Appendix S1

Interpreters of International Economic Law:
Corporations and Bureaucrats in Contest over Chile's Nutrition Label

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Description:

This appendix presents the data sources underlying our article's central empirical arguments. It contains excerpts from three types of sources: (1) public consultation comments submitted to the Chilean Ministry of Health during its 2015 public consultation (obtained on a USB drive and believed to be the complete set of submissions); (2) internal e-mails and documents received through freedom-of-information requests or directly from various institutions; (3) transcriptions and notes from in-depth interviews with key informants. Text parts highlighted bold are the parts directly cited in the manuscript. All translations are our own.

List of Abbreviations:

ASEAN	Association of Southeast Asian Nations
DG TRADE	European Commission, Directorate-General for Trade
Codex	The Codex Alimentarius Commission
DIRECON	*Dirección General de Relaciones Económicas Internacionales del Ministerio de Relaciones Exteriores* (Economic Affairs Directorate of the Foreign Ministry), Chile
FDA	US Food and Drug Administration
FOI	Freedom of Information
FTA	Free Trade Agreement
GAPMMI	*Gabungan Pengusaha Makanan dan Minuman Seluruh Indonesia* (Association of Indonesian Food and Beverage Entrepreneurs)
GMA	Grocery Manufacturers Association
INAPI	*Instituto Nacional de Propiedad Industrial* (National Institute of Intellectual Property), Chile
MOH	Ministry of Health
MINSAL	*Ministerio de Salud* (Ministry of Health), Chile
NCD	Non-Communicable Diseases
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
TBT	Technical Barriers to Trade
USTR	Office of the United States Trade Representative
USDA	United States Department of Agriculture
WTO	World Trade Organization

Data Sources:

Source 1

Description: E-mail from the Association of Indonesian Food and Beverage Entrepreneurs (GAPMMI) to Paul Mertenskötter, "Re: Questions About Indonesia's Food Labeling Regulation for Salt, Fat, and Sugar", 15 September 2017. On file with the authors.

Excerpt: "GAPMMI has asked the National Standardization Body as WTO contact point to ask MOH sharing the regulation in WTO. In the other hand, some international company who member of GAPMMI has asked their head office to inform each of government to review the regulations and shared their comments to WTO."

Source 2

Description: FoodDrinkEurope, "FoodDrinkEurope's comments on G/TBT/N/IND/84 – Indonesian MOH Decree on the Inclusion of sugar, salt, and fat content information, and 'health messages for processed food and Fast Food'", 20 February 2014. Document obtained through a FOI request to the European Commission. On file with the authors.

Excerpt: "FoodDrinkEurope has strong concerns about the Indonesian MOH decree, in particular the disproportionate nature of the *[…] mandatory health message for processed foods, translated roughly as: 'Consumption of sugar > 50g, sodium > 2000mg and Fat > 67g per person per day contributes to the risk of hypertension, stroke, diabetes and heart attack' has been introduced as part of this decree.*

Although, in principle, the industry supports the Ministry's objective to help improve nutritional literacy and raise awareness among Indonesians about positive lifestyle choices, significant concerns remain towards the approach suggested by the MOH also for the following reasons:

- the **lack of scientific evidence that the MOH Decree will help address noncommunicable diseases (NCD) in Indonesia**; namely that such a warning statement is well understood by consumers and will help them to make a healthier choice, nor is it clear that it will provide a stimulus for the food industry to change the composition of products.
- the fact that the Decree will set a labelling precedent in one country will increase labelling costs substantially for both producers and importers, and as such could potentially act as a barrier to trade; since ASEAN trade partners apparently do not intent to implement such a measure and prefer to act on a voluntary basis and invest more into education of consumers.
- It is widely acknowledged that nutrition information should be consistent across markets to support a common consumer understanding. Malaysia, Singapore and the Philippines for instance have all announced FOP voluntary guidelines and they all support the model of Guideline Daily Amount (GDA) labelling. We consider Indonesia should aim for better alignment with its neighbouring countries rather than take steps that would contravene the paramount ASEAN objective to achieve a single trade market by 2015.

FoodDrinkEurope calls upon the Commission to react to the WTO notification G/TBT/N/IDN/84 by the final date of 12 March 2014. Moreover**, we would appreciate if the issue could also be raised at the next TBT Committee meeting** on 19-20 March 2014 in Geneva.

Trusting that the request formulated in this letter will receive your due consideration.
With best regards,"

Source 3

Description: European Commission, Directorate-General for Trade, "Mission Report, WTO/TBT Committee Meeting – 3-6 November 2015, Geneva – Report on Specific Trade Concerns, 7th Triennial Review and other matters", 15 January 2016. Document obtained through a FOI request to the European Commission. On file with the authors.

Excerpt: "Indonesia explained that Regulation No 30/2013 has been recently amended by Regulation No. 63/2015 of the Minister of Health and that the implementation date, which was originally by 16 April 2016, is delayed of 4 years (April 2019). During the transition period, Indonesia provides dissemination and advocacy, both cross-sector (policy makers in ministries/agencies, professionals and industry sector) and cross-program (internally in the Ministry of Health), and is preparing the Ministerial Decree derivatives (especially on the type of processed food that would be required to implement Regulation No 30/2013). Indonesia will conduct continued studies on total diet to measure changes in consumption patterns, evaluating the results to determine the type of processed food needed for the requirement to include information about the content of sugar, salt and fat, as well as health messages. It will undertake programs to increase public awareness on the prevention and control of NCDs and their risk factors and will monitor and evaluate results. Indonesia committed to notify the changes in the implementation of these Regulations."

Source 4

Description: Letter from John Luik to Tony Wood regarding GATT/TRIPS process, 31 December 1993. Document obtained by Truth Tobacco Industry Documents. Available at: https://perma.cc/2TU4-P938.

Excerpt: "While I think that the Gatt/Trips process provides a useful entre to this problem, I believe that its **ultimate usefulness might well be limited**. This is because the antis will soon argue that where health is involved, adopting minimal regulation as a basis for trade harmonization is not acceptable. This will force the issue back to where it needs to be addressed now, namely developing good arguments as to why minimal intellectual property and trademark infringement is the only reasonable policy."

Source 5

Description: Parliament of Canada, House of Commons Standing Committee on Health, "Bill C-71, an act to regulate the manufacture, sale, labelling and promotion of tobacco products", 6 December 1996. Available at: https://perma.cc/ET8R-QZG7.

Excerpt: "Mr. Silye: Will it be a no-name package or will it be –
Ms Ferguson: No, we're not considering that at all.
Mr. Silye: So they could put their brand name on it. They could put Rothmans or du Maurier on it?
Ms Ferguson: Yes.
Mr. Silye: Oh, okay.
Mr. Dingwall: If I may, Mr. Chairman, to my colleague, they will be able to put their name on the product. If they weren't allowed that, we **would be in violation both of trademark** and of the Charter of Rights and Freedoms because the product is not deemed to be an illegal product. That's the balance here."

Source 6

Description: Grocery Manufacturers Association, "Proposed Amendment to the Chilean Food Health Regulations, Supreme Decree No. 977/96 (Notified to the World Trade Organization as CHL/282 on 22 August 2014)", 21 October 2014. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: “U.S. – Chile Free Trade Agreement Violations

The U.S.-Chile FTA goes beyond the TBT Agreement’s procedural obligations by requiring Chile to provide U.S. industry the opportunity to participate in the development of technical regulations on non-discriminatory terms. To date, this opportunity has not been granted.

Moreover, the proposed distribution, advertising, and promotional restrictions appear to violate Chile’s services-related trade commitments. Restrictions on the distribution and advertising of products covered by the Proposed Regulation constitute barriers to the performance of services. In the U.S.-Chile FTA’s services chapter, Chile’s market access commitments are provided on a ‘negative list’ basis, and Chile has taken no exceptions or non-conforming measures (NCMs) related to distribution or advertising services in the U.S.-Chile FTA that would allow it to discriminate or restrict market access to U.S. food and beverage companies.

Further, Chile is required by the FTA to maintain a mechanism for responding to inquiries from ‘interested persons,’ which includes representatives of U.S. industry.”

Source 7

Description: FoodDrinkEurope, “FoodDrinkEurope comments on WTO notification G/TBT/N/CHL/282 – Proposed Amendment to the Chilean Food Health Regulations, Supreme Decree No. 977/96”, 26 September 2014. Entry to Chile’s public consultation, obtained from Chile’s Ministry of Health. On file with the authors.

Excerpt: “Distortion to the trade liberalisation process decided on the basis of the EU-Chile Association Agreement

Under art. 18 §1 of the EU-Chile Association Agreement ‘cooperation on standards, technical regulations and conformity assessment is a key objective in order to avoid and reduce technical barriers to trade and to ensure the satisfactory functioning of trade liberalisation’. This cooperation should among others promote efforts in ‘compatibility of technical regulations on the basis of international and European standards’, ‘encourage any measures aimed at bridging the gaps between the Parties’, ‘promote a common approach to the use of international and regional standards’ and ‘encourage any measure aimed at improving convergence and compatibility between the respective system, including transparency, good regulatory practices and the promotion of quality standards for products and business practices’.

If adopted in its current form, the proposed amendment to the Chilean Food Health Regulations (Supreme Decree No. 977/96) in accordance with Law No. 20.606 will not only go against the international standards but will also diverge significantly from the EU approached adopted in the EU Regulation 1169/2011 on the provision of food information to consumers. EU decision makers backed the Guideline Daily Amounts (GDAs) approach to food labelling, which was found more appropriate to help consumers make informed food choices.”

Source 8

Description: Associayao Brasileira das Industrias da Afimentacao, “Consulta Publica sobre la modificacion del Reglamento Sanitario de Alimentos para aplicacion de la Ley 20.606 sobre composicion de alimentos y su publicidad”, 15 October 2014. Entry to Chile’s public consultation, obtained from Chile’s Ministry of Health. On file with the authors.

Excerpt: “Las normas de etiquetado vigentes en Brasil, aplicadas por la industria nacional incluso en productos destinados al mercado chileno, incluidas las informaciones de la composicion nutricional del alimento, se debaten y establecen en el ambito internacional, sin olvidar que, para los paises que

integran el MERCOSUR, su incumplimiento puede suponer la violacion del acuerdo internacional firmado, ademas de crear barreras tecnicas no tarifarias.

Las barreras tecnicas son evidentes si consideramos que las etiquetas elaboradas por las industries de alimentos brasilerias circulan por toda Latinoamerica, con informacion en lengua portuguesa y espanola.

La intencion de unir las reglas multilaterales de comercio se ratifico en el ambito del Acuerdo de Complementacion Economica (ACE) n° 35, firmado por los paises miembros de Mercosur y Chile. En el articulo 25 de ACE, las partes se comprometen a cumplir las obligaciones derivadas del Acuerdo sobre Barreras Tecnicas al Comercio y el Acuerdo sobre la Aplicacion de Medidas Sanitarias y Fitosanitarias.

En referencia al ACE, los paises tambien coinciden en la 'importancia de establecer directrices y metodos coordinados para la armonización de normas y reglamentos tecnicos' (art. 27). La propuesta de ley chilena se aleja de este acuerdo, al intentar modificar de forma unilateral y sin evidencias cientificas so1idas el etiquetado nutricional de los alimentos.

La existencia de obstaculos injustificados para el comercio Internacional tambien se contempla en el ACE mencionado, estableciendose que las Partes deben evitar emitir medidas sanitarias que comprometan la armonización y compatibilización de las normas creando dichos obstaculos (articulo 28).

Es evidente que el sistema multilateral de comercio articulado por la OMC, a tenor de los acuerdos mencionados de los cuales Chile forma parte, impone la adopcion de medida menos costosas y efectivas para la problematica abordada en la propuesta chilena en debate."

Source 9

Description: Grocery Manufacturers Association, "Comments on the Proposal from Chile: Proposed Amendment to the Chilean Food Health Regulations, Supreme Decree No. 977/96", 21 October 2014, pp. 17-19. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: "VIOLATIONS OF CHILE'S INTERNATIONAL COMMITMENTS" […] "An advertising ban as harsh as that called for in Chile's Proposed Regulation **would effectively destroy the value of producers' registered trademarks and therefore violate at least one of the TRIPS provisions**. Specifically, the Proposed Regulation, by banning the use on packages and in advertising of key trademarks of GMA members, could violate Articles 20 and 15(4) of the TRIPS Agreement. Article 20 of the TRIPS Agreement provides as follows: The use of a trademark in the course of trade shall not be **unjustifiably encumbered** by **special requirements**, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings… A regulation violates Article 20 if it (a) imposes a 'special requirement' on trademark use; (b) the requirement amounts to an 'encumbrance;' and (c) the encumbrance is 'unjustifiable.' If companies are only permitted to use their registered trademarks in marketing and advertising if their products fall below the proposed nutrient content limits, this constitutes a 'special requirement' on the use of registered marks affected by the regulation, such as those involving product mascots and slogans tending to appeal to children. These special requirements are 'encumbrances' on their use of those trademarks; affected companies would be unable to utilize registered trademarks on targeted products. The expansive definition of 'publicidad' (marketing) defined in the Proposed Regulation, which covers all instances in which such characters would be deployed, including on packages themselves, amounts to an effective ban on the use of the trademarked characters. […] Article 15(4) of the TRIPS Agreement provides that: 'The nature of the goods [ ] to which a trademark is to be applied shall in no case form an obstacle to the registration of the mark.' The protection of registered trademarks confers an implied right to its use, and therefore the

effective banning the use of a mark **effectively renders registration itself ineffective**. Further support for the inextricable linkage of registration and use comes from the fact that a stated intention to use a trademark is normally a requirement of its registration. Chile's Proposed Regulation therefore constitutes an effective ban on the use of registered trademarks."

Source 10

Description: Associacao Brasileira das Industrias de Alimentacao, "REF: Conulta Publica sobre la modificacion del Reglamento Sanitario de Alimentos para aplicacion de la Ley 20.606 sobre composicion de alimentos y su publicidad", 15 October 2014, p. 3. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: "Estas estipulaciones se confirmaron en varias comisiones establecidas en el marco de la OMC, donde se determino que un reglamento tecnico o norma crea obstaculos innecesarios al comercio, cuando las autoridades de un pals puede tomar otras medidas menos costosas o que viole en menor medida el comercio **multilateral para alcanzar el objetivo legitimo pretendido**. En opinion de la industria de alimentos, representada por la ABIA, las modificaciones propuestas al reglamento no son **medidas 'menos costosas' para resolver los problemas de salud enfrentados** por las autoridades chilenas, **pudiendo antes considerarse la implementación de politicas publicas que sean empiricamente mas efectivas, come los acuerdos voluntaries de reducción gradual de ciertos nutrientes**, entre otros."

Source 11

Description: FoodDrinkEurope, "FoodDrinkEurope comments on WTO notification of G/TBT/N/CHL/282 – Proposed Amendment to the Chilean Food Health Regulations, Supreme Decree No. 977/966", 26 September 2014, pp. 1, 4. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: "The European food and drink industries exporting and investing in production in Chile remain concerned about the disproportionate food labelling requirements and marketing constraints currently considered by the authorities of this country. The lack of conformity with Chile's WTO and bilateral commitments generate worries as regard the future access to the Chilean market for the European food and drink products.

For this reason, FoodDrinkEurope calls upon the European Commission and the EU delegates in Chile to intensify the dialogue with the Chilean Ministry of Health, possibly in cooperation with other commercial partners of Chile, in order to ensure that the European point of view is duly taken into account, as agreed under the EU-Chile Association Agreement, and the outcome of the regulatory process does not constitute an unnecessary and disproportionate hindrance to the EU-Chile trade and investment relation in food sector.

To support this request, the herewith note describes the nature and trade impact of the proposed requirements, **legal arguments speaking against the approach adopted by Chile**, as well as some examples of regulatory and voluntary measures applied in Europe that could constitute an alternative to the Chilean trade disruptive approach. On 24 January 2013, FoodDrinkEurope had shared similar concerns with the European Commission on Chile's Draft Amendment to the Sanitary Regulation on Food G/TBT/N/CHL/219.

[…]

The WTO TBT Agreement imposes an obligation on Chile to ensure that technical regulations be 'no more trade restrictive than necessary to fulfil a legitimate objective, taking into account of the risk non-fulfilment would create'. Considering the ways **the same objective** to provide food information to consumers is **pursued in Europe and some other countries with highly advanced food**

legislation, the approach adopted by Chile is by far more **trade restrictive** than necessary in light of the pursued objective."

Source 12

Description: Grocery Manufacturers Association, "Comments on the Proposal from Chile: Proposed Amendment to the Chilean Food Health Regulations, Supreme Decree No. 977/96", 21 October 2014, pp. 7-8. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: "The draft regulation also does not explain how the nutrient content limits were determined. In fact, in most cases, the nutrient content limits in the Proposed Regulation for sodium, sugar, fat and calories **far exceed science-based standards established by similar measures** in other countries, as demonstrated in the chart below. […] The nutrient content limits set forth in the Proposed Regulation were designed with the intent of providing the maximum nutrient and energy limits relevant for labeling obligations and restrictions on the advertising of food and beverages to children, in order to fulfill the requirements of Law 20.606 and ultimately, to lower the incidence of obesity and NCDs in the Chilean population. However, **no direct, causal links** have been demonstrated **between the marketing and advertising of food and beverages and rising rates of obesity**."

Source 13

Description: FoodDrinkEurope, "FoodDrinkEurope comments on WTO notification of G/TBT/N/CHL/282 – Proposed Amendment to the Chilean Food Health Regulations, Supreme Decree No. 977/966", 26 September 2014, p. 6. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: "The instruments provided for in the draft regulation are not harmonised with the guidelines issued by the Codex Alimentarius since the draft regulation establishes technical parameters for implementation of warnings in labelling concerning processed food but, the guidelines of the Codex Alimentarius with respect to nutrition labelling and use of nutritional and healthy statements or properties (guidelines CAC/GL 2-1985; CAC/GL 23-1997; CAC/GL 1 – 1979, and Codex Alimentarius-STAN 146-1995) do not establish declarations in labelling of foods with **'excess of...'** said nutrients, but only in case they contain low amounts or are exempt from them. **The warning message set forth in the draft regulation would therefore constitute a violation of article 2.4 of the TBT agreement**."

Source 14

Description: E-Mail from [FDA Official – International Policy Analyst], "Urgent Review: Mandatory labeling regimes in Latin America that include 'high in fat, sugar, and sodium' claims. (HFSS labeling) Need a policy discussion.", 19 December 2012. Document obtained through a FOI request to the U.S. Food and Drug Administration (FDA). On file with the authors.

Excerpt: "Folks,

I need your urgent consideration for a trade policy/public health issue. This issue is of very high concern to USTR, USDA, and the foods industry. ([colleague's first name], if I miss anything important please highlight for the group.)

A rising number of countries in Latin America are adopting marketing restrictions and labeling requirements on foods and beverages that can be considered 'high in fat, sugar (energy) and sodium' (HFSS foods). Ecuador, Chile and Peru are rapidly advancing mandatory labeling schemes related to HFSS foods. The rationale for the measures is to combat obesity. This issue needs to be teed up within FDA for a policy discussion and our position will likely require concurrence for Office of the

Secretary. This **issue is of high priority to USDA, USTR, and broadly across the pre-packaged foods industry** as it may have serious implications for food manufacturers and restaurants that market products in those countries and further implications for the region. USDA and USTR are under considerable pressure to raise industry's concerns about the new laws in Peru and Chile.

According to industry intelligence, implementing regulations could be put into effect (for Chile) as early as the end of 2012. Priority concerns from the industry include 1) departure from Codex 'low' claims use, 2) arbitrary nutrient thresholds not based on international standards (Codex has not set upper thresholds for the nutrients in question), 3) a 50 gram package or serving size could fundamentally change whether foods are in the 'high' group (Chile), 4) that some healthful foods will be deemed HFSS foods, and all HFSS foods will be cast in a negative light even though they can still be consumed in moderation as part of a healthy diet, and 5) that other less burdensome approaches that do not require product relabeling can provide similar information to consumers.

USTR and USDA are seeking guidance from HHS/FDA on how they can pursue the issue. In the U.S., in conjunction with our nutrition labeling regime, we follow the Codex model for labeling claims that include 'no added' and 'low in' claims when addressing 'negative' ingredients, such as 'no added sugar', 'low in sodium' or 'low in fat.' We also allow 'high in' claims to highlight 'positive' ingredients such as 'high in fiber.' Chile, Peru, and Ecuador's proposed measures would depart from the Codex labeling guidance for claims by highlighting the 'negative' ingredients **but there is nothing in the Codex guidance that prohibits them from adopting such a regime**.

As of right now, FDA has comments from CFSAN on the technical questions raised by Industry and compiled by USDA. These comments are attached. What we do not have is the proposed measures from any of the countries. We have been told that Peru's law reads like a technical regulation, however Chile's law is broad enough to allow their regulatory authorities some leeway. Generally FDA responses to proposed measures as it is easier to refute the science and assumptions than to develop policy positions without the details. I have described this problem to USTR and USDA, however industry is keen to slow down the proposed rule process and to allow for further discussion of its issues. At this point, it would not be possible for the U.S. to determine whether a proposed labeling regime would be misleading to consumer without the proposal regulation. FAS Santiago has advised that the nutrient limits will most likely be based the report made by The University of Chile's Nutrition and Food Technology Institute (INTA) which draws form the WHO FAO recommendations.

State of Play:
USTR, USDA, and State have been involved in this issue, primarily to seek clarification on the proposals, across the countries. Industry has been in contact with their counterpart trade associations in these countries to work with those associations to make sure their concerns are heard. USTR has advised industry to seek to address it directly with their counterparts while the USG comes to a position. USTR and USDA have been held to only asking transparency based questions such as when the proposed rules may be available and whether they will notified to the WTO and alerting those governments that our industry has concerns over mandatory labeling regimes in general.

USTR and USDA has developed two papers (one for Chile and the other for Peru) with talking points that they would like for us to review and clear which highlight industry's interest. Please see attached. (These are the original versions from FAS.) These papers give the flavor of what USTR is seeking to get information on, however these papers represent more of what they think we could clear than all the issues they would like to raise. The paper also provide further background to the specifics that we know on each of the countries' measure.

As I see it, here are the policy considerations on which HHS/FDA needs to
develop a position:
[portion withheld by FOIA, (b)5]
Please note that our responses (after our deliberations) to USTR's questions do not suggest that FDA supports the issue, but is intended to provide guidance to how they may approach the concern.

Expectations:
USTR and USDA are seeking our views on the policy considerations highlighted above and in the first attached document. They are also seeking our comments to the attached Peru and Chile papers. (Note: we have sent them earlier comments that focus on transparency and industry concerns about mandatory labeling regimes.) They would like our position before the end of the year.

Would the group be available to discuss this issue this week? Most of us are probably out next week. Please advise."

Source 15

Description: Consejo Mexicano de la Industria de Productos de Consuma, A.C. (ConMexico), 'Consulta Publica Modificacion del Reglamento Sanitario de los Alimentos Para La Implementacion de la Ley 20.606 Sobre Composicion de Alimentos y su Publicidad', (undated), p. 3. Entry to Chile's public consultation, obtained from Chile's Ministry of Health. On file with the authors.

Excerpt: "En este sentido, se considera que el etiquetado planteado en el reglamento ('Exceso de' y su representación gráfica) **violenta las disposiciones del Codex Alimentarius, al utilizar palabras y gráficos que pudieran inducir al temor o error a los consumidores**."

Source 16

Description: E-Mail from DG Trade to FoodDrinkEurope, "Chilean Legislation", 5 September 2012. Document obtained through FOI request to the European Commission. On file with the authors.

Excerpt*:* "We have been made aware of **this Chilean legislation, which establishes labelling and marketing requirements for foodstuffs**. Are you aware of it? Do you have any comments?"

Source 17

Description: E-Mail from FoodDrinkEurope to DG Trade, "Re: Chilean Legislation", 6 September 2012. Document obtained through FOI request to the European Commission. On file with the authors.

Excerpt: "**Thank you for your question**. **I have not been alerted by my members** but I will check with our Spanish association, as the one that is most likely having regular news from the Chilean market. Has it been notified to the WTO? Is there any deadline with which we need to comply?"

Source 18

Description: E-Mail from [Senior USTR official in charge] to [senior GMA employees], "Chile/TBT Committee Meeting", 23 March 2015. Document obtained through FOI request to USTR. On file with the authors.

Excerpt: "Could one of you call me today re: Chile Nutrition Labeling? Want to pass on what I heard from [senior Chilean trade bureaucrat] in my bilateral with him. [Senior GMA official], I also left you a VM on this. I'm at my desk for the next hour. Or you can call my cell at and I can jump out of other meetings."

Source 19

Description: E-Mail from [Senior GMA employee] to [USTR and USDA officials, including the USTR official in charge of this specific matter at the WTO], "Re: Chile/TBT Committee Meeting", 24 March 2015. Document obtained through FOI request to the Office of the United States Trade Representative. On file with the authors.

Excerpt: “Dear [Senior USTR official in charge],
Thanks again for updating me yesterday. I wanted to let you know I spoke to our Chilean industry counterparts yesterday and today, and while they do not have further information on the final text or any potential modifications, their contacts in the Ministry of Health indicated the regulation would enter into force in only six months. In addition to any substantive issues we will have to analyze, we hope the U.S. government would share our view that six months is an insufficient timeline for implementation and would raise this concern with the government of Chile.

Another thanks for sharing the news that Ambassador Froman will have an opportunity to raise concerns with DG Rebolledo this week, as well as opportunities for Ambassador Hammer to meet with appropriate authorities in Santiago. Given the urgent process of consideration ongoing in the office of the president, we believe USG contacts with officials in the cabinet (Ana Lya Uriarte), Segpres (Ministra Ximena Roncón; Patricia Poblete), and Ministry of Interior (U/S Mahmud Aleuy Peña y Lillo) are also critical.

Finally, we would be very grateful for any assistance Post can provide with seeking an industry meeting with Controlaria when the regulation is sent to them. At the risk of sounding like a broken record, thanks for your efforts. Very much appreciated.

Best,
[Senior GMA employee]”

Source 20

Description: Interview with DIRECON bureaucrat B. Interview recording on file with the authors.

Excerpt: “It’s an open process, because at the end they could do it from both sides if we are frank. If a private sector has some good linkages with the government, they could say ‘Hey, look, this is happening in another country, we are going to do it directly, but also raise the issue at the TBT Committee as well’.”

Source 21

Description: European Commission, DG Enterprise, “G/TBT/N/CHL/282 – Proposed amendment to the Food Health Regulations, Supreme Decree No 977/96”, 15 October 2014, p. 4. Entry to Chile’s public consultation, obtained from Chile’s Ministry of Health. On file with the authors.

Excerpt: “the EU would like to recall Article 2.2 of the TBT Agreement, which states 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: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information related processing technology or intended end-uses of products’.

The EU considers that the warning requirement provided for in the notified draft is **disproportionate and would welcome receiving the scientific studies** which have led the Chilean authorities to set the maximum levels of nutrients laid down in Table No 1 of the notified draft and to require the labelling of such warning statements. The EU also finds that the **proposed measure does not fulfil its objective of adequately informing the consumer** of healthy choices on food selection and intake.”

Source 22

Description: European Commission, DG Trade, "Mission Report, WTO/TBT Committee Meeting – 15-18 June 2015, Geneva Report on Specific Trade Concerns, on thematic sessions, and other matters". Document obtained through a FOI request to the European Commission. On file with the authors.

Excerpt: "Like in recent meetings of the TBT Committee, human health related measures were the main focus of the discussions under STCs. In this context, there was significant discussion on food labelling issues, in particular on health warnings on salt, fat and sugar content of foodstuffs (draft measures of Chile, Ecuador, Indonesia"

Source 23

Description: World Trade Organization, TBT Committee, "G/TBT/M/61 – Minutes of the Meeting 30-31 October 2013", 5 February 2014, para. 2.128. Available at: https://perma.cc/3W5S-G7LC.

Excerpt: "2.128. The representative of the United States associated herself with the previous speakers on Chile's regulation, including their view that Chile's proposed regulation could impose unnecessary barriers to trade. She also **noted the existence of alternate approaches, grounded in international standards, which could provide similar information to consumers in a less trade restrictive manner. Chile's regulation was not based on science and its labelling requirements could be misleading and stigmatize foods** that could be part of a healthy diet. Under the measure, imported foods would need to be labelled specifically for the Chilean market, raising their costs for Chilean consumers and making them less attractive than similar domestically produced goods. In this respect, she recalled that on 4 October 2013 the Chilean Ministry of Health's proposed regulation, currently under consideration by Contraloría General de la República, only marginally altered the requirements under the original proposal, ignoring alternative voluntary approaches and thus did not address WTO Members' underlying trade concerns. For instance, the regulation still required: (i) the use of 'STOP sign' shaped icons that would account for a significant portion of the package (7.5%); (ii) nutrient limits by food category that lacked a clear explanation of the scientific basis; (iii) category nutrient thresholds that required many 'healthy' imported foods to bears icons while Chile's traditional foods that were 'higher in fat, sugar and sodium' were exempted; (iv) front of pack icons that could mislead consumers or create fear about consuming food, even in moderation, as part of a healthy diet; and (v) insufficient time for implementation. The US asked Chile to delay finalisation of its regulation until these concerns were addressed."

Source 24

Description: Interview with MINSAL bureaucrat B (legal department), Santiago, 5 December 2017. Interview notes on file with the authors.

Excerpt: "[The MINSAL lawyer] started by apologizing that s/he could not help me very much. S/he told me that MINSAL's legal department was not involved in assessing the compliance of Law 20.606 or Decree 13 with international agreements. S/he also said that MINSAL's legal department was not involved in the public consultation about the decree. He said that all the compliance assessment (regarding international agreements) and the preparation of MINSAL's response to the public consultation were carried out by [MINSAL's Department of Nutrition and Food] in close cooperation with DIRECON and INAPI. Regarding compliance with WTO law, s/he stressed that [MINSAL's Department of Nutrition and Food] relied in particular on the advice and expertise of DIRECON. S/he said s/he did not know if DIRECON had written any formal assessment of Decree 13's compliance with the TBT agreement (similar to INAPI's assessment regarding IP law and the TRIPS agreement). […] Regarding the function of MINSAL's legal department, s/he said that they just assess compliance with national law. In some cases, the department had considered obligations under international

agreements (s/he cited one ILO agreement in particular), but in the case of this policy, they were not involved in it."

Source 25

Description: Interview with MINSAL bureaucrat A, Santiago, 7 December 2017. Interview recording on file with the authors.

Excerpt: "Pero nosotros, yo creo que, no sé si tan planificadamente, pero nosotros nunca entramos es esta discusión [del cumplimiento del acuerdo OTC]. Cuando decían esta [violación de la ley de OMC] acá nos decimos 'aquí los obesos ruedan por las calles', se van a morir, no nos importa esto. Incluso si la viola, no nos importa. Pero nosotros creemos que no violan ningún reglamento porque Codex dice esto, y la OMC dice esto. Este párrafo de Codex y de la OMC para nosotros fue súper importante. Pero tampoco entramos en esta discusión, porque Codex es un **acuerdo voluntario**, **no es un acuerdo a sangre**. O sea, no me voy a ir precia, presar a la cárcel por que violo este acuerdo. Y la salud de un país siempre, siempre, siempre está por sobre cualquier acuerdo. Entonces al principio la gente de Relaciones Económicas del Ministerio de Relaciones Exteriores, más el Ministerio Economía, más el Ministerio Agricultura, más el Ministerio de Hacienda estaban todos oponiéndose […] a morir. La única razón que tenían eran razones económicas. […] Este departamento [de MINSAL] es el que participa en todas las reuniones de Codex, de distintos temas. Y nos conocemos los principios generales, los conocemos bien. Y los principios generales de Codex dicen 'serán acuerdos, serán regulaciones, trataremos de hacer por consenso, que este facilita al comercio, *pero* nunca basta por sobre las razones de salud de los países'. **Este es lo que sabíamos, no nos dijo ningún abogado.** […] **En Chile hace muchos años que participamos en Codex. La persona que estaba en cargo de Codex durante muchos tiempo** que ya no está acá, el jubiló, es un mayor, [otro burócrata de MINSAL], el me enseñó a mi de Codex, y me enseñó eso, no sé porque lo sabía yo, pero **el me enseñó, y a otra persona en este departamento** […] que me ayuda en estas temas, que también se formó con [el otro burócrata de MINSAL] […]**. El y yo lo sabíamos,** bastaba con nosotros y todo que nos supiéramos y lo tuviéramos por escrito [el documento de Codex] y lo mostrábamos a la ministra, al subsecretario, al equipo, a los medios de prensa, y a nadie más usaste al argumento. […] No fue necesario [escribir un oficio como escribía INAPI por el tema de las marcas] por que una vez que lo mostramos y que además teníamos… por eso, yo siempre pienso que para defender este tipo de regulaciones lo más importante es tener los datos de epidemiologia nacional: obeso, muerto, infarto, hipertensión, diabetes. Además ayudó mucho este párrafo de Codex. Pero sinceramente no fue lo más importante. Cuando dijeron esto acá [incumplimiento de CODEX] nosotros dijimos 'no, porque Codex dice esto, pero también dice esto, y dice 'razones epidemiologias', aquí están, todas estas'. Entonces, la discusión no versó sobre el incumplimiento de los tratados internacionales, no que versó sobre los datos epidemiológicos. Nosotros nos llevaban por allá, y nosotros traíamos la discusión acá, y nos volvían llevar, y nos volvíamos a traer, hasta que se aburrieron. Se aburrieron de decir que era que los acuerdos internacionales y que los compromisos y que se viola el Codex. No. Eso no fue la principal discusión externa, interna [del gobierno] al principio fue. Pero, basta que uno le diga, **'perdón, no hay ningún acuerdo que este por sobre de razones sanitarias, y eso no lo digo yo, lo dice Codex'.** […] Entonces, eso no fue una gran discusión todo el tiempo. Al principio si, pero después no, porque nosotros no íbamos a ceder, no íbamos a ceder con.. y cuando fundamentamos, cuando hicimos los fundamentos en la consulta publica se hizo referencia a este articulo de Codex, que también lo tiene la Organización Mundial de Comercio. Entonces no fue una discusión como la de las marcas. La de las marcas si, porque la de las marcas está todavía no cien porcientos elucidada. […] Chile tiene un encargado internacional de Codex, que hoy día en la Agencia Chilena para la Inocuidad (ACHIPIA). […] En esta época, cuando fue la ley acá, la entidad era Salud, Salud estaba a cargo de Codex, y [el otro burócrata de MINSAL] que es el lo que digo. El estaba a cargo, por lo tanto el sabía En este época el era la entidad nacional a cargo de Codex. Después se creó la ACHIPIA, la Agencia Chilena para la Inocuidad, y ellos se hicieron cargo de Codex. Es un riesgo, porque es una agencia que depende de Agricultura, podría interesarle no decirlo [la interpretación correcto del Codex] […] Salud tiene que estar a tanto de todo."

Source 26

Description: Chilean Ministry of Health, "Consolidado de Respuestas A Observaciones Recibidas Durante Consulta Pública Nacional e Internacional Sobre Propuesta de Modificación del Decreto Supremo No 977/96, Reglamento Sanitario de los Alimentos, del Ministerio de Salud de Chile, Para la Ejecución de la Ley No 20.606, Sobre Composición Nutricional de los Alimentos y su Publicidad", pp. 6, 12. Available at: https://perma.cc/3EBR-ZRLT.

Excerpt: "**El Acuerdo OTC, específicamente su Artículo 2.2, permite la adopción de reglamentos técnicos por parte de sus Miembros, los cuales no restrinjan el comercio más de lo necesario para alcanzar un objetivo legítimo**, teniendo en cuenta los riesgos que crearía no alcanzarlo. En el caso de la regulación en estudio, **Chile ha adoptado un Reglamento Técnico que tiene por objetivo informar al consumidor, y no es considerado un obstáculo técnico al comercio, toda vez que su objetivo es legítimo**. […] Por último, cabe señalar que **no se incluye la definición de marca o marca comercial, ya que no corresponden al ámbito de aplicación de esta regulación**, y se rigen por la ley No 19.039 sobre Propiedad Industrial."

Source 27

Description: Interview with MINSAL bureaucrat A, Santiago, 7 December 2017. Interview recording on file with the authors.

Excerpt: "Quien nos ayudó fue la DIRECON, que es la Dirección de Relaciones Económicas. No nos ayudó, sino que lo revisó [la respuesta]. Nosotros lo hicimos, porque no eran muchos elementos jurídicos. Nosotros nos fuimos por los elementos técnicos. Cuando nos dicen 'es que los obstáculos técnicos al comercio', 'esto es salud', 'es que las disposiciones legales', 'esto es salud'. Entonces, la respuesta para la Organización Mundial de Comercio y todo lo que tiene que ver con obstáculos técnicos al comercio lo redactamos nosotros desde una mirada técnica y salud y los muertos y los obesos y los infartos y entonces, y salud. No nos metimos en este otro tema, salvo en un aspecto y eso es que nosotros nos conocemos y es que tanto Codex como las disposiciones de la Organización Mundial de Comercio tienen un párrafo que dice 'si, lo comercial es importante, pero la salud está antes', picamos este párrafo y lo pusimos al principio y de ahí la salud, salud, salud, salud, salud. Después, de todos maneras, lo miró el equipo de la Dirección de Relaciones Económicas, cuyo jefe en este tiempo era […] abogado, y él **le dio lo visto bueno**, él lo dio lo visto bueno." […] [Pregunta: Que fueron los argumentos de DIRECON para oponer el decreto?] "Nunca fueron los argumentos legales los más potentes. Los más potentes eran argumentos económicos. La [DIRECON] del Ministerio de Relaciones Exteriores es principalmente económica, y ellos ven los obstáculos técnicos al comercio como obstáculos desde la mirada económica, no jurídica. No habían muchos argumentos jurídicos, porque como casi todos los reglamentos internacionales de la Organización Mundial de Comercio, de Codex tienen este respeto, escrito, por los problemas sanitarias de países, y dicen, dicen, dicen, dicen, y después dicen 'pero, si hay un problema sanitario eso es lo que prima'. Nosotros 'pero aquí hay un problema sanitario'. Entonces no hubo mucho oposición con argumentos legales."

Source 28

Description: Interview with MINSAL bureaucrat A, Santiago, 16 November 2017. Interview recording on file with the authors.

Excerpt: "Después que hablamos, después de esta jornada [de la Asociación Chilena de la Propiedad Intelectual (ACHIPI)], [el burócrata de INAPI] dijo 'Tenemos que juntarnos' […] y nos juntamos con [el burócrata de INAPI], y ahí nos explicó que era él, que era el INAPI y dijo 'yo creo que **tienen muchas posibilidades de que esto resulte**', necesitamos juntarnos con el resto de INAPI, y ahí nos juntamos con su jefa en una reunión que fue más dura, y ella nos hizo preguntas, preguntas, preguntas, muchas preguntas […] y quedó conforme, y dijo 'si, esto **se puede defender**', y [el burócrata de INAPI] escribió este documento maravilloso, maravilloso […] escribió un primer documento que era,

como dice, o decimos, un ladrillo, pero a mi me encantó […] y de ahí vinieron como grupo, con [el director de INAPI] incluyo, al subsecretario [de Salud Publica] a presentarle este documento […] y [el director de INAPI] dijo 'disculpen que el documento sea tan difícil' y le dije 'ese documento es una **maravilla'** y yo lo había leído entero y lo había subrayado y le dije 'esto, esto era **todo que nosotros queríamos**, no nos pidan disculpa' […] y ahí entonces nos pusimos de acuerdo, y ahí fue que [el director de INAPI] de verdad dijo 'yo estoy de su lado'. […] [Sin el apoyo de la INAPI] habría sido terrible, terrible. El apoyo de la INAPI fue pero clave, clave, para el tema de las marcas. Porque si el tema de las marcas no subiera subsanado, todo sería marca y **el articulo que prohibida la publicidad estaría en el tacho**. […] La INAPI fue clave in términos de conocimiento por que **alguna de las cosas que nos dijo es que las leyes de propiedad intelectual, internacionales y nacionales, nunca ponen, o más bien, nunca dejan la política publica y la salud publica por debajo. Siempre la ponen por encima, y hay artículos de eso**. Entonces, el primer elemento clave que [el burócrata clave de INAPI] **nos dijo fue la propiedad intelectual deberá ser asegurada, *pero* los problemas de salud publica están siempre por encima**. Esta fue la primera clave, y **ese lo dice nuestra ley de propiedad intelectual y lo dice también la Organización Mundial de Comercio. Y eso fue clave, clave, clave.** [El burócrata de INAPI] también trabajó—Chile es observador de el problema que tiene Australia con la Organización Mundial de Comercio a propósito al tabaco, Chile es observador, y el abogado es [el burócrata de INAPI]. Entonces [el] ya tenía experiencia en el tema de tabaco y el hice suyo el tema de alimentos. Así, [el burócrata de INAPI] fue una persona clave. Súper clave. Clave, clave. […] Mi sensación es que [el burócrata de INAPI] estuvo de parte nuestra antes que se metieran los políticos detrás y creo que tuvo que ver con su rol en el tema de tabaco y que **él ha seguido el juicio de Australia línea por línea. Se lo sabe de memoria. Entonces tiene muchos argumentos**—y Australia esta ganando en eso, tu sabes que aunque no ha sido publicado, ya se filtró que le van a dar la razón a Australia—entonces el sabe todos estos argumentos, **y estos mismos argumentos sirven para este otro caso**. Entones yo te diría en la etapa inicial, inicial de la ley, el Senador Girardi clave. Pero en la etapa del reglamento hay otras personas clave, y dentro del reglamento el tema que tiene que ver con publicidad y marca, que ha sido muy relevante, INAPI clave, pero clave. Hubiéramos tenido el INAPI en contra habría sido otra escenario."

Source 29

Description: Letter from INAPI to MINSAL, "CARTA INAPI No 277 - Entrega opinión sobre normas de publicidad de 'alimentos altos en' dirigida a menores de 14 años en relación a la normativa sobre propiedad industrial", 7 December 2016. On file with the authors.

Excerpt: "7. La marca comercial en tanto derecho de propiedad industrial, está consagrada no sólo constitucionalmente sino que también en tratados internacionales de los cuales Chile forma parte, como el Anexo C del Acuerdo por el cual se estableció la Organización Mundial del Comercio, denominado Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio, conocido por su sigla en español 'ADPIC'. **Sin embargo, y al mismo nivel constitucional e internacional, se ha establecido que los derechos de propiedad industrial admiten limitaciones**. […] 9. En el ámbito internacional, **el artículo 17 del acuerdo sobre los ADPIC**, del cual Chile forma parte, **dispone**: '**Los miembros podrán establecer excepciones limitados a los derechos conferidos por una marca de fábrica o de comercio**, por ejemplo el uso leal de términos descriptivos, a condición de que en ellas se tengan en cuenta los intereses legítimos del titular de la marcas y de terceros.' 10. También en el ámbito internacional, **el párrafo 4 de la Declaración de Doha** relativa al Acuerdo de los ADPIC y la Salud Pública **establece que**: '4. **Convenimos en que el Acuerdo sobre los ADPIC no impide ni deberá impedir que los Miembros adopten medidas para proteger la salud pública**. En consecuencia, al tiempo que reiteramos nuestro compromiso con el Acuerdo sobre los ADPIC, **afirmamos que dicho Acuerdo puede y deberá ser interpretado y aplicado de una manera que apoye el derecho de los Miembros de la OMC de proteger la salud pública** y, en particular, de promover el acceso a los medicamentos para todos.' […] 17. En efecto, el hecho de que exista una marca que consista o esté asociada con una publicidad de aquella que ha sido limitada o prohibida, llevará inevitablemente a que esa limitación o prohibición alcance a la marca misma. Y no puede ser de otra manera, ya que **nadie podría invocar el uso de la propiedad industrial como una**

excusa para violar la citada limitación o prohibición legal respecto de la publicidad de productos 'altos en' cuando dicha publicidad esté dirigida a menores de 14 años. […] 20. Por consiguiente, **correspondería a la autoridad competente entrar a calificar**, en cada situación particular, **si el uso de las figuras en las situaciones referidas en la ley o el reglamento, estén o no registradas como marcas comerciales, constituyen o no publicidad de 'alimentos altos en', dirigida a menores de 14 años**."

Source 30

Description: Letter from Carlos R. Olarte and Ximena Forero (of the law firm Olarte Moure & Asociados Ltda. in Bogotá) to María Claudia Lacouture, Minister of Commerce, Industry, and Tourism of the Republic of Colombia, on behalf of Novartis de Colombia S.A., a subsidiary of Novartis A.G, "Request to open consultations under art. 11.1 of Law 1198 (2008) (Bilateral Investment Treaty Switzerland – Colombia", 21 July 2016. Document obtained by IP-Watch. Available at: https://perma.cc/4HJK-GCJG.

Excerpt: "CARLOS R. OLARTE, en nombre y reprcsentaci6n de Novartis AG. y XlMENA FORERO, actuando en representación de Novartis de Colombia S.A., nos dirigimos respetuosamente a su Despacho con el fin de dar alcance a la solicitud de apertura de consultas ('Solicitud de Consultas') presentada bajo el Articulo 11.1 de la Ley 1198 (2008), por medio de la cual se aprobó el Acuerdo de Inversión Bilateral suscrito entre Colombia y Suiza ('El Tratado'), radicada el 21 de abril de 2016.

En vista de la Declaración de Interés Público (DIP) por el Ministerio de Salud, a través de la Resolución 2475 de 14 de junio de 2016, el propósito de esta carta es reafirmar que (como se explicó en la carta de alcance radicada el 28 de abril de 2016) se continúa presentando un daño o perdida, como consecuencia de la interferencia del Estado colombiano, sobre el uso y disfrute de la inversión de Novartis, específicamente representada en la Patente colombiana No. 29.270. en violación de las obligaciones de Colombia en virtud del Tratado y el derecho internacional.

El artículo 11.1 del Tratado establece que 'si un inversionista de una Parte considera que alguna medida aplicada por la otra Parte es inconsistente con una obligación de este Acuerdo, y esto causa algún daño o perdida a él o a su inversión, el podrá solicitar consultas con mira a que se pueda resolver el asunto amigablemente.'

Como se mencionó en la Solicitud de Consultas presentada por Novartis, en este caso, la recomendación del Comité Técnico, seguida de la DIP emitida el 14 de junio de 2016, son medidas que: (i) son inconsistentes con las obligaciones que tiene Colombia bajo el Tratado y el derecho internacional; y (ii) causan 'un daño o perdida' a la inversión de Novartis.
[…]
Novartis no se opone al régimen general de control de precios farmacéuticos de Colombia. Sin embargo, tanto la rccomcndaci1in del Comité Técnico, como su adopción a través de la Resolución de DIP, son medidas específicas son incompatibles con la protección a la inversión que ofrece el Tratado.

Por lo anterior, y con e fin de resolver este asunto de una forma amigable, Novartis reafirma y, respetuosamente solicita la apertura formal de la etapa de consultas bajo el Articulo 11 .1 del Tratado.

El intento de Novartis de llegar a un acuerdo amigable en este asunto, se realiza sin perjuicio de sus derechos en virtud del Tratado, y sobre cualquier reclamación existente o futura que pueda tener en relación con su patente de Glivec en virtud del Tratado, el derecho internacional, o el derecho interno."