standards within the meaning of the SPS Agreement. Panel Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, WT/DS26/R/USA, adopted 13 February 1998, as

contaminants and toxins in food and feed, and the GLs for radionuclides included therein, certainly constitute "the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to…contaminants" for food safety within the meaning of Paragraph 3(a) of Annex A of the SPS Agreement.[106] Whether levels for radionuclides in food take a form of a GL or a "maximum level" (ML) does not change the conclusion above.[107] Therefore, WTO Members are required to base their SPS measures relating to radioactive contamination on the GLs included in the GSCTFF.

In this regard, it is worth emphasizing that a reference level for intervention exemption, from which the 2006 GLs were derived, does not constitute an international standard. Rather, it serves as a dose criterion or an ALOP for deriving the GLs.

3.2.1 Adopting More Stringent Levels of Activity Concentrations for Imported Products than the GLs

The question, here, is whether or not a Member adopting more stringent levels of radionuclide activity concentration in imported foods than the GLs can still be said to base its SPS measure on the GLs in the GSCTFF as international standards. Even in this case, however, it does not automatically mean that such SPS measures are not based on international standards, as long as their ALOPs are the same as ones assumed by the GLs.[108]

In this regard, the panel in *EC – Hormones* noted that "[o]ne of the determining factors in deciding whether a measure is *based on* an international standard is…the level of protection that measure achieves."[109] The panel also held that "for a sanitary measure to be *based on* an international standard in accordance with Article 3.1, that *measure* needs to reflect the same level of sanitary protection as the *standard*."[110] Moreover, after carefully reviewing the language used by this panel, one commentator argues that "a measure can no longer be said to be

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modified by Appellate Body Report WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:III, p. 699, paras. 8.69-8.70.

[106] It reads that "for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice".

[107] See e.g. Codex Alimentarius Commission, Codex Committee on Contaminants in Foods, 7th Session, Proposed Draft Revision of Guideline Levels for Radionuclides in Foods, CX/CF 13/7/6 (2013), para. 19.

[108] See e.g. Yamashita, Kazuhito, Shoku no Anzen to Boeki: WTO SPS Kyotei no Ho to Keizai Bunseki (*Food Safety and International Trade: Legal and Economic Analysis of the WTO's SPS Agreement*) (in Japanese) (Nippon Hyoronsha, Tokyo: 2008) 268-269, 331-332.

[109] Panel Report, *EC – Hormones*, para. 8.72 (Italic Original).

[110] Panel Report, *EC – Hormones*, para. 8.73 (Italic Original).

based on a standard if it achieves a level of protection which is significantly different from the one reflected in the international standard."[111] However, it is fair to note that some argue that this panel's reasoning was later rejected by the Appellate Body in *EC - Hormones*,[112] while others are cautious about such understanding, noting that the Appellate Body did not explicitly deny the panel's reasoning.[113]

In this regard, as explained before,[114] although the GLs in 2006 were derived from a reference level for intervention exemption of "around 1 mSv/year" as an ALOP (which is about five times more stringent than that in the 1989 GLs (i.e. 5 mSv/year)), the values in the 1989 GLs and the revised GLs are almost identical. This is because the GLs are derived from a dose criterion or an ALOP, as well as other assumptions. Thus, even if a dose criterion or an ALOP, itself, is set as a more stringent value, the derived GLs may still be identical, depending on other assumptions.

Likewise, even if a Member aims to achieve the same ALOP as the one in the GLs, it might take a more stringent level of radionuclide activity concentrations in food than the GLs, depending on other elements it assumes. In other words, the mere fact that a Member takes a more stringent level for radiation contamination in food than the GLs does not necessarily mean that it set a higher ALOP than that in the GLs. The Secretariat of the Codex Alimentarius Commission also recognizes the possibility that derived values of radionuclides contained in foods for domestic use deviates from the GLs when different assumptions are taken.[115] For example, in April 2012, Japan regulated the levels of radionuclide contaminated in food "on a basis of intervention exemption level of 1 mSv/year, equivalent to the Codex Standard and monitoring results accumulated".[116] Nevertheless, there are still differences in the derived values. For example, as to the level of caesium-134 contained in general foods, the derived values are 1,000 Bq/kg in the Codex GLs

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[111] Landwehr, Oliver, 'Article 3 SPS: Harmonization', in Rüdiger Wolfrum, Peter-Tobias Stoll and Anja Seibert-Fohr (eds), *WTO-Technical Barriers and SPS Measures* (Martinus Nijhoff Publishers, Leiden, Boston: 2007), para. 31.

[112] See e.g. Prévost, Marie D, *Balancing Trade and Health in the SPS Agreement: The Development Dimension* (Wolf Legal Publishers, Nijmegen: 2009) 617.

[113] See e.g. Gruszczynski, Lukasz, *Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement* (Oxford University Press, Oxford: 2010) 97; Scott, Joanne, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (2009) 254.

[114] See Chapter 3.1.2.3.

[115] Codex Alimentarius Commission, Fact Sheet on Codex Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency (2 May 2011) at 5, available at < http://www.fao.org/fileadmin/user_upload/agns/pdf/codex_guideline_for_radionuclitide_contaminated_food.pdf >, last visited 30 April 2020.

[116] MHLW, Measures against Radioactive Contamination of Food Caused by the Accident, available at <https://www.mhlw.go.jp/stf/kinkyu/0000020539.html>, last visited 30 April 2020.

and 100 Bq/kg in Japan's standard limits.[117]

In light of the above, even if a Member adopts more stringent levels of radionuclides activity concentrations in foods than the GLs (e.g. Japan's standard limits), this mere fact does not allow WTO adjudicators to conclude that this Member fails to base its measure on the GLs as international standards, as long as its ALOP is the same as the one in the GLs.[118] It is also worth noting that levels of radionuclides contained in imported foods above the GLs cannot be justified under Article 3.3 of the SPS Agreement,[119] as this provision only covers a situation where Members take SPS measures that result in a higher ALOP than would be achieved by the international standards.

3.2.2 Recourse to Import Ban When the GLs Are Exceeded

Article 3.1 of the SPS Agreement requires Members to base their SPS measures on the international standards. Thus, some might consider that Members imposing import bans on food contaminated with radionuclides at a lower level than the GLs fail to base their measures on the GSCTFF, which clearly requires such food to be treated as safe for human consumption. Given the ambiguity of the concept of GL and its contrast with the "maximum levels" (MLs), however, such SPS measures might not always be inconsistent with Article 3.1 of the SPS Agreement.

3.2.2.1 *Korea - Radionuclides*

In *Korea – Radionuclides*, Japan challenged the blanket import ban imposed by Korea in September 2013 on 28 fishery products from the 8 prefectures, including the *Fukushima* prefecture, regardless of the level of radionuclide activity concentration in food imported from these prefectures. At a glance, Korea's import ban appears to be inconsistent with the GSCTFF. However, Japan made no claims under Article 3.1 of the SPS Agreement regarding Korea's potential failure to base their measure on the international standards.

As explained before, it is recalled that national governments are given under the GSCTFF a wide range of discretion in the policies to be taken when radiation

[117] See also MAFF, *Post-accident Food Safety Management (September 2019)*, available at <https://www.meti.go.jp/english/earthquake/nuclear/decommissioning/pdf/20190912_maff.pdf>, last visited 30 April 2020.

[118] On the other hand, when it comes to residue standards in foods quantitatively expressed as maximum residue levels (MRLs), *Gruszczynski* considers that "it will be not possible to base a measure on an international standard without actually conforming to it." Gruszczynski (*SPS Agreement*) 96.

[119] Article 3.3 of the SPS Agreement reads that "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations…".

contamination levels in food exceed the GLs. In other words, the GSCTFF provides nothing about how government should treat food contaminated with radionuclides at a higher level than the GLs. It is noted in the GSCTFF that, when the GL are exceeded, "national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction."[120] It follows from this sentence that, once the GLs are exceeded in a lot, governments are entitled to stop imports of food in the future lots *even if* contamination level of the food in these lots is below the GLs. In *Korea – Radionuclides*, if Japan had made a claim under Article 3.1 of the SPS Agreement, Korea would have argued that its blanket import ban on 28 fishery products from 8 prefectures were taken as a reaction to the detection of fishery products exceeding the GLs after the *Fukushima* accident.

To this extent, Article 3.1 of the SPS Agreement is silent on the measures to be taken by Members with respect to such contaminated food. In this regard, the panel in *Korea – Radionuclides* rightly held, in analyzing Korea's defense on Article 5.7 of the SPS Agreement, that "[t]he Codex Standard does not call for the elimination of all trade or for the imposition of import bans, but rather for the establishment of intervention levels below which food can be safely traded."[121] To this extent, the GLs play only a limited role in regulating international trade on food accidentally contaminated with radionuclides.

3.2.2.2 Consequences of Detecting Food Exceeding MLs

The Codex Alimentarius Commission has set the maximum acceptable limits of contaminants in food so as not to cause health effects. Such limits are called MLs for food additives and contaminants, and "maximum residue limits" (MRLs) for pesticide and veterinary drugs. Both are set in a way that no adverse effects are caused to the human body from the ingestion of food contaminated at a lower level than MLs for a lifetime. Therefore, the Commission explains that "foods derived from commodities that comply with the respective Codex MRLs are intended to be toxicologically acceptable."[122]

The Codex Committee on Contaminants in Food (CCCF),[123] which is responsible for recommending risk management proposals, sets MLs for contaminants in food

[120] Codex Alimentarius Commission (CODEX STAN 193-1995) at 57.
[121] Panel Report, *Korea – Import Bans, and Testing and Certification Requirements for Radionuclides*, WT/DS495/R and Add.1, adopted 26 April 2019, as modified by Appellate Body Report WT/DS495/AB/R, para. 7.100.
[122] Codex Alimentarius Commission, Recommended Methods of Sampling for the Determination of Pesticide residues for Compliance with MRLs, CAC/GL 33-1999 (1999), para. 2.1.
[123] The CCFAC was split into the CCCF and the Codex Committee on Food Additives in 2006. Codex Alimentarius Commission (29th Session), paras. 26-29.

and feed commodities on the basis of the "provisional tolerable weekly intake" (PTWI)[124] determined by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which is responsible for performing the risk assessments.[125] The CCCF can endorse only MLs that are based on JECFA's risk assessments, while the GLs for radionuclides in food are based not on JECFA's risk assessments, but ICRP's recommendations. Therefore, MLs refer to the maximum concentration of that substance "to be legally permitted in that commodity".[126]

In light of the above, relatively simple conclusions when using MLs could be drawn as follows. National governments would be obliged under the GSCTFF to place food contaminated at a lower level than MLs in the market, and not to place food contaminated at a higher level than MLs in the market. Since it is provided that "MLs should apply to representative samples per lot",[127] import bans on food in excess of MLs would be implemented per lot. Thus, even if food exceeding MLs is detected in the current lot, the import of the next lot must be approved if such food is not detected. To this extent, a wide range of policy discretion granted to governments when GLs are exceeded would no longer be available to the governments when MLs are exceeded.

Therefore, unlike GLs, WTO Members maintaining import bans on food that was once found to be contaminated at a higher level than MLs always fail to base their measures on the GSCTFF pursuant to Article 3.1 of the SPS Agreement.

3.2.2.3 Rejection to Convert GLs into MLs for Radionuclides

As of 2019, the GLs are applied to radionuclides and other two contaminants in the GSCTFF. However, it is only radionuclides for which no risk assessment has been performed by the JECFA. In this regard, the Commission indicates its preference to a form of MLs for radionuclides by noting that "the present existing or proposed guideline levels [for radionuclides] shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by JECFA, if appropriate."[128] The Commission's preference for MLs stems from the fact that, as noted above, the government's discretion over the treatment of imported food exceeding ML is limited, contrary to GLs. As of 2011, however, there had been no request from the CCCF for the JECFA to conduct a risk assessment and convert GLs into MLs based it.[129]

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[124] It refers to permissible human weekly exposure to food contaminants. Codex Alimentarius Commission (CODEX STAN 193-1995) at 12.
[125] As to the relationship between CCCF and JEFCA, see Codex Alimentarius Commission, *Procedural Manual of the Codex Alimentarius Commission*, 26th edn (2018) at 139-144.
[126] Codex Alimentarius Commission (CODEX STAN 193-1995) at 3.
[127] Codex Alimentarius Commission (CODEX STAN 193-1995) at 7.
[128] Codex Alimentarius Commission (CODEX STAN 193-1995) fn. 1.
[129] Codex Alimentarius Commission (Fact Sheet) at 3.

It is noted that an attempt to convert GLs into MLs for radionuclides was rejected after the *Fukushima* accident. In March 2012, one year after the accident, it was reported by the WHO that "several countries struggled with the interpretation and application of the guideline levels for radionuclides in food".[130] Then, the CCCF agreed to establish an electronic Working Group led by the Netherlands and co-chaired by Japan to start new work reviewing the current GLs for radionuclides in food.[131] In July 2012, the Commission approved this new work.[132] The proposed new work focused on, among others, "the development of a clear guidance for national governments on the interpretation and application of the guideline levels, which may include recommendations for foods exceeding Guideline Levels".[133] It is important to note that the Working Group clearly intended to address a range of discretion widely given to government especially over the treatment of contaminated food exceeding the GLs.

In April 2013, the Working Group reached a conclusion that "there is no need for changing the GLs to MLs", and also confirmed that "GLs are more flexible".[134] As a result, it recommended to the CCCF "not to change the current GLs of radionuclides in foods into MLs", and then "to discontinue the work on the revision of GLs for radionuclides in the GSCTFF".[135] Then, based on the conclusions and recommendations by the Working Group, the CCCF also agreed not to change the current GLs to MLs for radionuclide.[136]

3.2.3 Summary

In sum, WTO Members are given, under Article 3.1 of the SPS Agreement, a wide range of discretion in regulating imports of food contaminated with radionuclides, mainly due to the adoption of GLs in the GSCTFF. First, a Member may adopt more stringent levels of radionuclide activity concentrations for imported food than the GLs without failing to base its measure on the GSCTFF under Article 3.1 of the SPS Agreement, so long as its ALOP is the same as one assumed by the 2006 GLs (i.e. around 1mSv/year). Second, a Member is not necessarily prevented under the GSCTFF from resorting to import ban on food contaminated with radionuclides even below the GLs.

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[130] Codex Alimentarius Commission, Report of the 6th Session of the Codex Committee on Contaminants in Foods, REP 12/CF (2012), at 50.
[131] Codex Alimentarius Commission (6th Session of the CCCF), para. 169.
[132] Codex Alimentarius Commission, Report of 35th Session of Codex Alimentarius Commission, REP12/CAC (2012), para. 145.
[133] Codex Alimentarius Commission, Proposals for the Elaboration of New Standards and Related Texts and for the Discontinuation of Work, CX/CAC 12/35/9 (2012), Annex 2.
[134] Codex Alimentarius Commission, Proposed Draft Revision of Guideline Levels for Radionuclides in Foods, CX/CF 13/7/6 (2013), para. 19.
[135] Codex Alimentarius Commission (Proposed Draft 2013), para. 27.
[136] Codex Alimentarius Commission (7th Session of the CCCF), para. 51.

Regulating imports of foods contaminated with radionuclides would be rather smoother if a form of MLs were taken. After the *Fukushima* incident, there was a chance to convert the current GLs into MLs for radionuclides in food. However, this attempt, which was led by the Netherlands and Japan, was declined, mainly due to concerns by countries for losing flexibility currently ensured under the GSCTFF in regulating imports of contaminated food.

In 2015, Japan launched the WTO dispute settlement procedure over a series of Korea's measures imposed on Japanese fishery products, but it did not claim under Article 3.1 of the SPS Agreement that Korea's blanket import ban failed to be based on the GLs in the GSCTFF. This is probably because of a discretion widely granted under the GSCTFF to Korea regarding the treatment of contaminated food exceeding the GLs.

Conclusion

An attempt was trigged by the protectionist trend taken by several countries after the *Chernobyl* accident in April 1986 to regulate international trade on foods contaminated with radionuclides following nuclear incidents. As a result, in 1989, the Codex Alimentarius Commission adopted the GLs for radionuclides in food to be traded internationally in emergency situations. In 2006, the GLs were further revised with a specific focus on addressing prolonged exposure situations. There were several international organizations involved in the process of establishing and developing the GLs. Among others, the ICRP played an important role of providing radiological criteria, or foundations, for the Codex Alimentarius Commission in deriving the GLs.

While the GLs for radionuclides in food has been established and developed, a wide range of discretion given to national governments in the policies to be taken, especially when the GLs are exceeded, has been consistently ensured in both the 1989 GLs and the GSCTFF. At least to this extent, the discipline of international trade on foods contaminated with radionuclides has not changed significantly since the *Chernobyl* accident. This proposition might be supported by the protectionist reactions various countries took against Japanese agricultural products right after the *Fukushima* incident in March 2011.

Thus, in the WTO, Article 3.1 of the SPS Agreement should not be the center of dispute over import restrictions on foods contaminated with radionuclides. This was the case in *Korea – Radionuclides* where Japan made no claim, under this provision, regarding Korea's blanket import bans. Rather, the query should be whether import bans or restrictions taken by a Member on food contaminated with radionuclides following a nuclear accident are more trade-restrictive than

required to achieve its ALOP in Article 5.6 of the SPS Agreement.

Chapter 4

Disciplines on International Trade in Foodstuffs in the WTO Agreement: Risk Assessment

Introduction

As explained in the introduction part of this dissertation, in 1989, the Codex adopted the Guideline Levels (GLs) relating to the levels of activity concentration for radionuclides in food to be traded internationally after a nuclear accident on the basis of the ICRP's recommendations. Thus, if radionuclide levels in food are below the GLs, it is noted that "the food should be considered as safe for human consumption."[1] It follows that any trade restrictions applied to food below the GL are likely to be inconsistent with Codex standards.

If and when the GLs are exceeded, it is left to the discretion of the importing country to decide whether or not to allow such food to be distributed on the domestic market. The relevant part of Codex standards reads as follows.

> When the Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction.[2]

In other words, Codex standards have no specific discipline for such a situation. Thus, once a sample food exceeding the GL is detected, the importing country is not necessarily prevented at least in Codex standards from prohibiting future imports of this food, let alone the lot containing the food samples exceeding the GLs, from the country where the accident occurred.

However, the fact that there is no clear discipline in Codex standards for the detection of food exceeding the GL does not mean that importing WTO Members have unrestricted discretion in the treatment of such foods. Rather, trade restrictions adopted by these Members as a response to such a situation still need to be consistent with the SPS Agreement.

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[1] See Chapter 3.1.1.2.

[2] Codex Alimentarius Commission, *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (1995) 57.

This chapter firstly attempts to categorize the trade measures that would normally be taken against food imports from the country where the nuclear accident occurred (4.1). Secondly, as is well known, a dispute between Japan and Korea occurred at the WTO over the consistency of the SPS Agreement with Korea's measures to restrict imports of Japanese fishery products and so on after the *Fukushima* accident (i.e. *Korea - Radionuclide*). In this section, the specific content and characteristics of Korea's measures challenged by Japan in the WTO dispute settlement procedures will be briefly reviewed (4.2). And, after confirming that the SPS Agreement widely applies to trade restrictions imposed on food imports from the country with the nuclear accident (4.3), it will be examined in the last two sections how such trade restrictions are disciplined in the SPS Agreement, in which Members are generally encouraged to adopt trade measures regarding food-related risks in accordance with a "risk analysis", including risk assessment (4.4).

4.1 Typology of Import Restrictions against Food Products from the Country Where the Accident Occurred

Trade restrictions imposed on the import of food products from the country where a nuclear accident occurred may take various forms. Nevertheless, import restrictions against such food products can be typified according to their characteristics. For example, after the *Fukushima* accident, it is said that around 54 countries and regions in the world immediately adopted a variety of import restrictions against food products from Japan, especially ones produced in the *Tohoku* area, which is composed of northeastern prefectures including *Fukushima* prefecture.[3]

The Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan typifies the import restrictions imposed on Japanese food products after the accident as follows.[4]

(i) Import ban
(ii) Import ban in accordance with the restriction of distribution in Japan
(iii) Certificate of pre-export testing of radionuclides
(iv) Certificate of production place
(v) Reinforced inspection (lot by lot, or sampling inspection at the border of

[3] Import restrictions were mainly applied to food products, such as rice, vegetables, fruits, tea, medicinal plants, dairy products, meats (beef, pork and poultry), fishery products and processed foods.
[4] See MAFF, *Lifting of the Import Restrictions on Japanese Foods following the Accident of Fukushima Daiichi Nuclear Power Plant (54 Countries and Regions) (March 2020)*, available at <https://www.maff.go.jp/j/export/e_info/pdf/thrm_en.pdf>, last visited on 7 April 2020.

importing country and region)

As to the restriction (i), a number of countries imposed the import ban on agricultural products from all over Japan as of May 2011, two months after the accident, although the area where the ground was contaminated by the spread of radioactive materials from the nuclear power plant was limited to parts of the *Tohoku* region.[5] In the context of *Korea - Radionuclides*, the import ban imposed by Korea on all fishery products from 8 prefectures in the *Tohoku* region, which is termed "blanket import ban" in the dispute, falls under the category of restriction (1).[6]

As to the restriction (ii), a few countries, mainly Korea and the US, took the import ban on certain Japanese food products that were also restricted in Japan from being placed on the market. For example, in the context of *Korea – Radionuclides*, Korea imposed the import ban on some food products from Japan as soon as Japan decided to restrict the placement of these food products on the market. In other words, such import ban is designed to "mirror" the distribution restrictions within the country where the accident occurred. Nevertheless, Japan challenged this Korea's measure in the WTO on the ground that Korea had maintained this measure even after Japan removed the distribution restrictions.[7]

As to the restriction (iii), importing countries might request food products imported from the country where the accident occurred to carry a certificate attesting that the concentration level of certain radionuclides (e.g. caesium) in food products are within their tolerance levels. In other words, the exporting country is required to carry out such testing at the pre-export stage within the country. For example, as of May 2001, two months after the accident, some countries simply banned the import of fishery products from all over Japan, while others only imposed the pre-export certification requirements on food products from either certain prefectures or all 47 prefectures.[8]

In the context of *Korea – Radionuclides*, the pre-export certification requirements imposed by Korea on food products from certain prefectures in Japan fall under this category.[9] Nevertheless, Japan did not challenge this certification requirement in the WTO.

[5] However, as of February 2020, most of the import bans against food products have been lifted.
[6] See Chapter 4.2.2.
[7] See Chapter 4.2.1.
[8] However, this does not necessarily mean that these countries only required the pre-expert certificate as a condition of importation. In addition, they often required the at-the-border testing for radionuclides, as will be described below.
[9] See Chapter 4.2.3.1.

As to the restriction (iv), importing countries might request food products imported from the country where the accident occurred to accompany a certificate of origin, which refers to the location where the products were cultivated and harvested (in case of agricultural products), or the products were harvested, processed and/or packaged (in case of fishery products). For example, in the context of *Korea – Radionuclides*, Korea required all food products imported from Japan to accompany a certificate of origin. However, Japan did not challenge the certificate of origin requirement in the WTO.[10]

As to the restriction (v), importing countries might strengthen the testing requirements at the border for food products imported from the country where the accident occurred. For example, they might require samples from "all consignments" of such food products to be tested for certain radionuclides, while food products from other countries are subject to the sample testing from "randomly selected consignments". Moreover, as was the case in *Korea – Radionuclides*,[11] if the concentration level of major radionuclides in food products is found to exceed the certain level at the border, importing countries might further require additional testing for other radionuclides in the products as a condition for importation.

4.2 Import Restrictions at Issue in *Korea - Radionuclides*

Since the *Fukushima* accident caused by tsunami as a result of the earthquake on 11 March 2011, Korea had imposed various types of trade restrictions on food products from Japan. On 21 May 2015, Japan requested consultation with Korea under the DSU. Although consultations were held on 24 and 25 June 2015, they failed to resolve the dispute. On 20 August 2015, Japan requested the establishment of a panel, and at its meeting on 28 September 2015, the DSB established a panel pursuant to a negative consensus under the DSU.

In *Korea – Radionuclides*, Japan did not challenge all of the measures taken by Korea in response to the *Fukushima* accident.[12] Instead, Korea's measures that Japan challenged in this dispute can be broadly divided into import bans and additional testing requirements.

(i) **Product-specific import bans** imposed between 2 May and 9 November 2012 with respect to Alaska Pollock from *Fukushima* prefecture and Pacific cod from 5 prefectures

[10] Panel Report, *Korea – Radionuclides*, paras. 2.88-2.89.
[11] See Chapter 4.2.3.2.
[12] Panel Report, *Korea – Radionuclides*, para. 2.112.

(ii) **Blanket import bans** imposed in September 2013 on 28 fishery products from 8 prefectures, which fully covers the coverage of the product-specific import bans

(iii) **Additional testing requirements** imposed in May 2011 for non-fishery products[13] (except livestock products) from all 47 prefectures

(iv) **Additional testing requirements** imposed in September 2013 on all fishery and livestock products from all 47 prefectures

It is important to focus on what Japan did "not" challenge about Korea's measures taken in response to the *Fukushima* accident. Japan expressed no objection to Korea's testing at the border whether or not the activity concentration levels of caesium and iodine in food products from Japan are below the tolerance levels established by Korea (e.g. 100 Bq/kg for general foods). Put it differently, Japan was not concerned about Korea's policy that, if imported food products were to exceed Korea's tolerance levels, they would not be allowed to be placed on Korean market.

Moreover, samples from "every consignment" of all food products from Japan were subject to the at-the-border testing, while it was limited to samples from "randomly selected consignments" for food products from countries other than Japan. Despite this different treatment against Japanese food products, however, Japan did not challenge this aspect of Korea's at-the-border testing requirements in the WTO.

4.2.1 Product-Specific Import Bans

For importing countries, it might be logical to ban the import of food products from the country where the distribution of these food products is also restricted due to radioactive contamination caused by the accident. As will be shown below, after the *Fukushima* nuclear accident, Korea adopted the import bans on specific food products in response to the distribution restrictions of the same food products implemented in Japan. In this regard, the Panel in *Korea – Radionuclides* rightly notes that "Korea adopted the product-specific import bans…to mirror these internal restrictions imposed by Japan".[14]

4.2.1.1 Distribution Restrictions of Food Products in Japan

In the following, an overview will be presented of how testing for radioactive

[13] It is noted that, in *Korea – Radionuclides*, the term "non-fishery products" is defined to cover "agro-forestry products, processed foods, food additives and health functional foods". Panel Report, *Korea – Radionuclides*, para. 2.87.
[14] Panel Report, *Korea – Radionuclides*, para. 7.86.

materials contained in food products is carried out in Japan after the *Fukushima* accident. First of all, it is important to note that not all food products distributed in Japan are being tested as to whether they are below the "standard limits" before being placed on the market. Otherwise, the cost of testing would be enormous and the food would not be promptly distributed within the country. Instead, Japan has focused its testing or monitoring on specific products and regions from which high levels of caesium are likely to be detected.

In 4 April 2011, almost one month after the accident, the Nuclear Emergency Response Headquarters[15] issued the first edition of guidelines on how to test radioactive materials in food products, and what to do if they are found to exceed the standard limits.[16] According to the guidelines, designated local governments, which are 17 prefectures as of today,[17] are required to develop their inspection plans and implement them with respect to the designated food products. Moreover, as noted below, if the Prime Minister issues an instruction to restrict the distribution of food products that exceed the standard limits, it is up to the relevant prefectures where such food products are detected that will enforce the restriction, not the Japanese government.

In order for the designated prefectures to implement inspections, they need a benchmark to determine whether or not the amount of radioactive materials in food products are acceptable. On 17 March 2011, six days after the accident, the Ministry of Health, Labor and Welfare (MHLW) urgently set provisional limits for radionuclides to be contained in food products without conducting a risk assessment.[18] In March 1998, the Nuclear Safety Commission had already set "indices" for acceptable amount of caesium to be present in food and drink for consumption,[19] but they only meant to be used as "a guideline for making

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[15] It was established under the Act on Special Measures for Nuclear Emergency Preparedness (Act No. 156 of 1999) in order to handle the nuclear emergency situation caused by the Fukushima accident. The English translation of the Act is available at <http://www.cas.go.jp/jp/seisaku/hourei/data/ASMCNEP.pdf>, last visited on 9 April 2020.

[16] Nuclear Emergency Response Headquarters, *Concepts of Inspection Planning and Establishment and Cancellation of Items and Areas to which Restriction of Distribution and/or Consumption of Foods Concerned Applies (4 April 2011)*, available at <https://www.mhlw.go.jp/stf/houdou/2r98520000017txn-img/2r98520000017ze4.pdf>, last visited on 10 April 2020 (in Japanese).

[17] As of 4 April 2011, the designated prefectures were Fukushima, Ibaraki, Tochigi, Gunma, Miyagi, Yamagata, Niigata, Nagano, Saitama, Chiba and Tokyo. As of 23 March 2020, Aomori, Iwate, Akita, Kanagawa, Yamanashi and Shizuoka are included.

[18] All vegetables, grains, meat, eggs and fish were set at 500 Bq/kg, while milk and dairy products were set at 200 Bq/kg. Incidentally, 137,034 inspections were conducted before the new standard came into effect on April 1, 2012, of which 1204 were found to be in excess of the provisional standard.

[19] Nuclear Safety Commission of Japan, *Indices for Food and Beverage Intake Restriction (March 1998)*, available at <https://www.mhlw.go.jp/stf/shingi/2r98520000018iyb-att/2r98520000018k4m.pdf>, last visited on 12 April 2020.

decisions on the introduction of consumption restrictions as a protective measure in an emergency situation". Then, the MHLW directly used these indices as provisional limits under Article 6(2) of the Food Sanitation Act.[20] It meant that, unlike the indices that were interpreted only as action levels, food products, the concentration level of which exceed the provisional limits, are prohibited from being placed on the market.

Thus, in Japan, although radioactive standards were set for imported food products after the *Chernobyl* accident in 1986,[21] there had been no standard limits, above which food products cannot be distributed to the market, until the *Fukushima* accident.

On 1 April 2012, the MHLW newly enforced the "standard limits" for caesium to be contained in food products, which are set 100 Bq/kg for general foods, and 50 Bq/kg for infant foods and milk. These new standard limits were set under Article 11.1 of the Food Sanitation Act,[22] and violators are subject to the penalties set forth under the Act. These limits are calculated based on the assessment of the adverse effect of radionuclides in food on human health by the Food Safety Commission of Japan (FSCJ).[23]

If caesium exceeding the standard limits is detected in food as a result of the inspections, such food will be firstly collected and disposed. Furthermore, if it is determined that the production area of the food is extensive, the Prime Minister is entitled to designate the area, in principle, by prefecture, and give instructions to ensure that the food will not be distributed outside the prefecture.

4.2.1.2 Korea's Import Ban on Certain Fishery Products

After the *Fukushima* nuclear accident, Korea imposed a number of

[20] Act No. 233 of December 24, 1947. Article 6.2 reads that "[t]he following food and additives shall not be sold…, or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of marketing: (ii) Articles which contain or are covered with toxic or harmful substances or are suspected to contain or be covered with such substances…".

[21] On 31 October 1986, the Ministry of Health and Welfare, the predecessor to the MHLW, set out a provisional limit of 370 Bq/kg for the total of caesium-134 and caesium-137, applying to certain imported food products from certain European countries affected by the *Chernobyl* accident. After the new standard limits took into force in April 2012, however, the standard limits (i.e. 100 Bq/kg for general foods) also apply to imported food products.

[22] Relevant part of Article 11.1 reads that "[f]rom the viewpoint of public health, the Minister of Health, Labour and Welfare…may establish standards for the ingredients of food or additives to be served for the purpose of marketing". Thus, in legal terms, the new standards limits correspond to "standards for the ingredients of food".

[23] On 27 October 2011, the FSCJ issued the conclusion of the risk assessment that more than "around 100 mSv" of the extra cumulative effective doses during lifetime could incr ease the risk of adverse effect on human health. FSCJ, *Abstract: Risk Assessment Report on Radioactive Nuclides in Foods (October 2011)*, available at <https://www.fsc.go.jp/english/emerg/abstract_risk_assessment_report.pdf>, last visited on 10 April 2020.

product-specific import bans on non-fishery products from Japan. The first import ban was adopted in March 2011 when the concentration level of radionuclides in spinach was found to exceed 500 Bq/kg, which was Japan's provisional caesium level for general food at that time.[24] When the panel in *Korea – Radionuclides* was established on 28 September 2015, Korea had maintained its product-specific import bans on 27 non-fishery products from 13 different prefectures.

In addition, between 20 April 2011 and 8 August 2013, Korea also imposed product-specific import bans on 50 fishery products from 8 prefectures. These import bans were in place on the same day that the restrictions on distribution of fishery products at issue were adopted in Japan.[25] Contrary to import bans against non-fishery product, Japan challenged Korea's import bans imposed on fishery products, especially two fishery products; that is (i) Alaska pollock from *Fukushima*, and (ii) Pacific cod from five prefectures, including *Fukushima*.[26]

Thus, since the import ban imposed Korea was directed at fishery products whose distribution was already restricted within Japan, one might consider that Japan would not challenge such import bans in the WTO. However, while the restrictions on the distribution of these fishery products were progressively lifted in Japan until February 2015, Korea continued to take its import ban on these fishery products. Thus, in *Kora – Radionuclides*, Japan challenged these Korea's import bans, specifically termed "2012 product-specific import bans" in this dispute, in the WTO.[27]

As will be explained in the next section, in September 2013, Korea adopted the import ban on 28 fishery products from 8 prefectures. Korea's product-specific import bans on Alaska pollock from *Fukushima* and Pacific cod from 5 prefectures were also covered by this wide import ban.[28]

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[24] On 21 March 2011, the Japanese Prime Minister ordered the Governors of the affected four prefectures, including *Fukushima*, to restrict the distribution of spinach into the mar ket. It was spinach produced in those prefectures that was firstly subject to the distributi on restrictions after the accident for exceeding the radiation level that was effective at th at time. Nuclear Emergency Response Headquarters, *Instruction (21 March 2011)*, availab le at <https://www.mhlw.go.jp/stf/houdou/2r98520000015p8a-img/2r98520000015p9r.pdf >, last visited on 4 April 2020 (in Japanese).

[25] For example, on 22 June 2012, the Japanese Prime Minister ordered the Governors of Fukushima and Miyagi prefectures to stop the distribution of 36 fishery products, includin g Alaska pollock and Pacific cod into the market. Nuclear emergency Response Headquart ers, *Instruction (Appendix 4) (22 June 2012)*, available at <https://www.mhlw.go.jp/stf/h oudou/2r9852000002dn49-att/2r9852000002dnbl.pdf>, last visited on 4 April 2020 (in Ja panese). On the same day, Korea adopted its product-specific import bans against these f ishery products from the corresponding prefectures. Panel Report, *Korea – Radionuclides*, para. 2.106.

[26] Panel Report, *Korea – Radionuclides*, para. 2.105.

[27] Panel Report, *Korea – Radionuclides*, para. 2.114.

[28] Panel Report, *Korea – Radionuclides*, para. 2.110.

4.2.2 Blanket Import Bans

As a result of the *Fukushima* nuclear accident, radioactive materials entered into the marine environment directly and indirectly.[29] However, the distribution of radioactive materials to the ocean did not occur only in the immediate aftermath of the accident. According to the Panel in *Korea – Radionuclides*, "more than 70 release events of varying magnitudes have occurred at multiple areas of the power plant with differing possible routes to the ocean between April 2011 and September 2015".[30] This was largely caused by contaminated groundwater on the FDNPS cite released into the ocean.[31]

On 9 September 2013, "soon after news report that there had been continuing releases of contaminated water into the ocean",[32] Korea adopted an import ban on all fishery products from 8 prefectures.[33] This is referred to as the "blanket import ban" in *Korea – Radionuclides*. In this dispute, Japan challenged Korea's blanket import ban only with respect to 28 fishery products,[34] including Alaska Pollock and Pacific cod, both of which had been subject to the product-specific import bans.[35]

4.2.3 Testing and Certification Requirements

Aside from import bans, Korea applied testing and certification requirement. They comprise of (i) pre-market testing requirements (i.e. pre-export from Japan, at

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[29] See UNSCEAR, *Sources, Effects and Risks of Ionizing Radiation: UNSCEAR 2013 Report to the General Assembly with Scientific Annexes, Volume 1 (Scientific Annex A)* (United Nations Publication, New York: 2014), paras. 47-51, available at <https://www.unscear.org/docs/reports/2013/13-85418_Report_2013_Annex_A.pdf>, last visited 19 April 2020. As direct release, highly-contaminated water from a trench of the plant, which is an underground tunnel housing pipes and cables, was leaked into the ocean. Weakly-contaminated water in storage tanks was also discharged into the ocean. As indirect release, radioactive materials were also distributed in the oceans either (i) by falling into the sea on the wind (i.e. radioactive fallout), or (ii) by falling on land and being transported to the sea via rivers and groundwater.

[30] Panel Report, *Korea – Radionuclides*, para. 2.58.

[31] UNSCEAR (*2013 Report*) para. 48.

[32] Panel Report, *Korea – Radionuclides*, para. 2.100.

[33] They included Aomori, Chiba, Fukushima, Gunma, Ibaraki, Iwate, Miyagi and Tochigi prefecture.

[34] In addition to Alaska Pollock and Pacific cod, they included Abalone, Albacore, Alfonsino, Anchovy, Bigeye tuna, Blue shark, Bluefin tuna, Chestnut octopus, Chub mackerel, Chum salmon, Common octopus, Common sea squirt, Giant Pacific octopus, Japanese amberjack, Japanese flying squid, Japanese jack mackerel, Japanese sardine, Pacific oyster, Pacific saury, Salmon shark, Scallop, Skipjack tuna, Southern mackerel, Striped marlin, Swordfish, Yellowfin tuna. Panel Report, *Korea – Radionuclides*, para. 2.107 (Table 7).

[35] Of these 8 prefectures, Gunma and Tochigi are inland prefectures. Thus, there is no harvest of these 28 fishery products in these two prefectures. According to Korea's blanket import ban, however, the importation would be also banned for fishery products processed or packed in these two provinces, irrespective of place of harvest. Panel Report, *Korea – Radionuclides*, para. 2.109.

the border, production stage for domestic products) and (ii) point-of-sale testing requirements. If the concentration level of caesium or iodine in food products from Japan exceeds 100 Bq/kg, shipment of such products is rejected. Moreover, if it is beyond 0.5 Bq/kg, those products must go the additional testing for at least strontium and plutonium. On the other hand, the testing requirements and the additional testing requirement are applied to Korean food products and food products from countries other than Japan in a way different from Japanese food products (except point-of-sale testing).

4.2.3.1 Pre-export Certification Requirements

The first measure introduced by Korea immediately after the *Fukushima* accident was the testing of each consignment of food products from Japan for caesium and iodine at the border.[36]

In addition, on 1 May 2011, about two months after the accident, Korea introduced requirements for a pre-export certificate of caesium and iodine on certain non-fishery products (except livestock products) from 13 prefectures where radioactive materials were detected in foodstuffs.[37] Later, between 4 May 2011 and 9 September 2013, Korea also applied the same certification requirements to all shipments of fishery and livestock products from 16 prefectures.[38] As noted in 4.2.2, since Korea imposed an import ban on fishery products from 8 of these 16 prefectures in September 2013 (i.e. blanket import ban), the pre-export certification requirement became relevant only to other 8 prefectures that were not subject to the import ban.[39]

This measure required the import of food products to attach a document certifying that the products had been tested prior to export and that the concentration levels of caesium and iodine were below the "tolerance limits",[40] which was 100 Bq/kg for general foods, established by Korea.[41]

The pre-export certificate was not required for food products imported from countries other than Japan. Nevertheless, Japan did not challenge the pre-export

[36] See Chapter 4.2.3.2.
[37] They were Chiba, Fukushima, Gunma, Miyagi, Ibaraki, Kanagawa, Nagano, Niigata, Saitama, Shizuoka, Tochigi, Tokyo and Yamagata. Panel Report, *Korea – Radionuclides*, para. 2.92.
[38] They were Aichi, Aomori, Chiba, Ehime, Fukushima, Gunma, Hokkaido, Ibaraki, Iwate, Kagoshima, Kanagawa, Kumamoto, Mie, Miyagi, Tochigi and Tokyo. Panel Report, *Korea – Radionuclides*, para. 2.93.
[39] Panel Report, *Korea – Radionuclides*, para. 7.43. Thus, fishery products from Aichi, Ehime, Hokkaido, Kagoshima, Kanagawa, Kumamoto, Mie and Tokyo were subject to not the blanket import ban but the pre-export certification requirement.
[40] The term "tolerance limits" used in *Korea – Radionuclides* means the activity concentration levels of radionuclides expressed in terms of Bq/kg. The term "maximum levels" is also used in this dispute interchangeably.
[41] Panel Report, *Korea – Radionuclides*, para. 2.91.

certificate requirements in the WTO dispute settlement procedures.[42]

4.2.3.2 At-the-border Testing Requirements

In March 2011, Korea introduced the requirements for samples from "every consignment" of food products from all 47 prefectures to be tested for caesium and iodine. On the other hand, only samples from "randomly selected consignments" of certain domestic products and certain products from other countries were subject to this testing requirement. In spite of this different treatment of Japanese food products, however, it is worth noting Japan did not challenge at-the-border testing requirements in the WTO. Rather, Japan's concern was on the "additional testing requirement" applying only to Japanese food products.

4.2.3.2.1 Testing for Caesium and Iodine

On 14 March 2011, as early as three days after the *Fukushima* accident, Korea began to test at the border for caesium and iodine in samples from "every consignment" of agro-forestry products and livestock products from all 47 prefectures, as well as of fishery products from 4 prefectures where radioactive materials were detected at that time.[43] By the end of March 2011, however, Korea extended the testing requirement to fishery products from all 47 prefectures.[44] If the concentration levels of caesium or iodine in samples exceeded 100 Bq/kg, shipment was rejected.[45]

Korea also imposed the at-the-border testing requirements for caesium and iodine on food products from countries other than Japan. Contrary to food products from Japan, only samples from "randomly selected consignments" were subject to this testing requirement.[46] If the concentration level of caesium or iodine was found to exceed 100 Bq/kg, shipment was rejected.

Moreover, Korea also imposed pre-market testing for caesium and iodine on domestic food products that were "randomly selected" at the stage of production

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[42] Panel Report, *Korea – Radionuclides*, para. 2.94. However, for example, *Ehime*, *Kumamoto* and *Kagoshima* prefectures are very far away from *Fukushima*, where the nuclear accident occurred, and the impact of the accident has hardly been confirmed. In addition, although there are other fishing ports closer to the coast of *Fukushima*, no pre-export certificate requirement is imposed on fishery products from there. Therefore, the reasonableness of this requirement remains in doubt, but as noted above, Japan did not challenge its consistency with the SPS Agreement. The reason is unclear.

[43] They were Fukushima, Aomori, Miyagi and Iwate.

[44] Panel Report, *Korea – Radionuclides*, para. 2.96.

[45] Although there was a dispute between Japan and Korea over the fact-finding, according to the Panel in *Korea – Radionuclides*, all fishery products from Japan that had already been tested for caesium and iodine at the pre-export stage still had to be tested again at the border for caesium and iodine. Panel Report, *Korea – Radionuclides*, paras. 7.46-7.47.

[46] Panel Report, *Korea – Radionuclides*, paras. 2.96, 7.45.

(e.g. factory, farm or distribution centre). The products to be tested were any of the most frequently consumed products in Korea.[47] Like imports, food product cannot be placed on the Korean market if its concentration level of caesium or iodine is beyond 100 Bq/kg.

In spite of such different treatment of food products from Japan, Japan did not challenge Korea's testing requirement for caesium and iodine conducted at the border in the WTO dispute settlement.[48]

4.2.3.2.2 Testing for Additional Radionuclides

It is recalled that all consignments of food products from Japan were subject to the at-the-border caesium and iodine testing requirement. Moreover, on 1 May 2011, Korea imposed the additional testing requirements on non-fishery products (except livestock products) from all 47 prefectures. On 9 September 2013, two and half years after the accident, due to news reports that water contaminated with radioactive materials is continuously leaking into the ocean from facilities at the Fukushima Daiichi Nuclear Power Plant (i.e. FDNPP), Korea further extended the additional testing requirements to fishery and livestock products from all 47 prefectures.[49]

While there was a wide range of disagreement between the parties about the facts as to how the additional testing operates,[50] the Panel in *Korea – Radionuclides* noted as follows. Firstly, if the concentration level of caesium or iodine was found to be above 0.5 Bq/kg (and less than 100 Bq/kg[51]) as a result of the at-the-border testing, it would trigger the additional testing.[52] Secondly, the testing for additional radionuclides was supposed to take place in Korea. Contrary to Japan's contention, even if the additional testing is triggered as a result of at-the-border testing, food products at issue do not have to be shipped back to Japan for conducting the testing for additional nuclides.[53] Thirdly, although the additional testing was normally conducted for "strontium and plutonium", the authorities were legally allowed to require further testing for "all the Codex radionuclides".[54] However, it was not specified anywhere "under what conditions the import authorities [in Korea] would make such a demand" for testing radionuclides other

[47] Panel Report, *Korea – Radionuclides*, paras. 7.41-7.42.
[48] Panel Report, *Korea – Radionuclides*, paras. 2.97, 7.47.
[49] Panel Report, *Korea – Radionuclides*, para. 2.100.
[50] Panel Report, *Korea – Radionuclides*, para. 2.102.
[51] As noted before, if it is above 100 Bq/kg, shipment is rejected at the border.
[52] Panel Report, *Korea – Radionuclides*, paras. 7.55, 7.65(b)(iii).
[53] Panel Report, *Korea – Radionuclides*, para. 7.64.
[54] Panel Report, *Korea – Radionuclides*, paras. 7.59, 7.65(e). It is recalled that the Codex GLs revised in 2006 cover 20 kinds of radionuclides. See Chapter 3.1.2.2.

than strontium and plutonium.[55]

On the other hand, the Panel found that there was no evidence that the additional testing was applied to domestic food products at the production stage.[56] In addition, the additional testing requirements were not imposed on food products from countries other than Japan at the border. In other words, even if the concentration level of caesium or iodine was found to exceed 0.5 Bq/kg in food products from other countries as a result of the at-the-border testing, they did not have to undergo the additional testing.

It is also worth noting that even in Japan, where the nuclear accident occurred, there are no standard limits for strontium and plutonium in food products, and thus they have not been tested. This is so, because it takes long time to measure the concentration level of radionuclides other than caesium in food. In other words, the standard limits set by the Ministry of Health, Labour and Welfare (MHLW) in 2012[57] are expressed in terms of caesium.[58]

Therefore, Japan challenged Korea's testing for additional radionuclides at the border applying only to food products from Japan in the WTO.[59]

4.2.3.3 Point-of-sale Testing Requirements

Korea's testing and certification requirements basically consisted of both (i) pre-market testing requirements (i.e. pre-export certificate, at-the-border testing) and (ii) point-of-sale testing requirements. Contrary to the pre-market testing, in Korea, products that were already in the market were randomly selected for caesium and iodine testing (i.e. point-of-sale testing). Such products could include domestic food products that had passed the at-the-production testing, as well as food products from Japan and other countries that had passed the at-the-border testing. To this extent, it is fair to say that the point-of-sale testing was the only requirement under which both domestic and imported food products were equally dealt with.

The range of products to be subject to the point-of-sale testing were any of the 150 most frequently consumed products in the Korean market. If the

[55] Panel Report, *Korea – Radionuclides*, para. 7.59.
[56] Panel Report, *Korea – Radionuclides*, para. 7.65(c).
[57] On 17 March 2011, only 6 days after the accident, MHLW urgently set the provisional limits for radionuclides in food products without conducting a risk assessment.
[58] However, it does not mean that the health effect from radionuclides other than cesium are ignored. Taking into account the proportion of radionuclides released by the accident and their half-lives, the Ministry of Health, Labour and Welfare (MHLW) set the standard limits in a way that the total dose from the ingestion of all radionuclides, including strontium and plutonium, would not exceed 1 mSv/year as long as such standards are met.
[59] Panel Report, *Korea – Radionuclides*, para. 2.102.

concentration level of caesium and iodine exceeded the specified amount (i.e. 0.5 Bq/kg), food products at issue must undergo the additional testing for at least strontium and plutonium.[60] The facts found by the Panel regarding the additional testing imposed at the border on food products from Japan also apply here.

In this regard, given that there was no evidence indicating that the additional testing was imposed on domestic food products at the border, as confirmed by the Panel, it means that Japanese food products were subject to the testing for caesium and iodine twice (i.e. at-the-border and point-of-sale testing), while Korean food products were sampled only once (i.e. point-of-sale testing).[61] However, Japan did not challenge the point-of-sale testing requirements in the WTO dispute settlement.

4.2.4 Summary

In *Korea - Radionuclides*, Japan's first challenge was Korea's import ban on 28 types of fishery products from certain 8 prefectures. Firstly, it is noted that Korea did not ban imports of Japanese fishery products immediately after the accident in March 2011. Between May and November 2012, Korea only banned imports of two products (i.e. Alaska pollock, Pacific cod) from certain prefectures in response to Japan's restriction on the distribution of these two products within these prefectures. Japan challenged these Korea's import bans on specific products on the ground that Korea had maintained these restrictions even after Japan removed the distribution restrictions of these products within Japan.

Secondly, it is also worth noting that Korea's import ban on all fishery products from 8 prefectures that Japan challenged in the WTO did not directly stem from the *Fukushima* accident in March 2011. Rather, Korea moved to this comprehensive import bans due to the news reports that contaminated water had leaked into the ocean from the facility in September 2013, two and a half years after the accident. As rightly described by the Panel, "[s]ome measures were adopted shortly after the accident, while others several years later."[62]

Japan's second challenge was the additional testing requirements implemented by Korea at the border. First of all, it should be emphasized that Japan had no objection to Korea testing at the border whether or not the activity concentration levels of caesium and iodine in Japanese food products are below the tolerance levels established by Korea. In other words, Japan was not concerned about the fact that, if Japanese food products were to exceed the tolerance levels set by

[60] Panel Report, *Korea – Radionuclides*, paras. 7.48-7.50, 7.65(d).
[61] Panel Report, *Korea – Radionuclides*, paras. 7.330, 7.441.
[62] Panel Report, *Korea – Radionuclides*, para. 7.83.

Korea, they would not be allowed to be exported to Korean market.

Moreover, Korea imposed the testing for caesium and iodine on samples from "every consignment" of Japanese food products, while only samples from "randomly selected consignments" were subject to this testing requirement for food products from countries other than Japan. In spite of this different treatment against Japanese food products, however, Japan did not challenge Korea's at-the-border testing requirement itself in the WTO.

Rather, what Japan was concerned about was the additional testing that might be triggered as a result of the at-the-border testing. Even if the concentration level of caesium and iodine in food products was found to be below Korea's tolerance levels (i.e. 100 Bq/kg for general foods), they would have to undergo the additional testing requirement if more than 0.5 Bq/kg of caesium or iodine was detected. One of the main reasons was that it was unclear how the additional testing requirement would operate. For example, as admitted by the Panel, the additional testing were in principle carried out for strontium and plutonium. In some cases, further tests can be required for other radionuclides, depending on the discretion of the authorities. However, the criteria for this were not clarified in the laws and regulations (see Table 6).

Table 6 Korea's Testing and Certification Requirements

	Pre-export Certificate	At-the-border (or Production) Testing	Point-of-Sale Testing
Japan	All shipments of non-fishery products (13 prefectures) fishery products (8 prefectures) If the level of caesium or iodine is more than 100 Bq/kg, food products cannot be exported from Japan.	All consignments If the level of caesium or iodine is more than 100 Bq/kg, shipment is rejected. If it is more than 0.5 Bq/kg, food products must undergo the additional testing.	Randomly selected samples If the level of caesium or iodine is more than 0.5 Bq/kg, food products must undergo the additional testing.
Other countries		Randomly selected consignments If the level of caesium or iodine is more than 100 Bq/kg, shipment is rejected.	
Korea		Randomly selected samples If the level of caesium or iodine is more than 100 Bq/kg, distribution is rejected.	

4.3 Applicability of the SPS Agreement

When WTO Members adopt trade restrictive measures against the import of food products from the country where the nuclear accident occurred, the first question will be whether such measures fall within the scope of the SPS Agreement. As far as such measures are taken to protect the public from internal exposure through the ingestion of imported food products containing radionuclides, it appears seems that there will be little doubt about the applicability of the SPS Agreement.

Article 1.1 of the SPS Agreement delimits the applicable realm of this Agreement by reading that it applies to (i) all SPS measures (ii) which may, directly or indirectly, affect international trade.[63] These two requirements will be discussed in turn below.

4.3.1 SPS Measures

SPS measures are defined in Annex A(1) of the SPS Agreement.[64] Especially, Annex A(1)(b) defines SPS measures as any measures "applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs". The primary question would be whether radionuclides in foods fall within the scope of "contaminants" in Annex A(1)(b).[65]

4.3.1.1 "Contaminants" in Annex A(1)(b)

The dictionary meaning of the term "contaminant" is "something which contaminates" or "a contaminating substance".[66] Moreover, as a reference, the Codex defines this term to mean "any substance not *intentionally* added to food…, which is present in such food…as a result of the production…, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food…, or as a result of environmental contamination."[67] Given the dictionary meaning and the Codex's definition, the panel in *EC – Approval and Marketing of Biotech Products* concludes that "a critical element for determining whether a substance can be considered to be a 'contaminant' is that the presence of the substance which is said to 'infect or pollute' be unintentional."[68] In contrast to contaminants, food additives are intentionally added to food, for example, for the purpose of improving the flavor and the appearance of food, or extending the

[63] Panel Report, *US – Poultry (China)*, para. 7.82.
[64] Article 1.2 of the SPS Agreement reads that "[f]or the purposes of this Agreement, the definitions provided in Annex A shall apply."
[65] In *Korea – Radionuclides*, however, this was not an issue between the parties as Korea did not dispute that their measures were applied to protect human health from risks arising from "contaminants" in food product in Annex A(1)(b). Panel Report, *Korea – Radionuclides*, para. 7.26.
[66] *Shorter Oxford English Dictionary on Historical Principles, Volume 1 (A-M)*, 6th edn (Oxford University Press, Oxford: 2007) 502. In the SPS Agreement, the term "contaminants" is further explained to "include pesticide and veterinary drug residues and extraneous matter". Footnote 4 of the SPS Agreement. For example, in *EC – Hormones*, the six hormones at issue were found to constitute "veterinary drugs" in Footnote 4. Then, the parties agreed that the risks at issue arose from "contaminants" in foods in Annex A(1)(b). Panel Report, *EC – Hormones (US)*, para. 8.21.
[67] Codex Alimentarius Commission, *Procedural Manual of the Codex Alimentarius Commission*, 26th edn (2018) 24 (italic added). However, it is noted that this Codex definition is not dispositive of determining the meaning of "contaminants" in Annex A(1)(b) of the SPS Agreement. Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.314.
[68] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.313.

shelf life. In addition, for example, genes *intentionally* added to genetically modified plants for edible or as input for processed foods are not considered as "contaminants" in Annex A(1)(b),[69] but as "additives in foods" in Annex A(1)(b).[70]

There are two major pathways by which agricultural products are contaminated with radioactive materials.[71] Firstly, radioactive materials are released into the air as a result of an accident, and then may fall further into the soil. As a result, radioactive materials might be directly attached to leafy vegetable, especially in the immediate aftermath of the accident. Secondly, radioactive materials released from an accident may fall into the soil, and agricultural products may absorb it through their roots. Especially if the radioactive materials in the soil have a long half-life, the agricultural products produced there will be contaminated over a long period of time.

In any case, radioactive materials are "unintentionally" present in food products as a result of the nuclear accident. Thus, when import restrictions are imposed on food products from the country where the accident occurred, they can be generally characterized as measures to protect human health from risks arising from "contaminants" in foods within the meaning of Annex A(1)(b).[72]

4.3.1.2 Objectives of the Measures Taken in Response to Nuclear Accidents

Although Korea agreed that the measures at issue fell under the scope of the SPS measures in Annex A(1)(b),[73] the Panel in *Korea – Radionuclides* analyzed the applicability of the SPS Agreement in this case. Especially, the Panel made a reference to the Appellate Body's decision in *Australia – Apples* that "the relationship of the measure and one of the objectives listed in Annex A(1) must be manifest in the measure itself or otherwise evident from the circumstances related to the application of the measure."[74] The Appellate Body continued to say that "the purpose of a measure is to be ascertained on the basis of objective considerations."[75]

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[69] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.313.
[70] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.301.
[71] MOE and National Institutes for Quantum and Radiological Science and Technology, *Booklet to Provide Basic Information regarding Health Effects of Radiation: Vol. 2 (Accident at TEPCO's Fukushima Daiichi NPS and Thereafter)* (2019) 56, available at <https://www.env.go.jp/en/chemi/rhm/basic-info/1st/pdf/basic-1st-vol2.pdf>, last visited 10 April 2020.
[72] Panel Report, *Korea – Radionuclides*, para. 7.32.
[73] Panel Report, *Korea – Radionuclides*, para. 7.26.
[74] Panel Report, *Korea – Radionuclides*, para. 7.25 (referring to Appellate Body Report, *Australia – Apples*, para. 172).
[75] Appellate Body Report, *Australia – Apples*, para. 172

It is not clear, however, why the Panel paid attention specifically to the "purpose" of Korea's measures. This is because, as addressed below, there is little doubt that the purpose of trade restrictions imposed on food products from the country where the nuclear accident occurred cannot be anything other than protecting the public from internal exposure through the ingestion of contaminated food.

Firstly, testing for radionuclides in food products, whether imported or domestic ones, is not carried out on a daily basis because it is costly. Rather, it is normally implemented at the border only on food products imported from the country where the major nuclear accident occurred.[76] Given this particularity of radiological testing, it is likely that testing measure for food products imported from such country will almost always fall within the scope of Annex A(1)(b) of the SPS Agreement.

Secondly, the timing of adopting import restrictions could be also taken into account as "the circumstance related to the application of the measure". In case that such restrictions are taken in response to an event that would lead to radioactive contamination of food in the country where the accident occurred, this fact itself would suggest that the purpose of the restrictions is also to protect the public from risks arising from the consumption of contaminated food. In *Korea – Radionuclides*, it is recalled that the product-specific import bans were imposed on certain fishery products in response to the distribution restrictions on these products within Japan.[77] Moreover, the blanket import bans against fishery products were implemented by Korea in response to continuing leaks of contaminated water into the ocean at the nuclear plant.[78]

Thirdly, as indicated by the Panel in *Korea-Radionuclides*, if the measure itself, or the press release announcing the implementation of this measure, refers to information, such as "the results of [monitoring] testing in Japan and whether they exceed or are within Korea's standards",[79] the purpose of the measure will

[76] As noted in Chapter 4.2.1.1, in Japan, the new standard limits took into effect on 1 April 2012 after the *Fukushima* accident. The limit 100 Bq/kg for general foods applies to both food products distributed domestically and imported food products. As a recent example, 150 Bq/kg was detected in French blueberry jam in 2017, and this product was declared backlogged. Cases in which caesium above the standard limits was detected at the border are available at <https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/ihan/index.html>, last visited 11 April 2020 (in Japanese).

[77] Chapter 4.2.1.

[78] Chapter 4.2.2.

[79] In addition, the Panel in *Korea – Radionuclides* found that Korea's measures were adopted for the purpose set forth in Annex A(1)(b) on the ground that the measure included a question and answer document that provides information on the risk, the monitoring mechanisms in Korea, test results, and the Codex guideline levels, and that the blanket import bans refer to the product-specific import bans taken in Korea since the *Fukushima* accident. Panel Report, *Korea – Radionuclides*, para. 7.26 (Underline Added).

be recognized as protecting the public from internal exposure due to the ingestion of radionuclides in foods. Such references would normally be made when imposing import restrictions on food products from the country where the nuclear accident occurred.

In light of the above, as was the case in *Korea – Radionuclides*, it is unlikely that the purpose of import restrictions adopted on food products from the country where the nuclear accident occurred are not found to fall within the realm of Annex A(1)(b), which is to protect human health from risks arising from contaminants in foods. Rather, it is more commonly disputed, for example, whether such restrictions are maintained without sufficient scientific evidence,[80] or are more trade-restrictive than required to achieve their objectives.[81]

4.3.2 Whether the Measures Directly or Indirectly Affect International Trade

In order for SPS measures to be subject to the SPS Agreement, they must directly or indirectly affect international trade.[82] As confirmed by a number of past panels and the Appellate Body, "an import ban is, by its very nature, intended to affect international trade."[83] Thus, there is no dispute that this requirement is met in relation to measures taking a form of import bans, such as the product-specific import bans and the blanket import bans in *Korea - Radionuclides*.

Moreover, trade measures imposed on food products from the country where the nuclear accident occurred may take a form of procedures, such as pre-export certificate, and testing requirement at the border. In this regard, "procedures to check and ensure the fulfilment of SPS measures",[84] the completion of which takes time, or which may impose information and documentation requirements, are also considered to have a direct or indirect effect on international trade.[85] Both the 2011 additional testing requirement for non-fishery products (except livestock products) and the 2013 additional testing requirement for fishery and livestock products were found by the Panel in *Korea – Radionuclides* to constitute "procedures" within the meaning of Article 8 and Annex C of the SPS

[80] Article 2.2 of the SPS Agreement. It is worth noting, however, that Japan did not make a claim under Articles 2.2 and 5.1 regarding the scientific basis of Korea's measures in *Korea – Radionuclides*.
[81] Article 5.6 of the SPS Agreement.
[82] Article 1.1 of the SPS Agreement.
[83] E.g. Panel Report, *India – Agricultural Products*, para. 7.157. See also Panel Report, *Russia – Pigs (EU)*, para. 7.234.
[84] Article 8 and Annex C(1) of the SPS Agreement.
[85] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.435-7.436.

Agreement.[86]

Given the jurisprudence, trade restrictions imposed on the import of food products from the country where a nuclear accident occurred are most likely to be found to directly or indirectly affect international trade. In *Korea – Radionuclides*, this was not disputed between the parties.[87]

4.4 Risk Assessment

Article 2.2 of the SPS Agreement provides for the general principle that requires SPS measures to be based on "scientific principles", and not to be maintained without "sufficient scientific evidence", except provisional measure in Article 5.7. Furthermore, Article 5.1 of the SPS Agreement, which is viewed as a "specific application of the basic obligations contained in Article 2.2",[88] requires SPS measures to be based on a risk assessment. Thus, when adopting SPS measures against the import of food from the Member where the nuclear accident occurred, other Members are in principle required to base their measures on a risk assessment. To be more specific, such trade measures need be based on the evaluation of the possibility that the consumption of food containing radioactive materials may cause adverse effects (i.e. stochastic effects[89]) on the human body.

The following will analyze how adverse health effects arising from radioactive materials contained in food need to be assessed in the SPS Agreement, and what is required for SPS measures to be based on a risk assessment, especially when there is no threshold for the hazard at issue, in the SPS Agreement.

4.4.1 Definition

In the SPS Agreement, two types of risk assessment are defined. One type of risk assessment, which pertains to food-related risks, is defined as "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."[90] As examined before,[91] it is noted that radionuclides in food are considered to fall within the scope of "contaminants" in Annex A(4) of the SPS Agreement above. Thus, when imposing SPS measures on food products imported from the country where the nuclear accident occurred, importing

[86] Panel Report, *Korea – Radionuclides*, para. 7.384.
[87] Panel Report, *Korea – Radionuclides*, para. 7.29.
[88] Appellate Body Report, *EC – Hormones*, para. 180.
[89] See Chapter 1.1.4.1.
[90] Annex A(4) of the SPS Agreement. The other type of risk assessment defined in the SPS Agreement is concerned with the risks arising from pests or diseases.
[91] See Chapter 4.3.1.1.

Members are obliged to base such measures on the assessment of the adverse effects (i.e. stochastic effect) resulting from the ingestion of radionuclides in food. The question then arises as to what risk assessment, which is often distinguished from risk management, is and what constitutes it.[92]

4.4.1.1 Codex's Definition of Risk Assessment

The FAO and the WHO have played a leading role in establishing the wide implementation of "risk analysis" in the field of food safety by clarifying its content and how it is applied in practice.[93] For this purpose, they convened a number of Joint FAO/WHO Export Consultations, including expert meetings on risk assessment in 1995, risk management in 1997 and risk communication in 1998. As to the risk assessment, upon the request of the Codex Executive Committee in 1994, a Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues, which was held from 13 to 17 March 1995, after the establishment of the WTO, issued a report that provides uniform definitions for various risk analysis terms, and advice on the practical approaches to the application of risk analysis to food safety issues.[94]

According to the Consultation, a risk analysis in food safety is defined as a process consisting of risk assessment, risk management and risk communication. Furthermore, the Consultation agreed on a risk assessment model, which consists of the four steps; that is (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization (see Figure 8). As will be discussed later,[95] in its 1995 report, the Consultation also set out definitions for each of the four components that constitute a risk assessment. In 1997, these definitions were adopted by the Codex,[96] and then included in the Codex Procedural Manual.[97]

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[92] One major rationale relied upon by Thomas Cottier in defending the conceptual distinction between risk assessment and risk management is the definitions adopted by Codex where these two concepts are also clearly distinguished. Cottier, Thomas, 'Risk Management Experience in WTO Dispute Settlement', in David Robertson and Aynsley Kellow (eds), *Globalization and the Environment: Risk Assessment and the WTO* (Edward Elgar Publishing, Cheltenham: 2001) 50-51. As to the distinction between risk assessment and risk management, see Messenger (*Development of the WTO Law*) 139-143.

[93] See Yamada, Yukiko, 'Importance of Codex Maximum Residue Limits for Pesticides for the Health of Consumers and International Trade', in Árpád Ambrus and Denis Hamilton (eds), *Food Safety Assessment of Pesticide Residues* (World Scientific Publishing, Hackensack, New Jersey: 2017) 271-273.

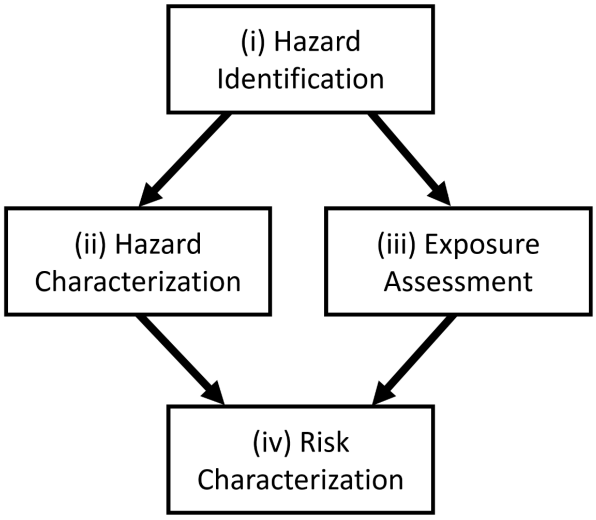
[94] WHO, *Application of Risk Analysis to Food Standards Issues: Report of the Joint FAO/ WHO Expert Consultation*, WHO/FNU/FOS/95.3 (1995), available at <https://apps.who.int/iris/bitstream/handle/10665/58913/WHO_FNU_FOS_95.3.pdf>, last visited 12 April 2020.

[95] See Chapter 4.4.2.

[96] Codex Alimentarius Commission, Report of the 22nd Session of the Codex Alimentarius Commission, ALINORM 97/37 (1997), paras. 29-31.

[97] These definitions were further amended in 1999. Codex Alimentarius Commission, Report of

Figure 8 Components of Codex's Risk Assessment



4.4.1.2 Components of Risk Assessment in the WTO

The panel in *EC – Hormones* seems to have interpreted the basic component of risk assessment in the SPS Agreement in light of the definitions adopted by Codex in 1997. Given the wording of Article 5.1 of the SPS Agreement, the panel emphasized that Members must conduct a risk assessment, taking into account the four steps of a risk assessment and relevant definitions adopted by the Codex,[98] which is one of the relevant international organizations recognized in the SPS Agreement.[99] As rightly summarized by Burkard, when interpreting the meaning of risk assessment in the SPS Agreement, this panel was "obviously inspired by the concept of risk analysis" developed by the Codex.[100]

Later, the panel in *US – Continued Suspension* relied on Codex's definitions in a more explicit way in interpreting an assessment of food-related risks in the SPS Agreement. The relevant part of the panel's findings reads as follows.

> Annex A(4) requires a Member to (a) identify the … contaminants… in food … at issue (if any); (b) identify any possible adverse effect on human…health; and (c) evaluate the potential for that adverse effect to

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the 23rd Session of the Codex Alimentarius Commission, ALINORM 99/37 (1999), para. 70.

[98] Panel Report, *EC – Hormones (US)*, paras. 8.103-8.104.

[99] See e.g. Annex A(3)(a) of the SPS Agreement. One commentator considers that the four-step approach adopted by the Codex for a risk assessment falls within the scope of "risk assessment techniques" in Article 5.1 of the SPS Agreement. Gruszczynski, Lukasz, *Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement* (Oxford University Press, Oxford: 2010) 125.

[100] Burkard, Michael, *Conflicting Philosophies and International Trade Law: Worldviews and the WTO* (Palgrave Macmillan, London: 2018) 287.

arise from the presence of the identified … contaminants … in food …[101]

This panel's finding appears to conform to the four-step approach adopted by the Codex in 1997.[102] Indeed, the panel found that the first step (a) was met because the EC had clearly identified both the "food (i.e. meat and meat products from cattle)" and "contaminants (i.e. oestradiol-17β)" at issue.[103] There is no doubt that this pertains to hazard identification. The panel also found that the second step (b) was met because the EC had identified the adverse effects of this contaminant on human health, such as carcinogenicity.[104] Obviously, this is related to the characterization of adverse health effects arising from the ingestion of oestradiol-17β in food. Moreover, the third step (c), which is about the evaluation of the potential for the adverse effect to occur, appears to expect Members to conduct an exposure assessment as a basis of risk characterization.

The Appellate Body appeared to agree with panel's interpretation regarding the four steps to be followed in risk assessment by noting that, while the utility of the panel's approach might be debated, it is not "substantively wrong".[105] However, as admitted by the panel in *US – Continued Suspension* itself, a failure to follow the Codex's four-step approach does not necessarily lead to a violation of Article 5.1 of the SPS Agreement. As clearly stipulated in Article 5.1, Members are merely required to "take into account", not to follow, Codex's risk assessment techniques.[106] In this regard, the Appellate Body also explained that, in performing a risk assessment, a Member was not obliged under Article 5.1 to adopt the methods used by the international body.[107]

Nevertheless, it is recalled that an assessment of food-related risk in the SPS Agreement is defined as the evaluation of the potential (i.e. possibility[108]) for adverse effects on human health to occur from the ingestion of contaminants in food.[109] And such a possibility cannot be evaluated without taking into account the extent to which consumers are exposed to such contaminants through the consumption of food. Suppose, for example, that a food has a tendency to be contaminated. In this case, there is a difference in the health risk arising from the

[101] Panel Report, *US – Continued Suspension*, para. 7.507.
[102] Interestingly, the Consultation noted that the definition of risk assessment in the SPS Agreement is "broader in scope than, but not inconsistent with, the definition" by the Consultation. WHO (*Application of Risk Analysis*) 6.
[103] Panel Report, *US – Continued Suspension*, para. 7.508.
[104] Panel Report, *US – Continued Suspension*, para. 7.508.
[105] Appellate Body Report, *EC – Hormones*, para. 184.
[106] The panel noted that "compliance with Codex…risk assessment techniques is not required by the *SPS Agreement*." Panel Report, *US – Continued Suspension*, paras. 7.467-7.468.
[107] Appellate Body Report, *US – Continues Suspension*, para. 685.
[108] Appellate Body Report, *EC – Hormones*, paras. 182-184.
[109] Annex A(4) of the SPS Agreement.

consumption of the same food between areas that do not have a habit of consuming this food at all, and areas where consumers prefer to eat this food (i.e. lower risk for the former, and higher risk for the latter). It is true that, as noted by the panel and the Appellate Body, Members are not obliged to follow the four steps defined by the Codex. However, when no exposure assessment, which is one the components of Codex's risk assessment, is undertaken at all, it is questionable whether such a risk assessment will fulfil the requirement defined in Annex A(4) of the SPS Agreement.

4.4.2 An Assessment of Risks Resulting from Radionuclides in Food

The following will examine how adverse effects (i.e. stochastic effect) on the human body arising from the ingestion of radioactive materials in food can be assessed in accordance with the four components drafted by the Consultation and then adopted by the Codex.[110] It is also worth noting that, in 2005, the FAO and the WHO jointly published a manual to provide essential background information and practical guidance on the application of food safety risk analysis for regulators and other officials.[111] Especially, Annex 2 of this manual sets out the basic tasks in a food additive safety assessment, which is similarly applicable to an assessment of contaminants in food.

4.4.2.1 Hazard Identification

According to the Codex Procedural Manual, hazard identification is defined as "[t]he identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in food."[112] Radionuclides in foods can be considered as physical agents capable of causing adverse health effects as follows.

Radionuclides emit radiation until they become stable nuclei. It is undisputed that exposure to radiation can be biologically harmful to human body because of ionization. As to the biological effect of ionizing radiation, it is generally explained that extensive damage can be caused to organic molecules of body cells either in the direct manner or in the indirect manner. As a result of ionization, an electron will be ejected from a water molecule in the body cells, and then it might directly breaks links in chain molecules. Moreover, as a different process, electrons ejected through ionization might also indirectly cause biological damage to the

[110] For a detailed analysis of the four components of the risk assessment presented by Codex, see Epps, Tracey, *International Trade and Health Protection: A Critical Assessment of the WTO's SPS Agreement* (Edward Elgar Publishing, Cheltenham: 2008) 159-163.
[111] FAO/WHO, *Food Safety Risk Analysis: Part I, An Overview and Framework Manual,* Provisional Edition (2005) 1.
[112] Codex (*Procedural Manual*) 132.

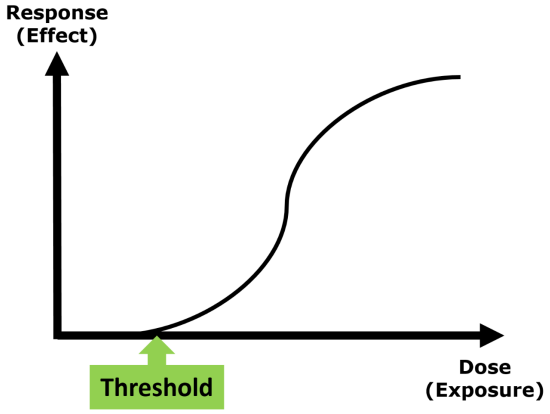
body cells, especially through highly reactive products.[113]

Health hazards caused by radiation can be generally classified into "deterministic effect" and "stochastic effect" in terms of the relationship between exposure dose and the appearance of symptoms.[114] In terms of biology,[115] DNA damaged by radiation exposure sometimes fails to repair its lesions, resulting in the mutation of somatic cells. Then, the proliferation of such cells may cause adverse effects on the human body, such as cancer and leukemia. In other words, long-term exposure increases the probability of dying from cancer. Thus, such effects are characterized as "stochastic".

4.4.2.2 Hazard Characterization

According to the Codex, hazard characterization is defined as "[t]he qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food." For this purpose, a "dose-response assessment" should be performed, so as to establish the relationship between the amount of exposure to a biological, chemical and physical agent, and the severity and frequency of adverse health effects.[116] An image of a dose-response assessment for a contaminant with a threshold, "[a] level (e.g. of radiation dose) below which there is no observable effect",[117] can be shown in Figure 9.

Figure 9 Image of dose-response assessment (contaminant)



[113] As to the mechanism of adverse effects on the human body through radiation exposure, see Chapter 1.1.2.
[114] See Chapter 1.1.4.
[115] See e.g. Martin, Alan, Harbison, Sam, Beach, Karen, and Cole, Peter, *An Introduction to Radiation Protection*, 7th edn (CRC Press, Boca Raton, Florida: 2019) 31-32.
[116] Codex (*Procedural Manual*) 132.
[117] Hall, Eric J and Giaccia, Amato J, *Radiobiology for the Radiologist*, 7th edn (Wolters Kluwer Health, Lippincott Williams & Wilkins, Philadelphia: 2012) 533.

Once the threshold value is known through animal experiments,[118] it is possible to calculate the amount of contaminants that can be ingested by humans in a way that does not exceed that value. For contaminants, the maximum weekly intake that is safe for human consumption over a lifetime, which is called the "provisional tolerable weekly intake (PTWI)",[119] can be established. For example, PTWI is expressed in the form of "0.05 mg/kg bw/week" for certain contaminant, meaning that there is no adverse health effect on the human body up to the consumption of 0.05 mg per kilogram of body weight in one week.[120] In this way, hazard characterization for contaminants can be represented by the PTWI.[121]

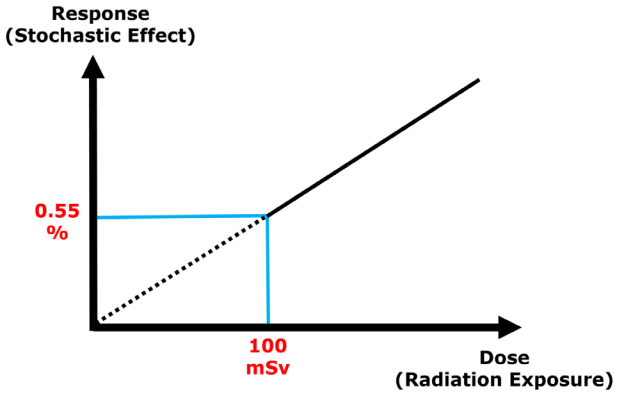
The relationship between the amount of radiation exposure to humans and the probability of causing adverse health effects on the human body (i.e. stochastic effects[122]) has been assessed by the ICRP.

In 1977, the ICRP recommended for the first time a quantitative risk assessment of the stochastic effects of radiation exposure. Moreover, in 2007, the ICRP estimated a risk factor for carcinogenesis as $5.5 \cdot 10^{-2}Sv^{-1}$ (i.e. 5.5%/Sv) for the whole population, which refers to the risk that 5.5 out of 100 people die for cancer through the whole body exposure of 1 Sv (1,000 mSv).[123] Put differently, exposure to the effective dose of 100 mSv increases lifetime cancer mortality rate by about 0.55% for the whole population. Stochastic effects are supposed to increase in proportion to the increase in dose exposure above 100 mSv. On the other hand, as confirmed by the ICRP, it is not clear from the current epidemiology whether there are any effects on the human body due to low-dose exposure of 100 mSv or less. This is because, at such low doses, the effects of radiation exposure are lost in other factors such as lifestyle.[124] Thus, it is not clear whether

[118] This value is specifically called no-observed-adverse-effect-level (NOAEL), meaning the maximum dose at which no adverse effects are observed on the animal when taken daily for a lifetime.
[119] PTWI is defined as "[a]n endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods." See Codex Alimentarius Commission, *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (1995) 12.
[120] For example, a consumer weighing 60 kg can consume up to 3 mg of this chemical per week without causing any adverse effects to the human body.
[121] In the case of pesticides and food additives that have a threshold, the "acceptable daily intake (ADI)" is used as the amount that can be ingested daily over a lifetime without appreciable health risk. Panel Report, *EC – Hormones (US)*, para. II.17.
[122] See Chapter 1.1.4.1.
[123] ICRP, The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37(2-4) (2007) paras. 7, 73, 83, A164.
[124] According to the ICRP, "[t]here is…general agreement that epidemiological methods used for the estimation of cancer risk do not have the power to directly reveal cancer risks in the dose range up to around 100 mSv." ICRP Publication 103, para. A86. While acknowledging that "a significant increase of cancer risk [is shown] at doses above 100 mSv", the WHO also notes that "[m]ore recently, some epidemiological studies in individuals exp

or not there exists a threshold dose for stochastic effects, below which no adverse effect is observable (see Figure 10).

Figure 10 Image of dose-response assessment (radiation exposure)



For the purpose of radiological protection, however, the ICRP has taken the conservative or cautious assumption that there is no threshold for stochastic effects, and that "there is no wholly 'safe' dose of radiation."[125] Put differently, the ICRP recommends a system of radiological protection based on the assumption that there is no threshold dose for stochastic effects. This assumption is generally called the linear non-threshold (LNT) hypothesis, and it is considered preferable in terms of the precautionary principle.[126] However, it is noted that this is only a hypothesis for radiation protection, and stochastic effects on the human body due to exposure below 100 mSv are still unknown as a hazard characterization.

The fact that there is no threshold for adverse health effects (i.e. stochastic effect) due to radiation exposure means that the risk is not zero no matter how much the exposure is reduced. Therefore, unlike contaminants that have a threshold, it is not possible, by definition, to set a lifetime intake that does not cause such adverse effect on the human body, which is often expressed by ADI or PTWI, in the case of radiation exposure.

4.4.2.3 Exposure Assessment

The term "risk" is generally explained as the probability of an adverse health

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osed to medical exposures during childhood (paediatric CT) suggested that cancer risk m ay increase even at lower doses (between 50-100 mSv)." WHO, *Ionizing radiation, health effects and protective measures: Key facts (29 April 2016)*, available at < https://www.who.int/news-room/fact-sheets/detail/ionizing-radiation-health-effects-and-protective-measures>, last visited on 10 May 2020.

[125] ICRP, Recommendations of the International Commission on Radiological Protection. ICRP Publication 9 (Pergamon Press, Oxford: 1966), para. 29; ICRP, Recommendations of the International Commission on Radiolonical Protection. ICRP Publication 1 (Pereamon Press, Oxford: 1959), para. 5.

[126] ICRP Publication 103, paras. 36, 64, 65, 99,

effect occurring due to the "hazard" in food multiplied by the magnitude or severity of that effect.[127] For example, an airplane accident, once it occurs, could cause significant damage (i.e. hazard), although its risk is still considered small since the probability of its occurrence is extremely limited. On the other hand, the risk of food poisoning, for which treatments have evolved, is still not considered as small because of the high frequency of its occurrence.

Therefore, even if a food product contains a contaminant as a hazard, the risk arising from this hazard (i.e. contaminant) in the food cannot be assessed without considering (1) how much of the contaminant is contained in the food, and (2) how much of the food is ingested by consumers. In other words, in order to assess the risk arising from the contaminant in food, it is also indispensable to evaluate the extent to which the consumers are exposed to the hazards. This evaluation is called an "exposure assessment".[128]

According to the Codex, an exposure assessment is defined as "[t]he qualitative and/or quantitative evaluation of the *likely intake* of biological, chemical, and physical agents via food as well as exposures from other sources if relevant."[129] Thus, it is important to note that, unlike other steps in the risk assessment, the exposure assessment is more of population-specific in nature, and thus is more likely to differ by region, country and products.[130]

4.4.2.3.1 An Example of Exposure Assessment

The health risk arising from the ingestion of radioactive materials in food cannot be properly assessed without assessing (1) how much radioactive material is contained in the food, and (2) how much of the food containing radioactive material is ingested by consumers. For example, even if the level of radioactive contamination in food is low, the risk might still be considered high provided when the food is consumed in large quantities. On the other hand, even if the level of food contamination is high, the risk will be small when such foods are rarely consumed. The following will overview an example where the exposure assessment was carried out in Japan on the consumption of foods containing radioactive materials.

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[127] According to the Codex, risk is defined as "[a] function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food." Codex (*Procedural Manual*) 131.

[128] It is explained that this assessment aims to identify "the amount of hazard that is consumed by various members of the exposed population(s)." WHO/FAO, 'Food Safety Risk Analysis: A Guide for National Food Safety Authorities', FAO Food and Nutrition Paper 87 (2006) at 53.

[129] Codex (*Procedural Manual*) 132 (Italic Added).

[130] For example, although the adverse health effects of radionuclides themselves do not differ from country to country (however, this does not apply if the sensitivity to radiation varies by race), the amount of radioactive material exposed to the human body through food consumption is greatly affected by the dietary habits of a country.

Since September 2011, six months after the *Fukushima* accident, the National Institute of Health Sciences in Japan, commissioned by the MHLW, has been assessing the intake of radioactive materials (i.e. caesium, strontium and plutonium) by consumers in Japan through food intake. In doing so, they have used the "market basket (MB) sampling" method,[131] which proceeds as follows.

Firstly, they purchase food products that are sold at supermarkets in 13-15 prefectures covered by the survey. Secondly, they classify the purchased foods into 14 groups, according to the average food intake in each prefecture.[132] Then, the foods in each group are mixed and homogenized, and then used as samples (i.e. MB samples). Once a sample is made, it is possible to measure the concentration level of radionuclides in the sample. Based on this sample, they can estimate the annual amount of radioactive materials that consumers in each prefecture ingest from food, if an average diet is followed.

For example, from February to March 2012, one year after the *Fukushima* accident, the MHLW assessed the intake of radioactive caesium from food in 10 prefectures, including *Fukushima*, based on MB samples. According to this survey, the annual intake of caesium from food was estimated to range from 62 to 620 Bq/kg depending on the prefecture.[133]

Once the amount of radioactive material ingested through food intake (Bq) is known, the degree of adverse effects on the human body (Sv) can be derived using the "effective dose coefficients" established by the ICRP.[134] Then, in light of the dose-response assessment presented in the hazard identification (i.e. a 0.55% increase in cancer mortality at 100 mSv exposure, and a proportional

[131] The results of the intake assessment conducted by the MHLW can be viewed on its website (in Japanese only), available at <https://www.mhlw.go.jp/shinsai_jouhou/shokuhin-detailed.html>, last visited 14 April 2020. Most of the survey conducted so far by the MHLW has used a market basket sampling method. Another method is called a "duplicate portion method", in which meals are collected from ordinary households (for example, a family of four is asked to prepare a meal for five people, and the remainder of one meal is collected), and then mixed and homogenized to form a sample. By using the actual diet, the sample will more accurately reflect the region, age and individual preferences. Consumer Affairs Agency of Japan, *Food and Radiation: Q & A (8th edition)* (2013) at 48, available at <https://www.caa.go.jp/disaster/earthquake/understanding_food_and_radiation/material/pdf/130902_food_qa_en.pdf>, last visited 14 April 2020.

[132] In 2008, before the *Fukushima* accident, the MHLW conducted a nationwide survey regarding the average food intake. MHLW, National Health and Nutrition Survey (2008). The outline of this report is available at <https://www.mhlw.go.jp/english/wp/wp-hw4/dl/health_and_medical_services/P65.pdf>, last visited 14 April 2020.

[133] MHLW, *Press Release: The results of the measurement of the intake of radioactive materials from food (2012)*, available at <https://www.mhlw.go.jp/stf/houdou/2r9852000002wyf2.html>, last visited 14 April 2020 (only in Japanese).

[134] ICRP, Age-dependent doses to members of the public from intake of radionuclides: Part 5 Compilation of ingestion and inhalation dose coefficients. ICRP Publication 72. Ann. ICRP 26 (1) (1996).

increase in cancer mortality with exposure thereafter), it is possible to assess the risk arising from food intake.

4.4.2.3.2 Specificity Requirement

In *EC – Hormones*, the Appellate Body has clearly interpreted that a risk assessment conducted pursuant to Article 5.1 of the SPS Agreement needs to be "sufficiently specific to the case at hand."[135] This is generally called the "specificity" requirement. However, it is not immediately clear what must be specific in a risk assessment. In this dispute, with respect to the evidence submitted by the EC to show the carcinogenic or genotoxic of the hormones at issue, the panel in *EC – Hormones* concluded that the EC's risk assessment lacked specificity for the following reasons.

> The scientific evidence included in these articles and opinions [submitted by the EC] relates to the carcinogenic or genotoxic potential of entire *categories* of hormones or the hormones at issue *in general*; not when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use. Moreover, these articles and opinions do not specifically evaluate, as is required on the basis of paragraph 4 of Annex A of the SPS Agreement, the potential for adverse effects arising from the presence *in food* (*in casu* meat or meat products) of residues of the hormones in dispute or from residue levels comparable to those present in food.[136]

In addition, the Appellate Body agreed with the finding and reasoning by the panel in *EC – Hormones* that the EC had failed to implement a specific risk assessment.[137]

The concerns for the non-specific nature of the EC's risk assessment expressed by the panel, and later agreed by the Appellate Body, was related to the hazard characterization phase in the risk assessment. The issue in *EC – Hormones* was concerned with the adverse health effects of ingesting residual hormones in meat of cattle raised with hormones for growth promotion. Therefore, the panel seems to have criticized the EC for submitting only the evidence showing the adverse health effects of hormones in general. In doing so, the panel implied that the EC should have submitted the evidence showing the adverse health effects of ingesting residual hormones in meat.[138]

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[135] Appellate Body Report, *EC – Hormones*, para. 200.
[136] Panel Report, *EC – Hormones (US)*, para. 8.130 (Italic Original).
[137] Appellate Body Report, *EC – Hormones*, para. 200.
[138] In order to evaluate the hazards of hormones ingested through food consumption, it is necessary to clarify, for example, (1) how much of the ingested hormone remains in the body

Moreover, the specificity requirement endorsed by the panel in *EC – Hormones* and the Appellate Body may support the view that an exposure assessment is an indispensable component for a risk assessment. As highlighted in italics in the extracts of the panel report above, the assessment of food-related risk in the SPS Agreement relates to the evaluation of the possibility that adverse health effects will arise from the ingestion of hazards *in food*. As well summarized by the Appellate Body, "[a] risk assessment is intended to identify adverse effects and evaluate the possibility that such adverse effects might arise."[139] This evaluation cannot be completed without knowing (1) how much of the hazard is contained in the food, and (2) how much of the food is consumed by consumers in a given area. In the absence of such data, the risk assessment cannot be specific. Therefore, the specificity requirement might endorse the need for an exposure assessment in risk assessments.[140]

As has already been pointed out by several commentators, the strict application of specificity requirement to a risk assessment would make it difficult for Members, especially ones with limited human resources, to rely on the risk assessment conducted by another country or international organizations.[141] In that case, while these Members would be able to rely on hazard characterizations evaluated by other Members or international organizations,[142] they would need to collect data by themselves on how much and how often, on average, their citizens consume the food that is said to contain the hazard at issue. As reiterated in this section, risks arising from the ingestion of hazards in food cannot be assessed without an exposure assessment.

4.4.2.4 Risk Characterization

Lastly, it is possible to evaluate the extent to which the consumers are exposed to health risk arising from the consumption of the contaminant in food at issue by comparing the average consumer's weekly intake of the contaminant calculated in

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(i.e. how much is excreted from the body), (2) whether different organs have different hormone tolerances, and (3) whether there are differences in the effects depending on the type of hormone.

[139] Appellate Body Report, *US – Continued Suspension*, para. 569.

[140] For example, Åhman notes that a risk assessment will not fulfil the specificity requirement "if it only examines the relationship between the adverse effect and the substance or organism." Åhman, Joachim, *Trade, Health, and the Burden of Proof in WTO Law* (Kluwer Law International, The Hague: 2012) 183.

[141] See e.g. Button, Catherine, *The Power to Protect: Trade, Health and Uncertainty in the WTO* (Hart Publishing, Oxford, Portland: 2004) 67; Prévost, Denise, *Balancing Trade and Health in the SPS Agreement: The Development Dimension* (Wolf Legal Publishers, Nijmegen: 2009) 643.

[142] For example, the manual published jointly by the FAO and the WHO in 2005 clearly notes that "[i]nformation on many of the known food additives is now widely available, which eliminates the need for countries to perform their own toxicological studies." FAO/WHO (Food Safety Risk Analysis Manual) 55.

the exposure assessment with the PTWI calculated in the hazard characterization. This last phase in the risk analysis is called the "risk characterization".[143]

For example, assume that the average consumer in a country consumes 100 kg of food (say, staple food) a year, and that this food contains 0.01 mg/kg of the specific contaminant. It means that the average consumer ingests 1mg of the contaminant per year from this food (i.e. 0.01mg/kg x 100kg), and that the weekly intake of the contaminant can be calculated as approximately 0.02 mg (i.e. 1 mg x 7/365). On the other hand, when the PTWI is set at 0.005 mg/kg bw/week for this specific contaminant, it means that it is acceptable for a consumer who weighs 60 kg to ingest up to 0.3 mg of this contaminant per week (i.e. 0.005 mg x 60). Therefore, the amount of the contaminant that the average consumer weekly ingests from this food (i.e. 0.02 mg) is smaller than the acceptable amount of this contaminant for a consumer whose weight is 60 kg to ingest per week (i.e. 0.3 mg). In light of the above, the health risk to which the average consumer in this country is exposed through the consumption of this food can be evaluated to be well below the acceptable level.

The understanding described above about risk characterization is also applicable in assessing the possibility of the adverse health effects (i.e. stochastic effect) arising from the ingestion of radioactive materials in food. Once the relationship is established between the amount of radiation exposure and the probability of adverse effects on the human body through a dose-response assessment (i.e. hazard characterization),[144] and it is also identified how much radioactive material is actually contained in the food, and how much of the food is consumed by the average consumers (i.e. exposure assessment), it can be evaluated how much health risk the average consumers are exposed to from the consumption of the food at issue (i.e. risk characterization).

4.4.3 Case Study: Risk Assessment Report by the FSCJ in 2011

This section surveys the assessment of the health effect of radioactive materials in food conducted by the Food Safety Commission of Japan (FSCJ)[145] right after the *Fukushima* accident. It analyzes it in comparison with the basic components of a

[143] According to the Codex, risk characterization is defined as "[t]he qualitative and/or quantitative estimation…of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment." Codex (*Procedural Manual*) 132.
[144] According to the ICRP, a 100 mSv exposure increases the carcinogenicity rate by 0.55%.
[145] The FSCJ was established as a part of Japan's Cabinet Office on 1 July 2003, independently from risk management organizations. It implements "science-based risk assessment of food in an objective, neutral, and impartial manner to protect the health of the people." See e.g. FSCJ, What We Do, available at < https://www.fsc.go.jp/english/what_we_do.html>, last visited on 7 May 2020.

risk assessment in the SPS Agreement.

As explained before,[146] before the *Fukushima* accident, there were no radiation levels in food that served as a standard for distribution restrictions in Japan. However, the release of radioactive materials into the atmosphere around the FDNPP due to the accident created an urgent need for the establishment of radioactive standards in food. On 17 March 2011, six days after the accident, the MHLW urgently set provisional limits for radionuclides to be contained in food. However, it was done without conducting a risk assessment. Therefore, on 20 March 2011, the MHLW requested the FSCJ to undertake an assessment of the adverse effect on human health arising from the ingestion of radioactive materials in food. In October 2011, after considering public comments (more than 3,000) on the proposed report, the FSCJ issued a final report entitled "Risk Assessment Report on Radioactive Nuclides in Foods". However, the FSCJ's assessment did not satisfy the basic requirements of a risk assessment within the meaning of the SPS Agreement in the following respects.

Firstly, the main conclusions of the FSCJ's assessment can be summarized as follows.[147]

> …more than around 100 mSv of the extra cumulative effective doses…of radiation during lifetime, could increase the risk of effect on health.
>
> …health effects from the extra cumulative exposure below 100 mSv are difficult to be verified based on the current available knowledge.

These conclusions were concerned with the relationship between the amount of radiation exposure and the probability of adverse effects on the human body, which clearly falls within the hazard characterization phase (e.g. dose-response assessment) in a risk assessment. Especially, it is recalled that the second conclusion regarding the health effects of additional lifetime exposure of less than 100 mSv is similar to that of the ICRP.[148] Moreover, these conclusions only noted that the adverse effects on human health can be observed with an additional lifetime exposure of more than about 100 mSv, but did not clarify the extent of the adverse effects.[149]

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[146] See Chapter 4.2.1.1.

[147] FSCJ, *Risk Assessment Report on Radioactive Nuclides in Foods (Working Group for an assessment of the effect of radioactive nuclides in food on health): Abstract* (2011), available at <https://www.fsc.go.jp/english/emerg/abstract_risk_assessment_report.pdf>, last visited on 6 May 2020. The full report is available in Japanese only. Available at <https://www.fsc.go.jp/sonota/radio_hyoka.data/radio_hyoka_detail.pdf>, last visited on 6 May 2020.

[148] See Chapter 4.4.2.2.

[149] For example, according to the ICRP, a 100 mSv exposure is estimated to increase the cancer

Secondly, although it was requested to assess the health effects by oral ingestion of radioactive materials, the FSCJ itself admitted that the literatures on this issue in general were limited, and therefore collected not only the reports on internal exposure, but also "findings related to the toxicity of chemical substances". Moreover, the FSCJ noted that "there were little data" on health effect by oral ingestion of specific radioactive materials (e.g. iodine, caesium), for which the MHLW set provisional limits in March 2020.[150]

However, the health effects from the ingestion of radioactive materials in food (i.e. internal exposure) are not the same as those of exposure to radiation from outside the body (i.e. external exposure). For example, while all types of radiation are involved in internal exposure, it is mainly gamma rays that cause external exposure.[151] Therefore, a risk assessment that relies too heavily on external exposure data may be considered not "specific" as an assessment of the health effects of radioactive materials from oral ingestion.[152]

Thirdly, the FSCJ did not properly characterize the health risks arising from the ingestion of radioactive materials in food by conducting an exposure assessment, or taking into account the exposure assessment conducted by the MHLW.[153] In particular, in a statement issued at the time of releasing the final report, the Chairperson of the FSCJ noted as follows.

> I hope appropriate management measures will be taken by risk management ministries in accordance with FSCJ's assessment, along with careful consideration of *the situation of detected radioactive materials in foods and the actual foods intake of Japanese people*.[154]

This statement clearly shows that, when conducting a risk assessment, the FSCJ did not take into account how much radioactive material is contained in food, and how much of the food is consumed by the average Japanese people, which is exactly what is supposed to be considered in an exposure assessment. And this approach appears to contradict the FSCJ's position, which was also expressed in this statement, that "[b]asically, the effect of food on health has to be assessed

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mortality rate by 0.55%.

[150] FSCJ (Risk Assessment Report: Abstract).

[151] As explained before, alpha rays have the property of not penetrating the substance. They stop at the surface of the skin, and do not reach inside the body. Beta rays are also extinguished when they travel a few meters through the air. See Chapter 1.1.1.

[152] As to the specificity requirement in a risk assessment, see Chapter 4.4.2.3.2.

[153] For a description of the exposure assessment conducted by the MHLW, see Chapter 4.4.2.3.1.

[154] FSCJ, *Remarks from the Chairperson of Food Safety Commission of Japan* (27 October 2011), available at < https://www.fsc.go.jp/english/emerg/remarks_fsc_chair.pdf>, last visited on 7 May 2020 (Italic Added).

based on *risk analysis* method on food safety."[155]

In light of the above, the conclusions alone presented by the FSCJ do not satisfy the conditions required for a risk assessment under the SPS Agreement.

4.4.4 Based on a Risk Assessment

Article 5.1 of the SPS Agreement requires Members to base their SPS measures on a risk assessment that meets the requirements set out in Annex A(4). In order for an SPS measure to be "based on" a risk assessment, the Appellate Body found in *EC – Hormones* that the results of the risk assessment must reasonably support the SPS measure, and that there must be a "rational relationship between the measure and the risk assessment".[156] It also held that whether or not there exists such a relationship is determined on a case-to-case basis.[157] The following will examine how the decision of whether an SPS measure is based on a risk assessment in Article 5.1 is affected by the presence or absence of a threshold for adverse effects on the human body associated with food intake. A typical example in which there is no threshold for adverse health effects is the stochastic effect resulting from radiation exposure.

4.4.4.1 Hazards for Which There is a Threshold

A risk assessment for a contaminant that has a threshold, below which there is no hazard in continuing to ingest this contaminant over a lifetime, basically proceeds as follows. Firstly, the chemical agents in food that cause adverse health effects need to be identified (i.e. hazard identification). Secondly, the nature of the adverse health effects caused by the identified chemical agents needs to be evaluated either qualitatively or quantitatively (i.e. hazard characterization). For example, if a contaminant has a threshold, it is possible to set a weekly intake (PTWI) that does not show any health effects after a lifetime of consumption (i.e. PTWI).[158] Thirdly, the amount of hazard that is ingested by consumer through a consumption of food products in a week needs to be determined. This can be determined by collecting date on how much of this contaminant is contained in the food, and how much of this food consumers ingest in a week (i.e. exposure assessment). Lastly, based on the above considerations, the extent to which the consumers are exposed to the health hazard through the consumption of this food can be estimated by comparing the average consumer's weekly intake of the

[155] FSCJ (Remarks from the Chairperson) 3.
[156] Appellate Body Report, *EC – Hormones*, para. 193. See also Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.3067.
[157] Appellate Body Report, *EC – Hormones*, para. 194. For a detailed examination of the "based on" requirement in Article 5.1, see e.g. Åhman (*Trade, Health*) 192-196.
[158] For an explanation of the PTWI, see Chapter 4.4.2.2.

contaminant with the PTWI.

If it turns out that the exposure is greater than the PTWI, it means that these consumers are being exposed to the level of hazard exceeding the maximum weekly intake that is safe to continue consuming for a lifetime. Thus, in this case, some risk mitigation measures will be needed.[159] In this case, even if a Member bans the import of this food, such a measure will be found to be based on the risk assessment. On the other hand, if the exposure is estimated to be less than the PTWI, it means that these consumers are merely being exposed to hazard that does not cause adverse effects to the human body. In other words, the consumption of such foods is not a risk for these consumers. Thus, the import ban on this food taken in such a case might be found not to be based on the risk assessment.

4.4.4.2 Hazards for Which There Is No Threshold

On the other hand, in the case of hazards with no threshold (e.g. radionuclides), health risk resulting from such hazards in food will never be zero no matter how much the exposure is reduced.[160] It means that exposure to these hazards, even if only marginally, will always result in a marginal risk. Thus, unlike contaminants that have a threshold, it is not possible, by definition, to set a limit of weekly intake that does not cause adverse health effect even if you continue to take it for a lifetime (i.e. PTWI) for such hazards. Instead, the risks arising from hazards with no threshold will be evaluated according to the amount of exposure. The more consumers are exposed to hazards in food, the higher the health risks arising from such food will be evaluated.

Since the consumption of foods containing hazards that do not have a threshold always poses certain level of risk, it might be likely that SPS measures imposed on such foods are found to be based on the risk assessment. On the other hand, when the risk arising from such hazards in food is evaluated to be negligible,[161] an exporting Member might argue that the SPS measures imposed on the food are disproportionate to such negligible risk, and thus are not based on a risk assessment.

In *Japan – Apples*,[162] the US alleged that Japan had prohibited the importation of

[159] E.g., FAO/WHO (Food Safety Risk Analysis Manual) 54.
[160] Needless to say, if you stopped eating such hazard-containing foods altogether, the health risks associated with it would be zero.
[161] For example, if such a hazard is rarely contained in food, or/and if food containing such a hazard is rarely consumed, the risk from the ingestion of such a food can be evaluated to be negligible.
[162] For literature analyzing this case, see e.g. Goh, Gavin, 'Tipping the Apple Cart: The Limits of Science and Law in the SPS Agreement after *Japan – Apples*' 40 (4) Journal of World Trade

apples from the US unless produced, harvested, and imported according to Japan's fire blight (*Erwinia amylovora*) measure. Since, according to the US, there was no scientific evidence that mature, symptomless apples could serve as a pathway for introduction of fire blight to Japan, the US claimed that Japan's measures were maintained without sufficient scientific evidence, and thus were inconsistent with Article 2.2 of the SPS Agreement.[163] Japan's fire blight measures included the requirements that a 500-meter buffer zone surrounding the orchard be established to prevent contamination of US apple fruit with fire blight, and that US export orchards be inspected at least three times annually for the presence of fire blight.

As had already found by the Appellate Body in the previous dispute, "the obligation in Article 2.2…requires that there be a rational or objective relationship between the SPS measure and the scientific evidence."[164] Then, the panel in *Japan – Apples* firstly found on the basis of the scientific evidence that "the risk that mature, symptomless apple fruit be a vector for the entry, establishment or spread of fire blight within Japan is negligible".[165] Moreover, given the negligible risk identified above, the panel found that Japan's measures at issue were "clearly disproportionate to the risk identified on the basis of the scientific evidence available", and thus were maintained without sufficient scientific evidence.[166]

However, this panel's decision, clearly endorsed by the Appellate Body,[167] has been criticized.[168] In particular, it was problematic for the panel to find that the relationship between the SPS measure and relevant risk is rational when the SPS measures are disproportionate to the risks identified as negligible. As noted by some commentators,[169] the panel effectively introduced the proportionality test in determining whether there is a rational relationship between the measures at issue and relevant risk. Rather, the fact that SPS measures are excessive in relation to the extent of relevant risk should be addressed as an issue of risk

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(2006) 655; Neven, Damien J, and Weiler, Joseph H H, 'Japan – Measures Affecting the Importation of Apples (AB-2003-4): One Bad Apple? (DS245/AB/R): A Comment', in Henrik Horn and Petros C Mavroidis (eds), *The WTO Case Law of 2003: The American Law Institute Reporters' Studies* (Cambridge University Press, Cambridge: 2006) 280.

[163] Article 2.2 of the SPS Agreement reads that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." Article 5.1 is viewed as a "specific application of the basic obligations contained in Article 2.2". Appellate Body Report, *EC – Hormones*, para. 180.

[164] Appellate Body Report, *Japan – Agricultural Products*, para. 84.

[165] Panel Report, *Japan – Apples*, para. 8.154.

[166] Panel Report, *Japan – Apples*, paras. 8.181, 8.198.

[167] Appellate Body Report, *Japan – Apples*, para. 163.

[168] See e.g. Mavroidis (*The Regulation of International Trade*) 481.

[169] Gruszczynski (*SPS Agreement*) 110.

management under Article 5.6 of the SPS Agreement.[170]

The series of debates over *Japan – Apples* also apply to the adverse effects of radiation exposure on the human body (i.e. stochastic effects). In the case of contaminants without a threshold, the PTWI cannot be set (because no matter how much the exposure is reduced, the risk will never be zero). Rather, the risk will be evaluated according to the amount of exposure. And even if, as a result of an exposure assessment, the amount of radioactive material ingested by a given population from food is found to be little, and then the risk is evaluated to be negligible (e.g. low-dose exposure), these facts do not necessarily lead to the conclusion that the measure at issue is not based on a risk assessment. Even if an import ban is imposed for a risk evaluated to be as negligible, such measure might be found to be based on the risk assessment. Rather, in the case of contaminants for which there is no threshold, the question would be whether the SPS measures at issue are more trade-restrictive than necessary to achieve the appropriate level of protection (ALOP) set by the importing country in Article 5.6 of the SPS Agreement.

4.4.5 Scientific Uncertainty

As confirmed by the ICRP, it is not clear from the current epidemiology whether there are any adverse effects on the human body due to low-dose exposure of 100 mSv or less.[171] Likewise, Dr Thompson, one of the experts appointed by the panel in *Korea – Radionuclides*, noted during the panel procedure that "uncertainty still exists at low (10-100 mSv) and very low (<10 mSv) doses."[172] Then, Members may invoke such scientific uncertainties to justify their SPS measures which are not based on a risk assessment.

Article 5.7 of the SPS Agreement allows Members to adopt provisional measures without basing their SPS measures on a risk assessment, provided four requirements set out in this provision are met.[173] One of the requirements is that

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[170] Matsushita, Mitsuo, Schoenbaum, Thomas J, and Mavroidis, Petros C, *The World Trade Organization: Law, Practice, and Policy*, 2nd edn (Oxford University Press, Oxford: 2006) 522 (noting that "they [the panel in *Japan – Apples* and the Appellate Body] should have, logically, left the territory of Art 2.2 SPS, and moved to discuss the *trade-necessity* of the measure under Art 5.6 SPS.").

[171] See Chapter 4.4.2.2.

[172] Panel Report, *Korea – Radionuclides*, para. 7.239.

[173] Article 5.7 of the SPS Agreement reads that "[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

the measure at issue is imposed in respect of a situation "where relevant scientific evidence is insufficient."[174] In this regard, the Appellate Body has taken the position of strictly distinguishing between "scientific uncertainty" and the "insufficiency of scientific evidence" on the basis of phrase used in Article 5.7, and the found that they are not interchangeable. Then, according to the Appellate Body, the application of Article 5.7 is triggered by the latter, not the former.[175]

Regarding the meaning of the requirement "where relevant scientific evidence is insufficient", the Appellate Body held in *Japan – Apples* as follows.

> …"relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*.[176]

According to the criteria set out by the Appellate Body, scientific uncertainties identified as a result of a risk assessment are not covered by the scope of Article 5.7. Instead, as noted by the panel in *EC – Approval and Marketing of Biotech Products*, "such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken."[177] It appears to mean that Members are allowed to determine their SPS measures in light of scientific uncertainties identified in the evaluation results.

The question is whether scientific uncertainties about the adverse health effects of low-dose exposure mentioned above fall within the case "where the relevant scientific evidence is insufficient". In the author's view, such scientific uncertainties do not justify the invocation of Article 5.7 for the following reasons.

Firstly, it is recalled that the FSCJ concluded in its risk assessment report issued in October 2011 that "health effects from the extra cumulative exposure below 100 mSv are difficult to be verified based on the current available knowledge",[178] only after reviewing a number of studies reporting health effects at low doses or no health effects at high doses on the basis of a large body epidemiological data.[179]

Secondly, in *US/Canada – Continued Suspension*, the Appellate Body found that

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[174] See e.g. Appellate Body Report, *Japan – Agricultural Products II*, para. 89.
[175] Appellate Body Report, *Japan – Apples*, para. 184.
[176] Appellate Body Report, *Japan – Apples*, para. 179.
[177] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1525.
[178] See Chapter 4.4.3.
[179] To be more specific, the FSCJ found that the data relied on by epidemiological studies showing health effects at doses of less than 100 mSv were not reliable, and that the possibility cannot be ruled out that the reported health effects of low-doses have not been verified by epidemiological studies. FSCJ (Risk Assessment Report: Abstract).

"[t]he possibility of conducting further research or of analysing additional information, by itself, should not mean that the relevant scientific evidence is or becomes insufficient."[180] Thus, research on the adverse effects of low-dose exposure on human health is still ongoing, but such a fact does not prove that the relevant scientific evidence is insufficient.

Thirdly, in *Korea – Radionuclides*, Korea argued that there was insufficient scientific evidence to conduct an assessment of the risks of consuming Japanese food products, because the information about the extent of the release of radionuclides during and after the *Fukushima* accident. Importantly, however, "Korea does not argue that there is insufficient scientific evidence to determine the risk of radionuclides to human health".[181] In other words, Korea appears to have argued that, while acknowledging that there was sufficient evidence for *hazard characterization*, Korea was only unable to complete an *exposure assessment* because, according to Korea, it had only insufficient information about how much radioactive materials were actually contained in Japanese food products. As a result, Korea alleged that it was unable to complete a risk assessment.[182]

Conclusion

As noted at the outset of this chapter, Codex standards do not have any provisions for what governments should do when food products exceeding the Codex GLs are detected, leaving it to the wide discretion of the governments. Therefore, once a food sample exceeding the GL is detected, the importing country is not necessarily prevented in Codex standards from prohibiting future imports of this food product, let alone the lot containing the food sample exceeding the GLs, from the country where the accident occurred. However, WTO Members still need to base such an import ban on a risk assessment, as required by Article 5.1 of the SPS Agreement.

The first question is concerned with a risk assessment. With regard to hazard characterization, which forms part of a risk assessment, the dose-response relationship presented by the ICRP that a 100 mSv exposure increases the cancer mortality rate by 0.55% is widely accepted. In addition, although the adverse effects on human health (i.e. stochastic effects) due to low-dose exposure below

[180] Appellate Body Report, *US – Continued Suspension*, para. 702; Appellate Body Report, *Canada – Continued Suspension*, para. 702.
[181] Panel Report, *Korea – Radionuclides*, para. 7.79.
[182] As a literature analyzing the panel's decision on this requirement in Article 5.7, see e.g. Cai, Yan, and Kim, Eunmi, 'Sustainable Development in World Trade Law: Application of the Precautionary Principle in Korea – Radionuclides' (2019) 11(7) Sustainability 1, 7-8.

100 mSv still remain uncertain, the LNT model, which is the idea that there is a linear relationship between radiation exposure and stochastic effects, [183] "currently represents the most widely accepted dose-response model relating exposure to radiation and increase in cancer incidence."[184] Therefore, once the amount of radioactive materials ingested from food is revealed through an exposure assessment, the health risk arising from food intake can be assessed by applying it to the dose-response relationship above.

The second question relates to the relationship between the risk assessment and SPS measures. On the one hand, for a contaminant that has a threshold, it is possible to set a weekly intake limit that does not cause adverse effects to the human body after a lifetime of consumption (i.e. PTWI). Then, the health risk can be evaluated by comparing the weekly intake of the contaminant, which is revealed by the exposure assessment, with the PTWI. If the weekly amount of contaminants ingested from food is below the PTWI, it follows that there is no risk from the ingestion of this food. In that case, if the import ban is taken as an SPS measure against this food, the conclusion that there is no rational relationship between the risk assessment and the measure can be drawn in a relatively clear manner.

On the other hand, for a contaminant that has no threshold, the PTWI cannot be set. As noted before, it is widely believed that there is no threshold for stochastic effects on the human body due to radiation exposure, and that there is a linear relationship between radiation exposure and stochastic effects (i.e. LNT model).

However, the absence of a threshold means that some risk will occur, no matter how small the exposure is. And even if disproportionately trade-restrictive measures are imposed on food whose health risk is evaluated to be negligible, the rational relationship between the risk and the measure is not necessarily denied (e.g. *Japan – Apples*). Moreover, if scientific uncertainty is found as a result of carrying out a risk assessment, Members are expected to base their SPS measures on the risk assessment, taking into account such scientific uncertainty (e.g. *EC – Approval and Marketing of Biotech Products*).

Based on the above, it follows that, in the case of radioactive materials for which there is no threshold, it is less likely that the SPS measures applied to protect human health from stochastic effects are found not to be based on the risk assessment, compared to the case of contaminants for which there is a threshold. Rather, the question in this case would be whether such SPS measures are more

[183] See Chapter 4.4.2.2.
[184] This is a comment by Dr Thompson, one of the experts appointed by the panel in *Korea – Radionuclides*. Panel Report, *Korea – Radionuclides*, para. 2.17.

trade restrictive than necessary to achieve the ALOP, which represents the "acceptable level of risk",[185] set by importing Members in Article 5.6 of the SPS Agreement. And it seems that this was also the reason why Japan did not make a claim under Article 5.1 in *Korea – Radionuclides* with respect to Korea's trade measures.

[185] Annex A(5) of the SPS Agreement.

Chapter 5

Regionalization Request in the Context of Radioactive Contamination

Introduction

As explained in detail before,[1] immediately after the *Fukushima* accident that occurred in March 2011, 54 countries and regions around the world imposed some form of import restrictions on Japanese food products. As soon as the situation at *Fukushima* began to show signs of stability, the Japanese government launched negotiations with those countries to seek the removal of the import restrictions against Japanese food products. However, instead of calling for the abolition of all of those restrictions, the Japanese Government rather requested the removal of import restrictions on food products that have been confirmed to be safe for consumption and are already allowed to be placed on the market within Japan.[2] Put it differently, the Japanese government's request is basically for the resumption of food imports from the areas that are no longer contaminated with radioactive materials released by the accident. Such a request is generally referred to as a "regionalization request".[3]

In general, when a regionalization request is made by the exporting Member of the WTO, the importing Member needs to initiate the procedure for recognizing the areas concerned as, for example, pest or disease free, and reauthorizing the import of relevant food products from the areas. Such a procedure normally includes an assessment for determining the pest or disease status of the areas

[1] See Chapter 4.1.

[2] In fact, as of today, there are some foods that are still not allowed to be placed on the market even (e.g. wild mushrooms). Mushrooms have physiological characteristics that make it easier to absorb radionuclides than other vegetables. However, the Japanese government is not seeking to lift the import ban imposed on such foods that are subject to the distribution restrictions within Japan. Furthermore, in *Korea – Radionuclides*, Japan did not challenge Korea's trade restrictions against food products that were also restricted for distribution within Japan. See Chapter 4.2.1.

[3] For example, China had suspended imports of rice produced in 10 prefectures, including *Fukushima* Prefecture, after the accident. Nevertheless, since November 2018, imports have resumed only for rice produced in *Niigata* Prefecture among them. See General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ), *Customs Notice No. 175 for Announcement on allowing the import of Japanese Niigata rice*, available at < https://www.aqsiq.net/gacc/Japanese-niigata-rice>, last visited 15 May 2020.

based on all the relevant evidence. And as has often been pointed out, the importing Member might take an excessively long time to complete (or in some cases, to initiate) the procedure. The same could happen when the exporting Member requires other Members to resume food imports from the areas where the soil is no longer contaminated by radioactive materials released by the accident. That is, the importing Members might not respond promptly to such a regionalization request, and then might be able to maintain import restrictions for an extended period of time.

One possible response to such a stalemate would be to patiently ask them to advance the procedures and resume imports. But another response would be to refer the case to the WTO dispute settlement system on the grounds that the procedures for processing a regionalization request made by the importing Member have been unduly delayed inconsistently with the SPS Agreement. And it was *US – Animals* where this issue was challenged by Argentina in relation to its request for the US to resume the import of animal products from disease-free areas.

The first section of this chapter will explain how non-contaminated areas emerge in the country where a nuclear accident occurred, and describe the characteristics of radioactive contamination of soil in comparison to pest and disease (5.1). The second section will show that the SPS Agreement obliges Members maintaining trade restrictions against food products from the exporting Member where a nuclear accident occurred to adapt their measures according to the emergence of non-contaminated areas within the exporting Member (i.e. regionalization principle). In order to implement this adaptation obligation, they might be required to allow food imports from such areas under certain conditions (5.2). Then, this chapter will move to the analysis of *US - Animals*, in which Argentina alleged that the US had not promptly responded to its regionalization requests to resume the imports of animal products (e.g. fresh beef) from FMD-free areas. After overviewing the facts of the case (5.3), it will be examined how delays in approval procedures for processing a regionalization request are regulated in the SPS Agreement (5.4). In light of the above, the concluding part will explore possible policy responses to the situation where the importing Member does not take a prompt action despite the request by the exporting Member where a nuclear accident occurred to resume imports from non-contaminated areas.

5.1 Localized Nature of Radioactive Contamination

As noted in the introduction chapter, a nuclear accident and international trade in food are intertwined in the following ways. The fallout of radioactive materials

released into the atmosphere as a result of the accident leads to radioactive contamination of soil, especially in the area around the facility. Given that some radioactive materials continue to emit radiation over long periods of time, the risk of radioactive contamination of agricultural products produced in such soils is also long-lasting. And, as explained before,[4] it has already been scientifically proven that internal exposure to radiation above a certain level will have adverse effects on the human body. Especially, in the immediate aftermath of the accident, the geographical extent and scale of soil contamination is unknown. Thus, many countries usually impose some sort of import restrictions on agricultural products from the entire country, not just the areas around the accident site.

However, it is worth emphasizing here that areas contaminated by radioactive materials as a result of a nuclear accident tend to be clearly distinguished from the uncontaminated areas due to the characteristics of radioactive contamination as follows.

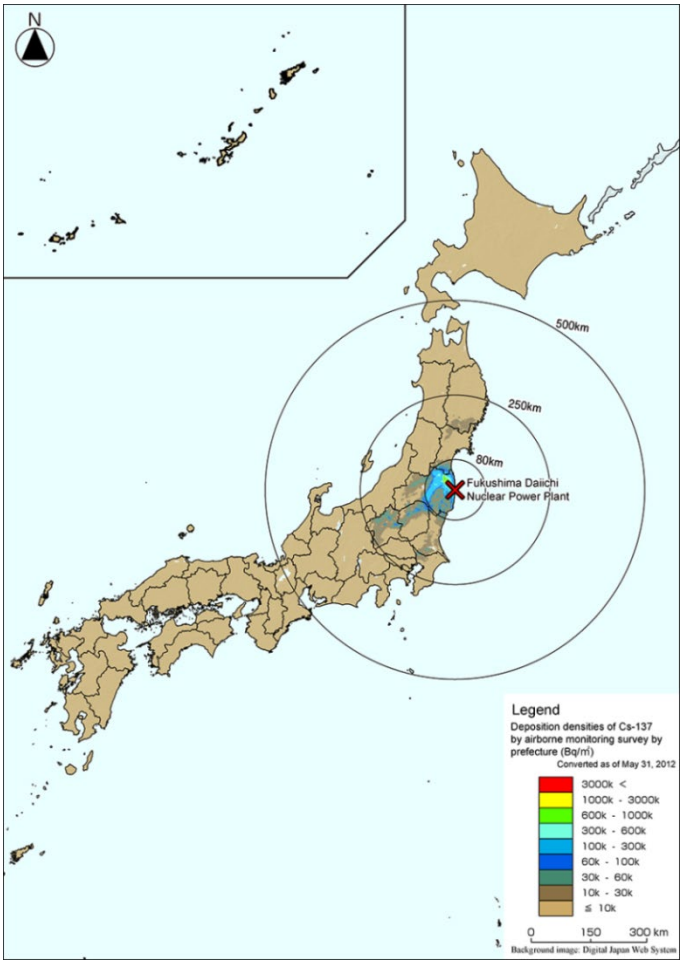
Firstly, the geographic extent of soil contamination by radioactive materials released from a nuclear accident is essentially non-expanding. Radioactive materials once attached to the soil will not be dispersed to other areas again by the wind.[5] Thus, contrary to livestock diseases, such as avian influenza and African swine, that can spread from the source to a wider area through a medium (i.e. migratory birds, wild boar, etc.), soil contamination by radioactive materials does not spread.[6] Rather than spreading, since radioactive materials have a half-life,[7] the amount of radiation emitted, as well as the geographic extent of the contaminated soil, will spontaneously decrease over time.

For example, one of the major radioactive materials released into the atmosphere as a result of the *Fukushima* accident is cesium-137.[8] It has a half-life of 33 years,[9] and thus is considered to be the dominant cause of long-term contamination.[10] Figure 11 shows the soil contamination caused by cesium-137

[4] Chapter 1.1.4.
[5] However, it may be possible that radioactive materials that have fallen into the soil could be mixed into groundwater by rain, which could flow with the groundwater and contaminate other areas.
[6] However, with respect to marine pollution, the extent of the pollution could be expanded as the currents can spread radioactive materials farther away.
[7] It refers to the time taken for the activity of a radionuclide to decay to half its initial value. Hall, Eric J and Giaccia, Amato J, *Radiobiology for the Radiologist*, 7th edn (Wolters Kluwer Health, Lippincott Williams & Wilkins, Philadelphia: 2012) 521.
[8] The main types of radioactive materials released into the atmosphere as a result of the *Fukushima* accident are iodine-131, cesium-134, cesium-137 and strontium-90.
[9] For example, the half-life of caesium-137, which is one of the radionuclides released as a result of the *Fukushima* accident, is 33 years. Law, Jonathan (eds), *A Dictionary of Science*, 7th edn (Oxford University Press, Oxford: 2017) 134.
[10] On the other hand, cesium-134 has a half-life of 2 years. Thus, nine years after the accident, it is calculated to be down to 1/64 (i.e. around 1.5%) of the original amount.

on a map of Japan as of 31 May 2012,[11] which is one year and two months after the accident. From this figure, it is possible to roughly identify the areas contaminated and uncontaminated by accidental radioactive materials. Furthermore, Figure 12 shows the contaminated area within 80 km of the FDNPP as of 28 June 2012.[12] This figure provides a more detailed picture of the distinction between the contaminated and uncontaminated areas. It should be noted that the lightest brown areas in both Figure 11 and Figure 12 are those not contaminated by cesium-137 as a result of the accident.

Figure 11 Results of Deposition of Caesium-137 of the Airborne Monitoring Survey by Prefecture (31 May 2012)

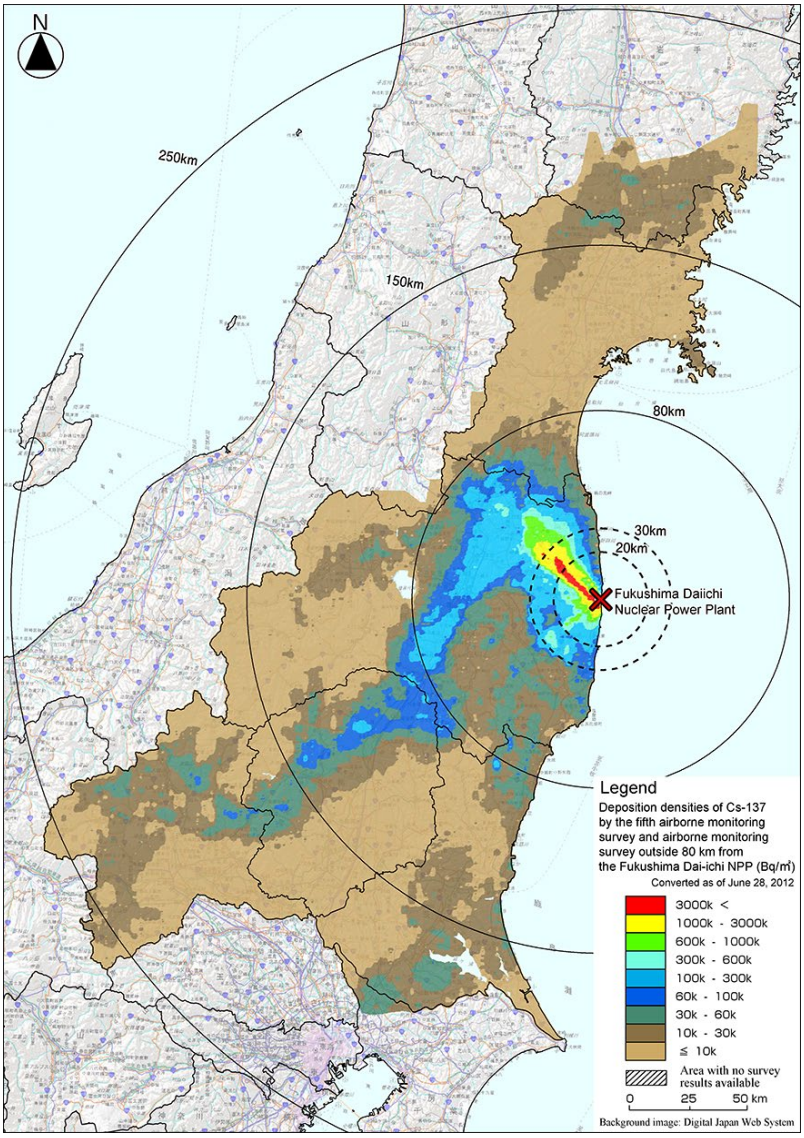


Source: JAEA, *Airborne Monitoring in the Distribution Survey of Radioactive Substances*

[11] JAEA, *Airborne Monitoring in the Distribution Survey of Radioactive Substances*, available at <https://emdb.jaea.go.jp/emdb/en/portals/b1020201/>, last visited 2 May 2020. Figure 9 is based on the measurement results of the airborne monitoring surveys for 47 Prefectures by MEXT. This is a method of measuring gamma rays from radioactive materials accumulated on the ground by installing highly sensitive radiation detectors on the aircraft.

[12] JAEA, *Airborne Monitoring in the Distribution Survey of Radioactive Substances*, available at <https://emdb.jaea.go.jp/emdb/en/portals/b1020201/>, last visited 2 May 2020. Figure 9 is based on the measurement results of the fifth airborne monitoring surveys by MEXT.

Figure 12 Results of Deposition of Caesium-137 of the Fifth Airborne Monitoring Survey (28 June 2012)



Source: JAEA, *Airborne Monitoring in the Distribution Survey of Radioactive Substances*

Secondly, the authorities usually carry out decontamination work to remove radioactive materials deposited on the ground as a result of a nuclear accident. When you hear the word "decontamination," you may have an image of spraying some kind of special medicine on the ground, so that the sprayed medicine will remove the radioactive materials from the soil. However, the method of decontamination, especially on farmland, is simple. In case of high level of radioactive contamination, the method is to physically remove the soil on the surface of the farmland by using a tractor. And the soil containing radioactive materials will be stored elsewhere. In case of relatively small level of

contamination, the method is to invert topsoil and subsoil, so as to reduce the radioactivity in the layer absorbed by the crop.[13]

By implementing decontamination, the level of radioactive contamination in the soil is supposed to be reduced. In reality, however, the amount of radioactive material removed from the farmland by decontamination is limited.[14] Thus, the area once contaminated by radioactive materials due to an accident might be recognized as "low contamination prevalence", instead of "contamination-free", after decontamination work.[15] This is similar to the argument that the implementation of vaccination in areas where livestock diseases are prevalent could subsequently qualify these areas as a "disease-free" or "low disease prevalence" area.[16]

In light of the above characteristics of soil contamination by radioactive materials, the following can be pointed out. Immediately after the accident, the scale and geographic extent of radioactive contamination is not clear yet. In view of this, it would be unavoidable for many countries to impose some kind of import restrictions on food from all parts of the country, without distinguishing between contaminated and non-contaminated areas.

However, as the geographic scope of the contaminated area is surveyed after the accident, and decontamination work is carried out, the distinction between contaminated and non-contaminated areas should become clearer. In this case, it is natural for the country with the nuclear accident to request importing countries to limit their restrictions to imports from the contaminated area, and to lift the ban on imports from other areas that are not being contaminated. As will be explained in the next section, in the SPS Agreement, WTO Members are obliged to adapt their SPS measures to the regional characteristics in the exporting Member,

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[13] In Japan, after the *Fukushima* accident, the MOE has been carrying out decontaminatio n work in the areas affected by the accident. For an explanation of decontamination, see MOE, *FY2014 Decontamination Report: A compilation of experiences to date on deconta mination for the living environment conducted by the Ministry of the Environment (Tentat ive Translation)* (2015) 131-134, available at <http://josen.env.go.jp/en/policy_document/pdf/decontamination_report1503_full.pdf>, last visited 2 May 2020. See also MOE, *Bookle t to Provide Basic Information regarding Health Effects of Radiation, Vol 2*, 1st edn (201 9) 83.

[14] According to the MOE's report as of 2015, the rate of reduction in air dose from decontamination in farmland, for example, was about 34%. MOE (*Decontamination Report*) 252.

[15] Even if caesium-137 is removed by decontamination, this does not mean that the soil will be free of any radioactive materials. As explained in Chapter 1.1.5, this is because the soil originally contains naturally occurring radioactive materials (NORMs), such as radium-226 and uranium-238, irrespective of a nuclear accident. Therefore, the term "non-contaminated areas" here does not mean that there is no contamination at all, as in the case of livestock diseases, but that the soil is only as contaminated as the soil in areas not affected by the accident.

[16] For an explanation of OIE's official disease status for six types of livestock diseases, see Chapter 5.3.1.

including the existence of areas that are no longer contaminated with radioactive materials released by a nuclear accident.

5.2 Regionalization and Radioactive Contamination of the Soil

The principle of regionalization, embodied in Article 6 of the SPS Agreement, requires WTO Members to adapt their SPS measures according to the regional conditions that exist within the exporting Member.[17] As explained in the previous section, non-contaminated areas may emerge within the country where a nuclear accident occurred due to in-depth investigations into the geographical extent of the contaminated areas, and decontamination work. Therefore, the question is whether Article 6 requires the importing Member to adapt its import restrictions, which were imposed on food products from all parts of the country where the nuclear accident occurred, in response to the emergence of the areas that are no longer contaminated by radioactive materials. The following will analyze how the regionalization principle embodied in Article 6 of the SPS Agreement applies in the context of radioactive contamination of the soil caused by the nuclear accident.[18]

5.2.1 Scope of Regional Conditions to Which SPS Measures Need to be Adapted

Article 6 of the SPS Agreement requires WTO Members to adapt their SPS measures to the regional conditions that exist within the exporting Member. At first glance, Article 6 appears to be only concerned with the regional conditions regarding pest or disease. And it does not appear that radioactive materials fall

[17] In addition, Members are obliged to adapt their SPS measure to regional conditions within their own territories. It is only *Russia – Pigs* where this aspect of regionalization was disputed in the past. Panel Report, *Russia – Pigs (EU)*, paras. 7.478-7.483. For example, in spite of the fact a livestock disease is already rampant within the country, country X might prohibit the importation of fresh meat from country Y which is also infected with the same livestock disease. In this case, import ban by country X might be found not to be adapted to its SPS characteristics (in this case, the spread of the disease). See also Panel Report, *US – Animals*, para. 7.642. However, this aspect of the regionalization principle falls outside the scope of this chapter.

[18] As to a recent analysis of the regionalization principle in the SPS Agreement, see e.g. Kim, Gaegoung, and Kim, Minjung, 'Regulatory Development and Challenges for the Regionalization Provisions in the WTO SPS Agreement and Regional Trade Agreements' (2019) 14(1) Asian Journal of WTO & International Health Law and Policy 147; Micara, Anna G, 'Regionalization within the SPS Agreement: Recent Development, in International Economic Law: Contemporary Issues' in Giovanna Adinolfi, Freya Baetens, Jose Caiado, Angela Lupone, and Anna G. Micara (eds), *International Economic Law: Contemporary Issues* (Springer, New York: 2017) 111; Furculita, Cornelia, 'Regionalization within the SPS Agreement after Russia – Pigs (EU)' (2018) 45(1) Legal Issues of Economic Integration 95; Saika, Naoto N, 'Seeds, Trade, Trust: Regionalization Commitments under the SPS Agreement' (2018) 20(4) Journal of International Economic Law 855. See also Landwehr, Oliver, 'Article 6 SPS', in Rüdiger Wolfrum, Peter-Tobias Stoll, and Anja Seibert-Fohr (eds), *WTO-Technical Barriers and SPS Measures* (Martinus Nijhoff Publishers, Leiden, Boston: 2007) 468-475.

under pest or disease. Thus, the first question is about what the scope of regional conditions to which SPS measures need to be adapted under Article 6 covers.

As indicated by the title Article 6, which is "Adaptation to *Regional Conditions*, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence",[19] Members are obliged to adapt their SPS measures to "regional conditions", which could be interpreted to cover a wide range of conditions, within the exporting Member. However, Article 6.1 limits the scope of regional conditions to the "SPS characteristics" of the area.[20] It follows that Members are not obliged to adapt their SPS measures regional conditions that are unrelated to SPS characteristics. There is no doubt that, as indicated by the title of Article 6, and the first sentence of Article 6.2,[21] (i) pest- or disease- free areas, and (ii) areas of low pest or disease prevalence, that exist within the exporting Member are included into the SPS characteristics.

Given the meaning of the terms "pest" and "disease" used in the SPS Agreement,[22] it is clear that the areas that are no longer contaminated by radioactive materials within the country where the accident occurred do not fall under (i) pest- or disease- free areas, or (ii) areas of low pest or disease prevalence.

However, it is worth noting that these two types of areas are merely the examples of the SPS characteristics of the area within the meaning of Article 6.1. Given the usage of the term "including" in the title of Article 6, and the phrase "in particular" inserted in Article 6.2, the Appellate Body clearly found that these areas are only "a subset of all the SPS characteristics of an area that may call for the adaptation of an SPS measure."[23] It logically follows that Members need to adapt their SPS measures to the SPS characteristics other than these two types of areas within the exporting Member.

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[19] Italic Added.
[20] Appellate Body Report, *India – Agricultural Products*, para. 5.131.
[21] The first sentence of Article 6.2 of the SPS Agreement reads that "Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence."
[22] There is no definition for the terms "pest" and "disease" in the SPS Agreement. The panel in *EC – Approval and Marketing of Biotech Products* held that "the term 'pest' in Annex A(1) encompasses destructive animals or plants, or animals or plants which cause harm to the health of animals or plants." Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.241. The panel also referred to the dictionary meaning of the term "disease" in the SPS Agreement that "a disorder of structure or function in an animal or plant of such a degree as to produce or threaten to produce detectable illness or disorder." Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.277.
[23] Appellate Body Report, *India – Agricultural Products*, paras. 5.133, 5.143; Appellate Body Report, *Russia – Pigs (EU)*, para. 5.122.

Then, the question is whether the areas that are longer contaminated by radioactive materials released by the nuclear accident fall within the scope of the "sanitary and phytosanitary" (SPS) characteristics of the area in Article 6.1. If not, Members would not have to adapt their SPS measures in response to the emergence of non-contaminated areas within the exporting country (in this case, the country where the nuclear accident occurred).

The meaning and scope of the terms "sanitary" and "phytosanitary" in the SPS Agreement are hardly in question. Since Annex A to the SPS Agreement provides a definition of SPS measures, the issue before the parties to the dispute has been not whether the measures at issue are about sanitary and/or phytosanitary, but whether they fall within the SPS measures defined therein. Nevertheless, most commonly, it is explained that sanitary refers to "human and animal health", and phytosanitary means "plant health".[24] Moreover, the dictionary definition of the term "characteristic" refers to "[a] distinctive mark; a distinguishing trait, peculiarity, or quality."[25] Therefore, the SPS characteristics in Article 6.1 might be interpreted to broadly cover the characteristics relating to the risks that SPS measures defined in Annex A(1) aim to address.[26]

If the soil in an area is contaminated with radioactive materials released by a nuclear accident, agricultural products produced in this area might also be contaminated. Hence, the consumption of such products may cause adverse effects (i.e. stochastic effects) on the human body. And as examined before,[27] trade measures to protect human health from risks arising from radioactive materials in food are generally considered to fall under the SPS measure in Annex A(1)(b). Therefore, whether or not the soil in an area is contaminated by radioactive materials released by the accident within the exporting country where the accident occurred can be considered as the SPS characteristics of the area within the meaning of Article 6.

In conclusion, if any import restrictions are imposed as SPS measures on food products from the Member where the nuclear accident occurred, the importing Member is obliged under Article 6 to adapt its SPS measures in response to the

[24] See e.g. WTO, Understanding the WTO Agreement on Sanitary and Phytosanitary Measures, available at < https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm>, last visited 4 May 2020.
[25] *Shorter Oxford English Dictionary on Historical Principles, Volume 1 (A-M)*, 6th edn (Oxford University Press, Oxford: 2007) 384.
[26] The Appellate Body held that "[t]he regional 'characteristics' that are relevant for the adaptation of an SPS measure are those relating to the specific risk that such a measure seeks to address." Appellate Body Report, *Russia – Pigs (EU)*, para. 5.57.
[27] See Chapter 4.3.1.

emergence of the areas that are no longer contaminated with radioactive materials released by the accident within the exporting Member.

5.2.2 Assessment of the SPS Characteristics of an Area

The first sentence of Article 6.1 of the SPS Agreement, which sets out the "adaptation obligation", requires WTO Members to ensure that their SPS measures are adapted to the SPS characteristics of the relevant area, especially within the exporting Member.[28] This obligation is considered as the "main and overarching" one among other obligations set forth in Article 6.[29] The question is what process the importing Member is obliged to follow in order for its SPS measures to be adapted to the SPS characteristics of the area in the exporting Member.

In this regard, the second sentence of Article 6.1 refers to the assessment of the SPS characteristics of a region.[30] According to the Appellate Body, this assessment "provides the basis, and therefore constitutes a prerequisite, for the adaptation" of Member's SPS measures to the regional conditions under the first sentence of Article 6.1.[31] In other words, there is a "logical progression" that Members are required to follow in order to adapt their SPS measures in Article 6.1, which is to firstly *assess* the SPS characteristics of the area, and secondly *adapt* their SPS measures to such characteristics.[32]

An assessment of the SPS characteristics of an area could be conducted "as part of a Member's risk assessment",[33] although the assessment in Article 6.1 itself does not constitute a risk assessment within the meaning of Annex A (4) of the SPS Agreement.[34] It logically follows that, if import restrictions are imposed on food products from the country where a nuclear accident occurred without making any assessment of the risks arising from the ingestion of such products, it will be

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[28] The first sentence of Article 6.1 reads that "Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area – whether all of a country, part of a country, or all or parts of several countries – from which the product originated and to which the product is destined."
[29] Appellate Body Report, *India – Agricultural Products*, paras. 5.141, 5.152, 5.157.
[30] The second sentence of Article 6.1 reads that "[i]n assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations."
[31] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.59.
[32] Panel Report, *US - Animals*, para. 7.646.
[33] Panel Report, *US – Animals*, para. 7.644. See also Panel Report, *Russia – Pigs (EU)*, paras. 7.481, 7.1025.
[34] Reference should be made to Article 5.2 of the SPS Agreement as a basis for supporting the view that the assessment in Article 6 is part of the risk assessment. As the factors to be taken into account in conducting a risk assessment, Article 5.2 also lists "prevalence of specific diseases or pests", and "existence of pest- or disease- free areas".

assumed that no assessment of SPS characteristics in the area at issue in Article 6 is carried out.[35] In practice, it is hard to imagine that only an assessment of the SPS characteristics of the area concerned is conducted independently of the risk assessment.

The elements that Members must take into account when assessing the SPS characteristics of a "region"[36] is specified in the second sentence of Article 6.1.[37] Such elements include, *inter alia*, (i) the level of prevalence of specific diseases or pests, (ii) the existence of eradication or control programmes, and (iii) appropriate criteria or guidelines which may be developed by the relevant international organizations.[38] As indicated by the use of the words "*inter alia*", they are non-exhaustive,[39] and all the evidence relevant to the SPS characteristics of an area must be evaluated.[40] Thus, at least, these three elements above need to be taken into account when assessing radioactive contamination of the soil in an area within the exporting Member where a nuclear accident occurred. In addition, the use of the phrase "take into account" in the second sentence of Article 6.1 appears to indicate that a failure to respect each of these elements would not necessarily mean that the assessment is not in conformity with Article 6.1.[41]

The following will discuss how to determine the existence of the areas that are no longer contaminated with radioactive materials released by the *Fukushima* accident in Japan as an assessment of the SPS characteristics of an area under Article 6.

Firstly, as the level of prevalence of radioactive contamination of the soil, the concentration of caesium-137 contamination in the soil of the area and its regional spread will be examined.[42] As shown in Figures 11 and 12, airborne

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[35] Panel Report, *Russia – Pigs (EU)*, para. 7.482.
[36] It is noted that, while the first sentence of Article 6.1 uses the phrase "SPS characteristics of the *area*", the second sentence of Article 6.1 uses the similar but different phrase "SPS characteristics of a *region*" (Italic Added). Although the terms "area" and "region" are not identical, the panel in *India – Agricultural Products* found that they are "sufficiently similar" in the context of Article 6. Panel Report, *India – Agricultural Products*, para. 7.684.
[37] Appellate Body Report, *India – Agricultural Products*, para. 5.135; Panel Report, *Russia – Pigs (EU)*, para. 7.463.
[38] In addition, the second sentence of Article 6.2 lists factors, such as (i) geography, (ii) ecosystems, (iii) epidemiological surveillance, and (iv) the effectiveness of SPS controls, to be based on when determining pest- or disease-free areas and areas of low pest or disease prevalence.
[39] Panel Report, *India – Agricultural Products*, para. 7.657.
[40] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.59.
[41] Panel Report, *Japan – Apples*, para. 8.241.
[42] As explained in Chapter 5.1, among the radioactive materials released by the accident and deposited in the soil, cesium-137 has a long half-life of 33 years and is considered to be the dominant factor of long-term exposure.

monitoring can be used to calculate the air dose rate and the amount of caesium-137 deposited on the ground surface.

Secondly, as the existence of control programmes, the implementation of decontamination work and the existence of a radiation monitoring plan could be taken into account.[43] In August 2011, the Monitoring Coordination Meeting established by the Japanese government formulated the "Comprehensive Radiation Monitoring Plan" in order to ensure detailed monitoring of a large amount of radioactive materials released into the environment due to the accident. One of the aims of this monitoring plan is "[t]o figure out a dispersion, deposition and migration of radioactive materials which were released to the environment".[44] Since August 2011, comprehensive and detailed monitoring, including soil surveys, has been carried out in accordance with the Plan.[45]

Thirdly, the second sentence of Article 6.1 also lists "appropriate criteria or guidelines which may be developed by the relevant international organizations" as one of the elements to be considered in assessing the SPS characteristics of an area. In the SPS Agreement, international standards, guidelines and recommendations for food safety are the ones established by the Codex relating to, for example, contaminants.[46] Nevertheless, the Codex does not provide any standards or guidelines on how to determine the areas that are no longer contaminated with radioactive materials, especially after the implementation of decontamination work, in the country where a nuclear accident occurred.

5.2.3 Relationship between Articles 6.1 and 6.3

Article 6.1 obliges Members to ensure that their SPS measure are adapted to the regional SPS characteristics mainly within the exporting Member. Meanwhile, Article 6.3 requires the exporting Members claiming that "areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence" to provide the necessary evidence to the importing Member in order to objectively demonstrate that contention.[47] In this regard, one might consider

[43] For more information on decontamination work implemented after the Fukushima accident, see Chapter 5.1.
[44] Monitoring Coordination Meeting, Japan, *Comprehensive Radiation Monitoring Plan (Revised on 1 February 2019)*, available at <https://radioactivity.nsr.go.jp/en/contents/14000/13317/24/274_190201.pdf>, last visited 12 May 2020.
[45] The results of the monitoring survey are available from the following link. NRA, Japan, *Monitoring information of environmental radioactivity level*, available at <https://radioactivity.nsr.go.jp/en/>, last visited 12 May 2020.
[46] Annex A(3)(a) of the SPS Agreement.
[47] Article 6.3 of the SPS Agreement reads that "[e]xporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of

that the importing Member's obligation under Article 6.1 does not arise unless the exporting Member complies with Article 6.3.[48] Therefore, the question is whether the adaptation obligation of the importing Member under Article 6.1 is triggered even in the absence of the exporting Member's provision of the necessary evidence to the importing Member pursuant to Article 6.3.[49]

On the one hand, the Appellate Body noted that an exporting Member making a regionalization request "will have difficulties succeeding in a claim" under Article 6.1 "unless that exporting Member can demonstrate its own compliance with Article 6.3."[50] This is so because the importing Member is usually not in a position to have sufficient information about the pest or disease status of the relevant areas within the exporting Member's territory.[51] On the other hand, according to the Appellate Body, this is not to say that a violation of Article 6.1 can occur only when Article 6.3 is complied. In other words, a Member adopting an SPS measure can still be found to have acted inconsistently with Article 6.1 even if the exporting Member fails to comply with the obligations provided for in Article 6.3.[52] As one of such situations, the Appellate Body held as follows.

> Rather, situations exist in which, "even in the absence of such objective demonstration by an exporting Member, a Member may still be found to have failed to ensure that an SPS measure is adapted to regional conditions within the meaning of Article 6.1." […] Second, pest- or disease-free areas and areas of low pest or disease prevalence "are only a subset of the SPS characteristics that may call for the adaptation of an SPS measure pursuant to the first sentence of Article 6.1".[53]

It is recalled that Article 6.3 applies only to a situation where the exporting Member claims that "areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence". Thus, as noted by the Appellate Body in the quotation above, when the exporting Member claims the existence of the regional SPS characteristics within its territory other than these two types of areas

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low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures."

[48] See e.g. Panel Report, *India – Agricultural Products*, paras. 7.644, 7.647, 7.652, 7.673, 7.711.

[49] For literature analyzing the relationship between Articles 6.1 and 6.3, see e.g. Furculita ('Regionalization within the SPS Agreement') 104-107.

[50] Appellate Body Report, *India – Agricultural Products*, para. 5.156. The Panel in *US – Animals* also recognized that there were some circumstances where "the ability of the importing Member to adapt a measure under Article 6.1 is dependent on the exporting Member's compliance with Article 6.3." Panel Report, *US – Animals*, paras. 7.664, 7.667.

[51] Appellate Body Report, *Russia – Pigs (EU)*, paras. 5.61, 5.99. See also Panel Report, *US – Animals*, para. 7.651.

[52] Appellate Body Report, *India – Agricultural Products*, para. 5.157.

[53] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.98.

(i.e. pest- or disease-free areas, areas of low pest or disease prevalence), Article 6.3 is not applicable.

In light of the above, it follows, at least logically, that the importing Members are obliged to adapt their SPS measures to the existence of non-contaminated areas within the exporting Member where a nuclear accident occurred, even if the exporting Member does not provide necessary evidence under Article 6.3. Nevertheless, in practice, as also noted by the Appellate Body, even if not required by Article 6.3, it would be difficult for the exporting Member (in this case, the country where a nuclear accident occurred) to succeed in a claim without providing the necessary evidence to demonstrate the emergence of non-contaminated areas within its own territory. And according to the Appellate Body, such evidence must be "sufficient to enable the importing Member ultimately to make an objective 'determination'" the contamination status of the area concerned.[54]

5.3 Delayed Response to Regionalization Requests: A Case Study

It is confirmed in the previous section that WTO Members are obliged in Article 6 to adapt their SPS measures imposed on food products from the exporting Member where a nuclear accident occurred to the regional SPS characteristics, that is the emergence of the areas that are no longer contaminated with radioactive materials released by the accident.[55] Thus, upon request from the exporting Member to lift the import restrictions imposed on food products from such non-contaminated areas (i.e. regionalization request), the importing Member must initiate proceedings to review such a request. Specifically, as discussed in the previous section,[56] the importing Member needs to (i) assess the SPS characteristics of the area, such as the level of radioactive contamination of the soil in the area concerned, and (ii) adapt its SPS measure to the SPS characteristics of the area. In practice, these proceedings cannot be completed instantly. Rather, as explained by the Appellate Body, the importing Member is supposed to take "a certain period of time" to carry out these proceedings.[57]

However, it is possible that Members take an unreasonably long time to complete such review proceedings.[58] Since import restrictions will remain in place during

[54] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.64.
[55] See Chapter 5.2.1.
[56] See Chapter 5.2.2.
[57] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.80.
[58] For example, since 2003, Japan has requested 20 countries to lift the ban on imports of beef, pork and chicken from Japan (animal quarantine), and the average period betwe en the request and the actual lifting of the ban is estimated to be "approximately 6 year

the review process, it is extremely important for the exporting Member that the review proceedings are completed without delay. And it was *US – Animals* in which this timeliness issue was mainly disputed. As explained in more detail later, in this case, although Argentina requested the US to resume the import of its animal products from FMD-free areas, the US took more than 10 years to review the requests (e.g. request for fresh beef) and did not reach any conclusions even at the time of the panel's establishment. Given that Article 8 and Annex C(1)(a) of the SPS Agreement require that control, inspection and approval procedures, including the procedures reviewing regionalization requests, be "undertaken and completed without undue delay", Argentina claimed that the US' application of its review procedure was inconsistent with its obligation under these provisions.[59]

As noted before, once a non-contaminated area is identified within the exporting Member where a nuclear accident occurred, it is natural that this Member requests other Members to resume the import of food products from this area. And the analysis of *US – Animals* will provide certain implications for the consistency with the SPS Agreement, especially when other Members do not respond promptly to such a regionalization request. Thus, this section will overview the facts of the case, such as the content of Argentina's requests and the historical response of the US to it.

5.3.1 FMD Outbreaks in Argentina and the US' Responses

Historically, Argentina had long experienced repeated outbreak of FMD[60] in its territory since the first case was confirmed in the 1860s. Especially between the 1960s and the 1980s, FMD outbreaks had repeatedly occurred in Argentina in spite of its vaccination programs implemented during this period. It is Title 9 of the US' Code of Federal Regulations, Part 94 (9 CFR 94),[61] that generally governs the importation of certain animals and animal products into the US in order not to introduce various animal diseases, including FMD. Especially, the importation into

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s". MAFF, *Export of Livestock Products such as Beef (April 2017)* (in Japanese), available at <http://www.maff.go.jp/j/syouan/douei/shuninsha/attach/pdf/h29-16.pdf>, last visited 13 May 2020.

[59] For a comprehensive research on the implementation of Article 6 of the SPS Agreement, including the timeliness issue, see e.g. Loppacher, Laura J, Kerr, William A, and Barichello, Richard R, 'The Debate on Improving Implementation of the Regionalization Chapter of the SPS Agreement: Real Problems or Disguised Protectionism?' (2007) 41(4) Journal of World Trade 667.

[60] FMD is a severe, highly contagious viral disease of livestock. The disease affects cattle, swine, sheep, goats and other cloven-hoofed ruminants. OIE, *Foot & Mouth disease (FM D) (August 2018)*, available at <https://www.oie.int/en/animal-health-in-the-world/animal-diseases/Foot-and-mouth-disease/>, last visited 13 May 2020.

[61] *Rinderpest, Foot-and-Mouth Disease, Exotic New-Castle Disease, African Swine Fever, Swine Vesicular Disease, and Bovine Spongiform Encephalopathy: Prohibited and Restricted Importations*, 9 CFR 94.

the US of "any ruminant or swine or any fresh (chilled or frozen) meat of any ruminant or swine" that originates in any region where FMD is considered to exist is prohibited in 9 CFR 94.1(b). Thus, until 1997, the US had prohibited the imports of these animals and animal products from Argentina pursuant to 9 CFR 94.1(b).

5.3.1.1 Fresh Beef Imports from Argentina Since 1997

In June 1997, however, given that there had been no reported case of FMD in Argentina since April 1994 due to vaccination, the US published a final rule to authorize the imports of fresh (chilled or frozen) beef from Argentina subject to the conditions set out in 9 CFR 94.21 without recognizing it as an FMD-free country.[62] In May 2000, the OIE officially recognized the entire country as FMD-free without vaccination.[63] In order for a country or a zone to be recognized by the OIE as FMD-free without vaccination, according to the Terrestrial Animal Health Code (OIE Code), a Member Country needs to show that, among others, "there has been no case of FMD" and "no vaccination against FMD has been carried out" during the past 12 months.[64]

However, on or about 22 July 2000, only two months after the OIE's official recognition, cattle from a neighboring country were illegally imported into Argentina, and on 16 August 2000, Argentina confirmed that one of the imported animals was infected with FMD. In response to this, the US imposed a temporary ban on the imports of fresh, chilled or frozen beef from Argentina that had been authorized under 9 CFR 94.21. Nevertheless, on the basis of its risk analysis concluding that "the August 2000 outbreak of FMD…had been quickly detected and contained", the US issued an interim rule on 29 December 2000 reauthorizing fresh (chilled or frozen) beef imports from Argentina on condition that additional

[62] USDA/APHIS, *Importation of Beef from Argentina*, 62 Fed. Reg. 34,385 (26 June 1997).
[63] OIE, *Resolution No. XII, Recognition of the Foot and Mouth Disease Status of Member Countries*, Final Report of the 68th General Session (22-26 May 2000). As to the OIE official disease status, a Member of the OIE is required to report outbreaks of certain infectious animal diseases to the OIE, and to take mitigation measures in accordance with the OIE Code. Once a Member can show that there has been no recent outbreak of a certain disease due to their disinfection measures, this Member may request the OIE to recognize its regions or the entire country as disease-free. Upon receipt of this request, the OIE determines its official position on the disease status of the regions or country in accordance with the Standard Operating Procedures for the official recognition of disease status. As to the brief explanation of the standard operating procedures in the OIE, see OIE, *Fact Sheets: Official Disease Status of Member Countries (2015)*, available at <http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Fact_sheets/STATUTS_EN.pdf>, last visited 13 May 2020.
[64] In the latest OIE Terrestrial Animal Health Code, Article 8.8.2 sets out the series of conditions for countries or zones to officially qualify by the OIE as FMD free without vaccination. OIE, *Terrestrial Animal Health Code*, 28th edn (2019), Vol. 2.

requirements were met.[65] In fact, as shown in Table 7, the number of FMD outbreaks in Argentina remained low from July to December 2000.

5.3.1.2 FMD Outbreaks in Mid-2001

Later on, the number of FMD outbreaks increased rapidly in northern parts of Argentina, reaching a peak of 563 cases in May and 570 cases in June 2001.[66] In response to the massive FMD outbreaks occurred in Buenos Aires and other regions on 12 March 2001, which was notified to the OIE,[67] Argentina immediately suspended its exports of fresh (chilled or frozen) beef to the US.[68]

In June 2001, the US also proposed an interim rule, which was effective retroactively to 19 February 2001,[69] repealing 9 CFR 94.21, suspending the importation of fresh (chilled or frozen) beef from the entire territory of Argentina (i.e. 2001 Interim Rule). In December 2001, the interim rule was affirmed by the final rule.[70] As a result, fresh beef from Argentina was no longer treated specially, and its export into the US was again banned pursuant to 9 CFR 94.1(b), which prohibits "any ruminant or swine or any fresh (chilled or frozen) meat of any ruminant or swine" from any region where FMD exists. The Panel in *US – Animals* calls these interim and final rules collectively as the "2001 Regulations" in its report.[71]

In response to the FMD outbreaks in Argentina in March 2001, other WTO Members, such as the EU,[72] Canada,[73] Singapore,[74] New Zealand,[75] and Israel,[76] also immediately took emergency measures to suspend the imports of fresh beef from Argentina.

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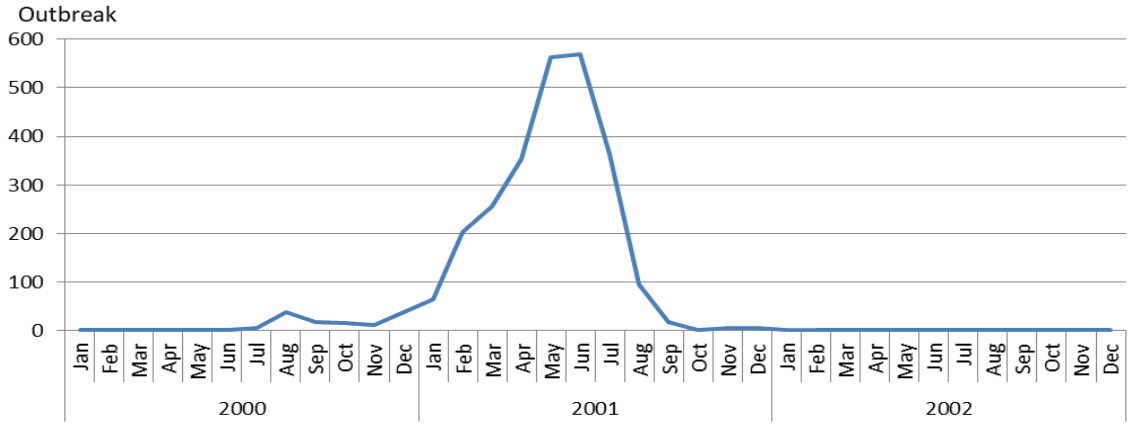
[65] USDA/APHIS, *Certification of Beef from Argentina*, 65 Fed. Reg. 82,894 (29 December 2000).
[66] See OIE, *World Animal Health Information Database (WAHIS) Interface*, available at < http://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home>, last visited 13 May 2020.
[67] See OIE, *Disease Information*, 14 (11) (16 March 2001) 56.
[68] Panel Report, *US – Animals*, para. 2.9.
[69] It is explained that this specific date was roughly determined based on the anticipation that the FMD virus had been already present in Argentina "several weeks" prior to the notification on 12 March 2001. USDA/APHIS, *Prohibition of Beef from Argentina*, 66 Fed. Reg. 29,897 (4 June 2001).
[70] USDA/APHIS, *Prohibition of Beef from Argentina*, 66 Fed. Reg. 63,911 (11 December 2001).
[71] Panel Report, *US – Animals*, para. 2.9.
[72] WTO, Committee on Sanitary and Phytosanitary Measures, Notification of Emergency Measures, G/SPS/N/EEC/115, 26 March 2001.
[73] WTO, Committee on Sanitary and Phytosanitary Measures, Notification of Emergency Measures, G/SPS/N/CAN/98, 26 March 2001.
[74] WTO, Committee on Sanitary and Phytosanitary Measures, Notification of Emergency Measures, G/SPS/N/SGP/16, 27 March 2001.
[75] WTO, Committee on Sanitary and Phytosanitary Measures, Notification of Emergency Measures, G/SPS/N/NZL/93, 29 March 2001.
[76] WTO, Committee on Sanitary and Phytosanitary Measures, Notification of Emergency

Table 7 Numbers of FMD Outbreak in Argentina, 2000-2002



Source: OIE, World Animal Health Information Database (WAHIS) Interface

In sum, the year 2001, when the US adopted the interim and final rules to add Argentine fresh (chilled or frozen) beef to its list of banned imports, was exactly the time when Argentina experienced the highest number of FMD outbreaks compared to other years (see Table 7). However, for about 17 years from January 2002 to the present, no FMD outbreak has been confirmed in Argentina, except only three outbreaks detected in Northern Argentina in August 2003 and February 2006.[77] Nevertheless, the US had continued to impose the import ban against entire Argentina for almost 12 years until the time of panel establishment (i.e. 28 January 2013) on the basis of the FMD outbreaks occurred from July 2000 to January 2002 in Northern Argentina.

5.3.2 Argentina's Regionalization Requests

It is important that the series of FMD outbreaks in Argentina that began in July 2000 and continued until January 2002 were geographically confined to Northern Argentina, a region occupying the northern half of Argentina (i.e. north of Patagonia South and Patagonia North B) (see Figure 13).[78] However, as is evident from Table 7, the number of FMD cases declined sharply in the second half of 2001, and from January 2002 onwards, the number of FMD cases remained zero.[79] In addition, other regions of Argentina had not experienced FMD outbreaks for a long time. Therefore, it was natural for Argentina to request the

Measures, G/SPS/N/ISR/5, 9 April 2001.

[77] That is, one outbreak in the Province of Salta in August 2003, two outbreaks in the Province of Corrientes in February 2006.

[78] USDA/APHIS, *Animal Health Status of Regions (29 February 2020)*, available at <https://www.aphis.usda.gov/animal_health/downloads/import/animals/argentina-patagonia-southandnorth-b.pdf>, last visited 13 May 2020.

[79] Moreover, since January 2002, the number of FMD cases in entire Argentina has remained zero until now, except for a total of three cases in August 2003 and February 2006.

US to lift the import ban imposed on fresh beef and other animal products from the areas where FMD cases had not been confirmed.

Figure 13 Administrative Divisions in Argentina

Source: USDA/APHIS, *Animal Health Status of Regions (29 February 2020)*

Firstly, in November 2002, Argentina requested the veterinary authorities of the US' Animal and Plant Health Inspection Service (i.e. APHIS) to reauthorize the import of fresh (chilled or frozen) beef originating from Northern Argentina. But, it did not request APHIS to add this region to a list of regions APHIS declares as FMD-free. It means that Argentina did not require the resumption of imports of animals and animal products other than fresh beef from this region.

In July 2003, the OIE officially recognized Northern Argentina as "FMD-free where vaccination is practiced",[80] according to the relevant provisions of the OIE Code.[81] However, this official recognition was subsequently withdrawn due to the three outbreaks occurred in August 2003 (Salta Province) and February 2006 (Corrientes Province), as referred to above. Thus, in May 2007, the OIE once again recognized Northern Argentina as FMD-free where vaccination is

[80] OIE, *Resolution XX, Recognition of the Foot and Mouth Disease Status of Member Countries*, Final Report of the 71st General Session, 18-23 May 2003, 71 GS/FR (2003) para. 198.
[81] It is Article 8.8.2 of the OIE Code (28th edn) that governs inclusion in the list of FMD free countries or zones where vaccination is not practiced.

practiced,[82] and this disease status remained at least until the establishment of the panel of this case (i.e. 28 January 2013). However, even after such OIE's official recognition, Argentina never requested APHIS to declare Northern Argentina to be FMD-free.

Secondly, in contrast to Northern Argentina, the Patagonia region (see Figure 13), which is composed of (1) Patagonia South, the region of Patagonia located south of the 42nd parallel, and (2) Patagonia North B, the region of Patagonia located between Northern Argentina and South Patagonia,[83] has long been FMD-free. Specifically, there has been no FMD outbreak in Patagonia South since 1976, and Patagonia North B since 1994.[84] The OIE officially recognized Patagonia South as "FMD-free where vaccination is not practiced" in May 2002,[85] and also Patagonia North B in May 2007,[86] according to the relevant provisions of the OIE Code.[87] Then, contrary to its request for Northern Argentina, Argentina requested APHIS to recognize Patagonia South and Patagonia North B as FMD-free, and reauthorize the imports of FMD-susceptible animals and animal products, including fresh (chilled or frozen) beef, originating from this region to the US, respectively in August 2003 and December 2008.[88]

5.3.3 US's Delayed Responses to Argentina's Requests

In October 1997, the APHIS published a final rule establishing procedures for recognizing an animal health status of foreign regions, and defining conditions for allowing imports of animals and animal products therefrom into the US.[89] According to 9 CFR 92.2,[90] upon request from an exporting county to recognize all or part of the country as FMD-free and authorize imports of FMD-susceptible animals and animal products therefrom, APHIS needs to assess the risks associated with the importation of animal and animal products, based on the information provided by the requesting country, obtained from the scientific

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[82] OIE, *Resolution XXI, Recognition of the Foot and Mouth Disease Status of Member Countries*, Final Report of the 75th General Session, 20-25 May 2007, 75 GS/FR (2007) 135-137.
[83] Panel Report, *US – Animals*, para. 7.4.
[84] Panel Report, *US – Animals*, para. 2.37.
[85] OIE, *Resolution XVII, Recognition of the Foot and Mouth Disease Status of Member Countries*, Final Report of the 70th General Session, 26-31 May 2002, 70 GS/FR (2002) 100-101.
[86] OIE (*Resolution XXI*) 135-137.
[87] It is Article 8.8.3 of the OIE Code (28th edn) that governs inclusion in the list of FMD free countries or zones where vaccination is practiced.
[88] Panel Report, *US – Animals*, para. 2.16.
[89] USDA/APHIS, *Importation of Animals and Animal Products*, 62 Fed. Reg. 56,000 (28 October 1997). See also USDA/APHIS, *Process for Foreign Animal Health Status Evaluations, Regionalization, Risk Analysis, and Rulemaking*, available at <https://www.aphis.usda.gov/import_export/animals/downloads/regionalization_process.pdf>, last visited 13 May 2020.
[90] *Application for Recognition of the Animal Health Status of a Region*, 9 CFR 92.2 (a)-(f).

literature, and gathered from a site visit by APHIS. In this case, the risk analysis is performed "[f]ollowing OIE guidelines",[91] or to be more specific, the risk assessment steps detailed in the OIE Code.[92]

If the region concerned is recognized as FMD-free as a result of the risk assessment, or "[i]f…APHIS believes the requested importation can be safely allowed",[93] APHIS communicates the outcome to the applicant country, and also publishes a proposed regulation in the Federal Register that contains the conditions under which imports of FMD-susceptible animals and animal products are authorized. After reviewing the proposed regulation based on the collected public comments, APHIS issues the final regulatory decision.

With respect to Argentina's regionalization requests, however, APHIS had still not reached its final conclusion even as of the date of the establishment of the Panel (i.e. 28 January 2013). It means that, since Argentina's requests were made in November 2002 for Northern Argentina, in August 2003 for Patagonia South, and in December 2008 for Patagonia North B, APHIS had maintained the import ban through the 2001 Regulations on fresh beef from Northern Argentina for more than 11 years, as well as on FMD-susceptible animals and animal products from Patagonia South for about 10 years, and from Patagonia North B for about four years.

Therefore, Argentina claimed in *US – Animals* that the review by APHIS of Argentina's regionalization requests was unduly delayed inconsistently with Article 8 and Annex C(1)(a) of the SPS Agreement, and thus that the import ban maintained during the review process was also inconsistent with the substantive obligations of the US in the SPS Agreement.

5.3.4 Progress after the Panel Establishment

As a unique feature of this dispute, it is noted that, even before the Panel report was issued on 24 July 2015, the US had partially proceeded with the approval procedures set out in 9 CFR 92.2 regarding Argentina's regionalization requests for both North Argentina and the Patagonia region.

Firstly, around one year after the establishment of the Panel, APHIS completed its risk assessment for the Patagonia region on 23 January 2014.[94] Then, on 28

[91] See USDA/APHIS (*Process for Foreign Animal Health Status Evaluations*) 3.
[92] According to Article 2.1.4 of the OIE Code (28th edn), the risk assessment is composed of the following steps; (1) entry assessment, (2) exposure assessment, (3) consequence assessment, and (4) risk estimation.
[93] Section 92.2 (e).
[94] USDA/APHIS, *Risk Analysis: Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Products from a region of Patagonia, Argentina* (January 2014), available at <

October 2014, one month after the second substantive panel meeting (i.e. 4 and 5 September 2014), APHIS added the Patagonia region to the lists of regions it considers to be FMD-free, and thus authorized the imports of animals and animal products, including fresh (chilled or frozen) beef, from this region into the US.[95] It should be recalled that 9 CFR 94.1(b) only prohibits the imports of animals and animal products originating in any regions where FMD exists into the US.

Secondly, with respect to Northern Argentina, APHIS completed its risk assessment for this region on 29 August 2014, concluding that fresh (chilled or frozen) beef can safely be exported to the US from Northern Argentina under certain conditions. Then, on 1 September 2015, which was about two months after the circulation of the Panel report to all Members, the import of fresh (chilled or frozen) beef from Northern Argentina into the US was approved provided that the conditions set out in 9 CFR 94.29 are met.[96]

It should be noted that APHIS has never declared Northern Argentina, in which vaccination has been long conducted, as FMD-free.[97] As a result, pursuant to 9 CFR 94.1(d),[98] the imports of animals and animal products other than fresh (chilled or frozen) beef into the US from Northern Argentina are still being prohibited. Since the imports of fresh (chilled or frozen) beef from Northern Argentina and of animals and animal products from the Patagonia region were already authorized, the Panel report was adopted by the Dispute Settlement Body without an appeal on 31 August 2015.[99]

5.4 Undue Delay in Annex C(1) of the SPS Agreement

Even if the substantive SPS measures themselves are consistent with the SPS Agreement, such measures can have a negative impact on international trade, depending on how they are applied. For example, in spite of a regionalization request made by the exporting Member, the importing Member would effectively be able to circumvent its adaptation obligation in Article 6.1 by delaying the procedures to review such requests.[100] Therefore, it is imperative to regulate not

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https://www.aphis.usda.gov/newsroom/2014/01/pdf/Patagonia_Region_Risk_Analysis_Final.pdf>, last visited 13 May 2020.

[95] USDA/APHIS, *Notice of Determination of the Foot-and-Mouth Disease and Rinderpest Status of a Region of Patagonia, Argentina*, 79 Fed. Reg. 51,528 (29 August 2014).

[96] USDA/APHIS, *Importation of Beef from a Region in Argentina*, 80 Fed. Reg. 37,935 (2 July 2015).

[97] Panel Report, *US – Animals*, paras. 7.229, 7.236.

[98] According to 9 CFR 94.1(b), with some exceptions, any ruminant or swine or any fresh (chilled or frozen) meat of any ruminant or swine from regions that are not declared by APHIS to be FMD-free cannot be imported to the US.

[99] WTO, Dispute Settlement Body, Minutes of Meeting Held in the Centre William Rappard on 31 August 2015, WT/DSB/M/367, 30 October 2015, para. 11.7.

[100] See e.g. Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1517.

only the substantive SPS measures themselves, but also the procedural measures that are designed to implement or administer the substantive SPS measures.[101] In this regard, Article 8 of the SPS Agreement requires Members to observe the provisions of Annex C "in the operation of control, inspection and approval procedures".[102] Moreover, Annex C(1) of the SPS Agreement states as follows.

> **ANNEX C Control, Inspection and Approval Procedures[7]**
>
> 1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> 7 Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

As is clear from the text, Article 8 and the *chapeau* of Annex C(1) of the SPS Agreement regulate the operation or "application"[103] of the procedures that determine the fulfilment of substantive SPS measures. Among others, Annex C(1)(a) requires Members to ensure that "such procedures [any procedures to check and ensure the fulfilment of sanitary or phytosanitary measures] are undertaken and completed without undue delay". Thus, the question here is whether these provisions apply to a situation where the importing Member takes a long time to review a regionalization request made by the exporting Member where a nuclear accident occurred to resume the import of food products from the non-contaminated areas. Even if so, the next question is under what conditions a delay in such review procedures would constitute an "undue delay" within the meaning of Annex C(1)(a) of the SPS Agreement.[104]

The following will firstly examine the systematic issue of what disciplines in the SPS Agreement the procedures in Article 8 and Annex C(1) are subject to. Then,

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[101] As to the distinction between substantive and procedural SPS measures, see Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, para. 7.156. For an analysis of the disciplines in the GATT over how trade or customs laws and regulations are administered, see Ishikawa, Yoshimichi, 'Regulating the Administration of Trade or Customs Law and Regulations: Reassessing the Role of Article X:3(a) of the GATT, 1994', in Won-mog Choi (ed), *International Economic Law: The Asia-Pacific Perspectives* (Cambridge Scholars Publishing, Cambridge: 2015) 164.

[102] Article 8 of the SPS Agreement reads that "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

[103] The usage of the term "operation", which means "[t]he condition of functioning or being active", may imply that this provision concerns the application of the procedures at issue. *Shorter Oxford English Dictionary on Historical Principles, Volume 1 (A-M)*, 6th edn (Oxford University Press, Oxford: 2007) 2009.

[104] It is established that a failure to comply with Annex C(1) will consequently lead to a violation of Article 8. Panel Report, *US – Animals*, para. 7.62. *See* also Appellate Body Report, *Australia – Apples,* para. 434.

it will further analyze how the requirement "without undue delay" in Annex C(1)(a) was interpreted and applied in *US – Animals*.

5.4.1 Relationship between SPS Measures and Procedures in Annex C

Given the phrase in Annex C(1) of the SPS Agreement that "with respect to any procedure to check and ensure the fulfilment of SPS measures", it appears clear that such procedures are conceptually distinct from SPS measures, which are defined in Annex A(1). This distinction is also upheld by the Appellate Body, when it found that, whereas many provisions of the SPS Agreement "focus directly SPS measures, as such", the obligations in Annex C(1) and Article 8 are "relating to *procedures*".[105] Based on this conceptual distinction between SPS measures and procedures, one might consider that the procedures to check and ensure the fulfilment of SPS measures are only subject to the disciplines of Annex C, but not the rest of the SPS Agreement that only applies to SPS measures.[106] Since the relationship between SPS measures and procedures in Annex C has been already explored by a number of commentators,[107] this section rather aims to update those arguments in light of the recent cases.

5.4.1.1 Conformity Assessment Procedure in the SPS Agreement

There is a view that the procedures covered by Annex C(1) are to be interpreted as setting out conformity assessment procedures. And such an interpretation might be (but not necessarily) associated with a position that the procedures in Annex C(1) are distinct from SPS measures themselves, and thus they are not subject to the provisions of the SPS Agreement other than those in Annex C.

The attention should be paid to the similarity between the wording of Annex C(1) and the relevant provisions in the TBT Agreement that explicitly set out conformity assessment procedures. Firstly, while Annex C(1) covers "any procedure to check and ensure the fulfilment of SPS measures", Annex 1(3) of the TBT Agreement defines conformity assessment procedures as "[a]ny procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled". They look identical in that they recognize both substantive requirements and procedures that determine the consistency

[105] Appellate Body Report, *Australia – Apples*, para. 435 (Italic Original).
[106] It is worth recalling that the first sentence of Article 1 of the SPS Agreement reads that "[t]his Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade."
[107] See e.g. Scott, Joanne, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (Oxford University Press, Oxford: 2007) 218-220; Epps, Tracey, 'Pre-market Approval Systems and the SPS Agreement', in Geert Van Calster and Denise Prévost (eds), *Research Handbook on Environment, Health and the WTO* (Edward Elgar Publishing, Cheltenham: 2013) 327-330.

with the substantive requirements. Secondly, procedures in Annex C include, "*inter alia*, procedures for sampling, testing, and certification", while the explanatory notes for conformity assessment procedures in Annex 1(3) of the TBT Agreement also state that they include, "*inter alia*, procedures for sampling, testing and inspection". There is a clear similarity between the two.[108]

Aside from the textual similarity, it is also pointed out that Article 8 and Annex C(1) of the SPS Agreement were codified on the basis of Article 5 of the Standards Code.[109] Article 5 of the Standards Code, entitled "Determination of conformity with technical regulations or standards by central government bodies", set out the obligations that central government bodies shall follow, when "a positive assurance is required that products conform with technical regulations or standards". [110] This historical aspect may also support the view that the procedures in Annex C set out conformity assessment procedures.

Such a view is generally accepted in academics. One commentator clearly notes that, on the basis of the similarity to the TBT Agreement, "there is no doubt that it [Article 8] deals with conformity assessment, as does Annex C of the SPS Agreement." [111] Bossche and Zdouc also take this view by noting that the procedures in Annex C(1) are referred to as conformity assessment procedures in the TBT Agreement.[112]

It is noted that, in the TBT Agreement, conformity assessment procedures are conceptually distinguished from technical regulations or standards. They are "not only distinct from one other, but mutually exclusive".[113] Assuming that there is a parallel between the SPS Agreement and the TBT Agreement, one might

[108] In this regard, the panel in *EC – Seal Products* agreed with the parties that "there are certain parallels in the terms and scope of Article 5.2.1 of the TBT Agreement [conformity assessment procedures] and Annex C(1)(a) of the SPS Agreement." Panel Report, *EC – Seal Products*, paras. 7.560-7.561. Article 5.2.1 of the TBT Agreement reads that Members shall ensure that "conformity assessment procedures are undertaken and completed as expeditiously as possible and in a no less favourable order for products originating in the territories of other Members than for like domestic products".

[109] See e.g. Böckenförde, Markus, 'Article 8 and Annex C SPS: Control, Inspection and Approval procedures', in Rüdiger Wolfrum, Peter-Tobias Stoll and Anja Seibert-Fohr (eds), *WTO-Technical Barriers and SPS Measures* (Martinus Nijhoff Publishers, Leiden, Boston: 2007) 489 (noting that "[c]entral parts of Art. 8/Annex C derive from Art. 5 of the Tokyo Round Standards Code").

[110] Article 5.1 of the Standards Code. For an in-depth analysis of the Standards Code, see Villarreal, Andrea B, *International Standardization and the Agreement on Technical Barriers to Trade* (Cambridge University Press, Cambridge: 2018) 102-108.

[111] Mavroidis, Petros C, *The Regulation of International Trade, Volume 2: The WTO Agreements on Trade in Goods* (The MIT Press, Cambridge, London: 2016) 483.

[112] Bossche, Peter van den and Zdouc, Werner, *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, 4th edn (Cambridge University Press, Cambridge: 2017) 976, fn. 201. See also Prévost, Denise, 'National Treatment in the SPS Agreement: A Sui Generis Obligation', in A. Kamperman Sanders (ed), *The Principle of National Treatment in International Economic Law: Trade, Investment and Intellectual Property* (Edward Elgar Publishing, Cheltenham/Northampton: 2014) 125, 151.

[113] Panel Report, *EC – Trademarks and Geographical Indications (Australia)*, para. 7.512.

understand that Annex C(1) sets out conformity assessment procedures, which should be also distinct from SPS measures themselves. However, the position of equating procedures in Annex C(1) as conformity assessment procedures does not necessarily lead to the conclusions that they should be distinct from SPS measures, and thus that they are not subject to the provisions of the SPS Agreement other than those in Annex C. Rather, such a conclusion is problematic in light of the unique structure of the SPS Agreement, as will be discussed in the next section.

5.4.1.2 Procedures in Annex C as A Subset of SPS Measures

The scope of SPS measures in Annex A(1) of the SPS Agreement is broadly defined. The final sentence of Article A(1) states that SPS measures include "all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, […] testing, inspection, certification and approval procedures". Given Annex C is similarly entitled "Control, Inspection and Approval Procedures", it follows that the procedures in Annex C are also subject to the disciplines of the SPS Agreement other than those in Annex C as SPS measures.

However, the question is whether procedures in Annex C(1) can take a form that does not qualify as SPS measures, and thus result in being subject only to Annex C, not the rest of the SPS Agreement. In other words, the question is whether or not the procedures in Annex C are merely a sub-set of SPS measures in Annex A(1). This question can be practically significant, because "there is no generally applicable necessity or reasonableness requirement in respect of all control, inspection or approval procedures" in Annex C.[114] For example, Annex C(1)(e) sets out reasonable and necessity tests, but they are applicable exclusively to procedures for "individual specimens of a product".[115] Therefore, if there are procedures in Annex C(1) that do not qualify as SPS measures, it means that control, inspection or approval procedures as such in Annex C that, for example, create unnecessary obstacles to international trade, will not be fully disciplined in Annex C.

However, this conclusion appears to be contrary to the preamble of the SPS Agreement referring to the disciplines on the application of SPS measures,[116] as

[114] Scott (*WTO Agreement on SPS Measures*) 219. On the other hand, Prévost notes that "Annex C contains detailed rules…which broadly aim to ensure that procedures [in Annex C] are not more lengthy and burdensome than is reasonable and necessary". Prévost, Denise, *Balancing Trade and Health in the SPS Agreement: The Development Dimension* (Wolf Legal Publishers, Nijmegen: 2009) 823.

[115] Annex C(1)(e) of the SPS Agreement reads that "any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary".

[116] The first paragraph of the preamble reads that "[SPS] measures are not applied in a manner

well as Article 8 requiring Members to ensure that "their [control, inspection and approval] procedures are not inconsistent with the provisions of this Agreement." In light of this unique structure of the SPS Agreement, the procedures in Annex C should be interpreted as a sub-set of SPS measures in Annex A(1), so as to subject them to the entire disciplines of the agreement. For example, Bossche and Zdouc appear to claim that control, inspection and approval procedures are subject to both Annex C and the other provisions of the agreement on the basis of Article 8.[117] In practice, however, not all relevant provisions of the SPS Agreement apply to the procedures in Annex C.

5.4.1.3 Jurisprudence

In recent cases, WTO adjudicators appear to have supported the view that procedures in Annex C are a sub-set of SPS measures in Annex A(1), and thus are also subject to the rest of the SPS Agreement.

In *US – Poultry (China)*, Section 727 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (AAA) of 2009 prohibited the Food Safety and Inspection Services (FSIS) from using funds for fiscal year 2009 (1 Oct 2008-30 Sep 2009) to establish or implement a rule allowing poultry products from China to be imported into the US.[118] Then, it was disputed whether Section 727 of the AAA unduly delayed the operation of the FSIS equivalence determination process for the importation of Chinese poultry products. Since both parties agreed that the FSIS process was a "procedure" in Annex C, it was specifically disputed whether the FSIS process was an "approval" procedure within the meaning of Annex C(1).[119] While the panel's view was not fully clarified, the US appears to have suggested that procedures in Annex C were a sub-set of the SPS measures when it maintained that "Annex C does not apply to every SPS measure, but rather to a subset of SPS measures, namely 'control, inspection or approval procedures'."[120]

In *US – Animals*, as will be examined in detail later,[121] Argentina claimed that APHIS' application of the approval procedures set out in 9 CFR 92.2 to Argentina's

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which would constitute a means of arbitrary or unjustifiable discrimination". See, e.g. Panel Report, *US – Poultry (China)*, para. 7.375.

[117] Bossche and Zdouc (*The Law and Policy of the WTO*) 976. Prévost also appears to support this interpretation on the ground that procedures in Annex C(1) are "a particular category of SPS measures", and specifically constitute "procedural" SPS measures to be distinguished from substantive SPS measures. Prévost (*Balancing Trade and Health*) 824-828. *See,* also Epps ('Pre-market Approval Systems') 331 (noting that "[t]he wording of the SPS Agreement suggests that procedural measures are a sub-set of SPS measures and are the only measures subject to the Annex C obligations.").

[118] Panel Report, *US – Poultry (China)*, paras. 2.2-2.4.

[119] Panel Report, *US – Poultry (China)*, paras. 7.348, 7.362, 7.370.

[120] Panel Report, *US – Poultry (China)*, para. 7.359.

[121] See Chapter 5.4.2.1.

regionalization requests had failed to be completed without undue delay. As was the case in *US – Poultry (China)*, both parties agreed that the procedures in 9 CFR 92.2 were "procedures" within the meaning of Annex C. Nevertheless, the Panel attempted to confirm it by relaying on its previous finding that they constituted SPS measures, either as "regulations" or "procedures" listed in the final sentence of Annex A(1).[122] According to the Panel, the approval procedures in 9 CFR 92.2 were "procedures" in Annex C because they were also "procedures" in Annex A(1).

In *Korea – Radionuclides*, Japan claimed that Korea's additional testing requirements dated 2011 for non-fishery products (except livestock) and dated 2013 for fishery and livestock products were inconsistent with Articles 2.3 and 5.6 of the SPS Agreement, as well as Article 8 and Annex C(1)(a). Thus, while these testing requirements were found to be SPS measures defined in Annex A, the panel also held that they constituted procedures within the meaning of Article 8 and Annex C(1)(a).[123]

In *Indonesia – Chicken*, Brazil claimed that Indonesia had failed to undertake and complete the approval of a veterinary health certificate for the importation of chicken products from Brazil without undue delay. Both parties agreed that the approval qualified an "approval procedure" within the meaning of Annex C, and the panel simply upheld it.[124]

5.4.2 Delays in Approval Procedures for Regionalization Requests in Article 8 and Annex C(1) of the SPS Agreement

As explained before,[125] Article 6 of the SPS Agreement requires Members to adapt their SPS measures to the SPS characteristics of an area, mainly in the exporting Member. To this end, they need to undertake an assessment of the SPS characteristics of the area, and then to adapt their measures to such regional characteristics. This assessment includes the determination of the pest or disease status of certain geographic areas within the exporting Member.[126] It is important to note that such an assessment is considered as a precondition to implement their adaptation obligations, and then to authorize the resumption of food imports from, for example, the pest- or disease free areas within the exporting Member. Therefore, the question is whether the procedures to assess the regional SPS characteristics and determine, for example, pest- or disease- free areas fall within

[122] Panel Report, *US – Animals*, para. 7.63.
[123] Panel Report, *Korea – Radionuclides*, paras. 3.1, 7.32, 7.381.
[124] Panel Report, *Indonesia – Chicken*, paras. 7.516-7.518.
[125] See Chapter 5.2.2.
[126] When assessing the SPS characteristics, Members must are required to take into account the elements listed in the second sentence of Article 6.1 of the SPS Agreement.

Annex C(1) of the SPS Agreement. If so, Members must make sure that such procedures are undertaken and completed without undue delay pursuant to Annex C(1)(a).[127] In the following, these issues will be discussed through an analysis of *US – Animals*.

5.4.2.1 Applicability

In *US – Animals*, Argentina did not challenge APHIS' approval procedures themselves detailed in 9 CFR 92.2 for recognizing a region or country as FMD-free. Instead, it claimed that APHIS' *application* of those procedure to Argentina's regionalization requests had failed to be completed without undue delay in accordance with Article 8 and Annex C(1)(a) of the SPS Agreement.[128]

Since the both parties agreed that the approval procedures set out in 9 CFR 92.2 were "procedures" within the meaning of Annex C and Article 8, the issue was rather whether they constituted one of the procedures falling within the scope of these provisions.[129] In response to Argentina's claim that the coverage of Annex C and Article 8 should be widely interpreted, the US contended that the procedures detailed in 9 CFR 92.2 only governed the determination of the disease status of certain geographic areas, and thus fell outside the scope of these provisions.[130]

The Panel upheld the position taken by previous WTO adjudicators that the titles of both Annex C and Article 8 do not serve for confining *a priori* the applicable scope of Annex C(1) and Article 8 to any specific types of procedures. As rightly summarized by the panel in *US – Poultry (China)*, the phrases "any procedure" in Annex C(1), "*inter alia*" in Footnote 7 to Annex C, and "including" in Article 8 suggest that Annex C(1) and Article 8 "cover a broad array of procedures".[131] Based on this view, the Panel in *US – Animals* rejected the US' argument that excludes the procedure determining the disease status of certain geographic areas from the applicable scope of these provisions.[132] Thus, the Panel concluded

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[127] See e.g. Kennedy, Kevin C, 'The Illegality of Unilateral Trade Measures to Resolve Trade-Environment Disputes', 2(1998) 2(2) William and Mary Environmental Law and Policy Review 375, 405.
[128] Panel Report, *US – Animals*, paras. 2.16, 7.39.
[129] Panel Report, *US – Animals*, paras. 7.63-7.64.
[130] Panel Report, *US – Animals*, paras. 7.54-7.58, 7.63-7.64.
[131] Panel Report, *US – Poultry (China)*, para. 7.372. See also Panel Report, *US – Animals*, paras. 7.66-7.68; Appellate Body Report, *Australia – Apples*, para. 438; Panel Report, *Russia – Pigs (EU)*, para. 7.514.
[132] Panel Report, *US – Animals*, para. 7.69. Moreover, even if the immediate object of the procedures in 9 CFR 92.2 was, as alleged by the US, only to determine the disease status of certain areas, the Panel understood that the procedures were ultimately related to the authorization of the imports of certain products from the areas recognized as disease-free pursuant to 9 CFR 92.2.

that the procedures set out in 9 CFR 92.2 were "any procedures" within the scope of Annex C(1).[133]

Thus, the next issue in *US – Animals* was whether the procedures set out in 9 CFR 92.2 were aimed "to check and ensure the fulfilment of SPS measures" within the meaning of Annex C(1). The Panel noted that both the 2001 Regulations and 9 CFR 94 were the SPS measures set out in Annex A(1) affecting directly or indirectly international trade.[134] It is recalled that 9 CFR 94 governs the importation of certain animals and animal products into the US in order not to introduce various animal diseases.[135] Therefore, the Panel concluded that the procedures detailed in 9 CFR 92.2 were aimed to check and ensure the fulfilment of the SPS measure (i.e. 9 CFR 94).[136]

In sum, it is important that the Panel in *US – Animals* clearly confirmed that the approval procedures to review regionalization requests, including the determination of the disease status of certain geographical areas, need to be undertaken and completed "without undue delay" in Annex C(1) and Article 8 of the SPS Agreement. Later, the panel in *Russia – Pigs (EU)* also found that "we see nothing in Article 8 and Annex C(1) that would exclude procedures linked to the determinations of the disease status of certain geographic regions from their scope of application."[137] Nevertheless, since the scope of the procedures in Annex C(1) has been interpreted broadly by past WTO adjudicators, the Panel's conclusion is not necessarily surprising. In addition, given the concerns expressed by a number of Members about delays in reviewing regionalization requests and recognizing pest- or disease-free areas,[138] the Panel's finding can be considered as desirable.

5.4.2.2 *US – Animals*

As already explained,[139] although Argentina's requests were already made in November 2002 for Northern Argentina, and in August 2003 for the Patagonia region, APHIS failed to complete its review process even as of the time of panel

[133] Panel Report, *US – Animals*, para. 7.70.
[134] Panel Report, *US – Animals*, paras. 7.34-7.36, 7.44-7.47.
[135] The importation of any fresh (chilled or frozen) meat of any ruminant or swine that originates in any region where FMD exists is prohibited pursuant to 9 CFR 94.1(b). On the other hand, if certain geographic areas are recognized as disease-free pursuant to the procedures in 9 CFR 92.2, the importation of such products from these areas into the US is authorized pursuant to 9 CFR 94. See Chapter 5.3.1.
[136] Panel Report, *US – Animals*, paras. 7.72-7.75.
[137] Panel Report, *Russia – Pigs (EU)*, para. 7.514
[138] See e.g. WTO, Committee on Sanitary and Phytosanitary Measures, *Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary* Measures: Report of the Committee, G/SPS/12, 11 March 1999, para. 21. See also Loppacher et al ('The Debate on the Regionalization') 675.
[139] See Chapter 5.3.2.

establishment (i.e. 28 January 2013). On the other hand, Argentina agreed that APHIS had initiated its review process promptly upon receiving Argentina's regionalization requests, and thus it only challenged APHIS' completion of the approval processes.[140]

The term "delay" in Annex C(1)(a) has been interpreted to mean "a period of time lost by inaction or inability to proceed on the part of the authority carrying out the procedure."[141] According to the Panel in *US – Animals*, inaction or inability to proceed would associate with "something outside the normal course of procedure", and whether there is a deviation from the normal course of procedure cannot be determined from a simple comparison with a standard or average time-period that would normally be required for the completion of the procedure. Instead, this must be determined in light of the "nature and complexity of the procedure".[142]

In light of the above, the Panel recognized the periods of inaction on the part of APHIS to proceed with the approval procedures detailed in 9 CFR 92.2 as follows; (i) Northern Argentina: from October 2003 to November 2004, and from September 2006 to January 2013 (in total, around 7 years and 5 months),[143] and (ii) the Patagonia region: from March to November 2004, from June 2005 to January 2007, from March 2007 to October 2008, and from February 2009 to January 2013 (in total, around 7 years and 9 months).[144]

The next question was whether the delays found above was found to be "undue" within the meaning of Annex C(1)(a). In this regard, it must be examined on a case-by-case basis "whether there is a legitimate reason, or justification, for a given delay, not the length of a delay as such."[145] With reference to the guidance provided by another panel in the past, the Panel in *US – Animals* found that (i) delays that are attributable to action or inaction of an applicant, not the

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[140] Panel Report, *US – Animals*, paras. 7.78, 7.122, 7.149. As was the case in *Indonesia – Chicken*, a Member might refrain from commencing the review procedure for regionalization requests unless an exporting Member submits all the relevant information to the importing Member in its request. It is believed, however, that the procedures must be triggered once an application has been received, regardless of whether the application completes the documentation. In this respect, it should be recalled that Annex C(1)(b) requires the competent body to "promptly examine[] the completeness of the documentation" "when receiving an application". Therefore, the incompleteness of the documentation in a regionalization request cannot justify a delay in undertaking and completing the procedures. Panel Report, *Indonesia – Chicken*, paras. 7.520-7.522.

[141] Panel Report, *US – Animals*, paras. 7.113, 7.121 (referring to Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1495). See also Appellate Body Report, *Australia – Apples*, para. 437.

[142] Panel Report, *US – Animals*, paras. 7.114.

[143] Panel Report, *US – Animals*, para. 7.127.

[144] Panel Report, *US – Animals*, para. 7.159.

[145] Panel Report, *US – Animals*, para. 7.115 (referring to Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1496). See also Panel Report, *US – Poultry (China)*, para. 7.354.

competent authorities, (ii) delays that are needed to determine with adequate confidence whether SPS measures are fulfilled, and (iii) delays needed to assess new or additional information that is submitted at a late stage in approval procedures, and that has a potential impact on the determination, should not be considered as undue.[146]

In light of the guideline above, the Panel concluded that one year delay in reviewing the regionalization request for Northern Argentina,[147] and eight month delay for the regionalization request for the Patagonia region,[148] were both attributable to inaction of Argentina's National Animal Health Service (SENASA) to provide APHIS with the requested information, and that these delays cannot be undue.[149] However, the periods other than those, which is the majority of the periods found to be delayed, were found to be undue.[150]

5.4.2.3 Relationship with Article 6 of the SPS Agreement

Article 6.1 of the SPS Agreement requires Members to adapt their SPS measures to the SPS characteristics of the area, mainly within the exporting Member. Upon receipt of a regionalization request, they are required to commence the approval procedures for recognizing the pest or disease free areas, and reauthorizing the imports of relevant food products from such areas.

However, it does not mean that the adaptation obligation must be implemented instantly. As a logical progression, Members must assess the SPS characteristics of the areas concerned before adapting their measure to such regional characteristics. In this regard, an assessment of the SPS characteristics of the area, which is often conducted as part of a risk assessment, must be undertaken taking into account "all the evidence",[151] including the evidence provided by the exporting Member pursuant to Article 6.3. Obviously, as clearly admitted by the Appellate Body, the importing Members need "a certain period of time" to carry out this assessment.[152] Moreover, even after completing the assessment, the importing Member will further need a certain period of time to adapt its SPS measure to the regional characteristics in light of its domestic regulatory,

[146] Panel Report, *US – Animals*, para. 7.116 (referring to Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1497-7.1498).
[147] It covers the period from October 2003 to November 2004.
[148] It covers the period from March to November 2004.
[149] Panel Report, *US – Animals*, paras. 7.130, 7.163.
[150] Panel Report, *US – Animals*, paras. 7.145, 7.172. For a position that the length of the delay itself could play a decisive role in determining whether there is undue delay, see Regan, Donald H, '*United States – Certain Measures Affecting Imports of Poultry from China*: the fascinating case that wasn't', (2012) 11(2) World Trade Review 273, 290.
[151] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.62.
[152] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.80. The panel in *Russia – Pigs (EU)* further noted that "[a] Member may even need to translate such information in order to properly assess it." Panel Report, *Russia – Pigs (EU)*, paras. 7.705, 7.1186.

legislative, or administrative processes.[153] As to the implementation of the adaptation obligation, Paragraph 31 of the guideline adopted by the SPS Committee in 2008 regarding the implementation of Article 6 is also clearly aware that "[i]f necessary, the importing Member modifies existing sanitary or phytosanitary regulations or elaborates new ones to support its recognition of the area in question as a pest- or disease-free area or an area of low pest or disease prevalence. In addition, the importing Member may circulate any modified or new regulation for public comment."[154]

In this regard, the Appellate Body took a position that the obligation to proceed the procedures without undue delay in Annex C(1)(a) of the SPS Agreement "helps shed light on the appropriateness of the period of time that the importing Member enjoys" to assess the SPS characteristics of the area and then adapt its measure to such regional characteristics.[155] In other words, the Appellate Body took the view that Members are allowed to take certain period of time to implement the adaptation obligation in Article 6 as long as it does not constitute undue delay within the meaning of Article C(1)(a). Thu, it follows that a finding that the approval procedures for regionalization requests are not completed consistently with Annex C(1)(a) might lead to a conclusion that the importing Member fails to implement its adaptation obligation in Article 6.1.

In *US – Animals*, Argentina claimed that the US had acted inconsistently with Article 6.1 by failing to adapt its import prohibition maintained through 9 CFR 94 and the 2001 Regulations to the SPS characteristics of the Patagonia region as FMD-free in Argentina.[156] After referring to its previous finding that Argentina had provided the necessary evidence to the US to objectively demonstrate that the Patagonia region was, and was likely to remain, FMD-free pursuant to Article 6.3, the Panel concluded that the US had failed to authorize the import of certain products from the Patagonia region, a FMD-free area, and thus acted inconsistently with Article 6.1.[157] Importantly, in reaching this conclusion, the Panel also referred to its own finding under Article 8 and Annex C(1)(a) that the delays in APHIS' review process of Argentina's requests were undue.[158] This reference clearly suggests that a mere finding that an importing Member's review process of regionalization requests is unduly delayed might be sufficient to uphold

[153] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.80.
[154] Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures*, adopted by the Committee at its meeting of 2-3 April 2008, G/SPS/48, 16 May 2008.
[155] Appellate Body Report, *Russia – Pigs (EU)*, para. 5.81.
[156] Panel Report, *US – Animals*, para. 7.668. It is noted that Argentina did not make a claim under Article 6 in relation to Northern Argentina.
[157] Panel Report, *US – Animals*, para. 7.674.
[158] Panel Report, *US – Animals*, para. 7.673.

a violation of Article 6.1. One commentator describes this part of the Panel's decision as "the most important determination in the Panel's analysis".[159]

Conclusion

From the discussion in this chapter, it was firstly clarified that Article 6.1 of the SPS Agreement requires WTO Members maintaining trade restrictions against food products from the exporting Member where a nuclear accident occurred to adapt their measures according to the emergence of non-contaminated areas, which can be considered as the "SPS characteristics of the areas", within the exporting Member (i.e. adaptation obligation). Moreover, it is undisputed from recent cases, including *US - Animals*, that Annex C(1)(a) apply to approval procedures set out by the importing Member to review and process a regionalization request made by the exporting Member. Thus, upon receipt of such a request, Members need to ensure that the approval procedures are undertaken and completed without undue delay.

The practical importance of the Panel's findings is that it linked Annex C(1)(a) to Article 6.1. That is, the Panel implied that, if the approval procedures for processing regionalization requests fail to be completed without undue delay, it will lead to a violation of not only Annex C(1)(a) but also Article 6.1. In other words, it appears that the Panel effectively integrated the "without undue delay" requirement in Annex C(1)(a) into the adaptation obligation in Article 6.1. On the other hand, from the importing Member's perspective, it can be said that they are entitled to take time to complete the approval procedures for assessing the SPS characteristics of the area, and adapting their measures to such regional characteristics, to the extent that they do not act inconsistently with Annex C(1)(a).

Although the exporting Member (in this case, the country where a nuclear accident occurred) is not obliged to provide the necessary evidence to the importing Member under Article 6(3),[160] the reality is that the approval procedures will not proceed smoothly without the evidence and information from the exporting Member that are necessary for undertaking the assessment of the radioactive contamination of the soil in the areas. Moreover, in terms of litigation strategy, it is also important for the exporting Member to provide the necessary evidence in order to succeed in its claim in the WTO dispute settlement

[159] Laneville, Nicholas W, 'Regional Disputes: It Is Not Just Ground Beef', (2017) 17(1) Sustainable Development Law and Policy 36, 38.
[160] It is recalled that this provision specifically applies to exporting Members claiming the existence of "pest- or disease-free areas or areas of low pest or disease prevalence".

procedures.[161] Although a failure to provide the necessary evidence does not lead to a violation of Article 6(3), this fact may be seen as a factor that legitimates the delay in approval procedures in Annex C(1)(a).

[161] Appellate Body Report, *India – Agricultural Products*, para. 5.156.

Conclusion

Once radioactive materials released by the nuclear accident are deposited on the ground, the agricultural products produced there are at risk of containing radioactive materials for a prolonged period of time. And the ingestion of a certain amount of radioactive materials contained in food (i.e. internal exposure) can cause adverse effects on the human body (i.e. stochastic effect). Immediately after the *Fukushima* accident, a number of countries imposed some import restrictions on Japanese food products. And even now, more than nine years after the accident, some countries still maintain the import restrictions. Given this reality, the question arises as to how trade restrictions imposed on food imports from the country where the nuclear accident occurred will be disciplined at an international level. This is the main theme of this doctoral dissertation.

The *Fukushima* accident is not the first time that this issue has received international attention. After the *Chernobyl* accident in April 1986, many countries imposed different levels of radioactive contamination on food products from the countries and regions affected by the accident. Then, in 1989, Codex adopted Guideline Levels (GLs) as the levels of concentration for radionuclides in food to be traded internationally following a nuclear accident. According to this, foods with radionuclides level below the GLs are considered as "safe for human consumption".[1] After a revision in 2006, the GLs are now in their current form. It was a historic event that, for the first time, countries reached an international agreement on concentration levels for radionuclides in food to be used for international trade.

However, as explained in the introduction to this doctoral dissertation, the Codex standards, in which the GLs are integrated, provide that, when the GLs are exceeded, it is left to the discretion of the importing country to decide whether or not to allow such food to be distributed within the domestic market.[2] In other words, Codex standards have no specific discipline for such a situation. Thus, once

[1] There is no threshold for adverse effect on the human body (i.e. stochastic effect) due to radiation exposure. Thus, "safe" here only means that the amount of exposure through the consumption of food remains below the level of risk that the Codex considers is acceptable to countries.

[2] The relevant part of Codex standards states that "[g]uideline Levels are intended for use in regulating foods moving in international trade. When the Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction." Codex Alimentarius Commission, *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (1995) fn. 1.

a sample food exceeding the GL is detected, the importing country is not necessarily prevented, at least in Codex standards, from prohibiting future imports of this food, let alone the lot containing this food sample exceeding the GLs, from the country where the accident occurred. To this extent, it is fair to say that there is not much difference between before and after the *Chernobyl* accident (i.e. in both cases, broad discretion has been granted to the importing country).

With the establishment of the WTO in 1995, Members are subject to the disciplines of the SPS Agreement with respect to their SPS measures taken even in a situation where the GLs are exceeded. In particular, as one of the basic principles of the SPS Agreement, Article 5.1 requires Members to base their SPS measures on a risk assessment. When it comes to the health risks for which no threshold exists, however, the following difficult questions arise in relation to this provision.

As repeatedly explained, there is no threshold for adverse effects on the human body (i.e. stochastic effect) due to natural radiation exposure. In other words, it is assumed that the radiation risk can never be zero no matter how small the exposure dose is, and instead that there is a linear relationship between radiation exposure and stochastic effects (i.e. LNT model). Based on this dose-response relationship confirmed as a result of hazard identification, it follows that there will always be some health risks, no matter what the results of the exposure assessment show. Due to these features of health risks with no threshold, it is more likely to be found that a "rational relationship" exists between such risks and the SPS measures, and thus that such SPS measures are based on the risk assessment in Article 5.1 of the SPS Agreement.

However, this would also mean that, when it comes to health risks with no threshold, the WTO's discipline on import restrictions taken in the event of a nuclear accident might be limited to the "risk management" aspect of such restrictions, [3] rather than the "scientific basis" for them. And such an interpretation might be inconsistent with the SPS Agreement, which requires a scientific basis for adopting SPS measures. If the relationship between the SPS measures and risk assessment cannot be effectively challenged when dealing with the health risks that do not have a threshold (e.g. stochastic effect), it would end up unduly narrowing the regulatory role of Article 5.1 of the SPS Agreement.

In addition, the above interpretation might render the exposure assessment, which is part of a risk assessment, meaningless. Assume that the degree of

[3] For example, Article 5.6 of the SPS Agreement requires Members to ensure that SPS measures shall not be more trade-restrictive than required to achieve their ALOP, taking into account technical and economic feasibility.

radiation exposure through the ingestion of a certain imported food is estimated to be only negligible as a result of evaluating the amount of radioactive materials contained in the imported food, as well as the amount of the imported food the domestic consumers ingest on average (i.e. exposure assessment). If, in this case, a rational relationship between the risk assessment and SPS measures is found to exist based on the dose-response relationship confirmed as a result of hazard identification (i.e. LST model), it would effectively render the results of the exposure assessment meaningless.

In sum, it remains to be seen how the consistency of SPS measures with Article 5.1 of the SPS Agreement can be assessed in the absence of a threshold for the health risks at issue. Nevertheless, in light of the above, it appears to be desirable that the WTO does not refrain from regulating the scientific basis for import restrictions taken in the event of a nuclear accident, and more specifically, whether or not they are based on risk assessments.

Apart from the WTO, the Codex also has a role to play towards more effective discipline of international trade in food after a nuclear accident.

With respect to the Codex, it is recalled that the Codex GLs for radionuclides are not based on a risk assessment performed by the JECFA. In this regard, the Codex clearly indicates its preference for the establishment of maximum limits (MLs)[4] based on a risk assessment.[5] The Commission's preference for MLs stems from the fact that the government's discretion over the treatment of imported food exceeding ML is limited, contrary to GLs. After the *Fukushima* incident, there was a chance to convert the current GLs into MLs for radionuclides in food. However, this attempt, which was led by the Netherlands and Japan, was declined, mainly due to concerns by countries for losing flexibility currently ensured under Codex standards over the treatment of contaminated food exceeding the GLs.[6]

Thus, instead of leaving it to the almost unfettered discretion of the importing country to decide whether or not to allow food exceeding the GLs to be distributed within its domestic market, the Commission should rather attempt, through negotiations between Codex members, to make new rules to be followed in this specific situation in Codex standards. Considering the recent failure to convert the

[4] The Codex Alimentarius Commission has set the maximum acceptable limits of contaminants in food so as not to cause health effects. Such limits are called MLs for food additives and contaminants. MLs are set in a way that no adverse effects are caused to the human body from the ingestion of food contaminated at a lower level than MLs for a lifetime. See Chapter 3.2.2.2.
[5] The relevant part of Codex standards notes that "the present existing or proposed guideline levels [for radionuclides] shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by JECFA, if appropriate." Codex Alimentarius Commission (CODEX STAN 193-1995) fn. 1.
[6] See Chapter 3.2.2.3.

GLs for radionuclides to MLs, it may be realistic to seek for the establishment of rules other than new MLs. Once this can be achieved, WTO Members will be required to base their SPS measures on the new rules, which will be regarded as international standards within the SPS Agreement,[7] in Article 3.1. For example, if a food sample exceeding the GLs for radionuclides is detected, it is almost undisputed that the importation of the entire lot containing this food sample cannot be allowed. Even in this case, however, subsequent imports of this food product should be permitted as before, as long as the sample is found to be below the GLs.

[7] Annex A(3)(a) of the SPS Agreement.

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