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Justification under International Economic Law: from the perspective of the SPS Agreement

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I Introduction

After the Japan's Great Earthquake in March 2011, many countries have imposed shipment restrictions upon Japanese goods. For example, in the U.S., as of July 18, 2016, milk from Fukushima prefecture is subject to refusal of admission pursuant to the Federal Food, Drug, and Cosmetic Act ("FD & C Act"), Section 801(a)(3)[1] because, according to the U.S. Food and Drug Administration ("FDA"), it appears to contain a radionuclide, a poisonous or deleterious substance which may render it injurious to health (adulteration, FD & C Act, Section 402(a)(1)[2][3]).

This measure taken by the FDA (the "measure") can be regarded as a sanitary or phytonsaitary measure (the "SPS measure") within the meaning of the sentence 1(b), Annex A to the Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement"). This is because the FDA clearly refers to the public health concerns as follows: "The Fukushima Daiichi nuclear plant houses several nuclear reactors that pose of a potential threat of radiological contamination to the surrounding areas. Due to the

public health concerns that are associated with radiation and nuclear contamination, FDA has increased surveillance of regulated products from Japan.[4]" It is clear that the objective of the measure taken by the FDA is to address the public health concerns within the United States, and the purpose of the measure is to "protect human ... health within the territory of the Member from risks arising from ... contaminants" (Sentence 1(b), Annex A to the Agreement on the SPS Agreement).

The question then arises: is this measure in accordance with the SPS Agreement? This paper is intended to analyze legal issues relating to this shipment restriction.

Free trade is one of the fundamentals in today's globalized economy.[5] However, it is also important to protect human, animal or plant life or health. In order to avoid "disguised protectionism," the SPS Agreement was negotiated during the Uruguay Round.[6]

The SPS Agreement provides the right of the Members to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health (Article 2.1 of the SPS Agreement). In the Australia-Salmon case (defined hereinafter), the Appellate Body pointed out that the level of protection deemed appropriate by the Member establishing a sanitary measure is a "prerogative of the Member concerned.[7]" The reason for admitting such a strong privilege to the Members is because sanitary and phytosanitary measures are designed to protect human, animal or plant life or health, the most important and essential value within the GATT Article XX(b). According to the preamble of the SPS Agreement, this agreement is conceived as an elaboration of this original GATT exception.[8]

On the other hand, the SPS Agreement requires the Members to ensure that any sanitary and phytonsanitary measure is "applied only to the extent necessary to protect human, animal or plant life or health" and that it is "based on scientific principles" and that it is not "maintained without sufficient scientific evidence" (Article 2.2 of the SPS Agreement). The Members should also ensure that their SPS measures are "based on an assessment" (Article 5.1 of the SPS Agreement). If relevant scientific evidence is insufficient, a Member may provisionally adopt SPS measures (Article 5.7 of the SPS Agreement).

To develop some prescriptive implications, I will examine three important cases regarding the SPS Agreement to the extent necessary, namely, (1) Appellate Body Report, European Communities-EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R; WT/DS48/AB/R, adopted on February 13, 1998, DSR 1998: I, 135 ("EC-Hormones"), (2) Appellate Body Report, Japan-Measures Affecting Agricultural Products, WT/DS76/AB/R, adopted on March 19, 1999, DSR 1999: I, 277 ("Japan-Agriculture"), and (3) Appellate Body Report, Japan-Measures Affecting the Importation of Apples, WT/ DS245/AB/R, adopted on December 10, 2003, DSR 2003: IX, 4391 ("Japan-Apples").

With regard to other cases, namely, Panel Report, European Communities-Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R, adopted on November 21, 2006 ("EC－Biotech"), Panel Report, United States- Certain Measures Affecting Imports of Poultry from China, WT/DS392/R, adopted on October 25, 2010 ("US-China (Poultry)"), and Appellate Body Report, Australia-Measures Affecting Importa-

tion of Salmon, WT/DS18/AB/R, adopted on November 6, 1998, DSR 1998: VIII, 3327 ("Australia-Salmon"), I will discuss these as may be necessary.

II SPS Agreement

1 The Concept of an SPS Measure

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.(9)

As a preliminary matter, it should be observed that in all cases measures will be excluded from the definition of an SPS measure where they seek to protect the relevant interests outside of territory of the Member concerned.(10) Thus, a prohibition on the import of goods which is concerned with the manner in which those goods have been manufactured would constitute an SPS measure, in so far as the ban is applied to protect one of the specified interests within the territory of the regulating state.(11)

As discussed above, in this case, it is obvious that the measure taken by the FDA constitutes an SPS measure, since the shipping restraint is applied to address public health concerns within the territory of the regulating state, i.e., the U.S. Therefore, it can be said

that the measure is applied to "protect … health within the territory of the Member" (Annex A.1(b) of the SPS Agreement).

A critical element for determining whether a substance can be considered to be a "contaminant" (Annex A.1(b) of the SPS Agreement) is that the presence of the substance which is said to "infect or pollute" be unintentional.[12]

In this case, the contamination of food resulted from an unexpected disaster, Fukushima nuclear accident. Therefore, a substance included in the milk from Fukushima prefecture can be considered as a "contaminant."

Imposing shipment restraint to contaminant, i.e., contaminated Fukushima milk, would enable the U.S. government to ensure public health of its nation, because it can stop such contaminated milk from being distributed in the domestic market. Therefore, we can conclude that the measure taken by the FDA constitutes an SPS measure as provided by Annex A.1(b) of the SPS Agreement.

2　Framework of the SPS Agreement

Article 2.2 of the SPS Agreement forms part of the "basic rights and obligations" laid down in the agreement.[13] It requires that Members shall ensure that any SPS measure is "applied only to the extent necessary to protect human, animal or plant life or health," and that it is "based on scientific principles" and "not maintained without sufficient scientific evidence," except as provided by Article 5.7.[14]

Article 5.7, referred to in Article 2.2, allows Members to take "provisional" measures where there is insufficient scientific evidence to be sure of the risks involved.[15]

Article 5.1 requires that SPS measures should be based on an

assessment of the risks to human, animal or plant life or health.[16]

Article 3.3 permits Members to refrain from basing their measures on international standards, if, inter alia, there is a scientific justification for so doing.[17]

As stated in EU–Hormones, Article 5.1 is a "specific application" of the basic obligations contained in Article 2.2 of the SPS Agreement.[18] In EC–Biotech, the panel recalls the Appellate Body's construction of this relationship, but further refines it, viewing Article 5.1 as a "specific application of the second and third obligations provided for in Article 2.2."[19] Such approach leads me to start by analyzing Articles 5.1 of the SPS Agreement, in accordance with the Panel's decision in US–Poultry (China). Although the SPS Agreement does not provide any guidance on a sequence for analyzing its provisions, the Panel decided to "commence with Article 5.1 and 5.2 because any inconsistency that the Panel finds with these provisions would by implication lead to a finding of inconsistency with Article 2.2 of the SPS Agreement."[20] One can also conclude that where a measure is not based on a risk assessment in accordance with Article 5.1, that measure will also, by implication, be inconsistent with Article 2.2.[21]

In discussing justification of the SPS measure by the FDA to restrict importation of milk from Fukushima prefecture, I would like to analyze Articles 2.2, 5.1, and 5.7 of the SPS Agreement.

3 Article 5.1 of the SPS Agreement

SPS measures must be based upon a risk assessment. The concept of risk assessment is defined in Annex A, paragraph 4 of the SPS Agreement.

The first definition is concerned with evaluating the risks as-

sociated with pests or diseases.[22] The second is concerned with evaluating risks to human or animal health, in so far as these arise from the presence of the specified substances in food, beverages or feedstuffs.[23] The first definition may also encompass risks to human health, but only in so far as these arise from pests or diseases, and other than as a result of their presence in food, beverages and feedstuffs.[24]

In the case of the SPS measure taken by the FDA, it is clear that such SPS measure falls within the second definition, because the FDA imposed shipment restrictions upon milk from Fukushima prefecture considering risks arising from radiation and nuclear contamination, not because of spread of a pest or disease within the territory of Japan. Therefore, I would like to focus on the second definition of risk assessment provided in Annex A, paragraph 4 of the SPS Agreement.

The constituent units inherent in the second definition of risk assessment are less clearly established. I would like to analyze the EC -Hormones case here.

(1) EC-Hormones

(i) Factual Aspects

Directive 81/602/EEC prohibits the administering to farm animals of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action.[25] Directive 88/146/EEC extended the prohibition of the administration to farm animals of trenbolone acetate and zeranol for any purpose, and oestradiol-17β, testosterone and progesterone for fattening purposes.[26] Directive 88/299/EEC lays down the conditions for applying the derogations, provided for in Article 7 of Directive 88/146/EEC, from the prohibition on trade in certain categories of animals and their meat. The

first derogation of the Directive requires EC Member States to authorize trade in animals intended for reproduction and reproductive animals at the end of their career (and of meat of such animals). The second derogation in Directive 88/299/EEC allows imports from third countries of treated animals and meat of such animals under guarantees equivalent to those for domestic animals and meat.[27] Directive 96/22/EC replaced Directives 81/602/EEC, 88/146/EEC and 88/299/EEC as from 1 July 1997. Of the six hormones involved in this dispute, three are naturally occurring hormones produced by humans and animals: oestradiol-17, progesterone and testosterone (hereinafter also referred to as natural hormones[28]). The other three hormones involved in this dispute are artificially produced hormones: trenbolone, zeranol and melengestrol acetate (MGA) (hereinafter also referred to as synthetic hormones[29]). In the United States, the three natural hormones may be used for medical treatment (therapeutic). Oestradiol-17β is also permitted for zootechnical purposes. In the United States, the six hormones are also approved for growth promotion purposes. Three of the hormones used for growth promotion purposes, trenbolone, zeranol, and MGA, have no zootechnical or therapeutic uses. For growth promotion purposes, five of these hormones (except MGA) are formulated as pellets (with approved and fixed amounts of compound) designed to be implanted in the ear of the animal. The ear is discarded at slaughter. MGA is administered as a feed additive.[30]

The United States claimed that the EC measures adversely affect imports of meat and meat products and appear to be inconsistent with the obligations of the European Communities under the GATT.[31]

(ii) Decisions

(a) The Standard of Review Applicable in Proceedings Under the SPS Agreement

This issue was raised in the appeal because the European Communities contested that the Panel failed to apply an appropriate standard of review in assessing certain acts of, and scientific evidentiary material submitted by, the European Communities.[32]

The Appellate Body first points out that the SPS Agreement itself and provisions in the DSU or any of the covered agreements (other than the *Anti-Dumping Agreement*) is silent on the matter of an appropriate standard of review for panels deciding upon SPS measures of a Member.[33] It then refers to Article 11 of the DSU and ruled that the applicable standard is the "objective assessment of the facts."[34]

(b) The Reading of Articles 5.1 and 5.2 of the SPS Agreement -Interpretation of "Risk Assessment"

The interpretation of "Risk Assessment" was one of the critical issues of this case. The Panel distinguished between "risk assessment" and "risk management." The Appellate Body reversed the Panel's holding.[35]

(c) Factors to be Considered in Carrying Out a Risk Assessment

The Appellate Body ruled as follows:

It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real

world where people live and work and die.[36]

(d) The Interpretation of "Based On"

The Appellate Body ruled that in order to regard that an SPS measure is "based on" a risk assessment, there should be a rational relationship between the measure and the risk assessment.[37] It also concluded that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. According to the Appellate Body, the risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view.[38]

(2) Analysis of EC-Hormones

(i) Risk assessment of Article 5.1

In the circumstances of the EC-Hormones case, the Panel identified two steps:[39] - identify the adverse effects on human [or animal] health (if any); - if such adverse effects exist, evaluate the potential of occurrence of those effects.

The Appellate Body conceded that this two-step analysis is not "substantially wrong," while nonetheless observing that its "utility" may be debated."[40]

Three specific points are of key importance in the dispute settlement bodies elucidation of this concept of risk assessment.[41] The first relates to the distinction between the concept of "likelihood" in the first definition, and that of "potential" in the second.[42] The second concerns the question of the specificity of the risk assessment required.[43] The third concerns the third "prong" of the first definition, and the obligation to consider alternative policy options.[44]

(a) Likelihood and Potential

Whereas the first definition of risk assessment is concerned with "evaluation of the likelihood of," the second is concerned with "the evaluation of the potential for." Whereas "likelihood" may be equated with "probability," "potential" is associated with mere "possibility."[45]

In EC-Hormones, the Appellate Body talks not only of "probability" (aka "likelihood") implying a higher threshold of possibility (or potential), it also seems to suggest that "probability" implies the introduction of a quantitative dimension; such a quantitative dimension being inappropriate in the case of "possibility" (aka "potential")[46]. Yet, in Australia-Salmon, the Appellate Body insisted that evaluation of "likelihood" need not be done quantitatively. While it is not sufficient for possibilities to be assessed, "[l]ikelihood may be expressed either quantitatively or qualitatively."[47]

Equally, evaluation of likelihood need not establish "a certain magnitude or threshold level of risk."[48] Hence while those responsible for risk assessment must turn their mind to a different question, depending upon whether they are acting pursuant to the first or second definition, in the absence of a minimum threshold of risk in relation to each, their having done so, it is hard to see how probability will imply a higher threshold of risk.[49]

(b) Specificity

There has been a heavy emphasis in the case law on the need for risk assessment to be sufficiently specific to the issue at hand. This has been true under both the first and second definitions.[50] The Appellate Body has emphasized that in prescribing a specificity requirement, it does not mean to constrain Members in the risk

assessment methodology which they wish to deploy.[51] On the contrary, they may proceed to evaluate risk on a disease by disease basis, or on the basis of various hazards arising in relation to a given commodity.[52] It is simply that regardless of the methodological basis on which they proceed, Members must ensure that their findings are sufficiently specific to the issue at hand.[53]

The specificity issue first came to the force in the EC-Hormones case.[54] Here the EC relied upon specific evidence in the form of "general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake-the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes … Those general studies, are in other words, relevant but do not appear to be sufficiently specific to the case at hand.[55]" As the Appellate Body expressed it in Japan-Apples:

> Under the SPS Agreement, the obligation to conduct an assessment of "risk" is not satisfied merely by a general discussion of the disease sought to be avoided by the imposition of a phytosanitary measure. The Appellate Body found the risk assessment in EC-Hormones not to be "sufficiently specific" even though the scientific articles cited by the importing Member had evaluated the "carcinogenic potential of entire categories of hormones, or of the hormones at issue in general." In order to constitute a "risk assessment" as defined in the SPS Agreement, the Appellate Body concluded, the risk assessment should have reviewed the carcinogenic potential, not of the relevant hormones in general, but of "residues of those hormones found in

meat derived from cattle to which the hormones had been administered for growth promotion of purposes." Therefore, when discussing the risk to be specified in the risk assessment in EC–Hormones, the Appellate Body referred in general to the harm concerned (cancer or genetic damage) as well as to the precise agent that may possibly cause the harm (that is, the specific hormones when used in a specific manner and for specific purposes)[56].

In keeping with this general conclusion, it has been found that the risk assessment must evaluate risk on a disease specific basis, and not simply address the overall risk related to a combination of different diseases[57]. Likewise, for a risk assessment to be sufficiently specific to the subject matter at hand, it must identify risk on a product specific basis, and not on the basis of a general assessment relating to a variety of different products[58]. This is particularly important where there is evidence of variation in risk as between different products[59].

(c) Consideration of Alternatives

The first definition of risk assessment has been understood to comprise three prongs[60]. The second definition, by contrast, encompasses only two[61]. Under the first definition, Members are required to evaluate risk according to the SPS measures which might be applied. Under the second definition, it seems that they are not[62].

The difference between the two definitions boils down, in this respect, to the existence of an obligation to consider alternative policy options, before settling on the regulatory approach to be adopted[63]. According to this, "a risk assessment should not be limited to an examination of the measure already in place or favored by the

importing Member.[64]" It should not be distorted by preconceived views on the nature and the content of the measure to be taken, nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions ex post facto.[65]

It seems reasonable to suppose that this requirement implies the existence of a corresponding prior requirement whereby Members have an obligation to identify alternative policy options available.[66] What is less clear is whether all such alternatives must be identified and included in the analysis, however numerous and complex these may be.[67] Japan-Apples was an easy case in this regard.[68] There has been no consideration of any phytosanitary policy other than that actually encompassed by the contested measure.[69] This included the absence of any attempt to assess the relative effectiveness of the ten constituent parts of the measure, or to consider why all of them in combination were required.[70] Two of the experts advising the Panel went so far as to suggest that the primary scientific evidence relied upon "appeared to prejudge the outcome of its risk assessment" and "was primarily concerned to show that each of the measures already in place was effective in some respect, and concluded that all should therefore be applied.[71]" In its Australia-Salmon compliance report, the Panel observed that this third prong neither specifies precisely which measures need to be evaluated, nor requires that "all possible measures (of which there could be a very great number) be evaluated.[72]" This viewpoint has been neither endorsed, nor clarified, by the Appellate Body.[73]

(d) Risk Assessment as Appropriate to the Circumstances

We have very little guidance on what it means to say that a risk assessment must be appropriate to the circumstances.[74] It has been said

to relate to the way in which risk assessment is carried out.[75] While it cannot "annual or supersede the substantive obligation" in Article 5.1,[76] it is said to inject "some flexibility for an assessment of risk on a case-by-case basis, in terms of product, origin and destination, in particular country-specific situations."[77]

(e) Factors to be taken into account in Risk Assessment

The concept of appropriateness, in relation to risk assessment, is noticeably vague.[78] The agreement seeks, however, to give clearer shape to what is required both by laying down definitions of risk assessment, and by identifying additional factors which Members are required to take into account.[79]

Before turning to the range of factors to be taken into account, it is important to consider the nature of the obligation which this imposes.[80] This was considered by the Panel in Japan-Apples.[81] The Panel distinguished the obligation for Members to take something into account, from an obligation to base their measures upon that something, or to ensure that they are in comformity with it.[82] In respect of the Article 5.1, obligation to take into account risk assessment techniques developed by relevant international organizations, the Panel observed that this implies that these techniques should be "considered relevant," but that "a failure to respect each an every aspect of them would not necessarily, per se, signal that the risk assessment is not in conformity with the requirements of Article 5.1."[83]

This issue has not been expressly considered by the Appellate Body.[84] There is, however, a suggestion that whereas the language of "based on" in Article 5.1 connotes an "objective relationship" between two elements, a requirement to take something into account "refer[s] to some subjectivity which, at some time, may be present in

particular individuals but that, in the end, may be totally rejected by those individuals.[85]" It is true that the Appellate Body is merely reporting on the Panel's conception of what it means to take something into account. The Appellate Body neither endorses, nor distances itself, from this understanding.[86]

(ii) Application

This is the first case regarding the SPS measures and is very significant because the Appellate Body made decisions on various legal issues of the SPS Agreement. The Appellate Body frequently referred to this case in Australia-Salmon, Japan-Agriculture, and Japan-Apples.

From this case, it can be inferred that it is important for the Member imposing measures to take measures "based on assessment … of the risks" (Article 5.1) in order to justify their measures. This requirement, as well as the requirement of "scientific principles and … scientific evidence" (Article 2.2) is very important as it balances the protection of life or health with free trade. However, there are many cases where science cannot provide answers.

The Appellate Body was very flexible on this point, because it ruled that the risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. In addition, it stated that the applicable standard is neither de novo review as such, nor "total deference," but rather the "objective assessment of the facts." From this, it can be inferred that the Appellate Body would respect the decision made by the Member imposing measures to a substantial extent, allowing much space for discretion in order to justify the measures.

4 The relationship between Article 2.2 and Article 5.1

The Appellate Body in EC-Hormones viewed Article 5.1 as a "specific application" of the basic obligation set out in Article 2.2.[87][88] It stresses that these two provisions should be constantly read together.[89] "Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1."[90] As such the Appellate Body expressed surprise that the Panel did not adopt the "logically attractive" course, and begin its analysis by focusing on the basic obligation in Article 2.[91]

It is though important to be aware that the Appellate Body's approach to the construction of Articles 2.2 and 5.1 is two-way.[92] Article 2.2 imparts meaning to Article 5.1.[93] But in addition, Article 5.1 (and Articles 3.3 and 5.7) are cited as providing context to the concept of sufficiency in Article 2.2.[94] The Appellate Body's conclusions on the meaning of Article 5.1 are deemed "useful" and to "provide guidance" in the construction of Article 2.2.[95] Thus, Articles 2.2 and 5.1 help to define each other, reinforcing their close relationship and parallel development.[96] Their relationship is circular, not linear, albeit Article 5.1 is presented as a specific application of the "more general" basic obligation in Article 2.2.[97]

Though not initially clear in EC-Hormones, it is now settled that where a measure is not based on a risk assessment in accordance with Article 5.1, that measure will also, by implication, be inconsistent with Article 2.2.[98] The Appellate Body endorsed the proposition of the Panel that a measure not based on risk assessment "can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence," and consequently to be incompatible with the second and third requirements in Article

2.2.[99] The nature of the presumption, or "implication,"[100] is not specified. Even if it is to be regarded as rebuttable, it implies a reversal in the burden of proof for Article 2.2 for measures not based upon a risk assessment in accordance with Article 5.1.[101] The presumption is surprising in many ways.[102] The scope of the obligations is quite different, and it hardly seems logical to suppose that just because there is no risk assessment, or no rational relationship between a measure and a risk assessment, that the measure is not in fact scientifically founded.[103] It may not have been demonstrated to be so by the responding Member, but that is hardly conclusive as to the state of play in current scientific thinking more generally.[104]

At the same time, it is apparent that a reverse presumption does not apply in either direction.[105] That a measure that does not violate Article 5.1 cannot be taken to imply that it is consistent with Article 2.2.[106] That a measure that is inconsistent with Article 2.2 cannot be taken to imply that it violates Article 5.1. First, in EC–Hormones, the Appellate Body observed that had it reversed the Panel's findings with respect to Article 5.1, it would have been logically necessary to inquire whether Article 2.2 had nonetheless been violated.[107] Second, in Australia–Salmon, the Appellate Body confirmed that "given the more general character of Article 2.2 not all violations of Article 2.2 are covered by Article 5.1 and Article 5.2."[108]

There is overlap between Articles 2.2 and 5.1 as construed by the Appellate Body.[109] In particular the concept of a rational relationship between available science and the measure in question has emerged as an element of each.[110] The Appellate Body has eschewed a procedural approach to the concept of risk assessment in Article 5.1,

allowing Members to take decisions on the basis of assessments carried out by other Members or international organizations.(111) Though the obligations remain distinct, in that the risk assessment relied upon must meet the definitions laid down in the agreement, the absence of an independent procedural obligation means that Panels are looking less to what Members have done, by way of assessment, and more at what they have found by way of available science, to rationally ground their measure.(112)

5　Article 2.2 of the SPS Agreement

(1)　Framework of Article 2.2

Any measure must satisfy all three tests (applied only to the extent necessary to protect human, animal or plant life or health; based on scientific principles; and not maintained without sufficient scientific evidence.) in order to be justified under Article 2.2. There has been no detailed discussion of the first two elements, and no discussion of the relationship between the parts.(113) However, it is interpreted that the requirements are cumulative.(114) Any measure must satisfy all three tests in order to be justified under Article 2.2.(115)

The key question in thinking about the relationship between the elements is whether the necessity test may be thought to impose any distinct obligations which go beyond those implied by the science-based requirements. Any observations on this point will necessarily be tentative, but a number of factors appear to militate in the direction of the conclusion that it dost not.(116)

First, it is not simply that the measure must be necessary, it must be necessary to protect one of the specified interests (protection of life or health of humans, animals or plants).(117) But for a measure to be

an SPS measure, it must, by definition, be applied to protect one or other of these interests.[118]

Second, necessity is a relational concept, pertaining to the existence of a logical connection between a measure and a specified objective.[119] The nature of the connection demanded is a matter for interpretation.[120] Elsewhere, the Appellate Body has understood this to imply that the measure need not be "indispensable" to be "necessary," but must rather be capable of making a contribution to the objective in question.[121] "Sufficiency" is also understood in relational terms, as demanding a rational relationship between the scientific findings and the measure in question.[122] The absence of any causal link between the measure and the mitigation of risk is construed as strong evidence of an absence of sufficiency; and would be pertinent also in an assessment of its necessity.[123] Third, even it should transpire that the necessity test will be read to encompass a proportionality test, the sufficiency of scientific evidence test might anyway be construed to encompass a proportionality dimension.[124]

With regard to "sufficient scientific evidence," "sufficiency" requires the existence of a sufficient or adequate relationship between two elements, in casu, between the SPS measure and the scientific evidence.[125] The Appellate Body finds that there is a scientific justification for a measure where there is a "rational" or "objective" relationship between that measure and the scientific evidence.[126] This is to be determined "on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of scientific evidence."[127]

Two cases, i.e. Japan-Agriculture and Japan-Apples considered

Article 2.2. I would like to analyze these two cases hereinafter.

(2) Japan-Agriculture

(i) Factual Aspects

Japan prohibited the importation of eight agricultural products originating from, inter alia, the United States on the ground that they are potential hosts of codling moth, a pest quarantine significant to Japan. The prohibited products are apples, cherries, peaches (including nectarines), walnuts, apricots, pears, plums and quince.[128]

The import prohibition on these products can be lifted if an exporting country proposes an alternative quarantine treatment which achieves a level of protection equivalent to the import prohibition.[129] In practice, the alternative quarantine treatment proposed is fumigation with methyl bromide, or a combination of methyl bromide fumigation and cold storage.[130]

(ii) Decisions

(a) Article 2.2. of the SPS Agreement

With regard to the meaning of the word "sufficient," the Appellate Body referred to the cases of EC-Hormones and Australia－Salmon, and agreed with the Panel as follows:

… the obligation in Article 2.2 that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship between the SPS measure and the scientific evidence. Whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.[131]

(b) Conclusion

The Panel found, and the Appellate Body confirmed, that the contested measure i.e. varietal testing requirements for agricultural products on which codling moth might occur, was maintained without sufficient scientific evidence.[132]

(3) Japan-Apples

(i) Factual Aspects

Under the Plant Protection Law and the Enforcement Regulations, importation of host plants of 15 quarantine pests, including fire blight bacteria (*Erwinia amylovora*) and pests of rice plant not found in Japan, is prohibited. The legislation, however, permits Japan to decide, on a case-by-case basis, to lift the import prohibition under certain conditions. Such conditions are summarized as follows:

(i) fruit must be produced in designated fire blight-free orchards.

(ii) the export orchard must be free of plants infected with fire blight and free of host plants of fire blight (other than apples), whether or not infected;

(iii) the fire blight-free orchard must be surrounded by a 500-meter buffer zone;

(iv) the fire blight-free orchard and surrounding buffer zone must be inspected at least three times annually; and

(v) harvested apples must be treated with surface disinfection by soaking in sodium hypochlorite solution (100 ppm or more effective chlorine concentration) for one minute or longer.[133]

The United States claimed that Japan prohibited the importation of apples unless they were produced, treated, and imported in accordance with Japan's highly-restrictive fire blight measures.[134] The

United States claimed that Japan's measures on the importation of apples were not consistent with Japan's obligations under the SPS Agreement.[135]

(ii) Decisions

In this case, the focus was on the third prong of Article 2.2, with the Panel concluding that the measure was not justified by sufficient scientific evidence.[136] The Panel concluded that the phytosanitary measure at issue is clearly disproportionate to the risk identified on the basis of the scientific evidence available.[137] It said that, in particular, some of the requirements applied by Japan as integral parts of the measure at issue are, either individually or when applied cumulatively with the other requirements of that measure, not supported by sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement.[138]

(4) Analysis

In Japan-Apples case, the Panel concluded that Japan's multi-faceted quarantine regime for apples, put in place to guard against the risk of transmission of fire blight, was not supported by sufficient scientific evidence.[139] The contested measure was deemed to consist of ten cumulatively-applied elements, consisting of a string of product and process requirements, relating to the growing environment, treatment, storage, and certification.[140] The Panel did not confine its analysis to mature, symptomless fruit, where the scientific evidence was weakest. It looked also to other categories of apples (immature or infected/infested apples) which might enter Japan by virtue of "errors of handling" or "illegal actions."[141]

For the latter category of apples, the Panel found that immature apples can be infected or infested, and that infected apples are

capable of harboring populations of bacteria that could survive through the carious stages of commercial handling, storage and transportation.[142] Nonetheless it concluded that scientific evidence does not support the conclusion that infested or infected cargo crates could operate as a vector for fire blight transmission, but rather that it is not likely to survive on crates.[143] Moreover, even if such infected apples were exported to Japan, and even if the bacteria survived, the introduction of fire blight into Japan would require transmission from imported apples to a host plant.[144] This "additional sequence of events" was "deemed unlikely" and it "has not been experimentally established to date."[145]

In the view of "negligible" nature of the risk, and the nature of the elements composing the measure, the Panel concluded that the quarantine regime as a whole was, on its face, disproportionate to the risk, and as such that no rational or objective relationship existed between the measure and the available scientific evidence.[146] The Panel went on to find that two individual elements of the regime were "most obviously" maintained without sufficient scientific evidence, either separately or in cumulation.[147] Taking the regime as a whole, and these two particularly problematic elements which form part of it, the Panel concluded that the regime was "clearly disproportionate" to the risk identified on the basis of available scientific evidence.[148]

Given the Panel's factual findings, the Appellate Body does not disagree. It is, however, somewhat enigmatic in its affirmation of the Panel's approach:

> We emphasize, following the Appellate Body's statement in *Japan—Agricultural Products II*, that whether a given approach or methodology is appropriate in order to assess whether a

measure is maintained “without sufficient scientific evidence”, within the meaning of Article 2.2, depends on the “particular circumstances of the case”, and must be “determined on a case-by-case basis”. Thus, the approach followed by the Panel in this case—disassembling the sequence of events to identify the risk and comparing it with the measure—does not exhaust the range of methodologies available to determine whether a measure is maintained “without sufficient scientific evidence” within the meaning of Article 2.2. Approaches different from that followed by the Panel in this case could also prove appropriate to evaluate whether a measure is maintained without sufficient scientific evidence within the meaning of Article 2.2. Whether or not a particular approach is appropriate will depend on the “particular circumstances of the case”. The methodology adopted by the Panel was appropriate to the particular circumstances of the case before it and, therefore, we see no error in the Panel’s reliance on it.[149]

There seems to be a note of caution here, but it is far from clear what the Appellate Body is feeling cautious about.[150] That it favors a relational approach, which must imply a comparison of something with something else, is not in doubt.[151]

For the Panel, the rational relationship test in Article 2.2, developed in part by reference to the rational relationship test in Article 5.1, is presented as encompassing a proportionality dimension.[152] “The phytosanitary measure at issue is clearly disproportionate to the risk identified on the basis of the scientific evidence available.”[153] The concept of proportionality is contested and unsettled, and the Panel does little to illuminate its understanding.[154]

On the other hand, it seems to suggest that disproportionality will result wherever the measure in question contains elements which are not sufficiently supported by scientific data.[155] It is the fact that the Japanese measure contains elements which are not supported by sufficient scientific evidence which "in particular" leads the Panel to its conclusion that the measure at issue is clearly disproportionate.[156] This might be construed as a "least onerous" (weak) conception of proportionality.[157] Due to the presence of these elements, the measure goes further than is necessary to guard against the risk identified.[158] Understood in this way, proportionality seems a needlessly provocative phrase to use, as it simply connotes a requirement that each element of a domestic measure must be supported by sufficient scientific evidence.[159]

On the other hand, it is at least credible to argue that the Panel endorsed a more far-reaching (strong) conception of proportionality in this case: "Given the negligible risk identified on the basis of the scientific evidence and the nature of the elements composing the phytosanitary measure at issue, the measure on the face of it is disproportionate to that risk."[160] This might seem to imply a balancing test, according to which the Panel will compare risk, with the "nature of the … measure."[161] The premises according to which the nature of the measure is assessed are nowhere specified.[162] In this case, the element of risk which was seen as relevant was its scale in terms of the propensity of the hazard to materialize.[163] The extent to which the seriousness or irreversibility of the potential hazard would be relevant to a balancing conception of proportionality is neither addressed, nor clear.[164] It seems inconceivable though that it would be excluded.[165] To the extent that the Panel may be thought to have endorsed

a balancing conception of proportionality, it does nothing to elucidate its methodology for comparing risk and policy reaction, or for evaluating the appropriateness of the relationship between them.(166)

However, its decision regarding the Article 5.7 is noteworthy. The Appellate Body upheld the Panel's decision; it stated that "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. Prior to this case, the concept of "sufficient" within the meaning of Article 2.2 and "insufficient" within the meaning of Article 5.7 was not clear. In Japan-Agriculture, the Appellate Body stated that a rational or objective relationship between the SPS measures and the scientific evidence is required to be "sufficient" within the meaning of Article 2.2. With the decision of the Appellate Body in this case, it is now clarified the actual meaning of both concepts.

6　Article 5.7 of the SPS Agreement

As stated before, Article 2.2 of the SPS Agreement provides that Members shall not maintain an SPS measure without sufficient scientific evidence, "except as provided for in paragraph 7 of Article 5." Article 5.7 provides that in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information.

(1)　The relationship between Article 2.2 and Article 5.7

Article 5.7 is treated as a "qualified exemption," not as an exception, to Article 2.2.(167) It is established in EC-Biotech, that it

operates as an exemption from the third prong. It may be relevant that Article 5.7 is deemed by the Panel to operate also as exemption to Article 5.1.[168] Therefore, any measure consistent with Article 5.7 will not be incompatible with Article 5.1, and consequently not automatically incompatible with either the second or the third prong of Article 2.2.[169] However, that a measure is not incompatible with Article 5.1 cannot be presumed to imply that it is not incompatible with Article 2.2.[170] It is simply that such incompatibility will have to be demonstrated and not assumed, even in the case of the second and third prongs.[171] Nonetheless, the construction of a relationship between the risk assessment obligation and the second as well as the third prong of Article 2.2, and between Article 5.7 and Article 5.1, might veer us in the direction of anticipating that Article 5.7 will be recognized as operating as an exemption in relation to the second as well as the third prongs of Article 2.2.[172]

(2) The relationship between Article 5.1 and Article 5.7

The relationship between Article 5.1 and Article 5.7 is nowhere defined. On the face of it, conformity with Article 5.7 does not serve to release Members from their risk assessment obligation under Article 5.1.[173] However, two factors seem to militate strongly against this "on the face" position.[174] These factors tend instead to lead us in the direction of the conclusion that conformity with Article 5.7 implies a time-limited reprieve from the requirements of Article 5.1.[175]

First, there is the way in which the Appellate Body has interpreted Article 5.7 in relation to Article 5.1.[176] Insufficiency in the context of Article 5.7 has been explicitly construed by reference to the Article 5.1 risk assessment requirement.[177] Scientific evidence will be regarded as insufficient under Article 5.7 where it is not such to allow, in

quantitative or qualitative terms, an adequate risk assessment.[178] The absence of an adequate risk assessment under Article 5.1 is thus a prerequisite for recourse to Article 5.7.[179] Unless Article 5.7 is regarded as a qualified exemption to Article 5.1, it would never be possible for Members to comply with both Article 5.1 and 5.7 simultaneously.[180] Where scientific evidence is insufficient it would be impossible for Members to base their measures on an Article 5.1 risk assessment.[181]

Second is regarding the relationship between Article 2.2 and 5.1. The two are to be read together, each deriving meaning from the other.[182] More particularly, Article 5.1 is regarded as a specific manifestation of Article 2.2 and, as such, a breach of Article 5.1 is recognized as implying a breach of Article 2.2.[183] Thus, conformity with Article 5.7 (and consequently Article 2.2) would be bought at the expense of conformity with Article 5.1.[184] A failure to conform with Article 5.1 in turn implies a failure to conform with Article 2.2.[185] It would, of course, be open to the Appellate Body to refine its understanding of the relationship between Article 2.2 and Article 5.1, whereby a breach of Article 5.1 would imply a breach of Article 2.2, except in the circumstances laid down in Article 5.7.[186] However, no such qualification has been established so far.[187]

Article 5.1, unlike Article 2.2, does not refer to Article 5.7. However, the Appellate Body has constructed a relationship between these articles by virtue of its relational understanding of the concept of sufficiency in Article 5.7.[188] The construction of this substantive relationship between Article 5.7 and 5.1 both increases the importance of the question of their structural relation, and would seem to militate strongly in the direction of Article 5.7 being seen as a qualified exemption to the Article 5.1 risk assessment requirement.[189]

This is the conclusion reached by the Panel in the EC-Biotech case. It stated that "we conclude that Article 5.7 should be characterized as a right also in relation to Article 5.1, rather than an exception from a "general obligation" under Article 5.1. In our view, Article 5.7 operates as a qualified exemption from the obligation under Article 5.1 to base SPS measures on a risk assessment."(190)

(3) Background condition: insufficient scientific evidence

Article 5.7 is applicable if relevant scientific evidence is insufficient. In Japan-Apples, the Appellate Body emphasized that the concepts inherent in Article 5.7 should be understood as relational concepts.(191) It stated that "'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."(192) Thus, the key question is whether available scientific evidence is such to permit the performance of a risk assessment meeting the demands of Article 5.1.(193)

(4) Additional latitude: basing measures on available pertinent information

Provisional measures must be based on available pertinent information. The questions that arise are: (i) what is to count as available pertinent information, and (ii) what it means to base a measure upon such information which is insufficient or insufficiently reliable to count as a fully fledged risk assessment.(194)

Regarding (i), what is to count as available pertinent information has not been defined. However, it is clear that this is to include information from the relevant international organizations as well as

from sanitary or phytosanitary measures applied by other Members.[195] There can be no doubt that information deriving from Codex Alimentarius Commission, the International Plant Protection Convention, and the Office of Epizootics (as defined in Annex A(3)) will be regarded as available.[196] In defining the scope of the concept of international standards, Annex A(3) looks also to other "relevant international organizations" in so far as these are open to all Members, and have been identified by the SPS Committee.[197] The committee has not, to date, identified any additional international organization as a source of international standards for the purpose of this agreement.[198] By contrast to the Annex, however, Article 5.7 would seem to make the "relevance" of the organization and the "pertinence" of the information, the only criteria.[199] As such, pertinent information deriving from any relevant body would seem to fall within the range of information to be considered.[200]

As for (ii), this has been deemed to require a rational or objective relationship between the measure and the evidence upon which it is said to be based.[201] In the context of Article 5.7, however, the information in question is, by definition, insufficient or insufficiently reliable, to ground a risk assessment.[202] Given the nature of the information, it is hard to know what it means to say that there is a rational relationship between this and the provisional measure in question.[203] Elsewhere, the Appellate Body has construed "based on" as requiring a strong and close relationship between a prospective measure and existing international standards.[204]

(5) Provisionality I : seeking additional information

In Japan–Agriculture, the Appellate Body observed that neither Article 5.7 nor any other provision of the SPS Agreement "sets out

explicit prerequisites regarding the additional information to be collected or a specific collection procedure." Nor does it "specify what actual results must be achieved."[205] The obligation is merely to seek to obtain the additional information, in order to allow the Member to conduct a more objective assessment of risk, in accordance with Article 5.1.[206] "Therefore the information must be germane to conducting such a risk assessment, i.e. the evaluation of the likelihood of entry, establishment or spread of, in casu, a pest, according to the SPS measure which may be applied."[207] In Japan–Apples, the Appellate Body confirmed the finding of the Panel that Japan had not satisfied this requirement.[208] The information collected by Japan did not examine the appropriateness of the SPS measure in question, and did not address the "core issue" of whether there is variation in quarantine efficiency as between different varieties.[209]

(6) Provisionality II: reviewing measures within reasonable period of time

In Japan–Agriculture, the Appellate Body confirmed that analysis of this temporal issue should proceed on a case-by-case basis, and that it will depend upon the specific circumstances of the case, including the difficulty of obtaining the additional information necessary for the review, and the characteristics of the SPS measure in question.[210] In the circumstances of this case, the Panel had found that collecting the additional necessary information would have been "relatively easy."[211] The failure of Japan to review its measure during the period since the entry into force of the WTO Agreement (a period of nearly four years) was thus deemed to constitute a failure to review the measure within a reasonable period of time.[212]

7　The measure and the Article 2.2 of the SPS Agreement

(1)　Overview

As stated above, the Article 2.2 of the SPS Agreement requires that the SPS measure is based on scientific principles, and should not be maintained without sufficient scientific evidence (except as provided for in paragraph 7 of Article 5).

According to the Appellate Body's decision at Japan-Agriculture, the obligation in Article 2.2 requires that there be a rational or objective relationship between the SPS measure and the scientific evidence, and that whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.(213)

(2)　Scientific principles of contamination

Based on the above argument, the next issue is whether the SPS measure is based on scientific principles. Specifically, the effects of radio-contaminated food on human body should be discussed.

According to the International Commission on Radiological Protection, the following is the data on effects exerted on human body by radiation.

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

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

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

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

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

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

(ii) Effects in the Embryo and Fetus

As regards effects of radioactive exposure on embryos and fetuses, the report offers the opinion that a threshold dose of 100〜200 mGy or higher exists; if the fetal dose exceeds this level, there is a possibility of posing damage on fetus, while its severity and scope vary with the dose and pregnancy stage.

(iii) Nonstochastic Effects *(ICRP Publication 40 (Appendix A: A1〜A7))*

Nonstochastic effects can appear in any organ or tissue that has been irradiated to a sufficiently high dose, the biological response and

threshold depending on the organ or tissue. Uniform irradiation of the bone marrow by acute exposure in the early phase of the whole, or a substantial part, of the body to penetrating radiation at a sufficiently high rate can lead to death within a few weeks. The value for the median lethal dose within 60 days (LD50/60) is thought to be in the range 2.5 to 5 Gy; below about 1.5 Gy there is little possibility of early death.

⑷ Stochastic Effects *(ICRP Publication 40 (Paragraph 27, Appendix A: A8))*

The likely incidence of stochastic effects in an irradiated population can be estimated by the use of risk factors, given that estimates of the dose equivalents in organs and tissues have been made.

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

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

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

1)　Herediatry defects in first two generations

(v) Risks of Leukemia and Childhood Cancer

It is assumed that throughout the pregnancy period, the embryo/fetus is exposed to the risk of latent carcinogenic effect to the same degree as infant. According to Paragraph (38) of the *ICRP Publication 84 (2000)*, relative risk of spontaneous cancer incidence at the fetal dose about 10 mGy is about 1.4 or lower.

(vi) Risk of Fatal Cancer

The risk figure for fatal cancers suggested by *ICRP (1987)* is about 2×10^{-2} Sv^{-1} averaged over age and sex. An average individual exposed to 5 mSv as a result of ingestion of radioactively contaminated foodstuffs in the first year after a radiation accident therefore has a notional lifetime risk of 1 in 10 000 (10^{-4}). This level of risk is some three orders of magnitude greater than the average individual risk of fatal cancer resulting from routine operations of nuclear power establishments.

(3) Summary

From above information, we can conclude that radio-contaminated food has certain effects on human body. The effects are (i) early and late reactions in tissues and organs, (ii) stochastic effects, and (iii) risk of fatal cancer.

As stated above, the Appellate Body admits broad discretions of Members imposing SPS measures, and it requires a rational relationship between the measure and the risk assessment as in EC-Hormones, and "a rational or objective relationship between the SPS measures and the scientific evidence" as in Japan-Agriculture. The above data regarding effects of radiological contamination to the human body demonstrates objective evidence as to the level of threshold dose as well as the specific outcomes; they are evidence of both

in terms of the quality and quantity, and therefore considered to verify a rational relationship between the SPS measure of the FDA and the scientific evidence. Therefore, one can conclude that the SPS measure of the FDA is not maintained without sufficient scientific evidence according to the Japan-Agriculture case. This also leads to a conclusion that there is a rational relationship between the SPS measure and the risk assessment as in the EC-Hormones case.

Therefore, the SPS measure of the FDA can be evaluated as necessary to protect human health and is justified under Article 2.2 of the SPS Agreement.

8 The measure and the Article 5.1 of the SPS Agreement

Article 5.1 of the SPS Agreement requires Members to ensure that their SPS measures are based on an assessment of the risks to human, animal or plant life or health in order to be justified. According to the Appellate Body in EC-Hormones, "it is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[(214)]" It is also worthwhile to note that the Appellate Body ruled that in order to regard that an SPS measure is "based on" a risk assessment, there should be "a rational relationship between the measure and the risk assessment.[(215)]" It also concluded that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. According to the Appellate Body, the risk assessment could

set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view.[(216)]

It may seem as though the SPS measure of the FDA violates Article 11.1 of the GATT. However, considering the effect of contaminated food to the human body, it is clear that radio-contaminated food has actual potential for adverse effects on human health, given that the dose level is clarified with respect to early and late reactions in tissues and organs, stochastic effects, and risk of fatal cancer.

Also, one should be able to say that there is a rational relationship between the SPS measure of the FDA and the risk assessment.

Accordingly, based on the data of adverse effects on human health, the SPS measure of the FDA is justified and does not violate Article 5.1 of the SPS Agreement.

9 The measure and the Article 5.7 of the SPS Agreement (provisional SPS measures)

In cases where scientific evidence regarding adverse effects on human health is considered to be insufficient, and therefore does not suffice the requirements provided by the Article 2.2 of the SPS Agreement, a Member may provisionally adopt SPS measures on the basis of available pertinent information (Article 5.7 of the SPS Agreement).

As stated above, according to Japan－Apples, "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.

If the legitimacy of the SPS measure of the FDA were argued at the Panel, the level of clarification with respect to adverse effect of radiological contamination both in terms of the level of threshold dose and specific content of adverse effect on human body would be one of the critical points.

10 Conclusion

Overall, it is highly likely that the SPS measure of the FDA is considered to be in accordance with the relevant provisions of the SPS Agreement. On this basis, Japan should continue a serious commitment to response to the Fukushima nuclear accident. At the same time, Japan should provide accurate information regarding radiological materials that are found from food produced in Fukushima prefecture. Should there be any other scientific evidence available that can alter the SPS measure of the FDA, Japan should demonstrate such evidence, so that it can mitigate consumers' concern over radiological contamination of food.

To conclude, Japan should seek its way to buttress its free trade policy through negotiation as opposed to using the dispute settlement process of the WTO; specifically, Japan should consider provision of new scientific evidence regarding radiological contamination and negotiation with the United States of America to lift the shipment restraint (proposition of easing of regulations or less restrictive alternatives).

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Footnotes

(1) 21 U.S.C. section 381(a)(3). "If it appears from the examination of such samples or otherwise that … (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. …"

(2) 21 U.S.C. Section 342(a)(1). "A food shall be deemed to be adulterated— (a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;"

(3) http://www.accessdata.fda.gov/cms_ia/importalert_621.html (accessed on January 10, 2017)

(4) Ibid.

(5) Simon Lester, Bryan Mercurio, and Arwel Davis, World Trade Law: Text, Materials and Commentary 46 (2nd. ed. 2012).

(6) Ibid., 557.

(7) Australia-Salmon (AB), para. 199.

(8) Joanne Scott, The WTO Agreement on Sanitary and Phytonsanitary Measures: A Commentary 9 (2007). The preamble of the SPS Agreement states that "Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary and phytosanitary measures, in particular for the provisions of Article XX(b)."

(9) Scott, *supra* note 8, at 77.

(10) Ibid.

(11) Ibid.

(12) EC-Biotech (Panel), para. 7.313. The Panel considered that genes intentionally added to GM plants that are eaten or used as inputs into processed foods would not be "contaminants" in and of themselves. Furthermore, the Panel concluded that substances such as proteins which are produced by GM plants, and which are intended, should not be considered to be "contaminants." (para. 7.313)

(13) Scott, *supra* note 8, at 81.

(14) https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (accessed on August 10, 2016)

(15) Lester et al., *supra* note 5, at 580.
(16) https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (accessed on August 10, 2016)
(17) Scott, *supra* note 8, at 82.
(18) EC-Hormones (AB), para. 180.
(19) EC-Biotech (Panel), para. 7.1439.
(20) US-China (Poultry) (Panel), para. 7.157.
(21) Scott, *supra* note 8, at 83.
(22) Scott, *supra* note 8, at 91.
(23) Ibid.
(24) Ibid.
(25) EC-Hormones (Panel), para. 2.2.
(26) Ibid., para. 2.3.
(27) Ibid., para. 2.4.
(28) Ibid., para. 2.8.
(29) Ibid., para. 2.9.
(30) Ibid., para. 2.10.
(31) Ibid., paras. I.4, II.2, II.3, II.4.
(32) EC's appellant's submission, para. 140.
(33) EC-Hormones (AB), para. 114.
(34) Ibid., para. 116.
(35) Ibid., para. 181.
(36) Ibid., para. 187.
(37) Ibid., para. 193.
(38) Ibid., para. 194.
(39) EC-Hormones (Panel), para. 8.98 (US); 8.101 (Canada).
(40) EC-Hormones (AB), para. 184.
(41) Scott, *supra* note 8, at 93.
(42) Ibid.
(43) Ibid.
(44) Ibid.
(45) EC-Hormones (AB), para. 184; Australia-Salmon (AB), para. 123.
(46) Scott, *supra* note 8, at 93.
(47) Australia-Salmon (AB), para. 124.
(48) Ibid.
(49) Scott, *supra* note 8, at 94.
(50) Ibid.

(51) Japan-Apples (AB), paras. 204-205.
(52) Scott, *supra* note 8, at 94.
(53) Ibid.
(54) Ibid.
(55) EC-Hormones (AB), para. 200.
(56) Japan-Apples (AB), para. 202.
(57) Australia-Salmon (Panel), para. 8.74, Japan-Apples (Panel), para. 8.257.
(58) Japan-Apples (Panel), paras. 8.266-8.271; (AB), para. 203.
(59) Japan-Apples (Panel), para. 8.271.
(60) Scott, *supra* note 8, at 95.
(61) Ibid.
(62) Ibid.
(63) Ibid.
(64) Scott, *supra* note 8, at 96.
(65) Ibid.
(66) Ibid.
(67) Ibid.
(68) Ibid.
(69) Japan-Apples (AB), para. 209.
(70) Scott, *supra* note 8, at 96.
(71) Japan-Apples (AB), para. 209.
(72) Panel Report, Australia-Measures Affecting Importation of Salmon-Recourse to Article 21.5 by Canada, WT/DS18/RW adopted on March 20, 2000, para. 7.70.
(73) Scott, *supra* note 8, at 96.
(74) Ibid.
(75) Australia-Salmon (Panel), para. 8.57.
(76) Ibid.
(77) Australia-Salmon (Panel), para. 8.47 and Japan-Apples (Panel), para. 8.239.
(78) Scott, *supra* note 8, at 98.
(79) Scott, *supra* note 8, at 99.
(80) Ibid.
(81) Ibid.
(82) Japan-Apples (Panel), para. 8.241.
(83) Ibid.

(84) Scott, *supra* note 8, at 99.
(85) EC-Hormones (AB), para. 189.
(86) Scott, *supra* note 8, at 99.
(87) Scott, *supra* note 8, at 82.
(88) EC-Hormones (AB), para. 180.
(89) Scott, *supra* note 8, at 82.
(90) EC-Hormones (AB), para. 180.
(91) Ibid., para. 250.
(92) Scott, *supra* note 8, at 83.
(93) Ibid.
(94) Japan-Agriculture (AB), para. 74.
(95) Ibid., paras. 76 and 77.
(96) Scott, *supra* note 8, at 83.
(97) Ibid.
(98) Australia-Salmon (AB), para. 138.
(99) Ibid., with the relevant quotation from the Panel reproduced in para. 137.
(100) Scott, *supra* note 8, at 83.
(101) Ibid.
(102) Ibid.
(103) Ibid.
(104) Scott, *supra* note 8, at 84.
(105) Ibid.
(106) Ibid.
(107) EC-Hormones (AB), para. 250.
(108) Australia-Salmon (Panel), para. 8.52, cited approvingly by the AB at para. 138.
(109) Scott, *supra* note 8, at 84.
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(111) Ibid.
(112) Ibid.
(113) Scott, *supra* note 8, at 85.
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(120) Ibid.
(121) Ibid.
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(124) Scott, *supra* note 8, at 86.
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(126) Scott, *supra* note 8, at 86.
(127) Japan-Agriculture (AB), para. 84.
(128) Japan-Agriculture (AB), para. 2.
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(131) Japan-Agriculture (AB), para. 84.
(132) Japan-Agriculture (Panel), para. 8.61.
(133) Japan-Apples (Panel), para. 2.19.
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(136) Scott, *supra* note 8, at 85.
(137) Japan-Apples (Panel), para. 8.198.
(138) Ibid.
(139) Scott, *supra* note 8, at 88.
(140) Japan-Apples (Panel), para. 15.
(141) Scott, *supra* note 8, at 88.
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(143) Ibid.
(144) Ibid.
(145) Japan-Apples (Panel), para. 8.171 and Japan-Apples (AB), para. 145.
(146) Scott, *supra* note 8, at 89.
(147) Ibid.
(148) Japan-Apples (Panel), para. 8.198.
(149) Japan-Apples (AB), para. 164 (footnotes omitted).
(150) Scott, *supra* note 8, at 90.
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(153) Japan-Apples (Panel), para. 8.198.
(154) Scott, *supra* note 8, at 90.
(155) Ibid.

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(159) Ibid.
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(170) EC-Hormones (AB), para. 250.
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(191) Scott, *supra* note 8, at 115.
(192) Japan-Apples (AB), para. 179.

(193) Scott, *supra* note 8, at 115.
(194) Scott, *supra* note 8, at 120.
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(200) Scott, *supra* note 8, at 121.
(201) Ibid.
(202) Ibid.
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(204) Appellate Body Report, European Communities－Trade Description of Sardines, WT/DS231/AB/R, adopted on October 23, 2002, para. 245.
(205) Japan-Agriculture (AB), para. 92.
(206) Scott, *supra* note 8, at 122.
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(208) Scott, *supra* note 8, at 122.
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(210) Scott, *supra* note 8, at 123.
(211) Japan-Agriculture (AB), para. 93.
(212) Scott, *supra* note 8, at 123.
(213) Japan-Agriculture (AB), para. 84.
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(216) EC-Hormones (AB), para. 194.