

Analysis of the Subsection 3.2.7 of the Annex to Regulation (EU) No. 488/2014 concerning the maximum cadmium content in chocolate and derived products under the WTO Sanitary and Phytosanitary rules

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Abstract:

The requirement for maximum levels of cadmium in cocoa and derived products established in subsection 3.2.7 of the Annex to the European Union (EU) Regulation No. 488/2014 shall be in accordance with the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) rules. Thus, through the dogmatic method it is analysed whether it is a SPS measure that affects international trade and if it complies with the basic principles of the SPS Agreement as if the measure: was issued under the sovereign right of the European Union (EU) Member States (MS) to adopt SPS measures, was adopted to protect human life or health, had scientific basis, and does not imply arbitrary or unjustified discrimination.

Keywords: Chocolate; cadmium; As Low As Reasonably Achievable (ALARA); WTO; SPS, National Treatment (NT); risk assessment

Resumen:

El requisito de niveles máximos de cadmio en el cacao y productos derivados establecido en la subsección 3.2.7 del Anexo del Reglamento No 488/2014 de la Unión Europea (UE), será ajustado a las Medidas Sanitarias y Fitosanitarias de la Organización Mundial del Comercio (MSF). Así, a través del método dogmático se analiza si se trata de una MSF que afecta al comercio internacional y si cumple con los principios básicos del Acuerdo sobre la aplicación de MSF como si la medida: fuera emitida bajo el derecho soberano de la Unión Europea (UE) Estados Miembros (EM) para adoptar medidas sanitarias y fitosanitarias, se adoptó para proteger la vida o la salud humana, tenía base científica y no implica una discriminación arbitraria o injustificada.

Palabras clave: Chocolate; cadmio; ALARA; OMC; MSF, Trato Nacional (NT); Evaluación de riesgos.

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1. Introduction

In May 12th, 2014 the European Commission (EC), issued the Regulation (EU) No 488/2014, which established maximum levels of cadmium content to chocolate and derived products based on the statements expressed in the Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the EC on cadmium in food 2009 (European Food Safety Authority, 2009), the European Food Safety Authority (EFSA), Scientific Opinion on tolerable weekly intake (TWI) for cadmium 2011 (EFSA Panel on Contaminants in the Food Chain, 2011 p.19), and the EFSA Report Cadmium dietary exposure in the European population 2012 (European Food Safety Authority, 2012), which suggested a TWI, of 2.5 mg/kg body weight (bw). However, the Joint FAO/WHO Expert Committee on Food Additives (JEFCA) Report 2010 (Food and Agriculture Organization/World Health Organization, 2010) that determined a TWI 5.28 µg/kg bw was not considered.

In response to these measures, Peru requested the WTO SPS Committee to distribute several communications²¹ asking for the exclusion of the chocolate and derived products of the EU Regulation (EU) No. 488/2014, until there is updated scientific information on the risk that it could represent for human health and the Codex standard has been finished or delayed of entering in to force until January 1st, 2022.

Moreover, several other countries exporting chocolate and derived products to the EU²² manifested their concern on the damage that could be caused to international trade and the strict level of protection determined which would not find basis in a real or potentially risk to consumers health. Thus, it is worth to ask: Is the requirement for maximum levels of cadmium in cocoa and derived products established in subsection 3.2.7 of the Annex to Regulation (EU) No. 488/2014 in accordance with the WTO SPS rules?

On the basis of the dogmatic method through an overview on the events from 12 May 2014 to the present, taking into account that Regulation (EU) No.488/2014 was published on that date, the collection of doctrinal and jurisprudential information seeks to verify that the measure at issue is not in accordance with the WTO SPS rules as it violates Articles 2.2 and 2.3 to SPS Agreement, because it lacks sufficient scientific evidence and generates an unjustified differentiation between exporting countries.

Thus, the first point analyse whether the measure at issue is an SPS Measure. The second point determine if it has a potential affection on international trade. The third point verify the accomplishment with the basic principles of the SPS Agreement. Finally, the fourth point expose the proposal of alternative measures less restrictive to trade than the measure at issue.

2. Determination of whether the measure analysed is an SPS measure

It shall be identified if the measure at issue keeps correspondence with a specified type of measure pointed out in the last paragraph of the Article 1 of Annex A to SPS Agreement which has a link to one of the purposes mentioned in the literal b) of the cited article (World Trade Organization, 2010).

2.1. Type of SPS measure

According to the last paragraph of Article 1 of Annex A to SPS Agreement, the SPS measures "(...) include all (...) requirements and procedures including, inter alia, end product criteria; (...)" (World Trade Organization, 1994)²³. So, considering that the measure at issue is included in the EU Regulation Annex and comprehends requirements to the final product as detailed in subsection 1.1.2 a) of this research related to the objective scope of its application, the fact that it complies with including requirements to the final product makes it meet one of the criteria determined by the Appellate Body in the case Australia-Apples (2010) to be a type of SPS measure.

2.2. Purpose or intention of the measure at issue

According to the criteria set by the Appellate body in *Australia – Apples (2010)*, we proceed to establish the measure at issue purpose or intention ascertained in basis of objective considerations like its objectives, its text and structure, its surrounding regulatory context and the way in which it is designed and applied.

Firstly, the objective of the measure at issue exposed by the EC is to protect the consumers, specifically infants and young children, from the exposure to high levels of cadmium as it's pointed out in the Regulation (EU) No.488/2014 explanatory statement, recitals sixth²⁴ and eighteenth²⁵.

Secondly, the following table exposes how the measure text and structure analysed correspond to the prerogatives established in Article 1, b) of Annex A to SPS Agreement.

Legal texts	Legal assumption
SPS Agreement	<ul style="list-style-type: none"> - Article 1, b) of Annex A: "1. Sanitary or phytosanitary measure — Any measure applied: (...) (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 (...)"
Regulation (EU) No. 488/2014	<ul style="list-style-type: none"> - Recital 8 of the explanatory statement "Chocolate and cocoa powder sold to the final consumer can contain high levels of cadmium and are an important source of human exposure". - Recital 3 of the explanatory statement "(...) adverse effects on kidney function are unlikely to occur for an individual exposed at this level, exposure to cadmium at the population level should be reduced". - Last paragraph of Article 3 "This Regulation shall be binding in its entirety and directly applicable in all MS". - Recital 7 of the explanatory statement "Maximum levels for contaminants are set according to the ALARA principle²⁶ (...) both for commodities for which maximum levels for cadmium currently already exist (...) and for commodities for which maximum levels are newly set (such as cocoa and chocolate products (...))". - Recital 6 of the explanatory statement "For some foodstuffs that are important contributors to the exposure for certain population groups (chocolate and cocoa products, foods for infants and young children) maximum levels have not yet been established".

Table 1

The measure at issue is adopted to protect human exposure as mentioned in recital eight of the explanatory statement. Besides, the measure adoption analysed is justified in a Scientific Panel on Contaminants in the Food Chain (CONTAM) report quoted in the explanatory statement, third recital which prevent about effects on kidney function and as mentioned in the last paragraph of Article 3, the whole Regulation under analysis is directly applicable in all MS.

Furthermore, cadmium is considered a contaminant as established in explanatory statement, recital 7 and the cocoa and derived products are considered as foodstuffs like it is mentioned in the explanatory statement, recital 6. Consequently, the text and structure of Regulation (EU) No.488/2014 complies with being a measure to protect human health within the MS territory from contaminants in foodstuff like the cocoa and chocolate products, as established in Article 1, b) of Annex A to SPS Agreement.

Thirdly, the disputed measure was issued in a context of deregulation on the maximum cadmium content of chocolate and cocoa-based products as mentioned in the sixth recital of the explanatory statement to the Regulation analysed. According to the fifth recital of the Commission recommendation of 4 April 2014 on the reduction of cadmium presence in foodstuffs "as well as

Maximum Levels [MLs] of cadmium established in 2001 in a range of foodstuffs, (...). Taking into consideration EFSA conclusions of 2009 and 2011, new MLs for baby foods and chocolate/cocoa products shall be considered shortly” (European Commission, 2014). So, in May 12^{ve} 2014, the EC adopted the Regulation under analysis.

Fourthly, regarding the way in which the measure is designed, in the ninth recital of the explanatory statement to SPS Agreement it is established that “(...) occurrence data of cocoa and chocolate products provided by countries with high cadmium levels in soil should be taken into account when establishing MLs of cadmium”. This suggests that the cadmium MLs in chocolate and derived products established by the EC should took into account the data provided by countries with high cadmium levels in soil.

Regarding to the application of the measure at issue, it shall be applied to all MS and food business operators equally as it is established in the explanatory statement, eighteenth recital to the EC Regulation. As established in Article 2.2 to EC Regulation the measure at issue shall be applied since 1 January 2019, but the chocolate and derived products that doesn't comply with the requirements pointed in subsection 3.2.7 of the Annex to EC Regulation may continue to be sold until their expiry date if they are already on the market.

3. Potential affection of the measure at issue on international trade

Article 1.1 to SPS Agreement²⁷ establishes that the measure at issue must directly or indirectly affect international trade. “This requirement is easy to fulfill, as any measure that applies to imports can be said to affect international trade. Moreover, (...) the panel in EC – Approval and Marketing of Biotech Products (2006) [established that] the measure may affect international trade” (Van den Bossche & Zdouc, 2013, p. 900). Thus, it is sufficient that it has had an effect on international trade even if this is not a current effect.

The table shows the countries In which the Committee on SPS Measures regular meetings have expressed concern about the impact on their exports of chocolate and derived products to the EU.

Minutes No.	Meeting	Concerned countries
G/SPS/R/99	25-26 June 2020	Perú, Colombia and Ecuador
G/SPS/R/93	1-2 November 2018	Colombia, Côte d'Ivoire, Peru, Plurinational State of Bolivia, Ecuador, Guatemala, Indonesia, Nicaragua, Trinidad and Tobago, El Salvador, Panama, the United States, and the Bolivarian Republic of Venezuela and Costa Rica.
G/SPS/R/92 Rev.1	12-13 July 2018	Ecuador, Colombia and Guatemala.
G/SPS/R/92		
G/SPS/R/90	1-2 March 2018	Peru, Brazil, Colombia, Costa Rica, the Dominican Republic, Guatemala and Panama.
G/SPS/R/88	2-3 November 2017	Peru, Colombia, Costa Rica, Côte d'Ivoire, the Dominican Republic, Ghana, Guatemala, Madagascar and Nigeria.

Table 2

Moreover, in the 2-3 November 2017 meeting “(...) the ECOWAS representative indicated that ECOWAS members also shared the concern” (Committee on Sanitary and Phytosanitary Measures, 2017), which means that fifteen countries that are MS of the Economic Community of West African States joined the same concern. Thus, considering that “When a measure is an SPS measure and affects international trade, actually or potentially, that measure falls within the substantive scope of application of the SPS Agreement” (Van den Bossche & Zdouc, 2013, p. 900), there is a potential direct impact on international trade about which thirty-one countries have expressed their concern.

4. Review of compliance with the basic principles of the SPS Agreement by the measure at issue

Once it has been determined that the measure in question is an SPS measure which potentially directly affects international trade, and therefore the SPS Agreement is applicable, it shall be analysed if it complies with the basic principles²⁸ enlisted in Article 2 to SPS Agreement, which will serve as criteria to determine if its adoption is justified.

4.1. Right to take SPS Measures as a cause for the reversal of the burden of proof

As mentioned in Article 2 to SPS Agreement, “Members have the right to take sanitary and phytosanitary measures necessary to protect human, animal, plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement” (World Trade Organization, 1994) [The highlight is mine]. In that sense, the MS have the right to adopt SPS measures as long as they comply with the basic principles²⁹ established in Articles 2.2 and 2.3. Under this agreement “(...) the complaining Member must show that the measure is inconsistent with the rules of the SPS Agreement” (Van den Bossche & Zdouc, 2013). So, the complaining party shall proof that the Member imposing the measure doesn't comply with at least one of the basic disciplines analysed below.

4.2. Assessment of the need to protect human life and health

The Article 2.2 of the SPS Agreement establishes that the necessity requirement “has not be interpreted by a dispute settlement but the Appellate Body suggested that violation of Article 5.6 may also imply violation of Article 2.2” (Van den Bossche & Zdouc, 2013, p. 905). So, it will be determined whether the measure in question is more trade restrictive than required.

In Australia – Salmon (1998) the Appellate Body determined a three-tier test to identify if Article 5.6 SPS Agreement is violated. Thus, there shall be another measure which “(1) is reasonably available considering technical and economic feasibility; (2) achieves the applying Member appropriate level of sanitary protection; and (3) is significantly less restrictive to trade than the sanitary measure contested” (World Trade Organization, 1998). These three elements are cumulative and the Member's concerned must demonstrate that they are met (World Trade Organization, 1998).

Firstly, to determine the existence of a measure available, in view of the fact that the MLs of cadmium content in chocolate and derived products determined by the new EU regulation could put the exports of member countries at risk. As from its 8th meeting, the CCCF decided to set up an Electronic Working Group (EWG) with the task of progressively determining the products affected by the regulation in question and the percentages and MLs of cadmium allowed in them.

The EWG results were submitted to the EU for comments and have so far resulted in the proposal exposed in the following comparative table of maximum levels proposed in Regulation (EU) No. 488/2014, the EWG and the European Union currently opinion after the Codex Committee on Contaminants in Foods (CCCF) sessions.

Specific cocoa and chocolate products as listed below	Regulation (EU) No. 488/2014 maximum levels	EWG proposal of maximum levels	EU currently opinion
Milk chocolate with < 30 % total dry cocoa solids	0,10 as from 1 January 2019	0.30 mg/kg	0.1 mg/kg. However, it can accept 0.3 mg/kg awaiting the outcome of the JECFA evaluation on cadmium and the postponement of the discussions on these MLs, until the code of practice for the prevention and reduction of cadmium contamination in cocoa has been finalized and implemented.
Chocolate with < 50 % total dry cocoa solids; milk chocolate with ≥ 30 % total dry cocoa solids	0,30 as from 1 January 2019	0.6-0.7 mg/kg (Codex Committee Contaminants in Food, 2019) based in the proportionality and ALARA principles, by an analysis from the cadmium presence database provided in GEMS/Food updated at the request of the WHO 10 July 2019.	0.3 mg/kg but agree on suspending the consideration of MLs awaiting the outcome of the JECFA evaluation on cadmium. The postponement of the discussions on these MLs, until the code of practice for the prevention and reduction of cadmium contamination in cocoa has been finalized and implemented.
Chocolate containing or declaring ≥ 50% to < 70% total cocoa solids on a dry matter basis	0,80 as from 1 January 2019	0.80 mg/kg	Agree
Chocolate containing or declaring ≥ 70% total cocoa solids on a dry matter basis		0.9 mg/kg	0.8 mg/kg because applying the concept of proportionality is not justified since milk chocolate is consumed by children, while dark chocolate usually isn't.
Cocoa powder (100% total cocoa solids on dry matter basis)		1.5 mg/kg	The EU proposes not to set a codex ML for cocoa powder in view of the lower significance of this commodity for international trade, but agree on suspending the consideration of MLs awaiting the outcome of the JECFA evaluation on cadmium (Codex Committee Contaminants in Food, 2020).
Dry mixtures of cocoa and sugars containing:	< 29% total cocoa solids on a dry matter basis	0.4 mg/kg	These MLs are disproportionately high compared to the global occurrence data for chocolate with similar amounts of cocoa solids. The EU proposes not to set a codex ML for mixtures of cocoa and sugar in view of the lower significance of this commodity for international trade.
	≥ 29 to < 50% total cocoa solids on a dry matter basis	0.6 mg/kg	
	≥50% total cocoa solids on a dry matter basis	1.0 mg/kg	
Cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate)	0,60 as from 1 January 2019	2.0 to 3.0 mg/kg	The EU cannot support the proposed ML in order to ensure sufficient protection of all consumers, in particular children.

Table 3

New product categories and percentages not specified previously in the measure at issue were introduced, like the consideration of a 70% cap on Chocolate containing or declaring ≥ 50%; chocolate containing or declaring ≥ 70% total cocoa solids on a dry matter basis; cocoa powder (100% total cocoa solids on dry matter basis); dry mixtures of cocoa and sugars containing < 29% total cocoa solids on a dry matter basis, ≥ 29 to < 50% total cocoa solids on a dry matter basis, ≥50% total cocoa solids on a dry matter basis.

Considering that “necessity” requirement does not mean, however, that members will automatically apply the most economically efficient measure. Indeed, it focuses on the necessity of the objectives and effects of the measure more than on the measure’s efficiency in delivering those effects (Karttunen, 2020, p. 31). So, an alternative measure with technical and economic feasibility exists because the maximum levels proposed by the EWG were accepted by the countries which consider that will be affected by the measure at issue.

Secondly, to determine if the alternative measure achieves the importing member’s appropriate level of protection,

“it is necessary to: (1) identify what is the importing member’s appropriate level of protection; (2) determine the level of protection that would be achieved by the complainant’s proposed alternative measure; and (3) determine whether the level of protection that would be achieved by the alternative measure would satisfy the importing member’s appropriate level of protection” (Van den Bossche & Zdouc, 2013, p. 924).

Considering that “the appropriate level of protection established by a Member and the SPS measure have to be clearly distinguished because the first is an objective and the second is an instrument chosen to attain or implement that objective” (Van den Bossche & Zdouc, 2013, p. 925), the EU has not expressly stated what is the appropriate level of protection it seeks to achieve.

In that sense, “(...) when a Member does not comply with its obligation to identify its appropriate level of protection, that level may be deduced from the SPS measure actually applied” (Van den Bossche & Zdouc, 2013, p. 925). So, according to the preamble of Regulation (EU) No.488/2014, the measure analysed is justified at the maximum cadmium TWI of 2.5 µg/kg body weight (bw) per week established by the “Scientific Opinion on tolerable weekly intake for cadmium” of 2011 EFSA CONTAM, which ratifies the same tolerable level in its 2009 report.

Also, EU notes that it adopts the cadmium ML of 2.5 mg/kg to meet the level of protection suggested by EFSA. In 2012 report, the EU states that the cadmium “TWI of 2.5 mg/kg established in 2009 should be maintained to ensure a high level of protection for all consumers, including exposed and vulnerable subgroups of the population” (European Food Safety Authority, 2012, p. 32). It can be inferred that the appropriate level of protection for the EU is a high level.

To achieve the high level of protection desired by the EU it sets MLs of cadmium in chocolate and derived products as detailed under “Regulation (EU) No.488/2014 MLs” in Table 3 of this research where can be seen that the alternative measure identified does not meet the appropriate level of protection desired by the EU importing member’s, as there is a consensus only on the requirement of 0.80 mg/kg for chocolate containing or declaring $\geq 50\%$ ³⁰ to $< 70\%$ total cocoa solids on a dry matter basis but in respect to the remaining categories the EU maintains the levels initially proposed for the following reasons:

- For the milk chocolate with $< 30\%$ total dry cocoa solids, the maximum content shall be 0,10 mg/kg in order to protect adequately children against the harmful effects from cadmium even if this ML is not proportionate to the previously agreed MLs for dark chocolates (Codex Committee Contaminants in Food, 2019). However, it can accept 0.3 mg/kg awaiting the outcome of the JECFA evaluation on cadmium³¹ and the discussions on these MLs, until the code of practice for the prevention and reduction of cadmium contamination in cocoa has been finalized and implemented (Codex Committee on Contaminants in Foods, 2021).
- For the chocolate with $< 50\%$ total dry cocoa solids and milk chocolate with $\geq 30\%$ total dry cocoa solids, the maximum content shall be 0,30 mg/kg but it agrees on suspending

the consideration of MLs awaiting the outcome of the JECFA evaluation on cadmium and the discussions on these MLs, until the code of practice for the prevention and reduction of cadmium contamination in cocoa has been finalized and implemented (Codex Committee on Contaminants in Foods, 2021).

- For cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate), the maximum content shall be 0,60 mg/kg to ensure sufficient protection of all consumers, in particular children.

Regarding to the categories of chocolate and derived products identified following the meetings of the Joint FAO/WHO Food Standards Programmes CCCF, the EU has stated:

- For chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis, the maximum content shall be 0.8 mg/kg because applying the concept of proportionality is not justified because milk chocolate is consumed by children, while dark chocolate usually isn't (Codex Committee on Contaminants in Foods, 2021).
- For the cocoa powder (100% total cocoa solids on dry matter basis), it shall not be established a codex Maximum level (ML) for cocoa powder in view of the lower significance of this commodity for international trade (Codex Committee Contaminants in Food, 2020) but it agrees on suspending the consideration of MLs awaiting the outcome of the JECFA evaluation on cadmium (Codex Committee on Contaminants in Foods, 2021).
- For dry mixtures of cocoa and sugars containing: $< 29\%$ total cocoa solids on a dry matter basis; ≥ 29 to $< 50\%$ total cocoa solids on a dry matter basis; $\geq 50\%$ total cocoa solids on a dry matter basis, it shall not be established a codex ML for mixtures of cocoa and sugar in view of the lower significance of this commodity for international trade. Besides, the MLs are disproportionately high compared to the global occurrence data for chocolate with similar amounts of cocoa solids.

Consequently, the alternative measure proposed by the EWG in the framework of the Joint Food and Agriculture Organization (FAO)/ World Health Organization (WHO) Food Standards Programmes CCCF meetings does not comply with the EU importing Member's appropriate level of protection.

Thirdly, the alternative measure significantly less trade restrictive than the measure at issue "criteria was analysed by the panel in the cases Australia -Salmon (1998) and Japan- Agricultural Products II (1999) which determined that the issue relates to whether market access would be substantially improved if an alternative measure were imposed" (Van den Bossche & Zdouc, 2013, p. 926) So, the measure at issue impact in the international trade shall be taken into account.

Considering the declaration made by thirty four chocolate and derived products exporting countries, including the Economic Community of West African States (ECOWAS) members; taking into account that the alternative proposal presented by the EWG presided by Ecuador contemplates less restrictive cadmium MLs; and, considering that the alternative proposal presented by the EWG presided by Ecuador and co-chaired by Brazil and Ghana contemplates less restrictive MLs of cadmium in chocolate and derived products, the alternative measure imply a less trade restrictive measure than the one at issue. It's possible to conclude that the measure in question is necessary to protect human life and health because, although there is a reasonable measure available which is significantly less trade restrictive, it does not achieve the appropriate health protection level desired by EU importing Member's.

4.3. Scientific basis for the SPS Measure at issue

Article 2.2 SPS Agreement points out that “an SPS measure shall be based on scientific principles and not be maintained without sufficient scientific evidence” (World Trade Organization, 1994). “These scientific requirements are further elaborated on Article 5.1 of the SPS Agreement, which provides that SPS measures must be based on a risk assessment (...) taking into account certain factors. A violation of Article 5.1 will necessarily imply a violation of Article 2.2” (Van den Bossche & Zdouc, 2013, pp. 905-908). Therefore, this subsection analyses whether the measure in question is based on a risk assessment and if it has sufficient scientific evidence.

It is important to note that the type of measure evaluated corresponds to an SPS measure aimed at food-borne risks (Van den Bossche & Zdouc, 2013, p. 915). With this in mind, it is worth mentioning that as established “(...) by the panel in EC-Approval and Marketing of Biotech Products (2006), two issues are addressed to determine whether: there is a violation of Article 5.1, (1) there is a ‘risk assessment’ within the meaning of the SPS Agreement; and (2) the SPS measure is based on a risk assessment” (Van den Bossche & Zdouc, 2013, p. 915).

Firstly, a risk assessment is defined in paragraph 4 of Annex A to SPS Agreement as

“(...) the evaluation of the potential for adverse effects on human (...) from the presence of additives, contaminants, (...) in food, beverages or feedstuffs.’ (World Trade Organization, 1994). Thus, this type of risk assessment “(...) must: (1) identify the adverse effects on human or animal health (if any) arising from the additive, contaminant, toxin or disease-causing organism in food/beverages/feedstuffs; and (2) if such adverse health effects exist, evaluate the potential for such adverse effects to occur”³².

On one hand, regarding the adverse effects, in the scientific opinion of EFSA 2011 “Statement on cadmium TWI” was pointed out that “The consumption of food is the main source of cadmium exposure for the non-smoking general population. Cadmium is toxic primarily to the kidney, particularly to the proximal tubular cells, where it accumulates over time, leading to renal dysfunction” (EFSA Panel on Contaminants in the Food Chain, 2011), and the consumption of food is the main source of cadmium exposure for the non-smoking general population.

The scientific report of EFSA 2012 “Cadmium dietary exposure in the European population” establishes that “this dietary exposure assessment used a larger dataset on consumption data (the EFSA comprehensive food consumption database) and new occurrence data compared to the assessment in 2009” (Codex Committee Contaminants in Food, 2021). Indeed, it mentions that

“Cadmium is primarily toxic to the kidney but can also cause bone demineralization either through direct bone damage or indirectly as a result of renal dysfunction; and has been statistically associated with increased risk of cancer in the lung, endometrium, bladder, and breast. The International Agency for Research on Cancer has classified cadmium as a human carcinogen (Group 1) on the basis of occupational studies (IARC, 1993)” (European Food Safety Authority, 2012, pp. 2-5).

Thus, adverse effects on human health arising from the consumption of cadmium in food have been detected.

On other hand, it shall be evaluated the potential for adverse health effects to occur. So, “the CONTAM Panel reaffirmed its previous conclusion that adverse effects are unlikely to occur in an individual with current dietary exposure (...)” (EFSA Panel on Contaminants in the Food Chain, 2011, p. 3) statement shared by EFSA³³. Nevertheless, it considers that there is a need to reduce exposure to cadmium at population level.

Besides, the CONTAM pointed that “The cross-sectional design of almost all published studies does not allow residual damage caused by past peak exposures to cadmium to be distinguished to effects resulting from much lower concurrent exposures” (EFSA Panel on Contaminants in the Food Chain, 2011, p. 13), which means that there is uncertainty about the residual damage caused by a person’s exposure to a lot of cadmium in a short time compared to another person’s exposure to little cadmium over a longer period of time, so it has not been possible to determine in what extent the intensity of cadmium exposure causes damage on humans.

Furthermore, the exposure effect relationships from people to cadmium could not be determined because the biomarkers of kidney damage used for the studies “(...) are very sensitive to changes in renal function and are influenced inter alia by factors such as gender, age, body mass index, physical exercise, meat meals, and diurnal variation”³⁴. Consequently, as affirmed in two opportunities by CONTAM and EFSA, it has been demonstrated that adverse effects are unlikely to occur in an individual with current dietary exposure.

So, there is a risk assessment covered in two reports: the EFSA Panel on Contaminants in the Food Chain (CONTAM) “Scientific Opinion on tolerable weekly intake for cadmium” of 2011 and the EFSA, “Cadmium dietary exposure in the European population” Scientific Report of 2012. However, it was found that such adverse effects are unlikely to occur. So, there is not a “risk assessment” within the meaning of the paragraph 4 of Annex to SPS Agreement.

Secondly, regarding of whether the SPS measure at issue is “based on” the risk assessment, shall be noted that in “EC-Hormones (1998) the Appellate Body held that, for an SPS measure to be ‘based on’ a risk assessment, there must be a ‘rational relationship’ between the measure and the risk assessment, and the risk assessment must reasonably support the measure” (Van den Bossche & Zdouc, 2013, p. 919). So, there is not a rational relationship between the measure at issue and the risk assessments identified for the following reasons.

The CONTAM Scientific Opinion of 2011 points out that “for cadmium the current TWI of 2.5 $\mu\text{g}/\text{kg}$ bw established in 2009 should be maintained to ensure a high level of protection of consumers and despite the CONTAM Panel reaffirmed its previous conclusion that adverse effects are unlikely to occur, there is a need to reduce exposure to cadmium at the population level” (EFSA Panel on Contaminants in the Food Chain, 2011, p. 16). Then, even when the consumption of cadmium is unlikely to cause adverse health effects CONTAM advice to maintain a TWI of 2.5 $\mu\text{g}/\text{kg}$ bw.

Moreover, the EFSA Report of 2012 identified “chocolate confectionary products as the 7th type of food that consumed in large quantities has a greater impact on the cadmium exposure diet and therefore recommended reducing the limits of its consumption as much as possible” (European Food Safety Authority, 2012, p. 34) In that sense, the EU considered a high level of protection in the measure at issue, although the report under comment suggests that cadmium concentration depends on the amount of chocolate that a person consumes.

In that sense, “Article 3.1 requires Members to base their SPS measures on international standards, guidelines and recommendations, where they exist, except as otherwise provided for in the Agreement” (Epps, 2008). Those guidelines and recommendations are the EFSA and CONTAM Reports commented on above, and the standards shall be determined in the Codex Alimentarius nevertheless it is in elaboration process.

Furthermore, the Article 5.1 “requires Members to ensure that their SPS measures are based on an assessment, as appropriate to the circumstances of the risks to human health considering risk assessment techniques developed by the relevant international organizations” (European Food Safety Authority, 2012, p. 34), like the EFSA and CONTAM, but none of them ensured that the consumption beyond 2.5 mg/kg imply a health risk to consumers.

None of the aforementioned research justifies the measure adopted by the EU, since although a cadmium ML consumption per person per week of 2.5 mg/kg was established, it was not determined what should be the recommended limits of cadmium consumption in chocolate and derived products. Thus, no ideal diet is suggested for a person to stay within the established maximum cadmium intake limit; however, the EU has adopted strict levels of cadmium content in chocolate and derived products without the support of the assessments mentioned.

Consequently, in view of the fact that there is no risk assessment within the meaning of the SPS Agreement and the measure at issue is not based on the risks assessments pointed out by themselves in the preamble of Regulation (EU) No.488/2014, the Article 5.1 of the SPS Agreement is being violated and Article 2.2 too. So, it's not necessary to determine whether this measure at issue has sufficient scientific evidence.

4.4. No arbitrary or unjustifiable discrimination

The principle of no arbitrary or unjustifiable discrimination is contemplated in Article 2.3 to SPS agreement, which, as mentioned by the panel in Australia – Salmon (Article 21.5 - Canada) (2000), can be considered to be violated if complies with “three requirements: 1) the measure discriminates between the territories of Members other than the Member imposing the measure, or between the territory of the Member imposing the measure and another Member; 2) the discrimination is arbitrary or unjustifiable; and 3) identical or similar conditions prevail in the territory of the Members compared” (Van den Bossche & Zdouc, 2013, p. 909).

Respecting the first requirement, the panel pointed out that the discrimination could occur between different products which differs from what is established in the General Agreement on Tariffs and Trade (GATT) where only “like” or “directly competitive or substitutable products” are comprehended. So, if the discrimination occurs between like products, depending on the analysis, the Article I referred to the Most Favoured Nation (MFN) treatment or the Article III related to the NT, both contemplated in the GATT 1994 could be violated.

But whether the discrimination occur between different products with same or similar health risks (World Trade Organization, 1998), the Article 2.3 of the SPS Agreement could be violated depending on the analysis of the criteria referred to this rule. It's important to remember that a violation of Article 5.5 of the SPS Agreement implies a violation of Article 2.3. Thus, if the importing member's appropriate level of protection for cadmium is not the same for other contaminants, that is discriminatory and consequently violates Article 2.3 of the SPS Agreement.

Firstly, it is important to determine if there is a discriminatory treatment by the EU in setting desired levels of protection for cadmium in chocolate and derived products compared to other products that are different but represent the same or similar health risks. According to the EFSA 2012 report “Cadmium dietary exposure in the European population”, a comparative table shows that products other than chocolate and its derivatives contribute to the dietary exposure to cadmium of the European population and involve the same or similar health risks as chocolate and its derivatives.

To practical effects at following it's showed a table to expose differences of chocolate and derived products in comparison to different products.

Different products with same or similar health risk	Contribution to dietary exposure	Maximum cadmium content levels determined by the EU and Regulation
Potatoes	13.2%	0.10 mg/kg in the Regulation (EU) No. 488/2014
Bread and rolls	11.7%	Not determined
Fine bakery wares	5.1%	Not determined
Milk chocolate with a total dry matter content of cocoa < 30 %	4.3%	0,10 mg/kg in the Regulation (EU) No. 488/2014
Chocolate with a total dry matter content of cocoa < 50 %; milk chocolate with a total dry matter content of cocoa ≥ 30 %		0,30 mg/kg in the Regulation (EU) No. 488/2014
Chocolate with a total dry matter content of cocoa ≥ 50 %		0,80 mg/kg in the Regulation (EU) No. 488/2014
Cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate)		0,60 mg/kg
Leafy vegetables	3.9%	0.20 mg/kg in the Regulation (EU) No. 488/2014
Water mollusks	3.2%	1,0 only for bivalve mollusks in the Regulation (EU) No. 488/2014

Table 4

Chocolate and derived products were differentiated in grey color. In comparison with the rest of the products, the equality between the MLs of cadmium content contemplated for potatoes and for milk chocolate with a total dry matter content of cocoa < 30% stands out, despite the fact that the latter contributes less than half of the dietary exposure to cadmium (4.3%) than potatoes (13.2%).

The EU has not determined cadmium MLs content for products such “Bread and rolls” and “Fine bakery wares” although these represent a higher level of dietary exposure to cadmium (11.7% and 5.1% respectively) than chocolate and derived products (4.3%), nor has it determined maximum cadmium content levels for all water mollusks, just for the bivalve mollusks (3.2%). It is also clear that the maximum cadmium content allowed for Leafy vegetables is twice as high (0.20 mg/kg) as that permitted for Milk chocolate with a total dry matter content of cocoa < 30%, even there is only a 0.4% difference in dietary exposure to cadmium between those products.

As mentioned before the EU importing members determined an appropriate high level of protection governing all provisions of Regulation (EU) No.488/2014 showing inconsistency with the findings on dietary exposure to cadmium set out in the EFSA 2012 report cited by the EU itself in the explanatory statement to the same regulation. Therefore, there is a violation of Article 5.5 of the SPS Agreement and consequently Article 2.3, although a high level of appropriate protection is expressly contemplated for all the products contemplated in the regulation in question, there is inconsistency between the cadmium MLs content imposed and the dietary exposure established or omitted to be imposed on products such as potatoes, bread and rolls, and fine bakery wares. Then, there is not a consistent level of protection³⁵.

Secondly, it assesses the possible violation of Article I GATT 1994 MFN standard which imply that the advantage granted to the EU by Regulation (EU) No.488/2014 concerning imports of chocolate and derived products originating in another country, should be granted immediately and unconditionally to any similar product originating in the territories of all other parties. So, considering these criteria: 1) the products properties, nature and quality, i.e. their physical characteristics; 2) the

products end-uses; 3) consumers tastes and habits, also consumers perceptions and behaviour, in respect of the products; and 4) the products tariff classification (Van den Bossche & Zdouc, 2013, pp. 327-389). The following products similar to chocolate and derived products listed in commodity code 1806³⁶ have been found:

- “Cocoa powder, containing added sugar or other sweetening matter.
- Chocolate and other preparations in blocks, slabs or bars weighing more than 2 kg or in liquid, paste, powder, granular or other bulk form in containers or immediate packings, of a content exceeding 2 kg.
- Chocolate and other food preparations containing cocoa; in blocks, slabs or bars, filled, weighing 2 kg or less.
- Chocolate and other food preparations containing cocoa; in blocks, slabs or bars, (not filled), weighing 2 kg or less.
- Chocolate and other food preparations containing cocoa; n.e.s in chapter 18” (United Nations, 2019).

Having identified the like products to chocolate and derived products, definitively there is no violation of Article I GATT 1994, since the MLs established by Regulation (EU) No.488/2014 apply equally to all countries exporting chocolate and derived products to the EU without granting any advantage.

For like products was not found that the EU gives any advantage to one or more of the countries exporting chocolate and derived products compared to other exporting countries because although there are similar products for which maximum cadmium levels have not been determined, this benefits all exporting countries equally. Regarding to the violation of Article III GATT 1994, once it has been determined which are the products similar to chocolate and derived products to which the cadmium MLs content should apply equally.

From the EU comments for the CCCF in the 14th Session and as exposed in the table 3 and the similar products to chocolate and derived products listed under the commodity code 1806, it appears that the EU has not imposed maximum cadmium content levels and proposes not to set a codex ML in “Cocoa powder, containing added sugar or other sweetening matter” because it is considered that there is a lower significance of this commodity for international trade (Codex Committee Contaminants in Food, 2021).

However, a review of the data from countries exporting cocoa powder containing added sugar or other sweetening matter (Commodity No. 180610) to the rest of the world shows that the following EU members have had significant exports of this product to the rest of the world during the 2019:

- “Germany (2do biggest exporter) with a commercial value of US\$ 43 456 043
- Ireland (4to biggest exporter) with a commercial value of US\$ 34 325 879
- Italy (8vo biggest exporter) with a commercial value of US\$ 18 532 913
- Hungary (10mo biggest exporter) with a commercial value of US\$ 18 092 906” (United Nations, 2019).

Clearly, the export of cocoa powder containing added sugar or other sweetening matter by EU member countries is relevant. Therefore, Article III on NT has been violated, since the assumptions of the three tier test of consistency because 1) the measure in question are requirements contained

in Regulation (EU) No.488/2014 that affect the sale of chocolate and derived products; 2) the imported products, which are chocolates and derived products and cocoa powder containing added sugar or other sweetening matter, are similar products since they have the same final uses, properties, are in accordance with the consumers' tastes and are in the same tariff classification; 3) the imported products, which are chocolates and derived products, are subject to compliance with certain levels of cadmium, which implies that they are subject to a less favourable treatment than cocoa powder containing added sugar or other sweetening matter exported to the world by the EU MS.

5. Proposal for alternative measures less restrictive of international trade

Having demonstrated that the measure in question was not based on a risk assessment within the meaning of paragraph 4 of the Annex to SPS Agreement, as well as violating Article 5.5 and the Article 2.3 of the SPS Agreement, and that the measure in question violates the MFN standard of Article III to SPS Agreement, alternative measures to the measure in question are set out below.

5.1. Labelling of chocolate and derived products

Let's take into consideration that the cadmium consumption in food depends on people's eating habits; that is, on their diet and living conditions. For example, if the person is a smoker, vegetarian, lives in a place with too much pollution³⁷ or eat a lot³⁸, it will accumulate a higher level of cadmium in the body. It is considered that it would be most appropriate to label chocolate and derived products by providing final consumers with a warning about the level of cadmium in each product, this measure does not unjustifiably restrict trade and allows consumers to make an informed choice.

Firstly, throughout the Proposition 65 settlement agreement, which "requires businesses to provide warnings to Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm" (California Government). "The Californian state has set the following MLs of cadmium in chocolate" (Tromba, 2019):

Cacao percentage in product	Cadmium concentration above which a warning is required (between 2019-2025)	"Drop down" Cadmium concentration above which a warning is required (from 2525)
< 65%	0.400 ppm	0.320 ppm
≥ 65% - ≤ 95%	0.450 ppm	0.400 ppm
> 95%	0.960 ppm	0.800 ppm ³⁹

The cadmium MLs in the aforementioned agreement are wider than those contemplated in Regulation (EU) No.488/2014. Moreover, it has been considered that they should be progressively reduced from their entry into force until 6 years later, which gives chocolate and derived products producers a reasonable margin of time to adapt to the new standard.

Under this provision, chocolates and derived products exceeding the established cadmium MLs content will be able to continue being marketed as long as they have warning labelling aimed at the end consumer. Besides, the modified text of Article 6 called "Clear and reasonable warnings regulations", section 25600.2 about the responsibility to provide consumer product exposure warnings of October 4th 2019, Title 27 of the California code of Regulations (California Office of Environmental Health Hazard Assessment, 2019), points out who should comply with product labelling, what pollutants should be considered on prevention labels and has legal responsibility in case of labelling omission as explained below.

Secondly, according to the considering b) of the Section 25600.2⁴⁰. The manufacturer, producer, packager, importer, supplier, or distributor of chocolate and derived products shall comply by introducing a warning on them or providing a written notice directly to the authorized agent for the business to which they are selling or transferring the product or to the authorized agent for a retail seller.

Everything in compliance of the Section 25249.6 Act (California Health and Safety Code, 2020) which points out that “No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10”. It is then clear that the subjects involved in the production and distribution chain of the product have the responsibility to include the warning label on the products or could transfer that responsibility in writing to the subject who made the sale to the final consumer.

In the second scenario, the written notice sent directly to the authorized agent for the business or to the authorized agent for a retail seller shall contain some details⁴¹. So, the manufacturer, producer, packager, importer, supplier, or distributor compose the subjective scope of this warning legal disposition who always have the possibility to transfer this duty to the authorized agent for the business or to the authorized agent for a retail seller that will offer the chocolate and derived products to the final consumers. In this way the consumer is allowed to make an informed choice about the consumption of the products.

Thirdly, as mentioned in recital (b) 1 of Section 25600.2, prevention labelling is done on products that result in the exposure of one or more chemicals detailed in the Proposition 65 list which “contains a wide range of naturally occurring and synthetic chemicals that include additives or ingredients in pesticides, common household products, food, drugs, dyes, or solvents, among others” (California Government).

Among the products listed is cadmium as a contaminant that could cause cancer and reproductive toxicity, the latter especially in males. Thus, the “safe harbor levels established were:

- Cancer, no significant risk level-inhalation of 0.5 mg/day.
- Reproductive toxicity, maximum allowable dose level-oral of 4.1 mg/day” (California Office of Environmental Health Hazard Assessment, 2019, p. 2).

These levels were determined based on the Report “Maximum Allowable Dose Level for Cadmium (Oral Route)” (Office of Environmental Health Hazard Assessment, 2001) and the Report “Evidence on Developmental and Reproductive Toxicity of Cadmium” (Office of Environmental Health Hazard Assessment, 1996), which evidently contemplate broader maximum levels of cadmium content in food than the Regulation (EU) No.488/2014.

Fourthly, the Section 25607.2 “Food Exposure Warnings – Content” contemplates that the warning labels shall include the following elements:

“(1) The word “WARNING” in all capital letters and bold print.

(...) (5) For exposures to a chemical that is listed as both a carcinogen and a reproductive toxicant, the words, “Consuming this product can expose you to chemicals such as [name of one or more chemical], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food” (Office of Environmental Health Hazard Assessment, 2016).

The label must count on the word “WARNING” in bold print letters, the name of the chemical (cadmium), the affirmation that these chemical element is known to the State of California to cause negative effects in the population, the specification of the illnesses that the mentioned chemical element can cause cancer and birth defects or other reproductive harm, and the URL direction of the Proposition 65 in order to enable consumers to get more information by themselves.

Besides, there are some examples of chocolate and derived products which mention the content of cadmium on them⁴². There are three labels (Saving the world one ingredient at time, 2018) which show the presence of cadmium in the products on the front side and as part of the advertising design of the brand, but this is not sufficient to comply with the elements requested by Proposition 65, possibly the text requested by the standard is on the back of those products. Otherwise, the parties responsible for marketing them would incur on legal liability.

While the rest of the products have included the text requested by Proposition 65 as highlighted; however, it is clear that the fourth product (Viva naturals, 2019) only complies with two of the elements requested by the standard which are the word warning in bold and capital letters, the diseases that cadmium can cause in people and the URL address for more information, but it is obvious to cite the name of the chemical element which in this case is cadmium and the fact that the state of California is aware of the probability of occurrence of the diseases mentioned above.

Fifthly, provided that the written notification was received in accordance with recitals (b) and (c) “The retail seller is responsible for the placement and maintenance of warning materials, including warnings for products sold over the internet, that the retail seller receives (...)” (California Office of Environmental Health Hazard Assessment, 2019, p. 3). So, the retail seller shall ensure that warning labels remain on products until they are purchased by the final consumer.

Moreover, the retail seller acquires the responsibility to provide the warning labels in the chocolate and derived products when is the owner of the brand under which the product is marketed or licensed by the retail seller or an affiliated entity; if manufactured a product containing one of the listed contaminants; hides a warning label that was already attached to the product; sell the product without the warning label knowing that there is a duty to put them; and there are no manufacturer, producer, packer, importer, supplier or distributor of the product is responsible for complying with this legal provision (Viva naturals, 2019).

Consequently, the “Penalties for violating Proposition 65 by failing to provide warnings can be as high as \$2,500 per violation per day” (California Government). So, the responsibility lies with the retail seller and failure to comply with warning labelling as required by the standard could result in fairly high financial penalties.

Sixthly, in respect to the justification in Article 5.5 SPS Agreement the labelling measure for chocolates and derived products adopted by California does not unjustifiably restrict trade by leaving it up to consumers to make an informed choice. The measure applied takes into account the disposition established in the second paragraph of Article 5.5 of the SPS Agreement about the guidelines adopted by the SPS Measures Committee in which one disposition establishes that “the exceptional character of human health risks to which people voluntarily expose themselves” (World Trade Organization, 1994) shall be taken into account by the WTO Members when establishing the appropriate level of protection for its population with respect to a product.

Thus, the guideline about the application of the appropriate level of protection concept A.8 establishes that

“A Member should clearly identify those situations which it considers justify its acceptance exceptionally of a lower level of protection for human health specifically with respect to risks to which people voluntarily expose themselves (...)” (Committee on Sanitary and Phytosanitary Measures, 2000).

Therefore, like California, the EU MS should have considered imposing a lower appropriate level of protection in relation to the cadmium MLs in chocolate and derived products, since the amount of cadmium consumed depends on consumers' tastes, habits, and daily diet. It is very likely that consumers will consume a greater amount of chocolate and derived products because such a decision is subject to their knowingly acceptance.

Population itself exposes to the greatest amount of cadmium in its body. It would be better if the decision of consumption is informed rather than to diminish the international trade imposing a high level of protection which will damage the quality of the product and in the long run affect its consumption quantitatively. This could eventually lead to "a violation of Article XI of the SPS Agreement for violating the ban on quantitative restrictions on trade"⁴³.

5.2. Precautionary Principle application

Since the CCCF has not yet finalized the Codex standard on the risk that cadmium content in chocolate and derived products would represent for human health, nor has the outcome of the JECFA evaluation on cadmium been issued. It would be most appropriate for the EU to adopt interim SPS measures as required by the Precautionary Principle.

In that way, the Precautionary Principle of Article 5.7 to SPS Agreement⁴⁴ was interpreted by the Panel and confirmed by the Appellate Body, in Japan – Agricultural Products II (1999) and US/Canada – Continued Suspension (2008)⁴⁵ and "(...) is reflected in the sixth paragraph of the Preamble and Article 3.3 of the SPS Agreement" (Van den Bossche & Zdouc, 2013 p.931). Thus, the requirements to comply with the legal disposition of Article 5.7 of the SPS Agreement will be reviewed at following.

Firstly, about the insufficiency of relevant scientific evidence, also the existence of evidence supporting other point of view shall be considered (Van den Bossche & Zdouc, 2013, p. 931). Shall be demonstrated that there is scientific evidence supporting more permissible levels of cadmium in chocolate and derived products. As explained in the point 4 c) of this research there is not a risk assessment within the meaning of the paragraph 4 of the Annex of the SPS Agreement to impose the MLs of cadmium content that were determined by the Regulation (EU) No.488/2014.

The EWG presided by Ecuador and co-chaired by Brazil and Ghana proposed MLs of cadmium content in chocolate and derived products as it is exposed in the Annex 1 of this research based in the proportionality and ALARA principles by an analysis from the cadmium presence database provided in Global Environment monitoring System (GEMS)/Food updated at the request of the WHO 10 July 2019. The EWG explains that ALARA principle previously employee by the "CCCF [which] used a figure of approximately 5% of samples as a 'cut-off' point for determining an achievable ML. So, if 95% of samples have a cadmium content below certain level, which is deemed achievable and may be proposed as a ML" (Codex Committee on Contaminants in Foods, 2015, p. 5). Then, the cadmium MLs content proposed by the EWG were based on ALARA Principle previously used by the CCCF.

The proportionality principle was also used "(...) to propose an ML for chocolate containing or declares $\geq 30\%$ to 70% total cocoa solids (0.9 mg/kg); as well as the ML proposed to the Codex Alimentarius Commission [CAC] 41 by the CCCF13 for chocolates with $< 30\%$ total cocoa solids (0.3 mg/kg)" (Codex Committee on Contaminants in Foods, 2020b), which was rejected by the EU since the public consuming these products is not the same (Codex Committee Contaminants in Food, 2021). There is lack of relevant scientific evidence presented by the EU and there is evidence which support the maximum levels proposed by the EWG based in the ALARA principle, the proportional principle and the data provided in the GEMS/Food updated at the request of the WHO 10 July 2019.

Secondly, in respect to the existence of available pertinent information, ‘the Appellate Body in the US/Canada – Continued Suspension (2008) cases, held that this refers to situations where there is some evidentiary basis indicating the possible existence of a risk, but not enough to permit the performance of a risk assessment’ (Van den Bossche & Zdouc, 2013, p. 930). Therefore, it is sufficient that there is evidence of risk to health for provisional health measures to be taken: The EFSA CONTAM Report of 2011 (EFSA Panel on Contaminants in the Food Chain, 2011) and the EFSA Report of 2012 (European Food Safety Authority, 2012 p. 29) which updates the information contained in the report of the EFSA of the 2009 (EFSA Panel on Contaminants in the Food Chain, 2011). Thus, it shall be noted that there is some evidence that the high level of cadmium in chocolates and derived products could represent a health risk for the consumer population, but this evidence is not sufficiently decisive for them to take definitive SPS measures.

Thirdly, in respect to seeking of information for a more objective assessment of risk the Appellate Body in Japan Agricultural Products II (1999) and US/Canada – Continued Suspension (2008) clarified this requirement in three aspects⁴⁶. From the development made by the appeal body in the above cases, it can be understood that the EU will have to make every effort to verify and demonstrate in a reliable and accurate manner that cadmium high levels represent a health risk and thus base the maximum limits imposed on a risk assessment as set out in Article 5.1 of the SPS Agreement assessed in subsection 2.3.3 a) of this research.

Fourthly, about the review within a reasonable period of time. The WTO not determined expressly a period of time in Article 5.7 instead made reference to a reasonable period of time, interpreted by “the Appellate Body in Japan Agricultural Products II (1999) as the one that depends on the specific circumstances of each case, including the difficulty obtaining additional information necessary for the review and the characteristics of the provisional SPS measure” (Van den Bossche & Zdouc, 2013, p. 931).

Thus, in order to determine a reasonable period of time to carry out a risk assessment on tolerable cadmium MLs content, it should be taken into consideration that, both the Codex Alimentarius and the JECFA report are under development. There are limitations regarding sampling to estimate what the cadmium MLs for the European population would be, as they are not representative of all member countries as recognized in section 5 of the EFSA Panel on Contaminants in the Food Chain (CONTAM) Report of 2011 called (2011).

Finally, regarding the characteristics of the SPS measure according of what was established in the case Japan-Agricultural Products II (World Trade Organization, 1999) it shall be considered that the requirements of the Article 5.6 of the SPS Agreement. There is an alternative measure reasonably available to the measure at issue, which was presented by the EWG presided by Ecuador and co-chaired by Brazil and Ghana that is significantly less trade restrictive than the contested measure, it does not comply with the high appropriate level of protection determined by the European importing members.

6. Conclusions

Firstly, despite there is an alternative measure proposed by the EWG which is reasonably available due to the countries which expressed themselves to be affected by the measure in question agree with the cadmium MLs set in the proposed alternative measure, which indicates that they have the technical and economic feasibility of making changes to enable them to produce chocolate and derived products according with these MLs. The alternative measure proposed by the EWG does not achieve the high level of protection determined by the importing European member countries. Thus, the measure at issue is not based on a risk assessment within the meaning of the paragraph 4 of the Annex to SPS Agreement because even when it took place, there is no potentially adverse effects in the health of the European consumers to occur. So, the measure at issue does not comply with the Article 5.1 of the SPS Agreement which necessarily imply a violation of Article 2.2 of the same legal Agreement.

Secondly, a consistent level of protection has not being determined by the European importing members due to there is inconsistency between the cadmium MLs content imposed and the dietary exposure that is imposed and/or omitted to be imposed on products such as potatoes, bread and rolls and fine bakery wares. So, there is a violation of Article 5.5 which implies a violation of Article 2.3 of the SPS Agreement.

Thirdly, the measure at issue does not comply with the standard of NT of Article III, GATT 1994 because the EU imposed cadmium MLs content for chocolate and derived products, but at the same time stated that it is not necessary to set cadmium MLs for cocoa powder containing added sugar or other sweetening matter because of its irrelevance in the market. However, European countries such as Germany, Ireland, Italy and Hungary present themselves as major exporters of this products to the world, which gives their nationals more favourable treatment than which is given to the foreigners.

Fourthly, there are two alternative options less restrictive to the international trade than the measure at issue: 1) Labelling of chocolate and derived products with a warning following determined parameters and 2) Issuing a provisional measure based on the precautionary principle contemplated in Article 5.7 SPS Agreement which is less restrictive to international trade.

Finally, the hypothesis raised was verified in its entirety, but not the sub hypotheses because even when the violation of Articles 5.1 and 2.2 to SPS Agreement was discovered, since the measure in question is not based on a risk assessment within the meaning of para. 4 of its Annex. Likewise, a violation of Articles 5.5 and 2.3 to SPS Agreement was found, because the European importing members did not impose a similar level of protection on different products that pose the same risk to consumers health. It was not demonstrated that the measure at issue generates an unjustified differentiation between exporting countries but between exporting and European countries, strictly speaking national countries.

1 G/SPS/GEN/1587, G/SPS/GEN/1602, G/SPS/GEN/1624 and G/SPS/GEN/1792.

2 Peru, Colombia, Ecuador, Côte d'Ivoire, Plurinational State of Bolivia, Guatemala, Indonesia, Nicaragua, Trinidad and Tobago, El Salvador, Panama, The United States, The Bolivarian Republic of Venezuela, Costa Rica, Brazil, The Dominican Republic, Ghana, Madagascar and Nigeria have expressed concern about the impact on their exports. Moreover, in the 2-3 November 2017 meeting "(...) the ECOWAS representative indicated that members also shared the concern" (Committee on Sanitary and Phytosanitary Measures, 2017).

3 The highlight is mine.

4 The sixth recital expressly mention the following: "(...) For some foodstuffs that are important contributors to the exposure for certain population groups (chocolate and cocoa products, foods for infants and young children) maximum levels have not yet been established. It is therefore necessary to establish maximum levels of cadmium for those foodstuffs" [The highlight is mine] (European Commission, 2014b).

5 The eighteenth recital points out that “MS and food business operators should be allowed time to adapt to the new maximum levels established by this Regulation for cocoa products and foods for infants and young children. The date of application of the maximum levels of cadmium for those commodities should therefore be deferred” [The highlight is mine] (European Commission, 2014b).

6 These “is a safety principle designed to minimize radiation doses and releases of radioactive materials. More than merely best practice, ALARA is predicated on legal dose limits for regulatory compliance and is a requirement for all radiation safety programs” (IDEXX Laboratories, 2009).

7 Article 1.1 to SPS Agreement establishes the following: “This Agreement applies to all SPS measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement” [The highlight is mine] (World Trade Organization, 1994).

8 “1) the sovereign right of WTO Members to take SPS measures; 2) the obligation to take or maintain only SPS measures necessary to protect human, animal or plant life or health (the ‘necessity requirement’); 3) the obligation to take or maintain only SPS measures based on scientific evidence (the ‘scientific disciplines’); 4) the obligation not to adopt or maintain SPS measures that arbitrarily or unjustifiably discriminate or constitute a disguised restriction on trade (the ‘non-discrimination’ requirement)” (Van den Bossche & Zdouc, 2013, p. 900).

9 At this respect Van den Bossche points out that “The basic disciplines are set out in Articles 2.2 and 2.3 and are further elaborated upon in other provisions of SPS Agreement. These provisions incorporate the existing GATT rules applicable to health measures and introduce new requirements for the use of SPS measures” (2013, p. 904).

10 The Regulation (EU) 488/2014 just considered this value: $\geq 50\%$ (European Commission, 2014b).

11 At this respect the EU is of the opinion of the need for a stricter ML to ensure sufficient protection of all consumers, in particular children (Codex Committee on Contaminants in Foods, 2021).

12 The highlight is mine.

13 At this respect, The EFSA Panel concluded that although adverse effects are unlikely to occur in an individual with current dietary exposure there is a need to reduce exposure to cadmium at the population level because of the limited safety margin (European Food Safety Authority, 2012, p. 3).

14 Ibid.

15 At this respect, Karttunen points that the “SPS Agreement adds a requirement specific to SPS subject matter, requiring all WTO Members to apply a consistent level of protection against risks to human life or health, or to animal and plant life or health, as well as to avoid discrimination or disguised restrictions to trade” (2020, p. 38).

16 This is the tariff classification. Specifically, “The first six digits refer to the classification in the WCO Harmonized System (HS). This classification is further subdivided by the European Union into the eight-digit Combined Nomenclature (CN) codes. For import declarations, these codes are subdivided further into ten-digit Taric codes. For import and export customs declarations, commodities need to be classified in the Combined Nomenclature” (Taric support, 2019).

17 “(...) subgroups of population, such as vegetarians, children, and people living in highly contaminated areas, may exceed the TWI by up to 2-fold” (EFSA Panel on Contaminants in the Food Chain, 2011, p. 11).

18 “Food consumed in larger quantities had the greatest impact on dietary exposure to cadmium” (European Food Safety Authority, 2012, p. 1).

19 These acronyms mean “parts per million” (United States Environmental Protection Agency, 2015).

20 “The manufacturer, producer, packager, importer, supplier, or distributor of a product may comply by providing a warning on the product label or labeling that satisfies Section 25249.6 of the Act, or by providing a written notice directly to the authorized agent for the business to which they are selling or transferring the product or to the authorized agent for a retail seller, so long as the business to which they are providing the notice is subject to Section 25249.6 of the Act.” (California Office of Environmental Health Hazard Assessment, 2019).

21 “(1) State that the product may result in an exposure to one or more listed chemicals; (2) Include the exact name or description of the product or specific identifying information for the product such as a Universal Product Code or other identifying designation; (3) Include all necessary warning materials such as labels, labeling, shelf signs or tags, and warning language for products sold on the internet, that satisfies Section 25249.6 of the Act; and (4) Be renewed annually during the period in which the product is sold in California by a retail seller” (California Office of Environmental Health Hazard Assessment, 2019, p.2).

22 Find labelling examples in: Saving the world one ingredient at time. (2018, February 1st). Good food fighter. <https://goodfoodfighter.com/chocolate-now-labeled-lead-content/>; Viva naturals. (2019, January 1st). Cacao Nibs. <https://vivanaturals.com/products/cacao-nibs>; Food pharmacy. (2019, January 1st). Rapunzel, organic cocoa powder, 7.1 oz (201 g). <https://foodpharmacy.blog/rapunzel-organic-cocoa-powder.html>. Rapunzel, organic cocoa powder, 7.1 oz (201 g). <https://foodpharmacy.blog/rapunzel-organic-cocoa-powder.html>; and, Cleppe, T. (2020, June 2nd). NUG Cannabis-Infused milk chocolate bar (2018 Review). NuggMD. <https://www.nuggmd.com/blog/nug-milk-chocolate-bar-edible-review>.

23 At this respect, in the case India – Quantitative Restrictions (1999) and India – Autos (2002) the Panel determined that to establish the violation of Article XI to SPS Agreement it's enough to “(...) identify not merely a condition placed on importation, but a condition that is limiting, i.e. that has a limiting effect (...) that limiting effect must be on importation itself” (Van den Bossche & Zdouc, 2013, p. 484).

24 Article 5.7: “In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt SPS measures on the basis of available pertinent information, including that from the relevant international organizations as well as from SPS measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time” (World Trade Organization, 1994).

25 “Panel and confirmed by the Appellate Body, in Japan – Agricultural Products II (1999) and US/Canada – Continued Suspension (2008), namely, that the measure must: (1) be imposed in respect of a situation where relevant scientific evidence is insufficient, (2) be adopted on the basis of available pertinent information; (3) not be maintained unless the Member seeks to obtain the additional information necessary for a more objective assessment of risk; and (4) be reviewed accordingly within a reasonable period of time” (Van den Bossche & Zdouc, 2013, p. 927).

26 “(1) the insufficiency of scientific evidence is not a perennial state, but a transitory one; as of the adoption of the provisional measure, a WTO Member must make best efforts to remedy the insufficiency; (2) Article 5.7 does not specify what actual results must be achieved; the obligation is to seek to obtain additional information; and (3) the information sought must be germane to conducting a risk assessment within the meaning of Article 5.1” (Van den Bossche & Zdouc, 2013, p. 931).

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