Globalization and health policy space: introducing the WTOhealth dataset of trade challenges to national health regulations at World Trade Organization, 1995-2016

Highlights

- Novel dataset of challenges to health regulations at the World Trade Organization.
- Data covers 250 challenges at Technical Barriers to Trade committee, 1995-2016.
- High-income members contested numerous public-health regulations.
- Several challenges concerned medical device safety and toxic chemical regulations.
- Challenges included highly contentious claims.

Abstract

Do international trade rules and agreements constrain health policy space? A multitude of global actors and institutions with different interests and power can shape national health policy, and trade rules provide one means through which to exert pressure on governments. Yet, the full scope of political pressure on health policy within the global trade regime is insufficiently understood, as previous research largely focussed on challenges to food, alcohol, and tobacco regulations and many studies used small-N case studies. This potentially overlooks other domains of influence and we lack an understanding of quantitative trends therein. In this article we introduce a novel dataset, WTOhealth, comprising all challenges to national health regulations at the WTO Technical Barriers to Trade (TBT) Committee between 1995 and 2016. The dataset is based on 1,496 pages of minutes from 71 TBT meetings. We describe how we developed this dataset and present an exploratory analysis of key patterns within the data. Our analysis shows that WTO members raised 250 trade challenges to health regulations between 1995 and 2016. 83.6% of challenges to low- or lower-middle income country (LMIC) members were raised by high-income countries (HICs). Many challenges centred on food (16.4% challenges), alcohol (10.4%), and tobacco (4.2%) policies, but a substantial proportion concerned other products, including toxic chemicals (9.1%), pharmaceuticals and medical devices (8.1%), machinery (7.8%), and motor vehicles (7.3%). This includes measures targeting medical device safety, increased access to pharmaceuticals, and reduced exposure to toxins harmful to both health and the environment. We further examine these challenges, finding that HIC members made claims with contentious scientific support. In short, diverse health regulations may be changed or delayed following contentious challenges at the TBT Committee. There is a need for further research investigating the nature and influence of WTO challenges to diverse health regulations.

Keywords

trade; globalization; political determinants of health; politics of health policy; policy space; health policy process; power asymmetries.

Introduction

The landmark 2008 report of the World Health Organization's (WHO) Commission on Social Determinants of Health demonstrated that the determinants of health span multiple, interacting domains, including daily living conditions, environmental hazards, and political empowerment (Marmot et al. 2008). Individuals and populations are affected by these determinants to differing degrees, leading to health inequities: 'systematic differences in health, between and within countries, that are avoidable by reasonable action' (Ruckert and Labonté 2012, 267). Nation states are typically responsible for taking such actions. But, with globalization, the freedom, scope and mechanisms that governments have to design and implement health policies, 'policy space', can be shaped by a multitude of global actors and institutions with different interests, resources, and power (Frenk and Moon 2013; Koivusalo, Schrecker, and Labonté 2009; Ottersen et al. 2014). For example, it is well-recognized that multi-national food corporations, aid organizations, and financial agencies can all influence national health agendas, priorities, and funding (Forster et al. 2019; Frenk and Moon 2013; Sridhar and Batniji 2008; Stuckler et al. 2012). As Kentikelenis and Rochford noted, "the global trade regime merits special attention" (Kentikelenis and Rochford 2019, 7).

Who sets and enforces the rules of global trade is critically important for population health and health equity (McNeill et al. 2017). Arguably, one of the most important arenas in which global actors define and uphold trade rules is the World Trade Organization (WTO), an intergovernmental organization that co-ordinates the rules of trade between countries. It currently has 164 member states, with 23 countries awaiting accession (WTO 2020a). WTO members agree to follow rules set out in a suite of agreements. These include, among others, rules requiring governments to reduce tariffs, limit unnecessary non-tariff barriers to trade, and uphold policy transparency. Governments often sign up to a suite of additional rules alongside these WTO agreements, including those in bilateral investment treaties and regional trade agreements, many of which incorporate and expand on WTO rules (Dür, Baccini, and Elsig 2014). Such rules are designed to promote trade, and they appear to be effective. For example, one study estimated that WTO membership associates with a ~171% increase in trade between member countries (Larch et al. 2019).

Although trade rules seem to promote trade, there are longstanding concerns that they could enable powerful global actors to wield influence on national health policies, particularly in less economically developed countries (Koivusalo, Schrecker, and Labonté 2009; McNeill et al.

2017). One set of rules that has been subject to extensive interest and debate are those set out in the WTO's Technical Barriers to Trade (TBT) Agreement (Lencucha, Drope, and Labonte 2016; O'Brien and Mitchell 2018; Thow et al. 2017). This Agreement seeks to minimize 'unnecessary' trade costs that are created by regulatory differences between states (Wijkstrom and McDaniels 2013). According to the rules, governments are required to submit any policy that may impact on trade to scrutiny by other WTO members. Other members can then challenge a policy that they deem to be inconsistent with the TBT Agreement, for example because the regulation creates trade costs that are considered to be higher than necessary to meet the regulation's objective, so-called 'unnecessary' trade costs. For regulations on harmful commodities, pharmaceuticals, and environmental toxins, for example, there is almost always at least one trade partner or corporate actor which will be disadvantaged and have strong incentives to voice opposition at WTO. Figure 1 summarizes this process.

[Figure 1 about here]

TBT rules and proceedings therefore provide one potential means through which powerful actors can pressure governments to change regulations that may protect populations from avoidable health harms (Hawkins and Holden 2016; Labonte and Schrecker 2007; McGrady 2011). Yet, the nature and full extent of political pressure on health policy within the global trade regime is not well understood, as research to date has focussed on food, alcohol, and tobacco regulations, primarily using small-N case studies. This may overlook other domains of influence and prevents an understanding of quantitative trends and patterns therein.

In this article we address these research gaps by introducing a novel, open-access dataset, WTOhealth, comprising all challenges posed to national health regulations at the WTO Technical Barriers to Trade (TBT) Committee between 1995 and 2016. The dataset is based on 1,496 pages of minutes from 71 TBT meetings. We describe how we developed this dataset and further present an exploratory analysis to identify key trends and patterns within the data, its potential to reveal new insights, and important areas for future research.

Background and previous literature

TBT Challenges, regulatory chill, and power asymmetries

Any WTO member can raise a 'Specific Trade Concern' or 'challenge' to question whether other members' regulations are consistent with the TBT Agreement at tri-annual meetings of the TBT

Committee (WTO 2015). A range of clauses in the TBT Agreement can be invoked in a challenge. For example, according to the Agreement governments must ensure that the policies do not create 'unnecessary' trade costs, as noted above. To demonstrate this, the burden of proof is on the member proposing the policy to show that their policies cannot otherwise be achieved using a less costly alternative. Members must further provide evidence connecting their proposed measures with expected health outcomes. This is particularly challenging when indirect evidence provides a strong indication that the measure is likely to be effective, but the policy being proposed will be the first of its kind anywhere in the world (Voon 2015). Furthermore, health regulations must follow pre-set international regulatory standards where applicable, and must not 'discriminate' because they pose larger costs on foreign producers compared with domestic producers, or on one foreign producer as compared with another.

The requirements in the TBT Agreement set the stage for members to challenge domestic health policies. As Hawkins and Holden (2016) argued, this creates a potential 'veto point' in the health policy process, whereupon governments attempt to block new policies that could protect health by invoking TBT rules (Hawkins and Holden 2016). Such challenges can be effective as they send a signal of opposition and of a potential legal dispute to follow, stoking fears of the political and economic costs of protracted legal proceedings. These fears can, in turn, lead governments to delay, alter or abandon a health regulation in order to avoid a dispute, so-called 'regulatory chill' effects (Tienhaara 2011).

The extent to which members use the TBT Committee to challenge national health regulations is, however, uncertain. In theory, the TBT Agreement grants WTO members adequate freedom to introduce desired health protections. The Agreement acknowledges that health is a legitimate policy goal and so contains specific exemptions which enable members to introduce health measures necessary for the "protection of human health or safety" (WTO 2015, 12). Yet as McGrady noted, there are uncertainties about the extent to which TBT rules inevitably "preserve sound public health measures" (McGrady 2011, 12). For example, it remains uncertain when and how health policies will be considered 'unnecessary barriers to trade' (McGrady 2011, 203). Furthermore, whether members acquiesce TBT challenges does not only depend on the technical-legal application of the Agreement's clauses. Political priorities also matter, and safeguarding trade can receive priority over health. In addition, TBT challenges are not necessarily subject to expert scrutiny to assess their validity, raising the possibility that claims

with ambiguous or even false basis in TBT rules are used to pressure governments to change or abandon their health regulations (Barlow et al. 2018).

A further uncertainty concerns the nature of the power dynamics which characterize informal TBT Committee challenges. One the one hand, TBT rules are seen as instruments that enable powerful, high-income country (HIC) members to pressure relatively less powerful low- and middle-income countries (LMICs) into changing, abandoning, or delaying policies that go against their political-economic interests (Hawkins and Holden 2016; McGrady 2011). Indeed, powerful, HIC members have an incentive to disproportionately challenge LMIC members among whom disputes are relatively costly or even unaffordable. These incentives are especially acute where LMICs are seeking to secure their political and economic relations with wealthy countries or lack the resources to devote to a protracted disagreement (Curran and Eckhardt 2017). On the other hand, some argue that rules-based WTO rules and meetings, like the TBT Committee, remedy this power orientation. This is because members raise and resolve grievances with reference to the technical applicability of the TBT rules, which are said to be neutral with respect to economic strength, rather than political preferences (Lindeque and McGuire 2007; McGrady 2011).

These uncertainties are compounded by the fact that TBT Committee challenges partially represent the demands of businesses, in addition to those of government. Many of the world's largest and most economically powerful businesses are headquartered in HICs (UNCTAD 2018). Yet, powerful international businesses registered in HICs may not only voice opposition by lobbying HIC governments. Today, many firms have globalized production, sales and supply-chains processes and are engaged in extensive lobbying efforts in LMICs (Delobelle 2019; Palmisano 2006). Multi-national corporations (MNCs) can pressure governments in LMICs to initiate challenges against health regulations on their behalf, and such challenges could be raised by LMICs against the HIC where they are headquartered, or against other third countries (LMICs or HICs) seeking to introduce measures that have a detrimental impact on their sales and profits (Eckhardt, Holden, and Callard 2016). For example, it was reported that the initiation of WTO proceedings against Australia's plain packaging legislation by five LMICs (Cuba, the Dominican Republic, Honduras, Indonesia and Ukraine[1]) followed extensive lobbying by multi-

[1] Ukraine later decided to withdraw its complaint in June 2015.

national tobacco firms, including Philip Morris International (Jarman 2013). It remains uncertain whether these dynamics extend beyond tobacco.

Previous literature

To date, a series of small-N case studies have identified that TBT rules were invoked by WTO members to challenge regulations targeting Non-Communicable Disease (NCD) prevention via reduced tobacco, alcohol, and ultra-processed food consumption in LMICs. For example, Thow et al. showed that HIC members challenged nutrition labelling schemes proposed by Thailand, Chile, Indonesia, Peru and Ecuador between 2006 and 2014 (Thow et al. 2017). Barlow et al. further found that several of these challenges were followed by implementation delays and consideration of alternative less effective measures (Barlow et al. 2018). Lencucha et al. (2016) and O'Brien and Mitchell (2018) similarly identified TBT challenges to novel tobacco and alcohol labelling policies.

A smaller number of studies has utilized larger-N samples to analyse the frequency and economic patterning of TBT challenges, but remained restricted in focus to NCD prevention measures. For example, Eckhardt et al. (2016) analysed all tobacco-related challenges and disputes at the WTO between 1995 and 2013, including at the TBT Committee. They found that tobacco control measures were discussed extensively, with opposition most frequently initiated by LMICs, likely acting in the interests of trans-national tobacco companies, against HICs. Barlow et al. (2018) similarly analysed all 93 challenges to tobacco, alcohol, and food regulations at the TBT Committee. They found that a vast majority (77.4%) of challenges against LMICs were raised by HIC members, whilst LMICs raised 49.4% of all challenges to HICs. Further textual analyses showed that some challenges were raised in response to domestic industry pressure.

Yet, the full scope, nature, and power dynamics which underpin trade challenges to health policy at the WTO is insufficiently understood, in part because there was a lack of systematic data available for mapping all trade challenges to all health policies at the WTO TBT Committee since its inception. Thus, much health policy research to date has necessarily focussed on a limited range of 'deductively' selected topics (Gerring 2008), i.e. challenges to NCD policies that have already received significant policy and scholarly attention. This may overlook other topics and issues deserving greater scrutiny, as can be identified via comprehensive and flexible data coding (Bradley, Curry, and Devers 2007; Stebbins 2001). Indeed, the TBT Agreement has been cited at

the formal dispute stage to contest regulations concerning a range of products that carry health risks, such as asbestos (Castleman 2002), suggesting that challenges at the TBT Committee may also be broader in scope than the NCD regulations analysed in previous studies.

Furthermore, without a comprehensive dataset of challenges to health regulations at the WTO, several researchers had to rely on small-N samples. It has not been possible with this approach to generate insights using quantitative methods, as these require large-N samples. For example, small-N samples preclude quantitative analyses mapping trends across health policy domains as well as statistical analyses of the determinants of challenges and their association with macro-economic and political characteristics (Gerring 2011). There is therefore a need for a systematically coded dataset to capture the full range of health policies discussed at the TBT Committee and to enable quantitative analyses of trends and patterns therein.

The WTOhealth dataset

To address these gaps, we developed the WTOhealth dataset of trade challenges to national health regulations at the WTO TBT Committee, 1995-2016. To construct the dataset, we coded all TBT discussions concerning national health regulations during this period to capture the full scope of policies challenged and associated political-economic dynamics. In this article, we introduce the WTOhealth dataset and further present an exploratory analysis to identify key trends and patterns within the data, its potential to reveal new insights, and important areas for future research.

The rest of the paper is as follows: first we describe how we developed the WTOhealth dataset. Then we present the results from an exploratory analysis of the data to illustrate the richness of the dataset and to identify issues requiring greater scrutiny. In the Discussion, we outline a series of topics for further investigation and the implications for health equity, health policy, and the political determinants of health. We further discuss the strengths and limitations of the dataset.

Methods

Data sources

The WTOhealth dataset contains the details of all regulations that governments stated were intended to 'protect human health or [human] safety', were notified to the WTO under members' transparency obligations, and were subject to a challenge by other members at the WTO TBT Committee between January 1995 and December 2016. We developed the dataset by

extracting and coding data from two sources: the WTO TBT 'Information Management System', which contained a list of all challenges to health policies, and the 'WTO Documents Online' repository, which held minutes from all TBT Committee meetings where these challenges were raised (WTO 2017b, 2017a). For our exploratory analysis of country-income patterns in TBT challenges we combined these data with country-income classification data from the World Bank World Development Indicators (World Bank 2018).

Figure 2 summarises our dataset construction procedures. In the first step, we screened the TBT Information Management System for all regulations notified to the WTO since January 1995. This database includes information about the regulation's original objective(s), as well as a unique ID for each regulation, the member that registered it, whether it was challenged at the TBT Committee, the names of any WTO members that challenged the regulation, the TBT rules they argued were contravened, and dates of the TBT Committee meetings where challenges were raised. From the Information Management System we further extracted data about all challenges (n = 527) that were raised through to the most recent date recorded in the Information Management System at the time of data collection, December 2016. We then restricted this list to challenges against policies with the registered objective of 'protecting human health or safety' (n = 250 regulations).

[Figure 2]

Next, we sourced the minutes of each TBT meeting where the health policies identified per the steps above were discussed. These minutes came from the WTO Documents Online repository (WTO 2017b). We linked trade challenges to corresponding minute discussions based on the unique TBT-Information Management System ID, which is referenced in both sources.

In the third step, we manually coded the description of the discussion in the minutes to identify the type of regulation being introduced, the products it applied to, the specific problems or issues with the regulation according to the country raising the challenge, and whether it had been proposed (but not ratified), ratified (but not implemented), or implemented. In total we manually extracted and coded this information using 1,496 pages of minutes from the 71 TBT meetings where the challenges were raised, 1995-2016.

To code the textual data, we used a four-step procedure, following recommended procedures (Miles, Huberman, and Saldana 2013). In step one we devised a preliminary 'start list' of codes based on a small sample of discussions. To ensure our product categorization corresponded to commonly used product definitions we drew from the nomenclature in the UN's Harmonized Commodity Description and Coding System Combined Nomenclature, 2007 edition (UN 2007). In the second step we coded extra sections of the data. We adopted a flexible approach by adding to or modifying the codebook where appropriate. Next we coded the remaining data, again modifying the codebook where necessary (step three). We further checked coding accuracy and reliability (step four) by randomly selecting ~10% (n = 25) of the challenge discussions and asking a Research Assistant at the lead author's host institution to code the data using the codebook. An ambiguity in coding arose in 1 case and was resolved by clarifying the codebook definitions.

Exploratory analysis

To analyse the data, we tabulated the frequency and proportion of trade challenges to health regulations across different products, measures, actors, and issues. We also describe in detail 6 challenges to medical device, pharmaceutical, and chemical regulations proposed by Brazil (n=2), China (n=2), Turkey (n=1), and India (n=1). These descriptions are intended to illustrate the ways in which TBT discussions are relevant for wide-ranging debates in health equity and policy, and may warrant greater scrutiny. We identified the 6 challenges using the following procedures. We first identified the health policies that were most frequently challenged at WTO. We then identified the top 2 topics which are relevant for contemporary health policy debates and have not been discussed extensively in the literature, i.e. we exclude NCD prevention policies targeting tobacco, alcohol, pre-packaged foods, and soft drinks (Lencucha, Drope, and Labonte 2016; O'Brien and Mitchell 2018; Thow et al. 2017). Given the emphasis on power dynamics between HIC and LMIC members by some scholars, we further focussed specifically on policies proposed by LMICs and subject to challenges by HICs (Curran and Eckhardt 2017; Koivusalo, Schrecker, and Labonté 2009; Ottersen et al. 2014).

Using these procedures, we identified two LMIC policy issues that were frequently discussed at the TBT, have received little attention in studies of the TBT and health policy space to date, and have been subject to important and highly contentious debates in the health policy literature more broadly: i) pharmaceutical and medical device safety and access regulations, and ii) chemical and e-waste regulations targeting reduced exposure to toxins (Mascarelli 2012; Wallach,

Ross, and Naci 2018; Wang, Zhang, and Guan 2016). We then identified the main arguments raised against regulations in these domains and conducted targeted literature searches to identify the significance of the specific issues discussed. We further used the health policy literature identified via these searches to explore whether the specific claims raised in challenges might be conducive to effective health policy.

Finally, we analysed country-income dynamics in TBT challenges by plotting trade challenge dyads and calculating the proportion of challenges to/ from countries in different income groups. We then estimated the reciprocity ratio: the proportion of challenges from HIC to LMIC members that are symmetrical because there is a corresponding challenge from the same LMIC to HIC member (Hanneman and Riddle 2005). We calculate the same figure for HIC to HIC members to compare reciprocity ratios across country-income groups and identify any asymmetries or imbalances therein. Descriptive analyses and data visualization were performed using R (version 1.1.453) (R Core Team 2020).

Results

Below we present the results from our exploratory analysis of the WTOhealth dataset. We first summarize trends in the number and scope of trade challenges, before describing in detail the specific issues raised at the TBT Committee, the health regulations being targeted, and the products concerned. We then outline specific arguments raised against pharmaceutical and medical device safety and access regulations, and chemical and e-waste regulations targeting reduced exposure to toxins. Finally, we illustrate the economic power dynamics that characterize challenges to LMIC and HIC members.

Trends in the number and scope of trade challenges

WTO members raised a total of 250 trade challenges to national regulations aimed at protecting human health or safety between January 1995 and December 2016. These challenges constituted 47.4% of all trade challenges (n = 527) in the period. Figure 3 plots the number of trade challenges to national health regulations per year. The number of challenges per year increased between 1995 and 2016. There was a sharp upturn in the number of trade challenges per year from 2002 onwards, and the number of trade challenges peaked at 30 in 2014. Although the number of WTO members also increased during the study period, the number of challenges per WTO member per year followed a similar pattern (see Appendix 1).

[Figure 3 about here]

Trade challenges were raised about measures designed to protect populations from the risks associated with diverse products. Many challenges centred on food (16.4% challenges), alcohol (10.4%), and tobacco (4.2%) policies, as identified previously. However, a substantial proportion of challenges concerned other products, including toxic chemicals (9.1% challenges), pharmaceuticals and medical devices (8.1% challenges), machinery and electrical appliances (7.8% challenges), motor vehicles (7.3% challenges), and cosmetics (7.3% challenges) and among others.

Figure 4 plots the specific measures that were challenged across a range of product categories. WTO members frequently challenged conformity assessment procedures used for determining whether an import meets a country's standards (28.7% challenges), product standards (e.g. minimum safety requirements) and product restrictions (28.5% challenges), and labelling regulations (22.7% challenges). WTO members most frequently challenged policies by arguing that the regulation was an 'unnecessary barrier to trade' (20.8% challenges), by requesting further information or a clarification about the regulation (19.1% challenges), and by questioning the rationale or legitimacy of the measure (14.5% challenges). Members further complained that the process of designing and notifying the regulation lacked transparency (13.7% challenges) and that the regulations were inconsistent with pre-defined international standards (13.5%) (see Appendix 2 for a full list of issues raised).

[Figure 4 about here]

Selected examples of member arguments against health policies

Debates about medical device, pharmaceutical, and chemical regulations proposed by Brazil, China, Turkey, and India illustrate the relevance of TBT challenges to contemporary health policy debates, beyond NCD prevention. Box 1 shows the outcome of our searches to explore whether these discussions were conducive to effective and safe health policy. These searches suggested that certain claims at the TBT Committee have questionable or contested scientific support.

[Box 1 about here]

First, at five TBT meetings between 2007 and November 2011, the US, Switzerland, EU and Canada challenged Brazilian legislation seeking to make medical product pricing strategies more transparent. The regulation required companies to disclose: the retail price of the product in Brazil and elsewhere, anticipated sales volumes, planned advertising and publicity costs, and a list of substitute products in the market, along with their respective prices (G/TBT/W/42). According to Brazilian documentation, the goal of the measure was to fulfil the government's obligations under the Brazilian Federal Constitution of 1988, which established that health is a right to all, guaranteed by State policies aimed at universal and equal access to healthcare and services (ANVISA 2006). At the TBT Committee, the US, Switzerland, EU and Canada argued that the measure was "burdensome and unnecessary" (G/TBT/W/42), and pressured Brazil to amend the pricing data requests due to confidentiality concerns raised by industry.

Second, in 2009, Brazil sought to introduce a new procedure for registering medical devices to be marketed within the territory (G/TBT/N/BRA/328). The regulation determined that a new type of certificate must be submitted when registering a product with Brazil's health regulation agency. Australia, China, the EU, Japan, Switzerland, Singapore and the US challenged the measure at the WTO TBT Committee on a total of 11 occasions between 2009 and 2013. The EU, Switzerland, Singapore, and Canada raised concerns that Brazil would no longer be accepting existing certification accepted elsewhere, whilst a US representative noted that, up until 2009, Brazil had been accepting inspection and quality system certification from the US Food and Drug Administration (FDA). The US delegation's opinion was that US medical device certification procedures "did not compromise safety or efficacy concerns" (G/TBT/M/48).

Third, in 2010 Turkey implemented new procedures for ensuring pharmaceuticals conformed to adequate standards following a large recall of unsafe products (G/TBT/M/50). The EU, Switzerland, and US challenged the measure at a total of ten TBT Committee meetings on between June 2010 and March 2013. They cited market access concerns and pressured Turkey to simplify the procedures, and either adopt measures used in their own countries, or revert to prior practices. Upon noting that the measure had been introduced following a product recall, a US official argued that "product recalls… should be viewed as a sign that the system to safeguard public health was working" (G/TBT/W/54).

Fourth, between 2014 and 2016, Canada, the EU, and the US raised challenges about China's attempts to increase the "security and effectiveness of medical devices" by specifying a list of

high-risk products requiring clinical trials in Chinese populations before approval, and a corresponding list of exemptions from this requirement (G/TBT/N/CHN/1022-1026; G/TBT/N/CHN/1029; G/TBT/W/67). By December 2016, WTO members had challenged the measure at 18 TBT Committee meetings. Members argued that that the list of devices exempted from additional clinical trials was "too limited" (G/TBT/W/64). Furthermore, they argued that China should accept the results from clinical trials conducted in other countries. For example, a Canadian representative cited a section of the regulation which stated that a focused clinical evaluation should be conducted in China for in vitro diagnostic products. The Canadian representative argued that this constituted "an unnecessary and duplicative clinical trial requirement for Canadian exporters that had received prior regulatory approval in other leading foreign jurisdictions" (G/TBT/W/64).

Fifth, in 2010 the US pressured India to reduce the scope of products included in a regulation designed to reduce hazardous 'e-waste' (G/TBT/N/IND/41), that is, electronic waste that can harm both the environment and human health via releasing toxic materials (Wang et al. 2016). At the WTO, the US stated that the measure would "jeopardize legitimate commercial interests" and requested India to delay its introduction (G/TBT/W/54). In 2011, the US also thanked India for reducing the scope of products included in the regulation from 20 to 6 in response to US requests (G/TBT/W/54). Whilst India noted on several subsequent occasions that it intended to introduce measures targeting the wider range of products, we did not find any further evidence that India had moved forward with these plans in the study period.

Finally, between 2006 and 2010, HIC WTO members challenged chemical testing regulations proposed by China (G/TBT/N/CHN/210; G/TBT/N/CHN/210/Rev1).[2] The regulations required a specific list of chemicals that had been safety-tested in other contexts to undergo additional testing in China. Members argued that this created an unnecessary duplication of testing (G/TBT/W/64). Later, in 2015 and 2016, the US argued against a subsequent Chinese regulation which required industry to demonstrate the safety of new chemicals brought to market using tests conducted in China (G/TBT/N/CHN/1170). The US official stated that the new measure would impose "significant administrative and compliance burdens on industry" (G/TBT/W/69).

[2] Reference indicates WTO Document reference in the WTO Documents Online Archive (WTO 2020b)

Country-income dynamics

The examples above illustrate how HIC members raised claims against LMIC member regulations aimed at protecting human health and safety. The HIC to LMIC country-income dynamic in the examples above represents a broader pattern in TBT challenges. Overall, HIC members most frequently raised (56.6% challenges) and defended (48.0%) challenges. HIC members were also much more likely than LMICs to reciprocate challenges from other HIC members. When we calculated the reciprocity ratio, we found that 30% of HIC to HIC member challenges were reciprocated. In contrast, just 8% of challenges raised by HIC members against LMIC members were reciprocated.

Figure 5 shows challenges raised by and against each WTO member, separated according to the income group of the members being challenged. The colour of each node corresponds to the income group of a particular country (challenged or raising a challenge) and the colour of each arrow corresponds to the income group of the country raising the challenge. Node size corresponds to the total number of challenges raised by each node to countries in the respective income group. Thicker arrows from one country to another also show a larger number of challenges raised by/ to the respective countries.

[Figure 5 about here]

The left panel of Figure 5 shows a predominance of thick green arrows from HICs directed to LMIC members. This illustrates how HIC members (green arrows) raised a large proportion of challenges to LMIC members (yellow nodes), and they often raised these challenges repeatedly to the LMIC members (e.g. India and China). Overall, HIC members raised 83.6% of challenges to LMIC members. The middle panel in Figure 5 shows a similar picture, although there is a greater diversity of line colours, reflecting the larger proportion of challenges raised by upper-middle income members to other upper-middle income members (32.0% challenges).

The right-hand panel in Figure 5 shows a different pattern: there is a larger number of thin arrows of from diverse income groups. This shows that challenges to HIC members were raised by members from a range of income groups. HIC members collectively raised most challenges to other HIC members (39.2% challenges), followed by LMIC and upper-middle-income country (UMIC) members in similar proportions (~30%). However, LMIC members were less likely to

raise challenges against HICs repeatedly, as repeated challenges were most often made from HIC members (e.g. USA) to other HIC members (e.g. the EU).

Discussion

Debates about health policy within the global trade regime have considerable potential to shape national health policy, especially where pressure is exerted by economically powerful actors. Here we present the novel WTOhealth dataset which provides an opportunity to ask and address critical questions about the political and economic forces which shape domestic health policy within the global trade regime and, ultimately, peoples' opportunities for living healthy lives (Frenk and Moon 2013; Koivusalo, Schrecker, and Labonté 2009; Ottersen et al. 2014). Which institutions play a role in shaping health policies, and where and how are efforts to alleviate health harms and associated inequities being subverted by political-economic interests? Who rules global health?' That is, whilst no single person, state or entity controls global trade, within trade institutions, which political actors are attempting to determine what policies are implemented? How and to what extent is power leveraged to shape policy in these institutions, and what policies and health issues are affected by these power dynamics?

The WTO is a key global institution in which these political-economic processes may yield influence on national health policies. However, in order to fully assessing these dynamics, it is necessary to first identify the full range of health policies discussed at the TBT Committee key trends and patterns therein. As an initial step, our data and analysis point to the previously hidden scope and frequency of trade challenges to diverse national health regulations at the WTO, and the economic power asymmetries which characterize them. By identifying all trade challenges to national health regulations at the TBT Committee, 1995-2016, we developed a rich dataset for studying whether and how economically powerful countries use trade rules to pressure other governments to change national health regulations and policies.

Three macro patterns emerged from our exploratory analysis of the WTOhealth dataset. First, a large and growing number of national health regulations are being challenged at the WTO due to their purported violations of trade rules. Second, LMIC members were disproportionately challenged by HIC members and were less likely to repeatedly raise challenges or to reciprocate HIC-member challenges via a counter-challenge. Third, certain arguments appeared to have contested support in health policy literature. Such arguments are being applied to a range of regulations. They include, for example, measures targeting medical device safety, access to

pharmaceuticals, and reduced exposure to toxins harmful to both health and the environment. In short diverse health regulations may be changed or delayed following contentious claims raised by WTO members at the TBT Committee. Furthermore, trade challenges to national health policies have economic power asymmetries and span diverse health regulations requiring further scrutiny.

Strengths and limitations of the dataset

The WTOhealth dataset has several important limitations. First, it is not possible to ascertain actual influence, only intent to influence. The WTOhealth dataset cannot determine whether and how every challenge corresponded to a change in domestic health policy. Such data are not available in WTO minutes and would require linking each TBT Discussion to national government documents. However, for country- or issue-specific specific studies, the WTOhealth dataset provides an important starting point.

Second, our description of 6 challenges identified contentious claims in TBT discussions, but it was not possible to codify the validity of all trade challenges in relation to WTO rules. Validity is not necessarily straightforward to ascertain, especially where governments introduce novel policy measures. Furthermore, challenge validity may not necessary determine whether challenges influence policy, as governments may be persuaded to change their policies in response to invalid claims made by powerful members with whom they wish to secure diplomatic and economic ties (Barlow et al. 2018).

Third, we coded a large number of challenges and sought to group regulations and the products they affected into meaningful categories. This may mask important differences which merit further scrutiny. Fourth, our dataset relies on accurate summaries of WTO members' statements in meeting minutes. It is possible that there may be additional details that are not captured in the minutes and hence our dataset too. Our dataset nevertheless provides the most comprehensive source of information to date about TBT challenges to diverse national health regulations.

Fifth, our dataset may not reflect the issues raised under recent, 'new generation' trade agreements, implemented since the mid-1990s, which have expanded the scope of trade protections provided under WTO rules (Friel, Hattersley, and Townsend 2015). Yet, investigations into the nature and influence of new generation trade agreements on policy has proven challenging, as discussions about trade rules citing these agreements are not publicly

available. The WTOhealth dataset may provide a partial insight into what is said elsewhere, as many WTO rules were incorporated into subsequent FTAs (Allee and Elsig 2015; Dür, Baccini, and Elsig 2014).

An agenda for research on trade and national health policy-making

Despite these limitations, the WTOhealth dataset begins to enable a systematic inquiry into whether, where, and how diverse health regulations are shaped and potentially subverted due to pressure from WTO members. As set out below, there are several of important questions to address through future research on this topic, much of which has now been made possible by the WTOhealth dataset. Research on these topics will provide broader insight into whether and how the political-economic interests of different actors, and global disparities in resources and power, shape the freedom, scope and mechanisms that governments have to design and implement health policies (Frenk and Moon 2013; Koivusalo, Schrecker, and Labonté 2009; Ottersen et al. 2014).

One major theme is to better understand what national interests motivate TBT challenges and explain specific trade challenge dyads, as well as the political and economic inequalities they may reflect. This could help reveal more generally how power asymmetries within and between countries might shape peoples' opportunities for living healthy lives, via WTO pressure. It will be fruitful to draw from diverse social science perspectives to explore different motivations for raising WTO challenges. As set out below, each of these motivations can be explored by using our data to scrutinise the precise claims being made and the way they are justified. Researchers may also wish to supplement these data with interviews and textual analyses of domestic policy documents.

For example, a rationalist economic approach suggests that TBT challenges from one WTO member to another may correspond to bi-lateral trade in specific products, reflecting governments' economic motivations to keep trade costs to a minimum and hence bolster trade and national economic prosperity (Hegre, Oneal, and Russett 2010; Jarman 2013; Kydd 2010). The WTOhealth dataset may be merged with product-level trade data from the UN to test this hypothesis by assessing whether bi-lateral exports of specific products, to a particular country, corresponds to the number of challenges by the exporter to that country, in that product domain (UN Comtrade 2020). Realist perspectives in international relations alternatively suggest that challenges to health regulations may be motivated by state security interests and a desire for

international political influence, as self-interested states compete for power and dominance within the international order (Ruckert et al. 2016). States may accordingly challenge health regulations at the WTO in order to maintain or expand political power in foreign jurisdictions. Challenge dyads may therefore be more common from HICs to LMICs which are important for the perpetuation of political dominance by HICs. This includes, for example, LMICs which are former colonies of HICs, or those which are fast growing and hence may pose a challenge to the dominance of HICs, including China (Drezner 2007). These hypotheses might be tested by drawing on existing studies of political conflict and by combining the WTOhealth dataset with relevant country-level political data, for example from the Centre d'Études Prospectives et d'Informations Internationales (Mayer and Zignago 2011).

Sociological and political-economy perspectives further indicate that TBT challenges may be the result of domestic pressure from wealthy, well-organized corporations, as they have the social, political, and economic advantages necessary to lobby governments and yield national political actions in their favour (Berry and Wilcox 2018; Mills 2000). As Hawkins and Holden have noted, for example, TBT rules create opportunities for businesses to 'veto' new policies aimed at protecting or enhancing public health by lobbying governments to raise challenges on their behalf (Hawkins and Holden 2016). Evidence to support this has been identified in case studies elsewhere (Barlow et al. 2018; Jarman 2013). Several WTO members also stated that a selection of their arguments against medical and pharmaceutical regulations reflected concerns raised by industry. Accordingly, trade challenges, including from LMICs, may correspond to pressure from MNCs to initiate challenges against health regulations elsewhere on their behalf; this is especially likely where these corporations have large investments in a given country (Eckhardt, Holden, and Callard 2016). Indeed, we observed that several LMICs did raise challenges against other LMICs and to HICs, which may be explained by MNC lobbying governments in LMICs. This hypothesis might be further tested by combining the WTOhealth dataset with data on investments by multinationals (e.g. from the World Bank and UN) and the extent of corporate capture and influence in a given country, as measured in the Corporate Permeation Index developed by Lima and Galea (Madureira Lima and Galea 2019).

A second major theme is to assess the nature and potential influence of challenges in specific regulatory domains. One topic of importance is environmental health. Our data identified that WTO members have challenged several policies designed to protect health via regulations targeting reduced exposure to environmental hazards and toxins, including unsafe chemicals and

hazardous e-waste. The WTOhealth dataset can be used as a starting point to conduct more detailed analysis to assess the specific environmental health policies that feature at the TBT Committee, key issues for WTO members, trends over time, and country-income patterns. This will identify whether and how TBT Committee debates may influence efforts to promote health equity via limiting pollution and chemical exposure, and the power disparities which characterize these discussions. As such, future analyses of environmental issues in the WTOhealth dataset will provide insights that are relevant for a growing body of literature the politics of environment policy and associated health inequities (Bohme 2015; Brisbois, Spiegel, and Harris 2019; Namin et al. 2020).

Future studies can also use our data to perform systematic assessments to grade the evidence behind members' claims. For example, our exploratory analysis found questionable scientific claims raised in challenges to Brazil, India, China and Turkey's health policies. By providing a resource that identifies the specific meetings when health policies were discussed and the relevant WTO meeting IDs, researchers can readily source the documentation needed to systematically evaluate the evidence base in such claims. This will help to ascertain whether WTO-pressure is conducive to best-practice, evidence-based health policies and regulations or whether, as our exploratory analysis indicates, such efforts are being undermined at WTO.

Finally, researchers may also use these data to map whether arguments at WTO feature in the ultimate wording in national policy documents. Given the difficulties in systematically tracking policy change across countries, assessments of such influence may most fruitfully be done by conducting case study analyses of specific policies. For such studies, our data provides a starting point to track the TBT meetings where policies are discussed and the scope of WTO members' demands for policy change.

Conclusions

Decisions concerning a wide range of health regulations may be resolved with recourse to issues raised at the TBT Committee and associated political-economic asymmetries. However, in order to fully assess these dynamics, it is necessary to first identify the full range of health policies discussed at the TBT Committee and key trends and patterns therein. Here we have introduced a novel dataset, WTOhealth, which provides the first comprehensive dataset of all trade challenges to national health regulations at the TBT Commtitee, 1995-2016. Our analyses of these data demonstrated that WTO members raised 250 trade challenges to diverse health regulations

between 1995 and 2016. Further examination of these challenges demonstrated that HICs have exerted extensive pressure on LMICs and that certain HIC member claims had contentious scientific support. These findings that the WTO is an important yet under-studied institution in which diverse national health policies have contested and potentially subordinated to other WTO members' political-economic interests.

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Figures

Figure 1. Summary of TBT challenges and WTO dispute escalation processes

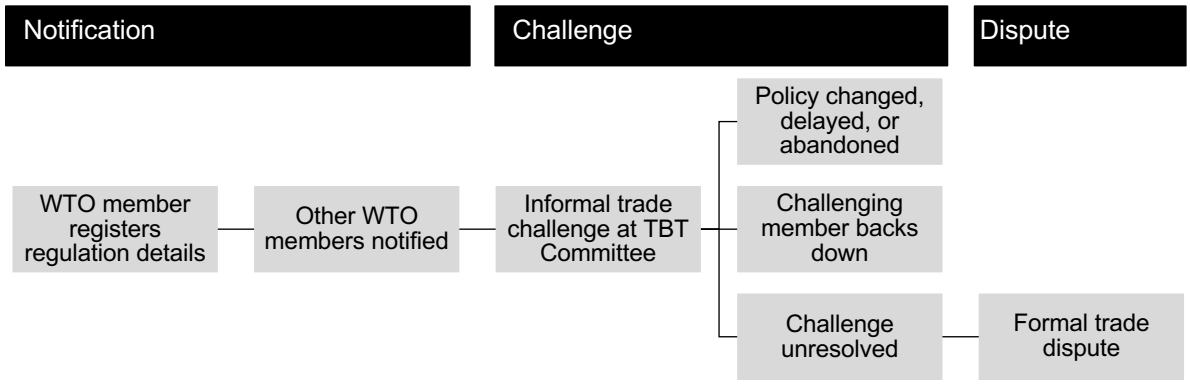


Figure 2. Dataset construction and coding procedures

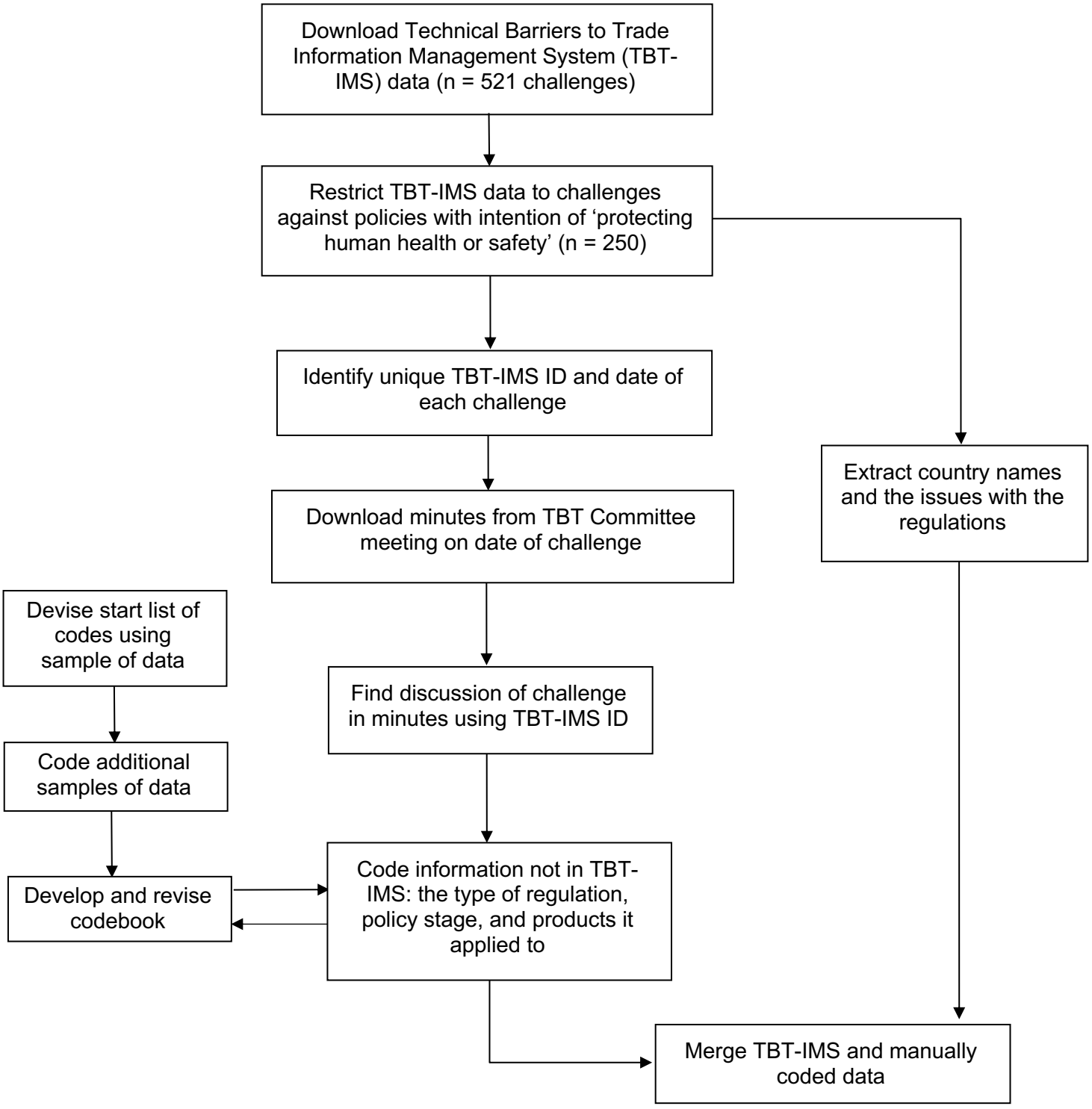
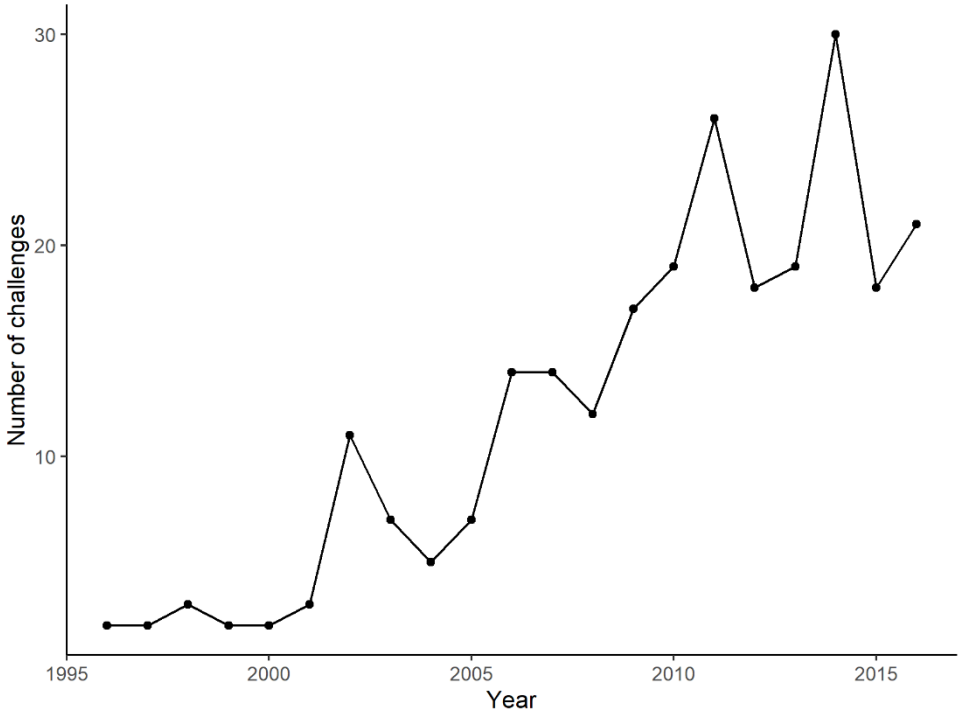
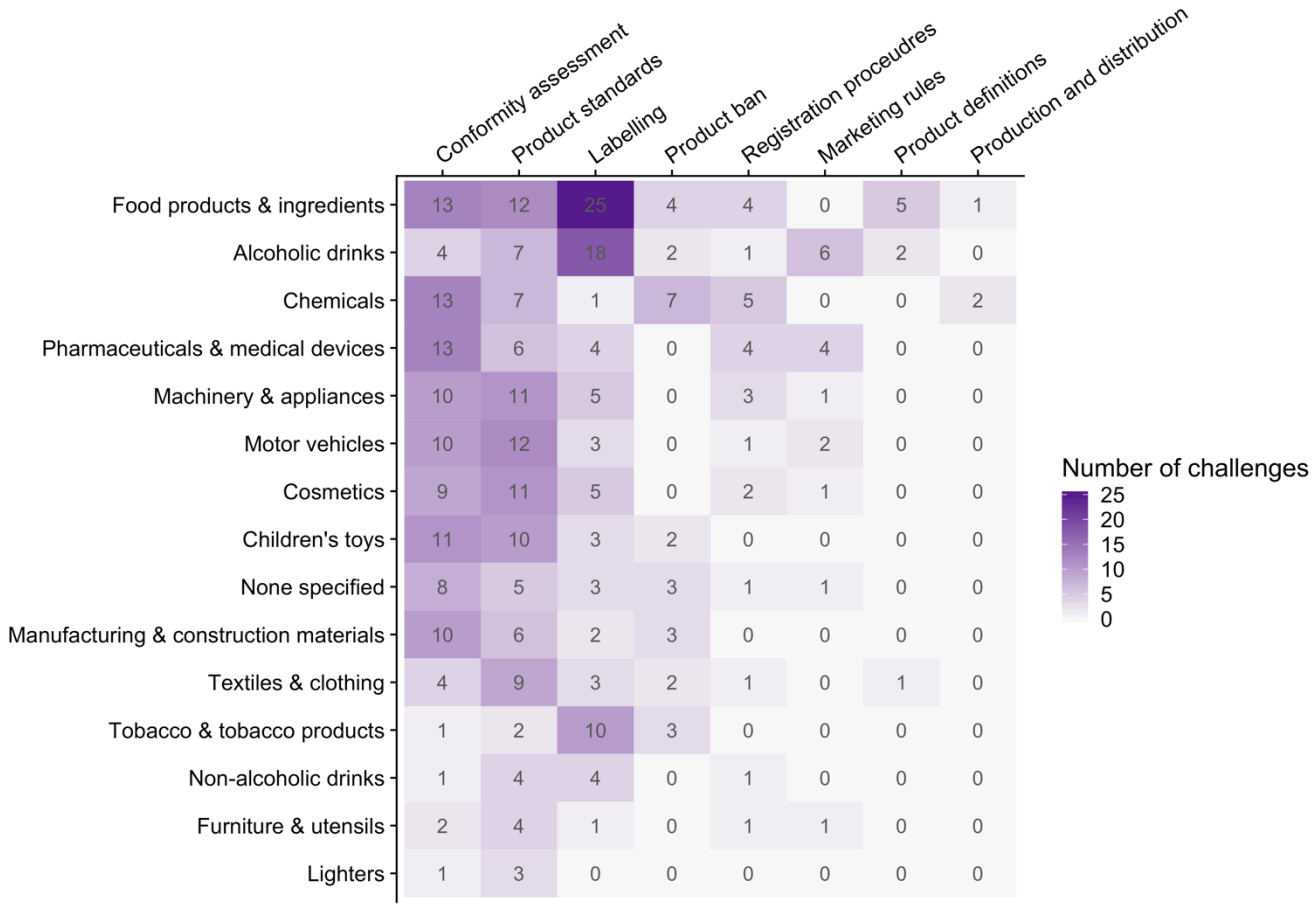


Figure 3. Trade challenges to national health regulations at the TBT Committee, 1996-2016



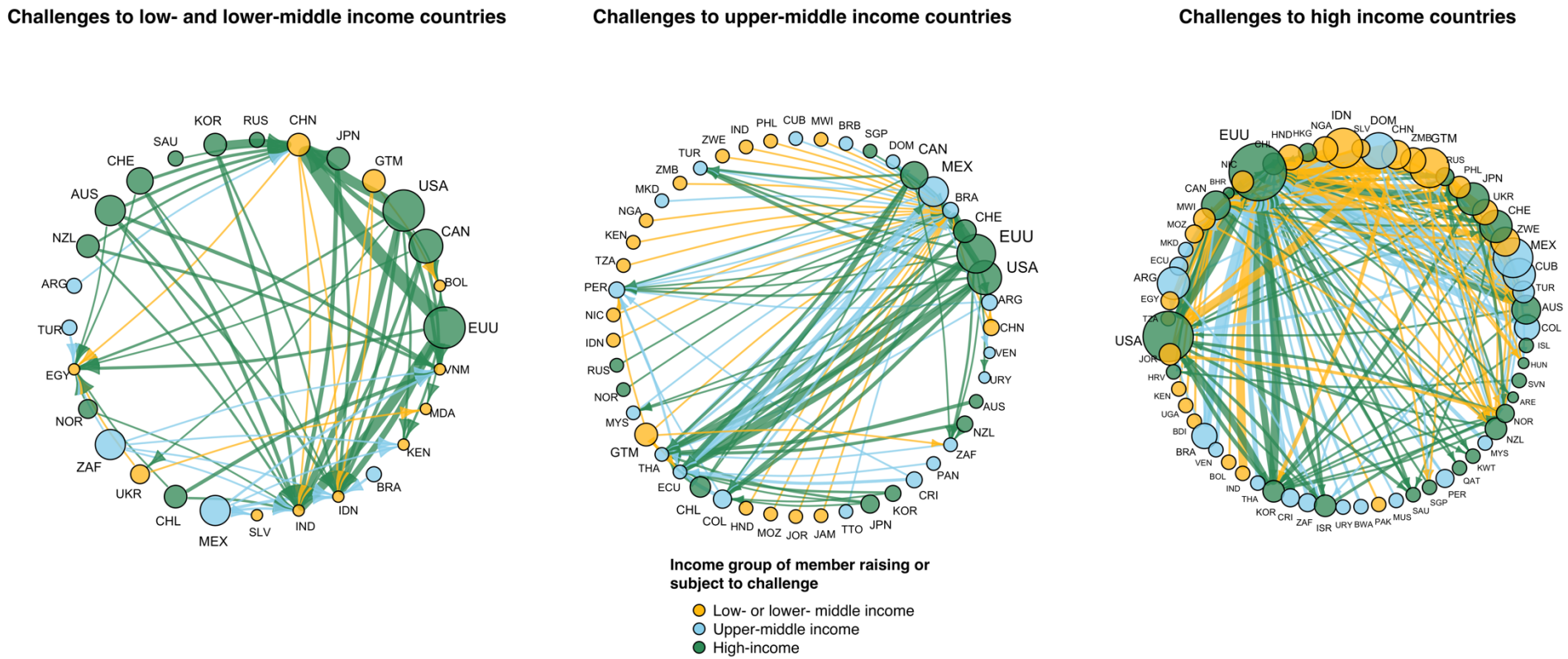
Notes: Figure shows number of trade challenges in each year at the TBT Committee to regulations registered with the objective of 'protecting human health or safety'. See Appendix 2 for figure showing trade challenges per WTO member.

Figure 4. Challenges to health regulations, by product category



Notes: See Appendix 3 for full product descriptions and Appendix 4 for full policy descriptions. Note that some challenges concerned regulations that applied to multiple products.

Figure 5. Challenge dyads, separated by income group of member being challenged



Notes: The figures show the challenges raised by and against each WTO member, separated according to the income group of the members being challenged. Node size corresponds to the total number of challenges raised by each node to countries in the respective income group. The colour of each node corresponds to the income group of a particular country (challenged or raising a challenge) and the colour of each arrow corresponds to the income group of the country raising the challenge. Line thickness corresponds to the number of challenges raised by/ to a country. The number and thickness lines of a particular colour in a network indicate the extent to challenges to members in an income group are dominated by challenges from WTO members belonging to a particular income group.

Boxes

Box 1. Are WTO challenges conducive to effective and safe health policy?

Pharmaceuticals and medical devices

In 2009, certain HIC members challenged Brazil's attempts to facilitate access to medicines through new pricing transparency regulations. They urged Brazil to abandon a regulation which required them to submit pricing information to the regulator, citing confidentiality concerns. They further argued that the regulations would limit sales and access to medicines in Brazil. However, a study by Vogler and Paterson illustrates several issues with this argument (Vogler and Paterson 2017). The pricing information requested is not necessarily confidential as such information is publicly available in other jurisdictions. Indeed, twenty-four EU countries use sales prices elsewhere as a cost-containment measure to control pharmaceutical prices and improve access to medicines. Furthermore, Vogler and Paterson identified that a lack of transparent pricing is often cited a barrier to equitable access to medicine, and argued that the claim that transparency requirements would reduce sales lacks robust scientific support.

Several HIC WTO members also challenged both Brazil's (2009), Turkey's (2010) and China's (2014) attempts to increase medical device safety and efficacy. In their comments at the WTO, the EU and US encouraged Brazil, Turkey, and China to relax safety protocols in line with existing standards adopted by HIC members, and to use certification and clinical evidence from other countries. However, the efficacy and safety of different medical device access and approval procedures is highly contested in the scientific literature, and evidence suggests that HIC member recommendations also carry health risks. For example, trial results can have limited applicability across populations, creating risks where devices are not adequately tested locally. Furthermore, contrary to the US officials' claims that the US protocols and certificates could be followed without compromising safety, some studies have concluded the inadequacy of existing safety and evidentiary standards, approval procedures, and product recalls in the EU and US are linked to excess patient injuries (Heneghan et al. 2017; Wallach et al. 2018).

Toxic 'e-waste' and chemicals

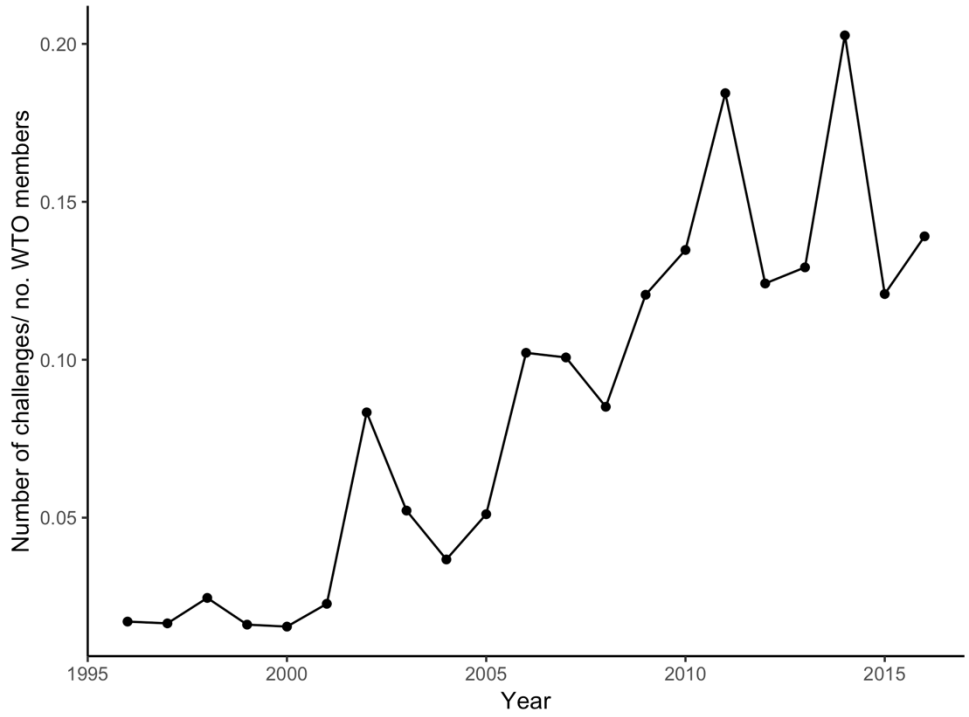
In 2010 the US pressured India to reduce the scope of products included in a regulation designed to reduce hazardous e-waste (WTO 2011:18). The WTO minutes subsequently noted that India had responded to US pressure by reducing the scope of substances covered. However, the US produces the largest amount of e-waste per year globally, estimated at 7.1 million tonnes in 2014, much of which ends up being exported to developing countries with weaker environmental standards, including India (Wang et al. 2016). Scientific experts have called for a comprehensive range of measures to address these harms (Awasthi et al. 2019). However, as the data show, India's attempts to mitigate these harms this faced significant opposition at WTO.

In 2006 and 2010, WTO members from HICs also challenged new Chinese chemical approval procedures which required new chemical risk-assessment tests to be conducted in China. WTO members argued that such tests were unnecessary as China could rely on tests performed elsewhere. However, contextual variation in the combinations of toxicants and in their interaction with local climates can affect the risks they pose (Gergs et al. 2013). Hence, relying on tests elsewhere may undermine chemical safety.

In addition, the US argued against Chinese requirements for industry to demonstrate the safety of new chemicals brought to market, an argument that reflected the US's broader approach chemical regulation, whereupon the burden of proof-of-safety for chemicals is placed on the state or an injured party rather than businesses proposing to sell a product (Mascarelli 2012; Silbergeld, Mandrioli, and Cranor 2015). This approach has been associated with increased exposure to toxic and pollution and other environmental hazards in the US (Brulle and Pellow 2006). The US therefore seems to have used WTO to pressure China into adopting an approach to risk assessment that has been associated with significant health harms.

Appendix

Appendix 1. Trade challenges to health policies at the TBT Committee, per WTO member, 1996-2016



Notes: Figure shows number of trade challenges in each year at the TBT Committee to regulations registered with the objective of 'protecting human health or safety', divided by the number of WTO members in that year.

Appendix 2. Issues raised in trade challenges to health policies at the TBT Committee, 1995-2016

Issue	**Number of challenges**	**Proportion of challenges (%)**
Unnecessary barrier to trade	168	20.8
Further information, clarification	154	19.1
Rationale, legitimacy	117	14.5
Transparency	111	13.7
International standards	109	13.5
Discrimination	75	9.3
Time to adapt	60	7.4
Unincorporated product and process method[a]	7	0.9
Special and differential treatment	6	0.7
Technical assistance	1	0.1

Notes: Note that members typically raise more than one issue against a given policy, hence the total number of challenges under each issue is larger than the total number of policies challenged (n=244). Process and production methods (PPMs) which leave no trace in the final product. Many countries argue that measures which discriminate between products based on unincorporated PPMs, such as some eco-labels, should be considered inconsistent with the TBT agreement. See Appendix 5 for full description of each issue.

Appendix 3. Product categories

Product	Description
Food products and ingredients	Food products and ingredients, infant milk formula
Alcoholic beverages	Alcoholic drinks e.g. beer, spirits, wine
Machinery and electrical appliances	Construction machinery, electrical devices, boilers, constructing machinery
Children's toys	Children's toys, pacifiers and dummies, and jewellery
Other manufactured consumer goods	Lighters, furniture and utensils
Chemical and industrial products	Chemicals, soap and surfactants, colouring and ink, fertilizers, and pyrotechnics
Motor vehicles	Fully assembled motor vehicles and their parts
Pharmaceuticals and medical devices	Drugs and medical equipment
Cosmetics	Make-up and other cosmetics (e.g. creams) and soaps
Textiles and clothing	Clothes and other textiles, footwear, leather
Manufacturing and construction materials	Steel, ceramic products, salt, sulphur, cement, wallpaper, wood products, wallpaper
Tobacco and tobacco products	Tobacco, tobacco flavourings, and cigarettes
Non-alcoholic drinks	Soft-drinks, fruit juices, infant milk formulae
None	No product specified (e.g. regulation applies to all products)

Notes: Products were identified from TBT-IMS database and TBT committee minutes, and then classified into different categories based on the World Custom's Organisation's Harmonized Commodity Description and Coding System, and aggregated into different product categories above.

Appendix 4. Policy categories

Measure	Description
Conformity assessment	The methods used to evaluate, test and certify whether a product meets the country's standards
Product	Product standards, including quality requirements, and limits to the use of certain materials
Labelling	Packaging and labelling requirements and restrictions
Product ban	Product ban applying both to importation and domestic production
Registration procedures	Regulations for registering a product for sale or production in a country
Marketing rules	Rules and restrictions on advertising and promotion of the product
Product definitions	Product definitions and classification requirements
Production and distribution	Regulations about production processes, transportation of goods, and disposal of waste

Notes: Policies were coded by first extracting the full description of the policy from the WTO TBT-IMS database and TBT Committee Minutes, writing a short summary of the measure, and then aggregating policies into common categories.

Appendix 5. Issue categories

Issue	Description
Discrimination	Concern about measure seen as discriminatory against foreign producers
Further information, clarification	Request for further information and clarification about the content and scope of the measure
International standards	Concern about consistency of measure with international standards (WTO rules state that measures should conform with international standards unless members can make a case that the standard should not apply; TBTs are immune from legal disputes if the measure conforms to a standard)
Time to adapt	Concern about the amount time given to adapt to the measure and the extent to which this length of time constitutes a 'reasonable interval'
Transparency	Concern about lack of transparency in the proposal, content of the measure, and its notification to the TBT/ WTO
Rationale, legitimacy	Concern about rationale and legitimacy of the measure
Unnecessary barrier to trade	Concern that the measure is unnecessarily trade restrictive i.e. an alternative measure could be introduced that achieves the stated objective but is less trade restrictive
Technical assistance	Concern about a developing country's need for technical assistance in developing standardizing bodies, assessment of conformity with standards, and the establishment and functioning of institutions and the legal framework to conform to WTO obligations
Special treatment	Concern that the measure does not take into account the special development, financial and trade needs of developing countries
Unincorporated product and process method[a]	Concern that the measure regulates a process or production method in which the method itself leaves no trace in the final product

Notes: Issues with a measure were registered by the countries who raise the trade challenge and were pre-coded in TBT-IMS database. The issue categories reflect the ways in which WTO members deemed a national health regulation to be incompatible with WTO rules according to the TBT Agreement.