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MEMORANDUM

TO: The Council for Responsible Nutrition

FROM: Sidley Austin LLP

RE: WTO Analysis of RDA-Based Maximum Levels for Vitamin and Mineral Food Supplements

DATE: August 24, 2011

I. EXECUTIVE SUMMARY

A number of Members of the World Trade Organization ("WTO") restrict the sale of vitamin and mineral food supplements by establishing maximum levels of nutrient content tied exclusively to the Recommended Dietary Allowance ("RDA"),[1] or they may be considering the adoption of such regulations. This memorandum explains why such regulations violate the disciplines of the WTO Agreements, and would likely be struck down if challenged before a WTO dispute settlement panel.

The regulations are either established in the form of food regulations that prohibit the production and/or sale of food supplements exceeding RDA-based limits, or, alternatively, they take the form of pharmaceutical regulations in WTO Members that classify all or some classes of food supplements as pharmaceutical drugs. While governments likely justify these measures as

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[1] The Recommended Dietary Allowance (RDA) was established in 1941 and periodically revised by the Food and Nutrition Board of the Institute of Medicine, the health arm of the National Academies. The 1968 version of the RDA became the initial basis for an alternative value, the Reference Daily Intake (RDI), which was established by the Food and Drug Administration for use in nutrition labeling. Dietary Reference Intakes (DRI) is the general term for a set of four reference values, *i.e.*, Estimated Average Requirement (EAR), Recommended Dietary Allowances (RDA), Adequate Intake (AI), and Tolerable Upper Intake Level (UL). *See* Council for Responsible Nutrition, Vitamin and Mineral Recommendations, http://www.crnusa.org/about_recs3.html; National Institutes of Health Office of Dietary Supplements, Nutrient Recommendations: Dietary Reference Intakes (DRI), http://ods.od.nih.gov/Health_Information/Dietary_Reference_Intakes.aspx.

The regulations referenced in this memo rely primarily on RDI – *e.g.*, "Ingestão Diária Recomendada" or "Ingestión Recomendada Diaria" (Recommended Daily Intake), Doses Diárias de Referência (Reference Daily Intake). However, we use the more commonly known term "RDA" throughout this memo to describe a set of recommended nutrient intakes used (incorrectly) as a basis for setting maximum levels of vitamins and minerals in food supplement products.

taken to protect human health, it appears that they have imposed these regulations without any risk assessment, and that they are not based in science.

Restricting the nutrient content of food supplements – whether regulated as food or drugs – to RDA-based maximums appears to violate several provisions of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("*SPS Agreement*"). In particular, such regulations appear to violate:

- Articles 2.2, 5.1, and 5.2 of the *SPS Agreement*, because the RDA-based maximums are not based on a risk assessment or maintained with sufficient scientific evidence;

- Articles 2.3 and 5.5 of the *SPS Agreement*, because the regulations require food supplement importers to comply with standards that are more burdensome than those applied to producers of certain conventional foods with qualities similar to food supplements.

In the alternative to claims made under the *SPS Agreement*, a WTO Member could also argue that RDA-based maximums in food and drug regulations violate provisions of the *Agreement on Technical Barriers to Trade* ("*TBT Agreement*"), particularly:

- Article 2.2 of the *TBT Agreement*, because the regulations have the effect of creating an unnecessary obstacle to international trade by being more trade-restrictive than necessary to protect consumer health from the adverse effects of an excessive intake of vitamins and minerals; and

- Article 2.1 of the *TBT Agreement*, because to the extent that imported food supplements are "like" conventional food products of national origin, the regulations accord treatment to imported food supplements that is less favorable than that accorded to domestically produced conventional food.

In addition, because they are inconsistent with the international guidelines adopted by the Codex Alimentarius Commission ("Codex"), food regulations setting RDA-based maximums on

food supplements appear to further violate Article 3.3 of the *SPS Agreement*, because the regulations exceed the level of sanitary or phytosanitary protection achieved by the relevant international guidelines without a scientific justification or risk assessment; and Article 2.4 of the *TBT Agreement*, because the regulations do not use the relevant international standard, or the relevant parts of the international standard, as their basis.

Finally, both food and drug regulations with RDA-based restrictions appear to violate Article III:4 of the *General Agreement on Tariffs and Trade 1994* ("*GATT 1994*" or "*GATT*"), because, to the extent food supplements are "like" certain conventional foods, the regulations discriminate against imported food supplements, in respect of laws, regulations, and requirements affecting their internal sale, offering for sale, purchase, distribution, or use. This violation is not justified under Article XX of the *GATT 1994*, because the regulations are not "necessary" to protect human health and are applied in a manner that would constitute a disguised restriction on international trade.

The *GATT 1994*, *SPS Agreement*, and *TBT Agreement* are three of the Uruguay Round Multilateral Agreements on Trade in Goods that form the basis of the present WTO legal framework. The *GATT 1994*, which is based on and read together with the original *GATT 1947*, governs the largest area of trade covered by the WTO, *i.e.*, trade in goods, while the *SPS* and *TBT Agreements* are separate agreements that cover specific issues of safety and standards related to trade in goods. Because these agreements are both designed to "further the objectives of *GATT 1994*"[2] and, in the case of the *SPS Agreement*, to "elaborate rules for the application of the provisions of *GATT 1994* which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b),"[3] claims made by WTO Members in dispute settlement proceedings will often be based on both the *GATT 1994* and one or more of these specific agreements.

[2] *TBT Agreement*, Preamble.
[3] *SPS Agreement*, Preamble. As discussed below in Section III.C, Article XX(b) of the *GATT 1994* provides a general exception for measures "necessary to protect human, animal or plant life or health."

II. BACKGROUND

As defined by the 2005 Codex Guidelines for Vitamin and Mineral Food Supplements ("Codex Guidelines"), vitamin and mineral food supplements are "sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet."[4] The Codex Guidelines provide direction regarding, *inter alia*, product composition, packaging, and labeling.

Article 3.2.2 of the Codex Guidelines specifically addresses maximum vitamin and mineral content in food supplements, providing that:

> Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:
>
> (a) *upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data*, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;
>
> (b) the daily intake of vitamins and minerals from other dietary sources.
>
> When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population. *This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes* (e.g. Population Reference Intake or Recommended Daily Allowance values).[5]

We note that the Codex Guidelines state that they apply only in those jurisdictions where such products are regulated as foods,[6] but this limitation in the Codex Guidelines does not limit

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[4] CODEX ALIMENTARIUS COMMISSION, GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS (CAC/GL 55 – 2005), www.codexalimentarius.net/download/standards/10206/cxg_055e.pdf, Art. 2.1. The Guidelines note that the term "small-unit quantities" refers to the physical forms of the vitamin and mineral food supplements and not to the potency of the supplements.

[5] Emphases added.

[6] *See* Codex Guidelines, Art. 1.3. We have been informed that, during the discussions before the Codex Committee on Nutrition and Foods for Special Dietary Uses, which led to the adoption of the Guidelines, an official from the WTO Secretariat noted that Codex lacked the authority to determine whether a WTO Agreement applied to particular regulatory measures, and that, accordingly, Article 1.3 had no effect on the legal interpretation of WTO Agreements.

the scope of the *SPS Agreement* and the *TBT Agreement*, which may apply to certain aspects of *both* food and drug regulations. Indeed, the practical impact of such a statement is quite limited given that the principles included in Article 3.2.2 of the Guidelines are also included in the similar obligations of the *SPS Agreement* and *TBT Agreement*, as detailed further below. For example, while Article 3.2.2 refers to the need to set upper safe limits in view of "scientific risk assessment based on generally accepted scientific data", the *SPS Agreement* requires that an SPS measure is "based on scientific principles", "scientific evidence", and a risk assessment.[7] Similarly, the *TBT Agreement* provides that assessment of risks should take into account "available scientific and technical information".[8]

Despite the express guidance against setting maximum levels for vitamins and minerals in food supplements based solely on recommended nutrient intakes, a number of countries regulate food supplements on precisely this basis. Venezuela, for example, requires that the maximum content of vitamins and minerals in supplements does not exceed 100 percent of Daily Values (DV),[9] which are determined with reference to RDI values. To take another example, Chile has set maximum daily limits of vitamins and minerals used in supplements at various multiples of RDI, without any indication as to whether those multiples are based on risk assessment or scientific evidence.[10] Most recently, Saudi Arabia has proposed a regulation that would classify and regulate food supplements as "drug products" in instances where, for example, the formulation of those supplements contains minerals and vitamins above the RDA.[11]

By contrast, Article 3.2.2 of the Codex Guidelines states that maximum amounts of vitamins and minerals should take into account upper safe levels as established by scientific risk assessment. Thus, in the absence of any risk-based assessment showing that vitamin and mineral

[7] *SPS Agreement*, Article 2.2 and 5.1.
[8] *TBT Agreement*, Article 2.2.
[9] *See* Rule No. 3863:2005 of the Foundation for the Normalization and Certification of Quality (FONDONORMA), August 31, 2005, Art. 5.2.1.
[10] *See* Exempt Resolution No. 394/2002, March 1, 2002, Art. 1, as amended by Exempt Resolution No. 730/03, August 1, 2003 and Exempt Resolution No. 1225/04, January 13, 2004.
[11] *See* Saudi Food and Drug Authority, Suggested Guideline/Regulation to Determine the Quantity of Vitamins and Minerals in Health and Herbal Products Introduced for Registration and the Extent to Which it Falls Under Drug Products or Health and Herbal, Draft Regulation, http://www.sfda.gov.sa/NR/rdonlyres/12CB3008-6644-4327-B5C4-D1601D3B8528/0/ProductsClassificationGuidelines.pdf.

intake above RDAs (or arbitrary multiples of RDAs) has the potential to cause harm to human health, the regulations at issue lack a scientific basis and are inconsistent with the Codex Guidelines.

III. ANALYSIS OF CONSISTENCY WITH WTO DISCIPLINES

Food and drug regulations restricting the content of food supplements principally on the basis of RDA values appear to violate the *SPS Agreement*, the *TBT Agreement* (to the extent they are not covered by the *SPS Agreement*), and the *GATT 1994*. In particular, the food regulations do not benefit from a rebuttable presumption of consistency with these agreements,[12] because the measures are inconsistent with the Codex Guidelines, which the *SPS Agreement* has designated the "international standards, guidelines and recommendations" for food safety.[13]

In Section III(A) of this Memorandum, we first discuss claims that may be advanced under the *SPS Agreement* with respect to RDA-based maximums for food supplements imposed in food and drug regulations. Second, in Section III(B), we present claims under the *TBT Agreement* with respect to the same measures, which would be made in the alternative to claims under the *SPS Agreement*. Finally, in Section III(C), we address the national treatment claim under Article III:4 of the *GATT 1994*, and explain why the regulations at issue cannot be justified as an exception under Article XX.

A. Consistency with the *SPS Agreement*

1. Overview

The *SPS Agreement* disciplines sanitary or phytosanitary measures ("SPS measures") aimed at the protection of human, animal, and plant life and health. It requires that SPS measures be enacted and maintained on the basis of scientific evidence and a risk assessment, or on the basis of a relevant international standard. Members must also ensure that their SPS measures are consistent with the principles of non-discrimination and national treatment.

[12] *See SPS Agreement*, Art. 3.2; *TBT Agreement*, Art. 2.5.
[13] *SPS Agreement*, Annex A, Art. 3(a).

Article 1.1 provides that the *SPS Agreement* "applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade."[14] Thus, to be covered by the *SPS Agreement*, a measure must: (i) be an SPS measure, as defined in Annex A; and (ii) directly or indirectly affect international trade.

The definition of "sanitary or phytosanitary measure" in Annex A of the *SPS Agreement* has two components. First, it must be a measure applied:

> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) *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;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.[15]

Second, it must take a legal form among those in the illustrative list in Annex A(1), which includes "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 labelling requirements directly related to food safety."[16]

[14] *SPS Agreement*, Art. 1.
[15] Emphasis added.
[16] *SPS Agreement*, Annex A(1).

Based on the ordinary meaning of the terms "food" and "beverage,"[17] food supplement regulations that set RDA-based maximums would qualify as "SPS measures" under the definition in Annex A(1)(b) of the *SPS Agreement*. The intent of the regulations appears to be "to protect human . . . life or health within the territory of the [WTO] Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs." The definition of the term "food" is "[a]ny nutritious substance that people or animals eat or drink in order to maintain life and growth; nourishment, provisions,"[18] while "beverage" is defined as a "drink, liquor for drinking; especially a liquor which constitutes a common article of consumption."[19] As substances that people eat or drink to supply additional nutrients to augment those provided by their regular diet, food supplements would appear to be included within these definitions.[20] Thus, a WTO panel assessing the WTO consistency of a measure regulating food supplements may find that food supplements are also "foods" and "beverages," and, as such, fall within the scope of the definition of an SPS measure in Annex A(1)(b) of the *SPS Agreement*.

The measures here are issued as laws, decrees, and regulations, which are all legal forms identified in Annex A(1). They also meet the requirement in Article 1.1 of the *SPS Agreement* that a measure directly or indirectly affect international trade. This is because, pursuant to these regulations, food supplements that do not adhere to RDA-based maximum levels cannot be sold in – and therefore cannot be imported into – these countries. Clearly, this directly affects international trade.

Importantly, the *SPS Agreement* may be applicable irrespective of whether food supplements are regulated under food or drug regulations. We understand that a number of

[17] WTO panels and the WTO Appellate Body interpret the treaty text in accordance with the customary rules of international law codified in the *Vienna Convention on the Law of Treaties 1969* ("*Vienna Convention*"). Textual interpretation begins with Article 31.1 of the *Vienna Convention*, which provides that: "A treaty shall be interpreted in good faith in accordance with the *ordinary meaning* to be given to the terms of the treaty in their context and in the light of its object and purpose." (Emphasis added).
[18] THE OXFORD ENGLISH DICTIONARY (3rd ed. 2008, online version 2011).
[19] THE OXFORD ENGLISH DICTIONARY (2nd ed. 1989, online version 2011). As used in this definition, the term "liquor" does not refer exclusively to alcoholic beverages; it is defined as "liquid for drinking; beverage, drink." *Id.*
[20] *See* THE OXFORD ENGLISH DICTIONARY (3rd ed. 2008, online version 2011) (defining "food supplement" as "a substance taken to supply additional nutrients augmenting those provided by a person's regular diet.").

WTO Members have reclassified and now regulate food supplements as pharmaceutical products. These Members might have acted under the mistaken impression that designating food supplements as pharmaceutical products would place them outside the definition of an SPS measure in Article 1(b) of Annex A of the *SPS Agreement*. As explained above, however, a WTO panel could find that the definitions of "food" and "beverage" encompass food supplements, making the definition of an "SPS measure" applicable to both food and drug regulations. In other words, whether or not a particular substance qualifies as a food or a beverage within the meaning of the *SPS Agreement* is ultimately a question of legal interpretation for a WTO panel, and cannot be dictated by individual WTO Members. Moreover, as discussed in Sections III(B) and III(C) below, even if food supplements were found to be something other than "foods" or "beverages," they would nonetheless be governed by the *TBT Agreement* and the *GATT 1994*.

2. Specific Violations of the *SPS Agreement*

To challenge a measure under the *SPS Agreement*, a WTO Member would first need to demonstrate that the Agreement applies to the contested measure, and advance a *prima facie* case of inconsistency of the measure with particular provisions of the *SPS Agreement*.[21] The burden of proof then would shift to the defending party, which must refute the claimed inconsistency.[22] WTO Members that set RDA-based maximum levels for food supplements appear to violate numerous provisions of the *SPS Agreement*, as detailed below.

a. *The Food Supplement Regulations Lack a Scientific Basis and a Risk Assessment, in Violation of Articles 2.2 and 5.1 of the* SPS Agreement

Articles 2.2 and 5.1 of the *SPS Agreement* require that all SPS measures be based on scientific evidence and a risk assessment, respectively. Article 5.2 provides additional guidance on the factors that must be taken into account in conducting a risk assessment. The WTO Appellate Body has held that Articles 2.2 and 5.1 must be read together, as these complementary

[21] Appellate Body Report, *EC – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998 ("Appellate Body Report, *EC – Hormones*"), para. 98.
[22] Appellate Body Report, *EC – Hormones*, para. 98.

provisions are "essential" for the maintenance of the balance in the *SPS Agreement* between the protection of life and health, and the promotion of international trade.[23] The Appellate Body has also noted that science "plays a central role in a risk assessment."[24] As detailed below, however, Article 5.7 of the *SPS Agreement* provides a limited exception to Articles 2.2 and 5.1 where "relevant scientific evidence is insufficient" and a Member is seeking additional information "necessary for a more objective assessment."

(i) The Regulations Are Maintained Without Sufficient Scientific Evidence

Article 2.2 of the *SPS Agreement* requires Members to "ensure that any [SPS] 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."[25]

The terms "sufficiency" and "scientific evidence" have been considered by the Appellate Body under Articles 5.7 and Article 5.1, in addition to Article 2. According to the Appellate Body, consistency with Article 2.2 must be determined on a case-by-case basis,[26] in part because sufficiency is a "relational concept."[27] The Appellate Body found in *Japan – Agricultural Products II* that "sufficiency" requires "the existence of a sufficient, or adequate relationship" between the SPS measure and the scientific evidence.[28] On this basis, the Appellate Body concluded that the Article 2.2 "sufficiency" requirement mandates that there be a "rational or *objective relationship* between the SPS measure and the scientific evidence."[29]

[23] Appellate Body Report, *EC – Hormones*, para. 177.
[24] Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/AB/R, adopted 14 November 2008 ("Appellate Body Report, *Continued Suspension*"), para. 527.
[25] Emphasis added.
[26] Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999 ("Appellate Body Report, *Japan – Agricultural Products II*"), para. 84.
[27] Appellate Body Report, *Japan – Agricultural Products II*, para. 73.
[28] Appellate Body Report, *Japan – Agricultural Products II*, para. 73.
[29] Appellate Body Report, *Japan – Agricultural Products II*, para. 84 (emphasis added).

"Scientific evidence" was described by the panel in *Japan – Apples* as evidence "gathered through scientific methods,"[30] excluding "insufficiently substantiated information, but also such things as a non-demonstrated hypothesis."[31] The panel stated:

> [R]equiring 'scientific evidence' does not limit the field of scientific evidence available to Members to support their measures. 'Direct' or 'indirect' evidence may be equally considered. The only difference is not one of scientific quality . . . it is obvious that evidence which does not directly prove a fact might not have as much weight as evidence directly proving it, if it is available.[32]

The Appellate Body agreed with the panel that both "direct" practical experience ("practical experience [] accumulated over the past 200 years")[33] and "indirect" scientific studies related to a particular risk were relevant to the determination of whether sufficient scientific evidence exists.[34]

In the present case, scientific evidence does not appear to support the food supplement regulations at issue. We understand that, while these countries use the RDA to effortlessly set upper limits for vitamins and minerals in supplement products, RDA values are not suited for this purpose because they represent the average daily level of intake *sufficient* to meet the nutrient requirements of most healthy people.[35] Indeed, many conventional foods contain vitamins and minerals in amounts above the RDA – *e.g.*, 100 grams of beef liver may contain up to 50 times the RDA for vitamin B12,[36] while a serving of boiled kale contains 660 percent of

[30] Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted 10 December 2003, upheld by Appellate Body Report WT/DS245/AB/R ("Panel Report, *Japan – Apples*"), para. 8.92.
[31] Panel Report, *Japan – Apples*, para. 8.93.
[32] Panel Report, *Japan – Apples*, para. 8.98.
[33] Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003 ("Appellate Body Report, *Japan – Apples*"), para. 187, citing Panel Report, *Japan – Apples*, para. 8.219.
[34] Appellate Body Report, *Japan – Apples*, para. 187; Panel Report, *Japan – Apples*, para. 8.98.
[35] *See* National Institutes of Health Office of Dietary Supplements, Nutrient Recommendations: Dietary Reference Intakes (DRI), http://ods.od.nih.gov/Health_Information/Dietary_Reference_Intakes.aspx.
[36] *See* Council for Responsible Nutrition, Comment by the Council for Responsible Nutrition (CRN) on the CCFNSDU Draft Guideline on Vitamin and Mineral Supplements, http://www.crnusa.org/pdfs/CRNCommentsCAC062804.pdf ("CRN Comment on the Codex Food Supplements Guideline"), at 1.

the DV of vitamin K[37] – yet are not generally considered to pose a risk to human health. Studies have also established that nutrient intake in amounts above RDA values can provide additional health benefits. Thus, sufficient scientific evidence does not exist to justify restricting the nutrient content of food supplements at RDA levels.

(ii) The Regulations Are Not Based on a Risk Assessment

Article 5.1 of the *SPS Agreement* requires that Members "ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health . . . ." For an SPS measure to be "based on" a risk assessment, within the meaning of Article 5.1, there must be a "certain objective relationship" between the conclusions of the assessment and the SPS measure.[38] In other words, the measure must be "sufficiently supported or reasonably warranted by the risk assessment."[39]

Annex A(4) of the *SPS Agreement* defines "risk assessment" in two ways, depending on the circumstances. The definition that is relevant to the analysis of the regulations at issue is:

> [T]he 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.

The Appellate Body has determined, in *EC – Hormones*, that risk assessment is a "two-step process" consisting of: *first*, the *identification* of any adverse effects on human health arising from the presence of the additive, contaminant, toxin, or disease-causing organism of concern; and, *second*, if any adverse effects exist, *evaluation* of the potential for occurrence of such effects.[40]

When conducting a risk assessment, Article 5.2 of the *SPS Agreement* requires Members to "take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests;

[37] *See* National Institutes of Health Office of Dietary Supplements, Important Food and Drug Information, http://ods.od.nih.gov/pubs/factsheets/coumadin1.pdf, at 2.
[38] Appellate Body Report, *EC – Hormones*, para. 189.
[39] Appellate Body Report, *EC – Hormones*, para. 186.
[40] Appellate Body Report, *EC – Hormones*, para. 183.

existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment." In *EC – Hormones*, the Appellate Body confirmed that the list in Article 5.2 is illustrative, and that any given risk assessment need not include all of the required elements.[41] Rather, the Appellate Body stressed that the risk assessment should eschew hypothetical or theoretical risk and focus on "actual potential for adverse effects on human health in the real world where people live and work and die."[42]

Although it must take into account the factors in Articles 5.2 and 5.3 when conducting a risk assessment, some discretion is left to the Member. For instance, a risk assessment need not precede the adoption of an SPS measure.[43] A Member is not required to conduct its own risk assessment, and may rely on an assessment prepared by an international organization or another Member.[44] In addition, the Appellate Body has noted that Article 5.1 requires that the assessment be "appropriate to the circumstances"[45] and that the risk assessment may be either quantitative or qualitative.[46] The Appellate Body has emphasized that the risk assessment must evaluate an *ascertainable* risk, as opposed to a risk that is purely theoretical.

A risk assessment must be specific. It must assess the threat to human or animal health posed by the *specific* additive, contaminant, toxin, or disease-causing organism that the Member seeks to control, in the *specific* product at issue.[47] The risk assessment must also examine the *causal connection* between the harm caused and the agent alleged to cause that harm. It must "connect the possibility of adverse effects with an antecedent or cause";[48] in other words, the risk must be given context.[49]

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[41] Appellate Body Report, *EC – Hormones*, para. 187.
[42] Appellate Body Report, *EC – Hormones*, para. 187.
[43] Appellate Body Report, *EC – Hormones*, paras. 188-89.
[44] Appellate Body Report, *EC – Hormones*, para. 190.
[45] Appellate Body Report, *EC – Hormones*, para. 129.
[46] Appellate Body Report, *EC – Hormones*, paras. 186-87.
[47] Appellate Body Report, *EC – Hormones*, paras. 187, 200.
[48] Appellate Body Report, *Japan – Apples*, para. 202, n. 372.
[49] Appellate Body Report, *Japan – Apples*, para. 202. In situations where multiple factors may contribute to a given adverse health outcome, a risk assessor is not required to differentiate the individual contribution made by each factor; the assessor must, however, establish whether there is a connection between the substance being evaluated and the possibility that adverse health effects could arise. Appellate Body Report, *Continued Suspension*, para. 562.

The risk assessment must be based on scientific evidence from "qualified and respected sources," and its conclusions should be based on "objective and coherent reasoning."[50] In *EC – Hormones*, the Appellate Body stated that a risk assessment need not "embody only the view of a majority of the relevant scientific community . . . governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources."[51] In *Continued Suspension*, the Appellate Body confirmed that Members may rely on minority science but emphasized that, nonetheless, the scientific basis for the risk assessment must come from a "respected and qualified source" and must "have the necessary scientific and methodological rigour to be considered reputable science."[52]

In the present case, we do not know of any risk assessment that demonstrates that vitamin and mineral content in food supplements should be capped at their RDA values. To the contrary, we understand from the information provided to us that a number of studies have documented the benefits of consuming nutrient quantities above the RDA – *e.g.*, clinical trials have shown that vitamin D, which has an RDA of approximately 200 to 800 International Units for adults, can reduce the incidence of falls, certain cancers, and other diseases with intakes of 1,000 to 2,000 International Units or more.[53] We also understand that RDA-based limits cannot be accurately derived for certain nutrients because they lack an established RDA value.[54] Thus, without a scientific risk assessment that identified the adverse effects on human health arising from intake of vitamins and minerals above RDA levels, and, if such adverse effects existed, the potential for their occurrence, regulations restricting food supplements to those levels would be found inconsistent with Articles 5.1 and 5.2 of the *SPS Agreement*.

(iii) The Regulations Likely Cannot Be Justified As Provisional Measures Under Article 5.7 of the *SPS Agreement*

It is possible that WTO Members may attempt to justify their RDA-based maximum levels as "provisional" measures within the meaning of Article 5.7. Article 5.7 serves as an

[50] Appellate Body Report, *Continued Suspension*, para. 591.
[51] Appellate Body Report, *EC – Hormones*, para. 194.
[52] Appellate Body Report, *Continued Suspension*, para. 591.
[53] *See* R.P. Heaney & M.F. Holick, *Why the IOM Recommendation for Vitamin D Are Deficient*, 26 J. BONE & MINERAL RES. 455-57 (2011).
[54] *See* CRN Comment on the Codex Food Supplements Guideline at 2.

exception to Articles 2.2 and 5.1 of the *SPS Agreement*, but it requires a defending Member to sustain a heavy burden.

The Appellate Body has held that "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence."[55] In *Japan – Agricultural Products II*, the Appellate Body interpreted Article 5.7 as encompassing four cumulative requirements which must be met in order for a provisional measure to be consistent with the *SPS Agreement*:

> (a) The measure must be imposed in respect of a situation where "relevant scientific information" is *insufficient*;
>
> (b) The measure must be adopted "on the basis of *available pertinent information*";
>
> (c) The Member must "*seek to obtain the additional information* necessary for a more objective assessment of risk"; and
>
> (d) The Member must review the measure "within a *reasonable period of time*."[56]

The Appellate Body analyzed the phrase "insufficient scientific evidence" and concluded that sufficient refers to "a quantity, extent, or scope adequate to a certain purpose or object."[57] In relation to Article 5.7, it considered the "certain purpose or object" to be completion of the risk assessment, finding that Article 5.7 may be relied upon only under circumstances where scientific evidence is insufficient to conduct the risk assessment required under the *SPS Agreement*.[58]

"Evidence" was deemed by the panel in *Japan – Apples* to consist of both scientific studies ("indirect" evidence) and "practical experience" ("direct evidence").[59] The panel applied this approach when determining whether the measure at issue was "based on scientific

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[55] Appellate Body Report, *Japan – Agricultural Products II*, para. 80 (emphasis in original).
[56] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphases added).
[57] Appellate Body Report, *Japan – Agricultural Products*, para. 73 (quoting THE SHORTER OXFORD ENGLISH DICTIONARY 2180 (3rd ed. 1983)).
[58] Appellate Body Report, *Japan – Apples*, para. 179 ("'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 defined in Annex A to the *SPS Agreement*").
[59] Panel Report, *Japan – Apples*, para. 8.98.

evidence," in the sense of Article 2.2, and also when determining whether Japan could rely on Article 5.7 as justification for its SPS measure.[60]

The determination that evidence is "insufficient" may be made in reference to a particular measure or to a particular risk, rather than in reference to the subject matter overall. In the words of the Appellate Body:

> The question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it "general" or "specific" . . . is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.[61]

In *Japan – Apples*, the Appellate Body found that because there was a significant volume of scientific evidence that could serve as the basis for a risk assessment, Japan could not rely on Article 5.7 as justification for its measure, even if it believed information related to certain specific aspects of fire blight disease transmission to be incomplete.[62] Because "scientific uncertainty" is not the same thing as "insufficient scientific evidence," the Appellate Body held that Members cannot invoke Article 5.7 when available scientific evidence is sufficient but does not offer *scientific certainty* with regard to a certain risk.[63]

In this case, it appears that there is ample scientific evidence upon which risk analysis may be conducted. The Codex Guidelines direct that "*upper safe levels* of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data" may be taken into account,[64] indicating that scientific evidence establishing upper safe levels of nutrient intake is available or can readily be generated. We also understand that the Nutritional Risk Analysis Principles of the Codex Committee on Nutrition and Foods for Special Dietary Uses recognize the Food and Agriculture Organization and World Health Organization

[60] Panel Report, *Japan – Apples*, para. 8.219.
[61] Appellate Body Report, *Japan – Apples*, para. 179.
[62] Appellate Body Report, *Japan – Apples*, para. 179; Panel Report, *Japan – Apples*, para. 8.219.
[63] Appellate Body Report, *Japan – Apples*, para. 184 ("The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence.").
[64] Codex Guidelines, Art. 3.2.2 (emphasis added).

("FAO/WHO") risk assessment method as the primary method for nutrient risk assessment, and that this method similarly provides evidence relating to safe levels of consumption for vitamins and elements.[65] Thus, it does not appear that a Member could sustain an objection about the sufficiency of scientific evidence with respect to food supplements that would qualify under Article 5.7.

b. The Food Supplement Regulations Arbitrarily and Unjustifiably Discriminate Against Imported Food Supplements

The *SPS Agreement* prohibits Members from using SPS measures for arbitrary and unjustifiable discrimination against imports. This prohibition is found in two separate articles: Article 2.3 and Article 5.5. Article 2.3 requires that Members' SPS measures "do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail." Similarly, Article 5.5 prohibits discrimination through the application of different levels of sanitary protection to comparable situations, without justification.

The Appellate Body has described the non-discrimination obligation in Article 2.3 as being of "fundamental importance," since it reflects the obligations set forth in Article I:1 and III:4 of the *GATT*, and incorporates aspects of the chapeau to Article XX of the *GATT*.[66]

The Appellate Body has established a three-part test for evaluating consistency with Article 2.3 and a similar three-part test for Article 5.5. These tests are very similar, with a few notable distinctions.

With respect to Article 2.3, three conditions must be fulfilled in order to establish a violation: (i) the measure at issue discriminates between the territories of Members other than the Member imposing the measure, or between the territory of the Member and that of another

[65] We understand that the FAO/WHO method is substantially similar to the Tolerable Upper Intake Level (UL) developed by the Institute of Medicine, which represents the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. *See* Food and Nutrition Board, Institute of Medicine, National Academies, Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Vitamins and Elements, http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~/media/Files/Activity%20Files/Nutrition/DRIs/ULs%20for%20Vitamins%20and%20Elements.pdf.

[66] Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998 ("Appellate Body Report, *Australia – Salmon*"), para. 251.

Member; (ii) the discrimination is arbitrary or unjustifiable; and (iii) identical or similar conditions prevail in the territories of the Members compared.[67] These conditions have been examined only once, in *Australia – Salmon*, in connection with the risk of introduction of diseases affecting fish.[68] The obligations in Article 2.3 have not yet been examined in relation to SPS measures aimed at protecting *human life or health* from additives, contaminants, toxins, or disease-causing organisms in food.

With respect to Article 5.5, the Appellate Body has identified three elements that must be present in order to establish a violation: (i) the Member has set different levels of protection in "different situations"; (ii) the levels of protection show "arbitrary or unjustifiable" differences in their treatment of different situations; and (iii) these arbitrary or unjustifiable differences lead to "discrimination or disguised restrictions" on trade.[69]

(i) The Regulations Discriminate Between Imported Food Supplements and Certain Domestic Food Products

Demonstrating that discrimination exists between the RDA-based maximums applied to imports of food supplements and those applied to certain domestic foods is relatively straightforward. The "appropriate level of protection," or ALOP, is defined as the "level of protection deemed appropriate by a Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."[70] Discrimination exists if the importing Member requires a higher ALOP for imported goods than it applies domestically to similar or comparable goods.

Under Article 2.3 of the *SPS Agreement*, discrimination exists if the importing Member applies different ALOPs where "identical or similar conditions prevail." Under Article 5.5, discrimination exists if the importing Member applies different ALOPs to "different situations"

[67] 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 ("Panel Report, *Australia – Salmon* (21.5)"), paras. 7.110-7.111.
[68] Appellate Body Report, *Australia – Salmon*, paras. 247-52; Panel Report, *Australia – Salmon* (21.5), paras. 7.109-7.114.
[69] Appellate Body Report, *EC – Hormones*, paras. 214-15; Appellate Body Report, *Australia – Salmon*, para. 140.
[70] *SPS Agreement*, Annex A(5).

that are nonetheless "comparable."[71] These analyses are closely related. The Appellate Body, in *EC – Hormones*, stated that situations exhibiting different levels of protection may be compared if they "present some common element or elements sufficient to render them comparable."[72] Similarly, in *Australia – Salmon*, the Appellate Body found that situations may be compared if they involve either a risk of entry, establishment or spread of the same or a similar disease, *or* a risk of the same or similar associated potential biological consequences. The Appellate Body further held that situations may be compared under Article 5.5 if they have in common a risk of entry, establishment or spread of just *one* disease of concern.[73]

In this case, identical or similar conditions prevail between food supplements and conventional food products to the extent that there is little or no distinction between the two types of products, in terms of their nutrient content and effect on human life or health. Alternatively, these are comparable situations to the extent that they both involve risks arising from excessive consumption of certain nutrients. As explained above, consumption of many conventional foods can result in intake of vitamins and minerals in excess of RDA values. Despite these similar conditions or comparable situations, however, these countries apply a much higher ALOP to food supplements than that applied to conventional food products.

(ii) The Different Levels of Protection Are Arbitrary or Unjustifiable

The second element of the tests for establishing violations of Articles 2.3 and 5.5 requires that distinctions in the ALOP be arbitrary or unjustifiable, in light of scientific or other evidence. In *EC – Hormones,* the Appellate Body examined the different treatment by the EC of hormones used for growth promotion purposes, on the one hand, and the EC's use of anti-microbial agents, on the other hand. It found that the lower ALOP applied to the anti-microbial agents was not justified on the basis of the available evidence, and concluded that the distinction in levels of protection applied to these different situations was "arbitrary and unjustifiable."[74] Similarly, in *Australia – Salmon*, the Appellate Body found as "arbitrary and unjustifiable" the distinction in

[71] Appellate Body Report, *EC – Hormones*, para. 217.
[72] Appellate Body Report, *EC – Hormones*, para. 217.
[73] Appellate Body Report, *Australia – Salmon*, para. 152.
[74] Appellate Body Report, *EC – Hormones*, paras. 226, 235.

the levels of sanitary protection applied by Australia to fish products, on the one hand, and to ocean-caught Pacific salmon, on the other hand, since available evidence indicated that the fish products represented at least as high a risk than that associated with ocean-caught Pacific salmon.[75] Scientific and other evidence has been central to assessment of consistency with this element.

In the case of RDA-based maximums for food supplements, the unjustifiable and arbitrary nature of the discrimination is straightforward. To the extent that WTO Members apply different ALOPs to food supplements and comparable conventional food products, they apparently do so without any rationale as to why one requires a higher ALOP than the other. Absent scientific or other evidence supporting this ALOP distinction, a WTO panel would likely find it to be a violation of Articles 2.3 and 5.5 of the *SPS Agreement*.

(iii) Identical or Similar Conditions Prevail

In *Australia – Salmon* (21.5), the implementation panel found that, due to different disease burdens in the territories of the Members compared, "identical or similar conditions" did not prevail; on this basis, and in light of its analysis of Canada's discrimination claim under Article 5.5, it concluded that Canada had not demonstrated a violation of Article 2.3.[76] There is nothing to suggest that different conditions exist between imported food supplements and comparable domestically produced conventional food products that would justify the discrimination resulting from the RDA-based maximums. Consequently, it does not appear that Members can justify their discrimination by pointing to the lack of "identical or similar conditions [that] prevail" between their territories and those of countries exporting food supplements.

[75] Appellate Body Report, *Australia – Salmon*, paras. 157-58. *See also* Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R and Corr.1, adopted 6 November 1998, as modified by Appellate Body Report WT/DS18/AB/R ("Panel Report, *Australia – Salmon*"), para. 8.134.
[76] Panel Report, *Australia – Salmon* (21.5), para. 7.113.

(iv) The Regulations Result in Discrimination or Disguised Restrictions on Trade

With regard to the third element of the Article 5.5 analysis, a violation occurs when the SPS measure enacted to achieve the different ALOPs results in "discrimination or a disguised restriction on international trade." According to the Appellate Body, whereas the first two elements relate to the distinction in ALOPs applied by the Members, the third element relates to the *SPS measure* embodying the stricter ALOP.[77]

Based on the relevant Appellate Body jurisprudence, confirmation of the presence of discrimination or a disguised restriction on trade must be made on a case-by-case basis, by weighing different factors.[78] In *EC – Hormones*, the Appellate Body agreed that factors such as a significant degree of difference in the ALOPs applied, together with the arbitrary or unjustifiable character of the difference in ALOPs, may be taken into account when determining whether the third element is present.[79] In *Australia – Salmon*, the Appellate Body endorsed a third, additional factor that had been taken into account by the panel: inconsistency with Article 5.1, *i.e.*, the absence of a risk assessment. The Appellate Body (and panel) referred to these three factors as "warning signals." The Appellate Body also endorsed the reliance by the *Australia – Salmon* panel on certain "additional factors," for instance "the substantial, but unexplained change in conclusion[s]" by Australian officials as to the risk posed by Pacific ocean-caught salmon within a short period of time.[80]

As explained previously, the difference in the requirements applicable to food supplements and certain comparable conventional food products is significant; *i.e.*, food supplements not conforming to RDA-based maximums may not be sold in these countries, whereas conventional foods containing nutrients significantly in excess of RDA values are not subject to any maximum nutrient content levels. This difference in the level of sanitary protection is arbitrary because it lacks scientific or other evidence, particularly in the form of a

[77] Appellate Body Report, *EC – Hormones*, paras. 214, 238.
[78] Appellate Body Report, *EC – Hormones*, para. 240.
[79] Appellate Body Report, *EC – Hormones*, paras. 215, 240.
[80] Appellate Body Report, *Australia – Salmon*, paras. 170–71.

risk-based assessment showing that restricting food supplements to RDA-based values is justified.

c. Food Regulations Imposing RDA-Based Maximums Are Inconsistent with the Relevant International Standard

One of the objectives of the *SPS Agreement* is to "further the use of harmonized sanitary and phytosanitary measures by Members, based on the relevant international standards, guidelines and recommendations."[81] For this reason, Members are urged to base their SPS measures on international standards developed by "relevant international organizations," which include the Codex Alimentarius Commission. SPS measures that "conform to" the relevant international standard also enjoy a presumption of consistency with the *SPS Agreement* and, in turn (pursuant to Article 2.4 of the *SPS Agreement*), the *GATT 1994*.[82]

Based on Article 3.3 of the *SPS Agreement*, Members also have the right to adopt a *higher* level of sanitary protection than would be achieved based on the relevant international standard, if there is a scientific justification or as a consequence of the level of sanitary protection deemed "appropriate" by that Member. The right of Members under Article 3.3 unilaterally to determine their ALOP, and to enact SPS measures providing protection that exceeds the protection achieved by the relevant international standard, is a "qualified right."[83] That is, SPS measures enacted on this basis must comply with all other requirements of the *SPS Agreement*, including the requirement to perform a scientific risk assessment, consistent with Articles 2 and 5.[84]

With respect to food regulations imposing RDA-based maximum levels on food supplements, the relevant international standard would be the Codex Guidelines for Vitamins and Mineral Food Supplements.[85] As introduced in Section II above, the Codex Guidelines

[81] *SPS Agreement*, Preamble.
[82] According to the Appellate Body, this is a "rebuttable presumption of consistency." Appellate Body Report, *Continued Suspension*, para. 532.
[83] Appellate Body Report, *Continued Suspension*, para. 532.
[84] Appellate Body Report, *Continued Suspension*, para. 532.
[85] Article 1.3 of the Codex Guidelines state that they apply only in those jurisdictions where food supplement products are "regulated as foods." However, as discussed in note 6 above, we understand that a WTO Secretariat official has expressed the view that Codex lacks the authority to determine whether a WTO Agreement applies to

expressly warn against setting maximum levels that are "solely based on recommended nutrient intakes" such as RDA values. Pursuant to Article 3.3, therefore, WTO Members that have adopted the RDA as a ceiling for nutrient content in food supplements must be able to demonstrate that there is a scientific basis for requiring a higher standard than that prescribed by the Codex Guidelines. We do not know of the existence of any such scientific basis.

B. Analysis of Consistency with the *TBT Agreement*

As discussed previously, a WTO panel will likely determine that food regulations limiting the nutrient content of vitamin and mineral food supplements are covered by the *SPS Agreement*, in view of the definition of "sanitary or phytosanitary measures" in Annex A(1), and the ordinary meaning of "foods" and "beverages." It follows that a panel may also find that when a Member simply reclassifies food supplements as pharmaceutical products, and regulates them as such, this would be *insufficient* to place the measure outside the *SPS Agreement*'s purview. However, even if a panel were to conclude that food- and/or drug-based regulations for food supplements were not covered by the *SPS Agreement*, a complaining party could still claim, in the alternative, that the regulations at issue violate the *TBT Agreement*.

1. Overview

The *TBT Agreement* disciplines all technical regulations, voluntary standards, and procedures for assessment of conformity with technical regulations and standards, to the extent that they are not covered by the *SPS Agreement*. The objective of the *TBT Agreement* is to ensure that such regulations, standards, and conformity assessment procedures do not act as unnecessary obstacles to international trade. All products, including industrial and agricultural products, are subject to the *TBT Agreement*,[86] but the agreement does not apply to sanitary and

certain regulatory measures, and that, accordingly, Article 1.3 has no effect on the legal interpretation of the WTO Agreements.

[86] *See TBT Agreement*, Art. 1.3.

phytosanitary measures as defined under the *SPS Agreement*.[87] In other words, claims under the *SPS Agreement* and the *TBT Agreement* are mutually exclusive.[88]

Annex 1 of the *TBT Agreement* provides definitions for the following:

> 1. *Technical regulation*
>
> Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which *compliance is mandatory*. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. . . .
>
> 2. *Standard*
>
> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which *compliance is not mandatory*. . . .
>
> 3. *Conformity assessment procedures*
>
> Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.[89]

To the extent that they do not constitute SPS measures, the regulations at issue would fall within the definition of a "technical regulation" because they lay down product characteristics in terms of the maximum levels of vitamin and mineral content in food supplements, with which compliance is mandatory. The regulations may also constitute "technical regulations" because of the additional regulatory consequences that may arise from classifying food supplements as pharmaceutical products. The products may, for example, become subject to certain restrictions with respect to processing or production methods, or pre-marketing approval requirements.

The Appellate Body, in *EC – Asbestos* and *EC – Sardines*, laid out a three-prong test, noting that a "technical regulation": (i) lays down product characteristics; (ii) is mandatory in its

[87] *See TBT Agreement*, Art. 1.5.
[88] *See also* Article 1.4 of the *SPS Agreement*, which contains similar wording noting that "[n]othing in this [SPS] Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement."
[89] Emphases added.

application; and (iii) is applicable to identifiable products.[90] This test is easily applied here, because the RDA-based limits laid down in the regulations constitute "characteristics" of food supplement products, and the regulations are "mandatory" in their application, and applicable specifically to food supplement products.

Thus, to the extent that the regulations do not fall under the *SPS Agreement*, they are "technical regulation[s]" in the sense of Annex I to the *TBT Agreement*. As detailed below, the regulations appear to violate Articles 2.2, 2.1, and 2.4 of the *TBT Agreement*.

2. Specific Violations of the *TBT Agreement*

a. The Food Supplement Regulations Are More Trade-Restrictive Than Necessary to Protect Human Health, in Violation of Article 2.2 of the TBT Agreement

Article 2.2 of the *TBT Agreement* provides, in pertinent part, that:

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be *more trade-restrictive than necessary to fulfil a legitimate objective*, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*, . . . protection of human health or safety . . . .[91]

The regulations at issue appear to violate Article 2.2 because they result in an "unnecessary obstacle to international trade" in the sense that they are "more trade-restrictive than necessary" to fulfill their objective.[92] Although there is no WTO jurisprudence as yet

[90] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001 ("Appellate Body Report, *EC – Asbestos*"), paras. 67-68 and 70. *See also* Appellate Body Report, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, adopted 23 October 2002 ("Appellate Body Report, *EC – Sardines*"), para. 176. Annex 1, paragraph 1 of the *TBT Agreement* provides that a technical regulation may lay down product characteristics "or their related processes and production methods."

[91] Emphasis added.

[92] Like Article 3.2 of the *SPS Agreement*, Article 2.5 of the *TBT Agreement* states that a technical regulation is "rebuttably presumed" not to create an unnecessary obstacle to international trade if it is "in accordance with" an international standard. As already discussed above, where food supplements are governed by food regulations, the relevant international standard would be the Codex Guidelines. Because these regulations are inconsistent with the Codex Guidelines, however, they do not benefit from the rebuttable presumption of consistency under this provision.

interpreting Article 2.2 of the *TBT Agreement*,[93] this can be demonstrated, in part, by showing that the same objective of protecting human health or safety can be achieved by using alternative, less trade-restrictive measures.

(i) Less Trade-Restrictive Alternatives Would Fulfill the Regulation's Legitimate Objectives

To successfully claim that a technical regulation is applied in a manner that violates Article 2.2, a WTO Member must demonstrate that the contribution made by the regulation to the specified objective is outweighed by its restrictive impact on international trade. Thus, the technical regulation is "more trade-restrictive than necessary" to fulfill this objective.[94]

We have established that imposing RDA-based maximums in food supplement regulations restricts international trade in goods because food supplements are subjected to more stringent requirements than those applicable to comparable conventional food products. WTO Members that regulate food supplements as pharmaceutical products, in particular, impose conditions that significantly exceed those applicable to comparable conventional foods. For example, drug regulations generally subject individual products to a pre-market approval process based on a risk/benefit analysis that requires a convincing demonstration of both safety and benefit, which goes far beyond anything required for conventional foods. Designation as drugs will also force food supplement producers to make significant and market-specific changes in manufacturing processes, labeling, and packaging to accord with the more restrictive requirements for pharmaceutical products.

While these measures could arguably contribute to protecting consumer health from the toxic effects of excessive vitamin or mineral intake, their trade-restrictive impact is greater than any contribution the measures make toward this objective. Moreover, less trade-restrictive alternatives, such as accurate labeling that provides information on maximum intake (combined with imposing higher maximum nutrient levels that are actually related to human health risks)

[93] Several WTO panels are expected to address claims under this provision in the near future, in the disputes *US – Tuna* (DS381), *US – Country of Origin Labeling* (DS384, DS386), and *US – Clove Cigarettes* (DS406).
[94] Because the criteria for assessing "necessity" in the context of Article 2.2 of the *TBT Agreement* largely draws from Article XX of the *GATT 1994*, this element will be addressed in further detail in Section III.C) below.

would effectively prevent consumers from using food supplements in excessive quantities while having a more modest impact on the importation of food supplements.

(ii) Less Trade-Restrictive Alternatives Would Not Create a Significant Risk for Food Supplement Consumers

Article 2.2 of the *TBT Agreement* requires that, in assessing whether a measure is more trade restrictive than necessary, WTO Members should take account of the "risks non-fulfillment would create." This recognizes that the more serious the risk being countered by a measure, the easier it is to justify a restriction on trade. In this case, however, imposing labeling requirements (combined with imposing higher maximum nutrient levels that are actually related to human health risks) would not lead to a significant risk of non-fulfillment of a Member's regulatory objective – to prevent excessive consumption of vitamins and minerals – because the labels would draw attention to limits based on a risk assessment, thereby preventing consumption in excess of the upper safe levels of each nutrient.

b. The Regulations Provide Less Favorable Treatment to Imported Food Supplements in Favor of Comparable Conventional Domestic Food Products

Article 2.1 of the *TBT Agreement* requires that WTO Members ensure that "technical regulations" accord treatment to products imported from another WTO Member that is no less favorable than that accorded to like products of national origin or like products originating in another country. Thus, to establish that certain food or drug regulations violate this provision, a complaining country must show that: (i) the regulations are a "technical regulation"; (ii) food supplements originating in another country and certain domestic food products are "like products"; and (iii) the imported food supplements are accorded "less favourable" treatment than that accorded to like products produced domestically or in any other country. Having shown in Section III.B.1 above that the regulations at issue qualify as a "technical regulation," we now address whether food supplements are products "like" domestically produced conventional food that are nonetheless accorded less favorable treatment.

(i) Imported Food Supplements Are "Like" Certain Conventional Food Products of National Origin

Pursuant to Article 2.1 of the *TBT Agreement*, the imported product alleged to be receiving less favorable treatment must be a "like product" to a domestic product or a product imported from a different country that is accorded better treatment. While WTO jurisprudence has not yet interpreted the meaning of "like product" in the specific context of Article 2.1, this term is often found in other WTO agreements and has been interpreted frequently – for example, in the context of Article III:4 of the *GATT 1994*.[95]

We understand that certain types of conventional food may be considered similar or comparable to food supplements. As an illustrative example, multi-vitamin/nutritional beverages are indistinguishable from conventional beverages in terms of their physical properties. They also serve the same end-use of quenching the consumer's thirst and would be perceived and treated by many consumers as alternative means for doing so. For such products, a WTO panel conducting a "like product" analysis may find that food supplements in beverage form are "like" conventional beverages in the market.

(ii) Imported Food Supplements Are Treated Less Favorably Than Certain Domestic Food Products

Article 2.1 of the *TBT Agreement* requires that products from any Member be afforded "treatment no less favourable" than that afforded to like domestic or imported products – *i.e.*, national and most-favored-nation ("MFN") treatment – with respect to technical regulations.

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[95] As detailed by the Appellate Body in *EC – Asbestos*, a "like product" analysis will often employ four general criteria, namely: (i) the properties, nature and quality of the products; (ii) the end-uses of the products; (iii) consumers' tastes and habits (more comprehensively termed consumers' perceptions and behavior) in respect of the products; and (iv) the tariff classification of the products. *See* Appellate Body Report, *EC – Asbestos*, para. 101 (footnote omitted); *see also* Report of the Working Party on *Border Tax Adjustments*, adopted on 2 December 1970, L/3464, para. 18.

A WTO panel applying these criteria to the regulations proposed in Saudi Arabia, for example, will likely find that the food supplements regulated as "drug products" are "like" other food supplement products regulated as foods because, despite the addition of certain vitamins and minerals to the former, the two types of food supplements have the same physical properties and end-uses, and fall under the same tariff classifications in the Harmonized System. While market research would be required to establish the similarity of consumer perceptions of the two types of food supplements, their "likeness" in terms of the other criteria strongly suggests that consumers would also perceive and treat them as alternative means of performing the same nutritional function.

Once again, because the jurisprudence on Article 2.1 remains relatively undeveloped, guidance may be drawn from the case law on the national treatment clause in Article III:4 of the *GATT 1994*.

Article III:4 jurisprudence sheds light on two interpretive points. First, it clarifies that a measure accords less favorable treatment to imported over domestic goods when it "modifies the *conditions of competition* in the relevant market to the detriment of imported products."[96] A formal difference in treatment between domestic and imported goods is not necessary for a finding that national treatment was not provided.[97] This is not to say that a complainant has to prove the challenged measure's "actual effects . . . in the marketplace."[98] Rather, a conclusion that the national treatment requirement was breached "must be founded on a careful analysis of the contested measure and of its implications in the marketplace."[99]

Second, the case law under Article III:4 addresses the fundamental question of what products, or groups of products, must form the basis of the assessment of whether national treatment is provided. The Appellate Body has found that the comparison must be between "the *group* of 'like' imported products [and] the *group* of 'like' domestic products."[100] Thus, if the group comprises different types of goods, they must all be considered together. The requirement to examine like products as a whole does not mean that more favorable treatment in some instances would be permitted to offset the existence of less favorable treatment in others,[101] or

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[96] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, adopted 10 January 2001 ("Appellate Body Report, *Korea – Various Measures on Beef*"), para. 137 (emphasis in original).

[97] GATT Panel Report, *United States – Section 337 of the Tariff Act of 1930*, L/6439 - 36S/345, adopted 16 January 1989, para. 5.11. Similarly, with respect to MFN treatment, Article 2.1 does not confine the obligation to instances of *de jure* discrimination (*i.e.*, discrimination as a matter of law), but applies it also to *de facto* discrimination (*i.e.*, discrimination as a matter of fact). *See* Appellate Body Report, *Canada – Certain Measures Affecting the Automotive Industry*, WT/DS139/AB/R, WT/DS142/AB/R, adopted 19 June 2000 ("Appellate Body Report, *Canada – Autos*"), para. 78.

[98] Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities*, WT/DS108/AB/RW, adopted 29 January 2002 ("Appellate Body Report, *US – FSC (Article 21.5 – EC)*"), para. 215.

[99] Appellate Body Report, *U.S. – FSC (21.5 – EC)*, para. 215.

[100] Appellate Body Report, *EC – Asbestos*, para. 100 (emphasis in original). *See also* Appellate Body Report, *Chile – Taxes on Alcoholic Beverages*, WT/DS87/AB/R, WT/DS110/AB/R, adopted 12 January 2000, para. 52.

[101] *See* Panel Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/R, adopted 20 May 1996, as modified by Appellate Body Report WT/DS2/AB/R, para. 6.14.

that every product within the group of like imported products must be treated less favorably than every like domestic product.[102] Rather, a violation is likely to arise when imported goods (such as food supplements) are primarily or predominantly subject to less favorable treatment than like domestic goods.

In the present case, to the extent that imported food supplements are "like" certain conventional domestic food products, imposing RDA-based restrictions or even drug-based regulations on food supplements discriminates against food supplements by subjecting them to more onerous regulatory requirements than conventional food products. This would constitute less favorable treatment in violation of the national treatment obligation under Article 2.1 of the *TBT Agreement*.

c. The Regulations Are Not Based on the Relevant International Standard, and Violate Article 2.4 of the TBT Agreement

Article 2.4 of the *TBT Agreement* mandates the use of international standards "where technical regulations are required and relevant international standards exist," stating that:

> Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

Food regulations imposing RDA-based limits violate Article 2.4 because, although a "relevant international standard" exists in the form of the Codex Guidelines, the countries concerned have failed to use the Guidelines, or the relevant parts of the Guidelines, "as a basis for" their regulations. Notably, whether the regulations preceded the Codex Guidelines is immaterial. As observed by the panel in *EC – Sardines*, this obligation applies also to technical regulations in place *before* the international standard was established because Article 2.4 of the *TBT Agreement* imposes an *ongoing* obligation on Members to reassess their existing technical

[102] Indeed, in *U.S. – FSC (21.5 – EC)*, the Appellate Body explained that the fact that the challenged rule may not give rise to discrimination in some instances did not overcome the fact that, in an "indefinite number" of other instances, it did result in less favorable treatment. Appellate Body Report, *U.S. – FSC (21.5 – EC)*, para. 221. *See also* Panel Report, *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain*, WT/DS276/R, adopted 27 September 2004, upheld by Appellate Body Report WT/DS276/AB/R, para. 6.349.

regulations in light of the adoption of new international standards or the revision of existing international standards.[103]

In order for a technical regulation to be based on the Codex Guidelines, the latter must "bear upon, relate to, or be pertinent to" the technical regulation.[104] As the Appellate Body noted, "at a minimum . . . something cannot be considered a 'basis' for something else if the two are *contradictory*."[105] This is in fact the situation here: whereas the Codex Guidelines specify that the provision governing maximum amounts of vitamins and minerals should *not* lead to the setting of maximum levels based solely on recommended nutrient values such as the RDA,[106] the regulations set maximum levels on precisely this basis. The food supplement regulations directly contradict the relevant international standard, and thus, the countries have failed to carry out their obligations to "use" the international standard as required under Article 2.4 of the *TBT Agreement*.

It will also be difficult for these countries to argue persuasively that the Codex Guidelines are an "ineffective or inappropriate means" for the "protection of human health or safety," which is among the legitimate objectives listed in Article 2.2 of the *TBT Agreement*.[107] Article 1.1 of the Codex Guidelines stipulate that they "apply to vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals," and the Preamble to the Guidelines further notes that the function of such food supplements is to supplement the daily diet in cases where dietary intake is insufficient or where consumers consider their diet requires supplementation. Guidelines regarding the supplementation of the daily diet to remedy insufficient dietary intake both have the function of accomplishing (*i.e.*, are

[103] *See* Panel Report, *European Communities – Trade Description of Sardines*, WT/DS231/R and Corr.1, adopted 23 October 2002, as modified by Appellate Body Report WT/DS231/AB/R ("Panel Report, *EC – Sardines*"), para. 7.78.
[104] Appellate Body Report, *EC – Sardines*, para. 229.
[105] Appellate Body Report, *EC – Sardines*, para. 248 (emphasis in original).
[106] *See* Codex Guidelines, Art. 3.2.2.
[107] The Appellate Body in *EC – Sardines* approved the panel's conclusion that the legitimate objectives referred to in Article 2.4 of the *TBT Agreement* were to be interpreted in the context of the description and illustrative list of legitimate objectives in Article 2.2. *See* Appellate Body Report, *EC – Sardines*, paras. 285-86.

effective) and are specially suitable (*i.e.*, are appropriate) for fulfilling the objective of protecting human health or safety.[108]

C. Analysis of Consistency with the *GATT 1994*

Finally, WTO Members with regulations imposing RDA-based maximums on food supplements appear to violate their national treatment obligation under Article III:4 of the *GATT 1994*. The three elements of a violation of this obligation were explained by the Appellate Body in *Korea – Various Measures on Beef*, as follows:

> [i] that the imported and domestic products at issue are "like products"; [ii] that the measure at issue is a "law, regulation, or requirement affecting their internal sale, offering for sale, purchase, transportation, distribution, or use"; and [iii] that the imported products are accorded "less favourable" treatment than that accorded to like domestic products.[109]

The argument that imported food supplements may be "like" certain conventional food products, and that, despite this "likeness," food supplements are nonetheless accorded treatment less favorable than that accorded to conventional food, has already been addressed with respect to the *TBT Agreement* above. We therefore examine the second element: whether the food supplement regulations at issue are laws, regulations, or requirements "affecting their internal sale, offering for sale, purchase, transportation, distribution, or use."

The term "affecting" assists in defining the types of measures that must conform to the obligation not to accord "less favourable treatment" to like imported products as set out in Article III:4. The Appellate Body and WTO panels have found the term "affecting" to broadly mean having "an effect on," thereby encompassing measures that modify the conditions of competition between domestic and imported goods in the market.[110] The Appellate Body, in

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[108] *See* Appellate Body Report, *EC – Sardines*, para. 261 (noting that "ineffective" refers to something which is not "having the function of accomplishing," "having a result," or "brought to bear," whereas "inappropriate" refers to something which is not "specially suitable," "proper," or "fitting") (quoting from Panel Report, *EC – Sardines*, para. 7.116).
[109] *See* Appellate Body Report, *Korea – Various Measures on Beef*, para. 133.
[110] *See* Panel Report, *Turkey – Measures Affecting the Importation of Rice*, WT/DS334/R, adopted 22 October 2007, paras. 7.221-22. *See also* Panel Report, *Canada – Certain Measures Affecting the Automotive Industry*,

particular, noted that the term "affecting" in GATT Article III:4 has "a broad scope of application,"[111] and that it operates to connect identified types of government action (*i.e.*, "laws, regulations and requirements") with specific transactions, activities and uses relating to products in the marketplace (*e.g.*, "sale", "purchase", or "use").[112] Further, the Appellate Body and WTO panels have found measures that "create an incentive" for domestic over imported goods to "affect[]," *inter alia*, the internal "use," "purchase," or "sale" of those goods.[113]

In the present dispute, a concrete link exists between food supplement regulations at issue and the internal sale, offering for sale, purchase, or use of food supplements in these countries. The regulations expressly prohibit the production and sale of food supplements that do not adhere to the mandated RDA-based maximums, thereby preventing imported food supplements with nutrient content exceeding RDA values from being sold, offered for sale, or purchased in these markets. Where drug regulations are imposed on food supplements, additional restrictions may be placed on the distribution and use of the products. Thus, the regulations detrimentally "affect" imported food supplements, violating the national treatment obligation owed under the *GATT 1994*.

In addition, this violation would likely not be justified under Article XX of the *GATT 1994*, because the regulations are not "necessary" to protect human health and may be applied in a manner that would constitute a disguised restriction on international trade. Article XX(b) of the *GATT 1994* allows for Members to take measures "necessary to protect human, animal or plant life or health," but this exception is subject to the requirement stated in the *chapeau* to Article XX, namely, that "such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade."

WT/DS139/R, WT/DS142/R, adopted 19 June 2000, para. 10.80 and Appellate Body Report, *Canada – Autos*, para. 158.

[111] Appellate Body Report, *US – FSC (Article 21.5 – EC)*, para. 210.

[112] *See* Appellate Body Report, *US – FSC (Article 21.5 – EC)*, para. 208.

[113] *See* Appellate Body Reports, *China – Measures Affecting Imports of Automobile Parts*, WT/DS339/AB/R, WT/DS340/AB/R, WT/DS342/AB/R, adopted 12 January 2009, para. 196; Panel Report, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R and Corr.1, adopted 5 April 2002, paras. 7.195-98 and 7.305-09; Appellate Body Report, *US – FSC (Article 21.5 – EC)*, para. 212.

In interpreting Article XX, the Appellate Body has explained that:

> In order to determine whether a measure is "necessary" [. . .] a panel must assess all the relevant factors, *particularly the extent of the contribution to the achievement of a measure's objective and its trade restrictiveness*, in the light of the importance of the interest or the values at stake. If this analysis yields a preliminary conclusion that the measure is necessary, this result must be confirmed by comparing the measure with its possible alternatives, which may be less trade restrictive while providing an equivalent contribution to the achievement of the objective pursued.[114]

As discussed in Section III.B.2.a above, while the regulations may contribute to protecting consumers from the adverse effects of excessive vitamin and mineral intake, this contribution is significantly outweighed by the severe impact of an outright prohibition on production and/or sales of non-conforming food supplement products. Safety-based labeling requirements and other less trade-restrictive alternatives also exist that would protect consumers similarly to RDA-based limitations on nutrient content. Therefore, these regulations would not be considered "necessary" under the Appellate Body's interpretation and would not qualify for the exception provided by Article XX of the *GATT 1994*.

[114] Appellate Body Report, *Brazil – Retreaded Tyres*, para. 156 (emphasis added).