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The politics of the commercial determinants of health

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The politics of the commercial determinants of health

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The 2018 public consultation on standardized packaging in Singapore: Analysis of policy actors' submissions

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After a public consultation in 2018, Singapore implemented standardized tobacco packaging as part of its portfolio of tobacco control policies in 2020, in compliance with Article 11 guidelines for implementing the World Health Organization Framework Convention on Tobacco Control. This study analyzed policy actors in opposition to standardized packaging in Singapore and their submissions to the public consultation. Policy actors were profiled, and their arguments were then coded and compared across submissions. Descriptive results were then summarized in a narrative synthesis. In total, 79 submissions were considered for final analysis that opposed plain packaging in Singapore. Thematic analysis shows that transnational tobacco companies and their subsidiaries in Singapore, along with a variety of policy actors opposed to the standardized packaging policy, have significant similarities in arguments, often with identical statements. Industry tactics included framing tobacco as a trade and investment issue; utilizing trade barriers, intellectual property, and investment rights; pursuing litigation or threat of litigation; mobilizing third-party support and citing policy failure. This study provides evidence that further contributes to the growing literature on commercial determinants of health particularly industry tactics and, in this case, where the tobacco industry and its local and global allies, utilize to counter evidence-based tobacco control measures.

KEYWORDS

standardized tobacco packaging, tobacco industry, Singapore, illicit trade, public consultation, commercial determinants of health

Introduction

The World Health Organization Framework Convention on Tobacco Control Guidelines for implementation of Article 11 encourages parties to the FCTC to consider standardized packaging by eliminating the effect of advertising or promotion on the packaging (WHO FCTC Conference of Parties, 2008). After Australia's success in defending its 2012 plain packaging law that was legally challenged by the tobacco industry, several countries followed suit, including France and the United Kingdom in 2017; New Zealand, Norway, and Ireland in 2018; Turkey and Thailand in 2019 and Singapore in 2020.

Singapore proposed to implement standardized tobacco packaging and launched a public consultation on the proposed measure in 2018 (Ministry of Health Singapore, 2018b). In February 2019, the Singapore Parliament passed the amendments to the Tobacco Act with the enabling regulations for standardized packaging to take effect after 1 year. On 1 July 2020, the Tobacco (Control of Advertisements and Sale) (Appearance, Packaging, and Labeling) Regulations 2019 was implemented after a 12-month transition since the standardized packaging regulations were announced in July 2019. The policy process leading to the announcement of the policy in July 2019 and enforcement in July 2020 is shown in Supplementary Figure 1. Buttressed by a public health goal to move toward a tobacco-free society, Singapore implemented strict tobacco control policies that have been lauded globally, from its high tobacco taxes, smoke-free environment measures, comprehensive ban on tobacco advertising, promotion, sponsorship, and display to its progressive raising of minimum legal age to 21 (Amul and Pang, 2018a). Singapore has already made substantive progress in reducing smoking prevalence from 18.3% in 1992 to 12% in 2017, the lowest in Southeast Asia (Amul and Pang, 2018b). The last decade, however, has shown stagnation in smoking rates, hovering between 12 and 14% (Amul and Pang, 2018a).

The tobacco industry has opposed plain packaging based on the key argument that it will increase the illicit tobacco trade (Lie et al., 2018; Crosbie et al., 2019; Gallagher et al., 2019). However, research evidence does not substantiate this argument (Joossens, 2012; Evans-Reeves et al., 2015; Scollo et al., 2015b; Haighton et al., 2017). Additionally, post-implementation studies in countries that have implemented plain packaging have shown that it has contributed to the reduction of smoking prevalence and facilitated the easier identification of illicit cigarettes from other countries (Brennan et al., 2015; Durkin et al., 2015; Scollo et al., 2015a; Wakefield et al., 2015). Moreover, analysis of the framing of the tobacco industry's public relations campaigns and public consultation submissions in various countries against plain packaging point to a strategic coordinated approach—with similarities in structure and content, lack of transparency, and quality of evidence—toward delaying the adoption of plain packaging (Hatchard et al., 2014; Evans-Reeves et al., 2015; Lie et al., 2018; MacKenzie et al., 2018). This analysis of policy actors' submissions to the public consultation on plain packaging in Singapore aims to contribute to this literature.

To examine the potential challenges from the tobacco industry to Singapore's implementation of standardized tobacco packaging in 2020, the study involves a systematic content analysis of documents submitted by policy actors to the 2018 public consultation process that Singapore's Ministry of Health conducted on its proposed plain packaging measures. It aims to answer the question: what strategies did the tobacco industry use to influence the policy on plain packaging in Singapore? The study contributes to strengthening the evidence base not only on industry framing of plain packaging and illicit tobacco trade but also on industry interference in Southeast Asia, with a focus on the case of Singapore.

Materials and methods

Inclusion and exclusion criteria

Submissions were reviewed according to a systematic screening process. Submissions were screened to only include submissions from policy actors (organizations and their representatives) and exclude submissions from private or non-affiliated individuals (see Figure 1). The submissions analyzed include only those that opposed plain packaging in Singapore. The policy actors were also grouped by their home country and classified by whether these countries have tobacco trade relations with Singapore. The policy actors were then mapped according to the type of entity: (1) whether it is a national or multilateral or civil society organization; and (2) whether it is tobacco industry-related or trade-related. This profiling of policy actors also included cross-checking with existing profiles of third-party lobby groups, astroturf groups, and front groups of the tobacco industry in the existing literature and on the University of Bath-Tobacco Control Research Group's TobaccoTactics.org website.

Thematic analysis

Arguments and policy recommendations were coded (deductive and inductive) and compared across submissions. The arguments that form the basis of the policy actor's position, as interpreted by the researcher, were then compiled, and analyzed according to four sets of known discursive (argument-based) and instrumental (action-based) strategies according to the policy dystopia model that inherently assumes that proposed policies are doomed to fail. These strategies include: framing tobacco—a health issue—as a trade and investment issue; utilizing trade barriers, intellectual property, and investment rights; pursuing litigation (or threat of litigation); and mobilizing third-party support (Crosbie et al., 2019). Other arguments identified through the policy dystopia model but cannot be categorized in the above four sets of tobacco industry strategies were also included in the thematic analysis using an inductive approach (Ulucanlar et al., 2016; Matthes et al., 2021).

The policy dystopia model offers a comparative framework with which to understand elements of the political power of corporations to influence public health policies. For this study, the model helps primarily to identify corporations' discursive power through ideas, norms and arguments (e.g., framing tobacco as a trade and investment issue, and utilizing trade barriers, intellectual property and investment

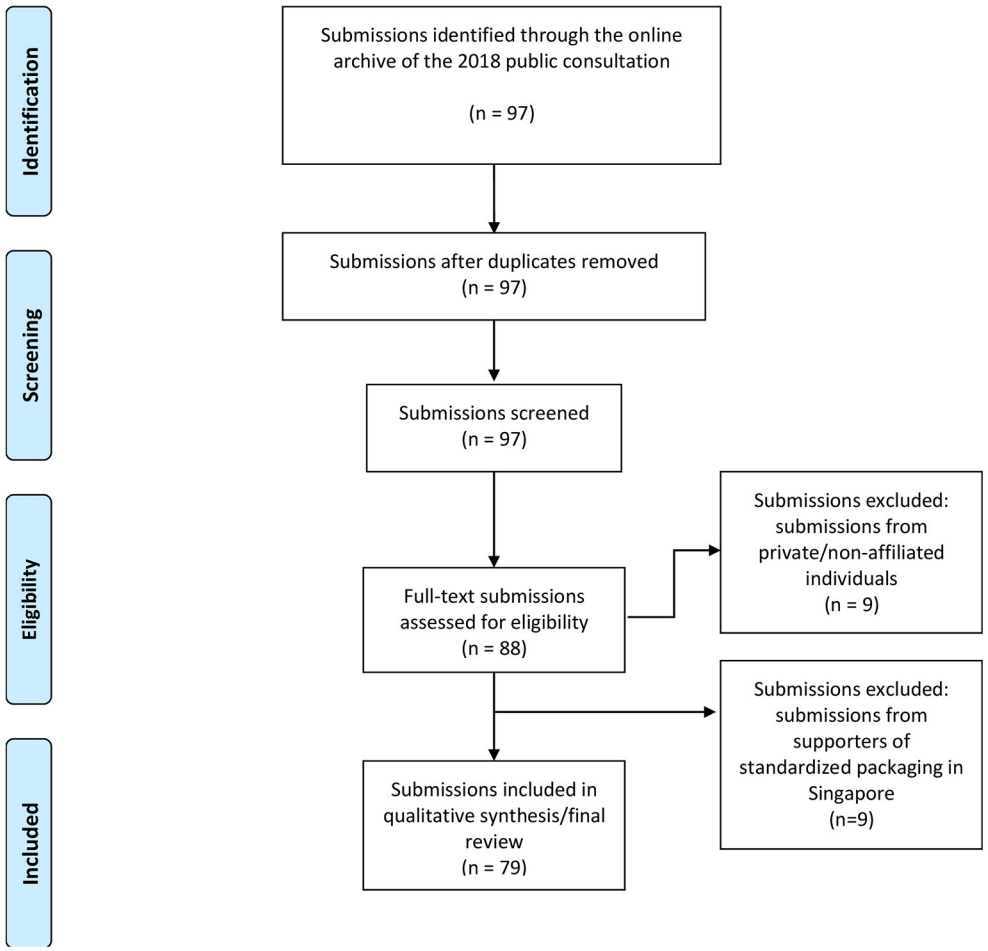

FIGURE 1
Selection criteria and study flowchart for qualitative analysis of stakeholder submissions.

rights) that not only promote corporate interests (a narrative that proposed policies are undesirable by deeming them costly and by dismissing potential benefits) but also project that these interests are synonymous to the state's interests (Fuchs, 2007; Mikler, 2018; Matthes et al., 2021). Political communication, which includes corporations' submissions to public consultations on public health policies, lends to the increasing perception of corporations as legitimate political actors (Fuchs, 2007).

Additionally, the model also helps to identify corporations' instrumental power through lobbying strategies (e.g., the threat of litigation, and mobilizing third-party support) that support the construction and dissemination of its narratives to convince policymakers to proceed with policy action or inaction that favor corporations' interests (Fuchs, 2007; Matthes et al., 2021). Instrumental power primarily plays out in state-corporate relations which includes directed and strategic efforts to directly lobby and influence states (Mikler, 2018).

While the model emphasizes discursive and instrumental power, a missing element of the policy dystopia model is the structural power of corporations. Such power is exercised by corporations through capital mobility (movement of investments and employment opportunities) and more recently, through self-regulatory mechanisms and public-private partnerships (Fuchs, 2007).

While no intercoder reliability analysis was performed as the researcher is the only coder, the researcher compared the identified strategies with existing studies of tobacco industry strategies globally to ensure the validity of the results (Amul et al., 2021; Matthes et al., 2021). The researcher also benefited from feedback on the identified strategies from three subject matter experts on a working paper that this study is based on.

The descriptive results were then summarized in a narrative synthesis. All submissions included in this study are archived on the Singapore Ministry of Health's website and are publicly available (Ministry of Health Singapore, 2018a). Ethical approval

was not necessary for the study which included only publicly available secondary data for analysis.

Results

The policy process and online submissions to the public consultation

Singapore's Ministry of Health received 97 submissions in total from February to March 2018 and June 2018. Only seven policy actors responded to the second round of consultations in June 2018, six of which had original submissions to the first round of consultations from February to March 2018. In total, 82 unique policy actors responded to the public consultation process. After screening, 79 submissions were considered for final analysis (see Figure 1).

Local and international policy actors that opposed plain packaging in Singapore

About 16 (22%) of the 73 policy actors that opposed the policy are based in Singapore, including three major transnational tobacco companies and their subsidiaries in Singapore, particularly Philip Morris International, British American Tobacco, and Japan Tobacco International (Japan Tobacco International, 2018) (see Supplementary Map). Singapore is the sixth top exporter of cigarettes globally (Food and Agriculture Organization , 2017a).

Fifty-nine policy actors opposed to standardized packaging are from 22 countries that Singapore has tobacco trade relations with (see Supplementary Table 1). About 14 policy actors that challenged standardized packaging were from the top 20 tobacco-producing countries, particularly the Philippines, the US, Indonesia, and Italy (Food and Agriculture Organization, 2018). Nineteen policy actors were from the top 20 tobacco-exporting countries, including the Philippines, the US, Indonesia, Belgium, Italy, the Netherlands, and Bulgaria (Food and Agriculture Organization, 2017b). Seventeen policy actors were from the top 20 exporters (by quantity) of cigarettes globally, particularly Indonesia, the Netherlands, Russia, South Korea, Switzerland, Ukraine, and the US (Food and Agriculture Organization, 2017b). Consequently, all these countries have tobacco trade relations with Singapore (see Supplementary Table 1). The Dominican Republic, one of the four countries (along with Indonesia, Honduras, and Cuba) which disputed Australia's plain packaging to the WTO, was also represented in the public consultations. Belarus, despite having no tobacco trade relations with Singapore, had at least two policy actors that contributed to the public consultations.

Type of policy actors that opposed plain packaging of tobacco products in Singapore

The typology of tobacco industry-related and trade-related policy actors was further expanded to include various subtypes of policy actors that were involved in the public consultation process including (1) foreign government offices; (2) industry associations; (3) manufacturers' and exporters' associations; (4) retailers' associations; (5) intellectual property rights groups; (6) industry interest groups; (7) consumer interest groups; (8) academic institutions; (9) research organizations, and; (10) professional associations (see Table 1).

Of the 73 policy actors that opposed standardized packaging in Singapore (Table 1 and Supplementary Map), only eighteen policy actors have previously been profiled in TobaccoTactics.org as third-party lobby groups, astroturf groups, and front groups of the tobacco industry, most of which are either funded by the tobacco industry or have ties to transnational tobacco companies as their listed members (see Table 2).

Policy actors' strategies to oppose plain packaging

Applying the classification of tobacco industry strategies against plain packaging by Crosbie et al., thematic analysis shows that transnational tobacco companies and their subsidiaries in Singapore, along with a variety of policy actors that submitted their opposition to the standardized packaging policy, have significant similarities in arguments, often with identical statements across different submissions (Crosbie et al., 2019). These rubber-stamped submissions often bear the same references, with signatories as the only difference across several submissions. Figure 2 shows the breakdown of the number of policy actors citing identical arguments.

Framing tobacco as a trade and investment issue

As a strategy to exercise discursive power, framing tobacco as a trade and investment issue is one of the most common arguments from the policy actors that opposed Singapore's standardized packaging proposals. The most prominent was that plain packaging will increase illicit trade, particularly smuggling contraband tobacco products, bootlegging, and the proliferation of counterfeit tobacco products. Illicit trade was cited by 64 policy actors, with about 88% of all policy actors against plain packaging. Figure 3 shows the various sectors and specific policy actors framing tobacco as an illicit trade issue.

TABLE 1 Policy actors opposed to standardized packaging in Singapore.

Type of policy actor	Name of policy actor (home country)
Foreign government: government institution/legislators	• Committee on Agriculture and Food, House of Representatives (Philippines) • Members of Congress (Philippines) • National Standardization of Indonesia (Indonesia) • Government of Indonesia, Directorate General of International Trade Negotiation • National Free Zones Council of the Dominican Republic (Dominican Republic)
Industry associations/chambers of commerce	• Singapore International Chamber of Commerce (Singapore) • Spanish Chamber of Commerce in the Dominican Republic (Dominican Republic) • International Chamber of Commerce Georgia (EU-Georgia Business Council) • International Chamber of Commerce Switzerland (Switzerland) • European Chamber of Commerce, Intellectual Property Rights Committee (Singapore) (2 submissions) • International Chamber of Commerce Malaysia (Malaysia) • International Chamber of Commerce, Business Action to Stop Counterfeiting and Piracy (France) • Malaysian International Chamber of Commerce and Industry (Malaysia)
Industry associations/business councils/business federations	• EU-ASEAN Business Council (Singapore) • EU-Georgia Business Council (Belgium/Georgia) • The Federation of Philippine Industries (Philippines) • Japan Business Federation (KEIDANREN) (Japan) • Association of European Businesses (Russia) • Economiesuisse (Switzerland) • Association of European Business (Belarus)
Manufacturers' associations/exporters' associations (external)	• Association RusBrand (Association of Branded Goods Manufacturers) (Russia) • Asociacion Dominican de Exportadores Inc (ADOEXPO) (Dominican Republic)
Intellectual property rights groups (external)	• ASEAN Intellectual Property Association (Philippines) • ANDEMA (Spanish Trademarks Association) (Spain) • UNIFAB (Union des Fabricantes) (France) • Trade-related IPR Protection Association (TIPA) (South Korea) • International Trademark Association (US) (2 submissions) • Istituto di Centromarca per la lotta alla contraffazione (Bergonzi) (Italy) • Japan Intellectual Property Association (Japan) • Property Rights Alliance (US) • Romanian Scientific Association for Intellectual Property (The Romanian Scientifically Association for Intellectual Property) • Association for Intellectual Property Protection (BelBrand) (Belarus)
Advocacy group/consumer interest groups (external)	• Hibernia Forum (Ireland) • Taxpayers Protection Alliance (US) (2 submissions) • Forest EU – Freedom Organization for the Right to Enjoy Smoking Tobacco in the European Union (Belgium) • Australian Taxpayers' Alliance/MyChoice Australia (Australia) • Ukrainian Economic Freedoms Foundation (Ukraine) • Consumer Choice Center (US)
National organization/retailer associations (external)	• European Travel Retail Confederation (Joossens, 2012) • Malaysia-Singapore Coffee Shop Proprietors General Association (Malaysia) • Australasian Association of Convenience Stores (Australia) • Spanish National Tobacco Retailers Association (Spain) • Federation of Sundry Goods Merchants Associations of Malaysia (Malaysia) • UK Tobacco Retailers Alliance (Joossens, 2012) (2 submissions) • Scottish Grocers' Federation (SGF) (Joossens, 2012) • Australian Retailers Association (Australia)

(Continued)

TABLE 1 (Continued)

Type of policy actor	Name of policy actor (home country)
Local organization/retailers/retailer associations	• Singapore Retailers Association (Singapore) • DFS Venture Singapore (Singapore) • Asia Pacific Travel Retail Association (Singapore)
Tobacco industry-related/licensed tobacco retailers (local)	• Group of licensed tobacco retailers (no formal association) (Singapore) • Group of licensed tobacco retailers (no formal association) (Singapore)
Aviation industry	• Changi Airport Group (Singapore)
Research organization (external)	• Minimal Government Thinkers (Philippines) • Institute of Economic Affairs (IEA) (Joossens, 2012) • Institute for Democracy and Economic Affairs (Malaysia) • Institute of Public Affairs (Australia) • Institute for Market Economics (Bulgaria)
Tobacco industry (local)	• Seng Lee Tobacco Factory (Singapore) • Japan Tobacco International (Singapore) (2 submissions) • Philip Morris Singapore Pte Ltd (Stanley Lai of Allen and Gledhill) (Singapore) • British American Tobacco Sales & Marketing Singapore Pte Ltd (Singapore) (2 submissions)
Tobacco industry (external)	• Japan Tobacco Inc (Japan)
Tobacco industry/tobacco manufacturers' associations (external)	• Mesa del Tabaco (Spain) • Adelta (Spanish National Manufacturers of Tobacco Products Association) (Spain) • Gabungan Produsen Rokok Putih Indonesia (Indonesian White Cigarette Manufacturers Association) (Indonesia) • PROCIGAR (Dominican Association of Cigar Manufacturers) (Dominican Republic)
Tobacco industry-related/packaging industry	• Amcor Specialty Cartons (of Amcor Group) (Singapore/Switzerland) • GD Machinery Southeast Asia Pte Ltd (a COEASIA company) (Singapore) • European Carton Makers Association (Netherlands) • Consumer Packaging Manufacturers Alliance (Joossens, 2012)
Tobacco industry-related/design/advertising agency	• Design Bridge (Singapore) • International Advertising Association (US)
Tobacco industry-related/non-profit organization	• Tobacco Institute of the Republic of China (Taiwan)

These policy actors cited reports of counterfeit plain packs in the UK and France, the increase of confiscated counterfeit tobacco, and the increasing proportion of illicit tobacco in Australia. The International Trademark Association, for example, noted that:

> *"Standardized packaging will benefit the trade in counterfeit products. By making packaging simple and uniform, the currently complex techniques of packaging will be cheaper to produce, lowering the barriers of entry for criminals to enter this market, while at the same time increasing profit margins for these actors* (de Acedo, 2018b)*."*

Moreover, the International Chamber of Commerce's Business Action to Stop Counterfeiting and Piracy alludes to enforcement issues noting the burden on police and customs authorities in dealing with "a growing illicit market and other unintended consequences" and citing that the authorities will have difficulty in differentiating illicit products from legal and duty-paid products (International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018). Similarly, the UK's Institute of Economic Affairs noted how plain packaging made "branded cigarettes only available on the illicit market" and lowered costs for counterfeiters (Institute of Economic Affairs, 2018). The US Taxpayers Protection Alliance also cited the Oxford Economics and ITIC's reports on increasing illicit tobacco trade in Singapore, despite the methodological issues of the report that have been flagged by tobacco control scholars and despite other sources reporting a decrease in Singapore's illicit tobacco trade (Williams, 2018a). The US Taxpayers Protection Alliance as well as the INDICAM (Italy) cited the KPMG study about the increase of illicit tobacco in Australia, noting that the "absence of branding removes numerous

TABLE 2 Policy actors profiled as third-party lobby groups, astroturf groups and front groups of the tobacco industry.

Type of policy actor	Name of policy actor
Tobacco industry-funded organization	Tobacco Institute of the Republic of China (Taiwan) (Eckhardt et al., 2017)
Industry associations	International Chamber of Commerce (Bialous and Corporate Accountability International, 2015)
Retailer associations	European Travel Retail Confederation (Joossens, 2012; Tobacco Control Research Group, 2020d)
	Tobacco Retailers' Alliance (Joossens, 2012; Tobacco Control Research Group, 2020l)
	Scottish Grocers' Federation (Joossens, 2012; Tobacco Control Research Group, 2020k)
Industry interest groups	International Trademark Association (US) (Bialous and Corporate Accountability International, 2015)
	Property Rights Alliance (US) (Tobacco Control Research Group, 2020j)
	UNIFAB (France) (Crosbie et al., 2019)
	BelBrand (Belarus) (Tobacco Control Research Group, 2020h)
Consumer interest groups	Taxpayers Protection Alliance (US) (Tobacco Control Research Group, 2020h)
	Australian Taxpayers' Alliance (Australia) (Tobacco Control Research Group, 2020h)
	Forest EU – Freedom Organization for the Right to Enjoy Smoking Tobacco in the European Union (Belgium) (Tobacco Control Research Group, 2020e)
	Consumer Choice Center (US) (Tobacco Control Research Group, 2020a)
Research organizations	Institute of Economic Affairs (Joossens, 2012; Tobacco Control Research Group, 2020f)
	Institute of Public Affairs (Australia) (Tobacco Control Research Group, 2020g)
Tobacco industry-related groups	Amcor (Singapore/Switzerland) (Tobacco Control Research Group, 2020i)
	European Carton Makers' Association (Netherlands) (Tobacco Control Research Group, 2020c)
	Consumer Packaging Manufacturers' Alliance (Joossens, 2012; Tobacco Control Research Group, 2020b)

protections in place to prevent counterfeiting and makes illicit products relatively less unattractive compared to legal products (Bergonzi, 2018; Williams, 2018a)." Additionally, Malaysia's Institute for Democracy and Economic Affairs argued that plain packaging will lead to an increase in the consumption of illicit tobacco and "forces consumers to make uninformed decisions and forces them to enter the illicit black market in search of goods (Salman, 2018)." Furthermore, the International Advertising Association also claimed that Australia's plain packaging facilitated counterfeits and bootlegging without any decrease in smoking rates (Szulce, 2018). The Australasian Association of Convenience Stores grossly exaggerated how the market for illicit tobacco has "spiraled out of control" and "coincided directly with the increase in the regulation governing the sale of legal tobacco products (Spanish National Tobacco Retailers Association, 2018)." This was also cited by Amcor Specialty Cartons, noting how plain packaging can lead to "misinformation of customers by removing the ability of consumers to authenticate and differentiate between legitimate and illicit tobacco products (Czubak, 2018)."

Six policy actors linked illicit trade to tax evasion and the "tax gap" from the related losses in government revenue from excise and customs duties due to price competition and down trading (Heng, 2018a; International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018; Japan Tobacco, 2018; Japan Tobacco International, 2018; The Romanian Scientifically Association for Intellectual Property, 2018; van Schaik, 2018; Zimmerman and Michael, 2018). For example, the UK Tobacco Retailers Alliance noted how plain packaging will "exacerbate the tax gap," which they estimated to be at GBP 3.1 billion in lost revenue (Khonat, 2018a). Moreover, the Taxpayers Protection Alliance (US) cited AUD 1.5 billion in lost revenue due to illicit tobacco trade in Australia that they attributed to plain packaging measures (Williams, 2018a). Five policy actors—including the International Trademark Association, Consumer Choice Center, France's Union des Fabricants (UNIFAB), and the Institute of Public Affairs further pointed out the economic costs of illicit trade mostly for governments and businesses (Davidson, 2018; de Acedo, 2018b; Roeder, 2018; Sarfati- Sobreira, 2018).

Eight policy actors—including Japan Tobacco, the European Chamber of Commerce in Singapore and the International Chamber of Commerce, and associations of licensed tobacco retailers in Singapore—linked illicit tobacco trade, purportedly fueled by plain packaging, with a growth in organized crime, including human trafficking, drug trafficking, money laundering, and terrorism financing (Hin et al., 2018; International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018; Japan Tobacco International, 2018; Khonat, 2018a,b; Roeder, 2018; Seah, 2018a,b; Zimmerman and Michael, 2018). For example, the Taxpayers Protection Alliance (US) specifically highlighted smuggling as an issue, citing

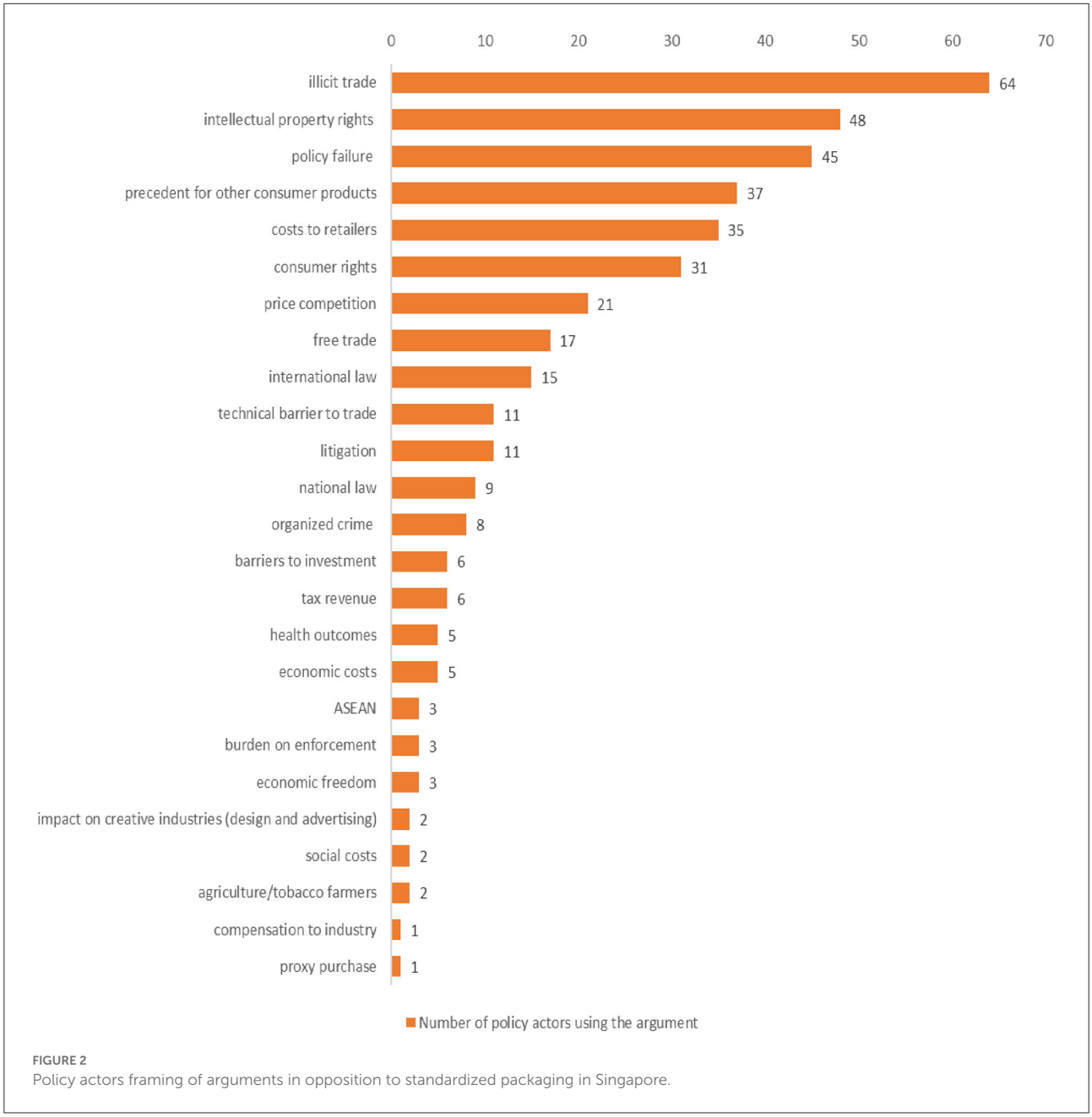

FIGURE 2
Policy actors framing of arguments in opposition to standardized packaging in Singapore.

the US State Department and US House of Representatives Homeland Security Committee Report on how illicit tobacco trade provides a source of financing for international terrorist networks, narcotics, and human trafficking (Williams, 2018a). At the local level, licensed tobacco retailers in Singapore also saw plain packaging as a "security threat" with the rise of gangs involved in smuggling cigarettes (Hin et al., 2018; Licensed Tobacco Retailers, 2018).

Moreover, six policy actors, particularly Japan Tobacco International and its parent company Japan Tobacco, the Japan Business Federation, the International Chamber of Commerce Switzerland and the International Chamber of Commerce Joint Task Force on Labeling and Packaging Measures, BelBrand, the Association of Dominican Cigar Manufacturers (PROCIGAR) also framed plain packaging around Singapore's investment potential, citing Singapore's reduced appeal for investment and innovation, which in turn "undermine a country's international reputation as a good place to do business (Gough, 2018; Hara, 2018; Japan Tobacco, 2018; Japan Tobacco International, 2018; Kelner, 2018; Pletscher, 2018; Taipov, 2018)." Citing reputational damage through alleged violations of investment rights is a known discursive strategy that has been used by

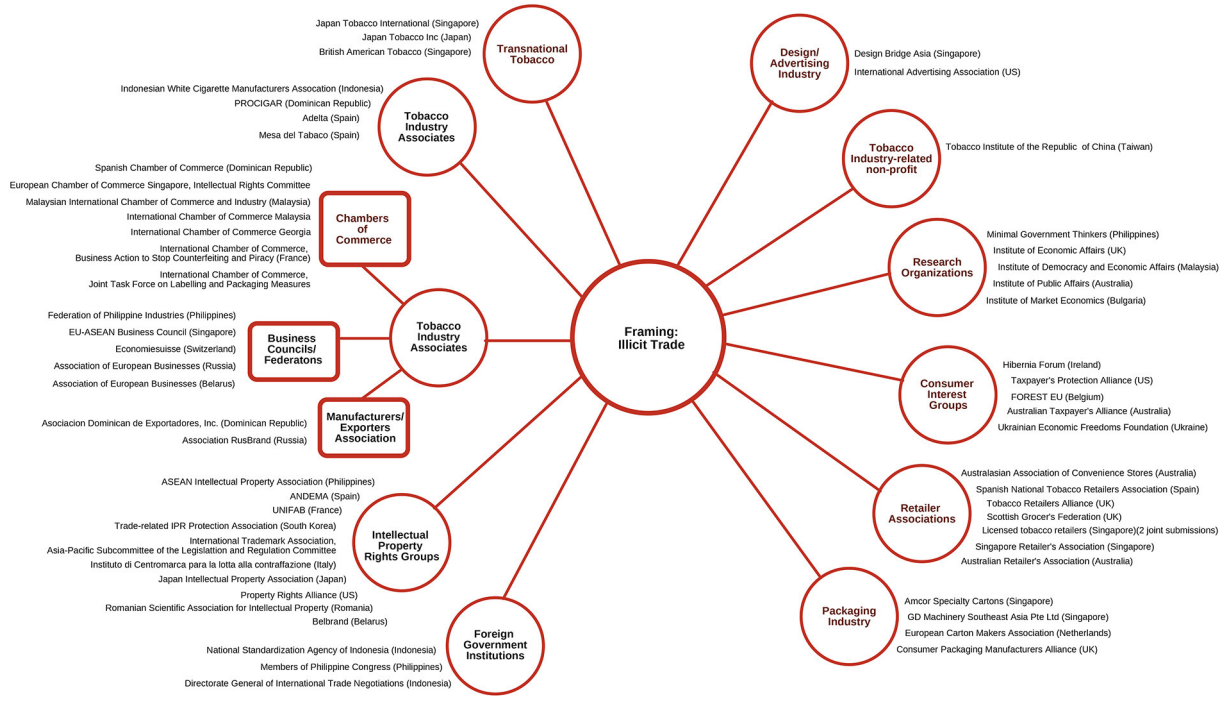

FIGURE 3
Policy actors that framed plain packaging as an illicit trade issue.

the tobacco industry and its coalition of allies to block plain packaging measures in other countries (Crosbie et al., 2019). It also alludes to the structural power of corporations with reference to the "ease of doing business index" where the World Bank ranks states according to the context for conducting business and is now being reformulated as the "business enabling environment."

Thirty-four policy actors – including consumer groups like Consumer Choice Center, Ukrainian Economic Freedoms Foundation, Forest EU and various retailer associations like the Australasian Association of Convenience Stores, Malaysia-Singapore Coffee Shop Proprietors General Association, Spanish National Tobacco Retailers Association, Asia Pacific Travel Retail Association, and European Travel Retail Confederation exerted that standardized packaging negatively affects consumer rights and encroaches upon economic freedom with the deprivation of consumer choice and consumer protection, and increased consumer risks with the increase in illicit trade (Barrett, 2018; Mong, 2018; Périgois, 2018; Roeder, 2018; Rogut, 2018; Spanish National Tobacco Retailers Association, 2018; Spinks, 2018; Zablotskyy, 2018).

However, such recommendations around strengthening measures to suppress illicit trade, while worthwhile in themselves, are not necessitated by vulnerabilities specifically created by adopting plain packaging measures, despite the claims by the tobacco industry and its coalition of third-party groups of allies.

Despite tobacco being a health issue, only five policy actors – including the Tobacco Institute of the Republic of China (Taiwan), Amcor Specialty Cartons, Australasian Association of Convenience Stores, Scottish Grocers' Federation, and Minimal Government Thinkers (Philippines) – opposed to standardized packaging cited health inequalities, health outcomes, and the health risks from illicit tobacco trade (Czubak, 2018; Lee, 2018; Oplas, 2018; Rogut, 2018; The Tobacco Institute of the Republic of China, 2018). The ASEAN Intellectual Property Association even cited the UK Department of Health's findings that "tobacco smuggling exacerbates health inequalities and discourages younger smokers from quitting because of the cheaper price (ASEAN Intellectual Property Association, 2018)."

Utilizing trade barriers, intellectual property, and investment rights

Another discursive strategy that the tobacco industry has utilized is citing trade barriers, intellectual property rights, and investment rights in their arguments. Eleven policy actors – including members of the Philippine Congress, Indonesia's Directorate General of International Trade Negotiation, and various chambers of commerce, argued that plain packaging is

a technical trade barrier that is "more restrictive than necessary," "excessive," "unreasonable" and will negatively impact exports of tobacco-producing countries (de Acedo, 2018a,b; Duran, 2018; Heng, 2018a,b,c; International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018; Moeftie, 2018; Pambagyo, 2018; Panganiban, 2018; Pletscher, 2018; Rodriguez et al., 2018; Sagala, 2018; Seah, 2018a,b). Seventeen policy actors – all international policy actors from Indonesia, Malaysia, the Philippines, Taiwan, South Korea, Spain, Switzerland, Russia, and Belarus – highlighted Singapore's status as a supporter of free trade and how plain packaging negates free trade principles (Andreu, 2018; Arranza, 2018; Campos, 2018; Cheng, 2018; Karas, 2018; Katchkatchisvili, 2018; Minsch and Herzog, 2018; Nam-Ki, 2018; Ors, 2018; Pambagyo, 2018; Panganiban, 2018; Pletscher, 2018; Rodriguez et al., 2018; Sagala, 2018; Spanish National Tobacco Retailers Association, 2018; The Tobacco Institute of the Republic of China, 2018).

More importantly, 48 policy actors – about 66 per cent of the policy actors opposed to the measure - also argued that plain packaging constitutes a violation of intellectual property rights, particularly of trademarks and brands, claiming plain packaging's inconsistency with international law and Singapore's domestic laws (de Acedo, 2018a,b; Gough, 2018; Japan Tobacco, 2018; Montanari and Thompson, 2018; Pambagyo, 2018; Seah, 2018a; Szulce, 2018). This is in contrast with the World Intellectual Property Rights Organization's response to British American Tobacco in 1994 that limiting trademarks under national law does not constitute a violation of the Paris Convention (Latham, 1994).

About fifteen policy actors from the tobacco industry, industry associations, intellectual property rights groups, foreign government agencies, and tobacco industry-related sectors (packaging) referred to the conflicts of plain packaging with Singapore's bilateral trade agreements and bilateral investment treaties, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Paris Convention for the Protection of Industrial Property, the General Agreement on Tariffs and Trade (GATT), and the Technical Barriers to Trade Agreement (TBT). At least nine policy actors – only one of which is based in Singapore, the European Chamber of Commerce – referred to Singapore's domestic laws, including the Trademarks Act and Registered Designs Act (Seah, 2018a). Three policy actors from the Philippines and Indonesia referred to the issues that plain packaging would trigger for regional economic integration in ASEAN, regional frameworks like the ASEAN Framework Agreement on Intellectual Property Cooperation, and the Asia Pacific Economic Cooperation (APEC) (Pambagyo, 2018; Panganiban, 2018; Rodriguez et al., 2018).

The Property Rights Alliance (Montanari and Thompson, 2018) and Taxpayers Protection Alliance also cited Singapore's ranking in the Intellectual Property Rights Index (which is also published by Property Rights Alliance) where Singapore was ranked seventh in the world and second in the region (Williams, 2018a). Additionally, the International Chamber of Commerce and its various country offices argued how countries' standardized packaging regulations will lead to the tobacco industry's loss of "valuable" trademark rights that merit compensation to the industry (Cheng, 2018; International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018; Katchkatchisvili, 2018; Pletscher, 2018).

Furthermore, 13 policy actors including profiled tobacco industry front groups also utilized the "slippery slope" or "policy spillover" argument, particularly how plain tobacco packaging will impact not only health but also trade policies and serve as a precedent for other "unhealthy" consumer products and other industries including "alcohol, meat, sugar-sweetened food, sugary beverages, salty food, junk food, fatty food, cereals, infant formula, cosmetics, clothing, and toys (Andreu, 2018; Arranza, 2018; ASEAN Intellectual Property Association, 2018; Baba, 2018; Bergonzi, 2018; Campos, 2018; de Acedo, 2018a; Delaney, 2018; Ganev, 2018; Hara, 2018; Heng, 2018b,c; Humphrey, 2018; International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018; Katchkatchisvili, 2018; Meng, 2018; Minsch and Herzog, 2018; Montanari and Thompson, 2018; Nam-Ki, 2018; Oplas, 2018; Ors, 2018; Pambagyo, 2018; Páramo, 2018; Périgois, 2018; Pletscher, 2018; Popovichev, 2018; Roeder, 2018; Salman, 2018; Sano, 2018; Sarfati- Sobreira, 2018; Schauff, 2018; Seah, 2018a; Spanish National Tobacco Retailers Association, 2018; Szulce, 2018; Taipov, 2018; The Romanian Scientifically Association for Intellectual Property, 2018; Zablotskyy, 2018; Zimmerman and Michael, 2018).

Pursuing litigation or threat of litigation

The threat of litigation can be considered as both a discursive and instrumental strategy in this context. For plain packaging measures, the threat of litigation was looming as there was litigation against Australia's plain packaging measures at the time of the public consultation.

At least 11 policy actors, including known third-party lobby groups for the tobacco industry, alluded to litigation with reference to the recently settled appeal to the WTO Appellate Body on the dispute against Australia's plain packaging. According to these policy actors, the then-pending appeal in 2018 warrants that Singapore delays the implementation of plain packaging until the WTO Appellate Body releases its report, conducts a hearing and decides on the appeal (Andreu, 2018; Arranza, 2018; Campos, 2018; Duran, 2018; Katchkatchisvili, 2018; Nam-Ki, 2018; Ors, 2018; Popovichev, 2018; Spanish National Tobacco Retailers Association, 2018; The Romanian Scientifically Association for Intellectual Property, 2018; The Tobacco Institute of the Republic of China, 2018). Several of these policy actors are from the Dominican Republic which challenged Australia's plain packaging laws at the WTO.

Mobilizing third-party support

An instrumental strategy, building a coalition of third-party supporters or allies was vital for building the volume of submissions that Singapore received in the public consultation process for standardized packaging. Table 1 shows the number and types of policy actors opposed to standardized packaging, some of which have disclosed their ties to the tobacco industry along the tobacco supply chain – from tobacco-producing countries, manufacturing and packaging sectors, exporters, designers, and advertisers, to retailers. These interest groups, which mobilized to lobby against standardized packaging policies in Singapore, constitute a wide network of actors acting to reinforce not only their sectoral interests but also the interests of the tobacco industry (see Table 1 and Figure 3). These third parties echoed the majority of the tobacco industry's discursive framing strategies.

Tobacco farmers and manufacturers

Policy actors from tobacco-producing countries, including members of the legislature in the Philippines and government agencies in Indonesia– two of the top 20 tobacco-producing countries – cited standardized packaging's indirect impact on their tobacco farmers (Philippines) and those working in the supply chain industries for tobacco products (Pambagyo, 2018; Panganiban, 2018; Rodriguez et al., 2018; Sagala, 2018). The Dominican Republic's submission also centered on its dependence on the tobacco industry, particularly its tobacco farming and processing, and cigar manufacturing industry (Ors, 2018). Similarly, cigar manufacturers in the Dominican Republic highlighted that cigars are a luxury good and should be treated differently from cigarettes (Kelner, 2018). Notably, 10 policy actors, including manufacturers' associations and industry associations from Russia, Spain, the Philippines, Indonesia, an intellectual property rights group in South Korea, and the International Chamber of Commerce in Georgia submitted almost identical position papers with the primary argument that plain packaging does not work (Andreu, 2018; Arranza, 2018; Katchkatchisvili, 2018; Moeftie, 2018; Nam-Ki, 2018; Popovichev, 2018).

Retailers

Thirty-five policy actors, including industry associations and retailer associations, highlighted how plain packaging will increase costs, risks, and burden to retailers, including the display, labor and training costs, tobacco sales leakage (for duty-free retailers), and security risks to retailers (Hirst, 2018; Khonat, 2018a; Lee, 2018; Licensed Tobacco Retailers, 2018; Meng, 2018; Páramo, 2018; Spanish National Tobacco Retailers Association, 2018). Duty-free retailers, travel retail associations and even Singapore's Changi Airport Group also voiced their opposition to standardized packaging by framing their argument from the narrative of retailers, particularly duty-free retailers and with specific reference to "tobacco sales leakage" to regional competitors (Changi Airport Group, 2018; Spinks, 2018).

Citing policy failure

Another major argument espoused by at least 45 policy actors against plain packaging is that it is essentially a policy failure in the countries where it has been implemented, citing post-implementation reviews, industry-commissioned reports, and industry-funded market research. A key assumption of the policy dystopia model, citing policy failure is included here as part of the tobacco industry's strategy and exercise of discursive power. According to these policy actors, these reports showed that there has been no decrease in smoking prevalence in Australia, France, and the UK after the implementation of plain packaging, despite evidence to the contrary. These policy actors –including transnational tobacco, various chambers of commerce, and business associations similarly highlighted that there is an increasing number of countries and industry associations rejecting plain packaging as a tobacco control measure (EU-Georgia Business Council, 2018; Gough, 2018; Heng, 2018b,c; Japan Tobacco, 2018; Japan Tobacco International, 2018; Karas, 2018; Katchkatchisvili, 2018; Minsch and Herzog, 2018; Moeftie, 2018; Schauff, 2018; Seah, 2018a).

Citing policy failure, fifteen policy actors proposed that Singapore should review its current tobacco control policies before considering the introduction of plain packaging and conduct a regulatory impact assessment of plain packaging. At least seventeen policy actors also proposed that instead of introducing plain packaging, Singapore should instead conduct public information/awareness campaigns and targeted education programs. Several policy actors recommended youth smoking prevention campaigns, including raising the minimum legal age, negative licensing schemes, imposing stiff penalties for sale to children (which are already being implemented in Singapore), and criminalizing "proxy" purchasing. Moreover, a number of these policy actors, including the tobacco industry, proposed that Singapore should consider implementing larger graphic health warnings only or allowing "minimum" trademarks but with larger graphic health warnings. Eight policy actors suggested that Singapore should delay consideration of plain packaging or delay implementation until the resolution of the trade dispute appeal against Australia at the World Trade Organization. Five policy actors, including British American Tobacco, the Taxpayers Protection Alliance, Australian Taxpayers Alliance, the Institute of Economic Affairs, and Forest EU proposed that Singapore should repeal its ban on electronic cigarettes and vapor products, and increase support for smoking cessation through harm reduction measures (Heng, 2018b,c; Institute of Economic Affairs, 2018; Marar and Andrews, 2018; Périgois, 2018; Williams, 2018a,b). At least five policy actors suggested the exemption of cigars,

other non-cigarette tobacco products, and duty-free tobacco products from standardized packaging. Three policy actors, including the ASEAN Intellectual Property Association, the International Chamber of Commerce, and the Consumer Packaging Manufacturers Alliance encouraged Singapore to engage in stakeholder participation and collaboration in the formulation of plain packaging measures (Joossens, 2012; ASEAN Intellectual Property Association, 2018; International Chamber of Commerce Business Action to Stop Counterfeiting Piracy, 2018).

Discussion

The findings in this study confirm and substantiate previous findings in the literature about the tobacco industry's discursive (framing or argument-based) and instrumental (action-based) strategies to counter plain packaging measures in public consultations globally (Evans-Reeves et al., 2015; Ulucanlar et al., 2016; Lie et al., 2018; MacKenzie et al., 2018; Crosbie et al., 2019; Hawkins et al., 2019). This study offers an additional case from Southeast Asia of how the tobacco industry and its network of associated interest groups – third-party lobby groups, astroturf groups, and front groups – are reusing similar frames of arguments to persuade countries to either delay the implementation of standardized packaging or to drop the policy entirely. This study corroborates previous findings that this network of policy actors supports the position of the tobacco industry by framing plain packaging through trade and investment, particularly illicit trade, intellectual property rights, international and domestic law, the threat of litigation, and the slippery slope argument that plain packaged tobacco will serve as the precedent for plain packaging of other unhealthy consumer products (Evans-Reeves et al., 2015; Lie et al., 2018; MacKenzie et al., 2018; Crosbie et al., 2019). It also contributes to the discourse on policy dystopia or "policy failure" metanarrative built by the tobacco industry to convince and persuade policymakers to adopt the industry's preferred policies over evidence-based public health measures (Ulucanlar et al., 2016). Contrary to the arguments posited by the policy failure metanarrative, there was no evidence of an increase in the use of illicit tobacco, or impact on retailers and small businesses in countries where standardized packaging was implemented (Wesselingh, 2018).

The resolution of the WTO dispute against Australia's plain packaging offers concrete evidence that the plain packaging of tobacco products is a pragmatic tobacco control measure and justifiable public health agenda. Even with Australia's victory against the appeal to the WTO resolution, this points to the challenge that countries like Singapore that are implementing plain packaging, and other countries considering the implementation of plain packaging, still need to prepare for possible interference (if not litigation) to delay, amend, or weaken plain packaging measures at the local, regional, bilateral, and multilateral levels. As the case of Australia shows, transnational tobacco corporations with their resources can profusely engage in "forum shopping," which includes institutional trade and investment regimes such as the WTO Dispute Settlement System and Investor-State Dispute Settlement Mechanisms within bilateral investment treaties to challenge domestic policies (Eckhardt et al., 2016; Hawkins and Holden, 2016).

In the case of Singapore, the sheer number of policy actors that opposed and tried to influence the timeline of Singapore's standardized packaging proposal, compared to those supporting the policy, is stark. As noted above, this strategy of mobilizing third-party groups has already been documented in the literature on tobacco industry interference. The results of the policy process seem to show that the 1-year transition was a generous compromise given by the Singapore government to provide tobacco manufacturers, wholesalers, and retailers time to prepare for the full implementation of the standardized packaging measure. This is relatively a long timeline since Singapore has been considering plain packaging measures since 2015 and included it in wider public consultations on potential tobacco control measures in 2016. Several of the policy actors involved in the 2018 public consultations even attached copies of their submissions to the 2016 public consultations, which formed the basis of their 2018 submission or simple reiterations of those submissions. However, it is encouraging for countries in the region that while Singapore received this barrage of submissions from the tobacco industry and its allies – albeit flawed and often identical – nonetheless proceeded to implement standardized packaging.

It is also interesting to note that the number and types of organizations that oppose tobacco control measures are becoming more diverse. The emergence of new policy actors trying to influence tobacco control policy outside of their sectors and geographic limits can also point to the alliance-building process that the tobacco industry continues to engage in, essentially building a coalition to support its strategies (Matthes et al., 2021). This lends support to the argument in the literature about the political power of corporations, such that the power of the global corporate sector – in this case, the tobacco industry and its network – rests on what Freudenberg termed the "corporate consumption complex" and was described by May as "the work of a complex and extensive network of agents all in their interests seeking to further and reinforce elements of the agendas that favor corporations" which includes financial institutions, trade associations, advertising, public relations firms, law firms, lobbying groups, think tanks and research organizations, astroturf citizen groups, and media platforms (May, 2015; Freudenberg, 2016). This points to the challenge of increased civil society-led monitoring of tobacco industry tactics, including their use of front groups and third parties, and other sectors to lobby against plain packaging measures not only

on tobacco but also on other harmful consumer products, and against other evidence-based public health policies. The history of tobacco industry interference in the region has been widely documented (Amul et al., 2021).

Limitations of the study

A limitation of this study is the lack of access to previous public consultations on standardized tobacco packaging in Singapore. The results of the 2016 public consultations are not publicly available and could not be included in this study for analysis and comparison. While some of the policy actors – particularly transnational tobacco companies – participated in the 2016 public consultation and attached their previous submissions to their 2018 submissions, the author does not have access to the rest of the public consultation submissions from 2016. Due to limited space, this study did not include policy actors' submissions supporting standardized packaging in Singapore (see Supplementary Table 2 and Supplementary Note).

Conclusions

Identifying the strategies with which corporations, particularly that of the tobacco industry and its allies, exercise their instrumental and discursive power contributes to the increasing literature on the politics of commercial determinants of health. With the tobacco industry's history of political strategies in obstructing and interfering in public health and given that illicit trade remains an argument of the tobacco industry, Singapore needs to be vigilant and stringent in the enforcement of tobacco control measures, and more specifically to prevent and control the illicit tobacco trade in Singapore. This becomes more critical since the tobacco industry uses think tanks and research organizations to overestimate illicit tobacco trade, influence the debate over illicit tobacco trade, and undermine the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products with an industry-developed track and trace system (Evans-Reeves et al., 2015; Gilmore et al., 2015, 2019; Gallagher et al., 2019). The next possible step it can take is, to begin with, a comprehensive evaluation of Singapore's current policies to prevent illicit tobacco trade and consider accession to the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products. As of this writing, there are 65 parties to the Protocol. While none of the ASEAN member states has ratified the Protocol, Singapore can serve as a regional leader in reinforcing measures to control the illicit tobacco trade in the region.

Four critical challenges remain for Singapore in controlling the illicit tobacco trade. First, it needs to prepare for claims from the tobacco industry that standardized packaging is a policy failure and that it contributed to illicit trade. Second, Singapore should continue to cooperate and share information about the tobacco industry's tactics and its complex network of lobby groups, front groups, and astroturf groups. Third, Singapore needs to continuously monitor the size of illicit trade (beyond seizure statistics) and generate an independent estimate of the size of the problem. Last but not the least, Singapore needs to strictly enforce its current policies to control illicit tobacco trade, but at the same time gradually consider its accession to the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

On a global level, parties to the WHO FCTC that are implementing standardized tobacco packaging and other evidence-based tobacco control measures – including high-income and especially low- and middle-income countries – that are considering the implementation of plain packaging, still need to prepare for industry tactics to delay, amend, or weaken other tobacco control measures. Parties to the WHO FCTC should also consider acceding to the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products to contribute to global tobacco control efforts. Policymakers need to recognize tobacco industry tactics that can also be utilized by other health harmful industries (alcohol, sugary beverages) against other evidence-based public health policies.

Civil society organizations and public health advocates, especially those seeking corporate accountability, can utilize the results of this research to counter tobacco industry arguments against plain packaging measures, not only in low- and middle-income countries in the Southeast Asian region but also, globally. Researchers, investigative journalists, and civil society organizations alike can also support policymakers and the public in exposing, identifying, and monitoring policy actors from other health harmful industries (alcohol, sugary beverages) and raising public awareness of the tactics utilized by these industries to prevent effective evidence-based health policies from being proposed or implemented.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found at: https://www.moh.gov.sg/proposed-tobacco-control-measures.

Author contributions

GA conceptualized and designed the study, compiled, analyzed the data, prepared, revised, finalized the manuscript, and is accountable for the content of this article.

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Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpos.2022.943120/full#supplementary-material

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China's practical wisdom: Assumption of liability for endangering public health in bankruptcy proceedings—A case study of the Changchun Changsheng Biotechnology vaccine incident and the Johnson & Johnson baby powder incident

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The assumption of liability for endangering public health has always been a legislative challenge in bankruptcy proceedings. Although it has been theoretically proven that the tort creditor should hold a position higher than that of unsecured creditors in bankruptcy proceedings, both legislation and judicial practice have been found wanting in many countries. China has witnessed large-scale domestic public health incidents where the tort debtor has entered bankruptcy proceedings while the tort claims were being settled. In Changchun Changsheng Biotechnology vaccine incident, to maintain social order and protect the rights and interests of the tort creditor, the Chinese government required the tort debtor to set up a special compensation fund of RMB 500 million and hand it over to a third party for management. This approach was mainly adopted because tort creditors can only participate in the bankruptcy distribution as an unsecured creditor, according to the Enterprise Bankruptcy Law of China, and as a result, their rights and interests cannot be guaranteed. In the context of the Enterprise Bankruptcy Law of China, this approach face predicaments of legitimacy and effectiveness. Moreover, even if the legislators follow scholars' advice and grant the tort creditor priority in bankruptcy proceedings, that would still not be enough to protect the rights and interests of the tort creditor, not to mention the possibility that the tort debtor might follow the example of Johnson & Johnson to avoid liability in practice. In fact, the Chinese government's approach is similar to that of Johnson & Johnson's, but more advisable. The Enterprise Bankruptcy Law of China (Bill of Amendment) will be submitted to the Standing Committee of the National People's Congress for preliminary deliberation this year, and the Chinese government's approach to the Changchun Changsheng vaccine case

is very likely to be codified. This will resolve the predicaments of legitimacy and effectiveness that the government's current approach is facing and serve as a point of reference for the future revision of U.S. bankruptcy law and the handling of related cases.

KEYWORDS

bankruptcy, public health, tort creditor priority, Changchun Changsheng Biotechnology, Johnson & Johnson, tortious liability

Introduction

Between 2014 and 2018, Changchun Changsheng Biotechnology (hereinafter referred to as "Changsheng") blended two or more batches of a stock solution to prepare a freeze-dried rabies vaccine for human use (Vero cell) and created the batch numbers for the blended stock solution. From 2016–2018, Changsheng altered the batch numbers or actual production dates of 184 batches of the products involved, indirectly postponing their expiration dates. From March to April 2018, Changsheng produced nine batches of products using the expired stock solution created in 2017. In addition, Changsheng sent some poor-quality stock solutions with low antigen content for secondary concentration so that they would reach the preparation standards and then be used for production. To cover up these illegal actions, Changsheng destroyed the original production records and created false records. According to the National Medical Products Administration, Changsheng destroyed relevant evidence by replacing and processing the surveillance video memory cards and some computer hard disks (1).

Timeline of events

- In July 2018, President Xi directed relevant government departments to handle sternly Changsheng's vaccine case to safeguard the legitimate rights and interests of the people (2).
- On July 24, 2018, all 15 people involved, including Gao Junfang, president of Changsheng, were detained by the Public Security Bureau of Changchun New District according to the law as suspects of criminal offenses (3).
- On August 16, 2018, Chinese Premier Li Keqiang held an executive meeting of the State Council in which the results of the investigation into Changsheng's problematic vaccine were shared and the relevant decisions were made (4).
- On October 16, 2018, Changsheng was given administrative penalties; its drug production license was revoked and it was fined 9.1 billion yuan by the Drug Supervision and Administration Department (5, 6). Consequently, on January 14, 2019, the Shenzhen Stock Exchange decided to delist the company's stock for serious violations. The company's stock entered the delisting clearing period on October 16, 2019 and was eventually delisted on November 27, 2019 (7).
- On October 16, 2018, Changsheng and China Life Insurance Co., Ltd. entered into the Entrusted Management Agreement on Compensation for Changchun Changsheng's Faulty Rabies Vaccine according to the Implementation Plan on Compensation for Changchun Changsheng's Faulty Rabies Vaccine that was jointly developed by the National Medical Products Administration, the National Health Commission, the China Banking and Insurance Regulatory Commission, and the provincial government of Jilin on October 12, 2018 (8). On October 22, 2018, Changsheng made a payment of RMB 500 million to China Life Insurance Co., Ltd. to set up a special compensation fund (9).
- On June 27, 2019, Changchun Intermediate People's Court accepted and heard Changsheng's bankruptcy liquidation case (10).

Notably, the fine (RMB 9.1 billion) imposed on Changsheng remains the highest imposed on pharmaceutical companies for illegal acts in China (11).

Structure of this paper

The remainder of this paper consists of a chapter (Chapter 2) presenting reflections on the predicament of legitimacy and effectiveness facing approach adopted by Chinese government then three chapters (3, 4, and 5) on assessment of policy/guidelines options and implications, followed by Actionable Recommendations (Chapter 6), and the Discussion (Chapter 7). Chapter 3 analyzes the logic of the Chinese government's approach of handling public health liability in the Changsheng case. Chapter 4 compares the Changsheng case and the Johnson & Johnson case and concludes that they are essentially the same in dealing with public health liability, but that the approach of the Chinese government is likely to be more desirable. The fifth chapter analyzes why the Chinese government's approach is more worthy of recommendation.

Although the paper argues that the Chinese government's approach to handling the public health liability in bankruptcy

proceedings is more commendable, as indicated in Chapters 2 and 3, there are also urgent problems to be solved in the Chinese Government's approach, which should be done in the aspect of legislation. This reflected in the sixth chapter ("Actionable Recommendations"). Finally, the "Discussion" chapter examines different reasons for the same choices in China and the United States. The paper contends that although the approach adopted in dealing with the problem of endangering public health in the Changsheng case and the Johnson & Johnson case in the United States are essentially the same, the factors behind the consideration are different. The Chinese government's approach is mainly based on maintaining social stability, not on improving the efficiency of society; however, it is argued here that the judges in the Johnson & Johnson case acted improve the efficiency of the society as a whole.

Reflections: Predicaments of legitimacy and effectiveness facing approach adopted by Chinese government

After the Changsheng vaccine incident, Chinese people mainly focused on how to compensate the victims and how to punish those responsible, and few scholars in the theoretical field paid attention to whether the Enterprise Bankruptcy Law of China could serve as a basis for solving the problem of victim compensation. Although Changsheng finally entered the bankruptcy procedure, the Chinese government did not solve the problem of victim compensation within the framework of the Enterprise Bankruptcy Law of China, instead issuing special policies to solve the problem. Through the study of those policies and the judgments made by the courts, it can be concluded that there are many predicaments requiring urgent resolution, including both the legitimacy predicament and the effectiveness predicament.

The predicaments of legitimacy and effectiveness facing the Chinese government's approach stem from the Enterprise Bankruptcy Law of China does not have any special provision for the settlement of tort liability in bankruptcy proceedings, let alone for the assumption of liability for endangering public health. Some scholars who have carried out systematic research on the settlement of tort liability in bankruptcy proceedings in China opine that a certain proportion of the amount of the creditor's rights secured with property should be regarded as unsecured creditors' rights, and the secured property corresponding to the quota of the creditor's rights should be used prior to paying off tort liability against secured creditor (12). Wang Xinxin, a well-known bankruptcy jurist in China, holds the same view. He also points out that the scope of prior repayment of creditors' rights should be clarified (13). However, in the face of an incident endangering public health in Changsheng vaccine incident, instead of adopting the solutions proposed by scholars, the Chinese government used other approach without a bankruptcy law basis. The Chinese government did not adopt the scholars' proposals mainly because allowing the priority use of a certain percentage of the amount of secured claims for paying off the debts for personal tort would have had a negative impact on the stability of commercial transactions and would infinitely increase the costs of commercial transactions. Given the impact of the Changsheng vaccine incident in China and the fact that the tort debtor, Changsheng, entered bankruptcy proceedings, it is of great significance that the legitimacy and effectiveness of the relevant practices of the Chinese government—based on the provisions of Chinese law, in this case—are examined. Theoretically, the first things to be questioned are as follows: (a) What is the nature of the special fund set up by the Entrusted Management Agreement on Compensation for Changchun Changsheng's Faulty Rabies Vaccine between Changsheng and China Life Insurance Co., Ltd.; and (b) whether the special fund would be considered the property of the debtor after Changsheng entered bankruptcy proceedings. If yes, was it still considered a "special fund for a special purpose," and could it be distributed to other creditors? If the special fund was considered a "special fund for a special purpose" and not the property of the debtor, what was the legal basis thereof? If it was not the property of the debtor, could the tort creditor get compensation from Changsheng's other property under the circumstance that the special compensation was insufficient in amount?

The special fund for compensation was not the property of the debtor in nature, and the bankruptcy administrator had no right or need to exercise its administrative authority

On the question of whether the special fund is the property of the debtor, the documents issued by the Chinese government do not give a clear answer, but we can get the answer from the judgments of Chinese courts. The judgment in the case *Weihai Municipal Center for Disease Control and Prevention v. Changchun Changsheng* suggests that the tort creditor can only claim rights against China Life Insurance Co., Ltd. and not Changsheng. In the (2020) Ji 01 Min Chu No. 83 judgment given by Changchun Intermediate People's Court of Jilin Province for the case of *Weihai Municipal Center for Disease Control and Prevention v. Changchun Changsheng*, the court found the following:

> On October 16, 2018, Changsheng signed the Entrusted Management Agreement on Compensation for Changchun Changsheng's Faulty Rabies Vaccine with China Life Insurance Co., Ltd. On October 22, 2018, Changsheng

transferred the vaccine compensation of 500 million yuan to the account of China Life Insurance Co., Ltd., as agreed in the Agreement. Therefore, Changsheng set up the special compensation fund according to the instructions and entrusted China Life Insurance for management thereof. Even if Weihai Municipal Center for Disease Control and Prevention had corresponding expenses for subsequent and supplementary vaccination, the expenses should be covered by China Life Insurance after a due audit. Weihai Municipal Center for Disease Control and Prevention should not claim such expenses from Changsheng.

Based on said judgment and the relevant provisions on the centralized jurisdiction of bankruptcy cases in the Enterprise Bankruptcy Law of China (according to article 21 of the Enterprise Bankruptcy Law of China, bankruptcy cases are under the centralized government, i.e., after a debtor enters bankruptcy proceedings, all cases related to the debtor can only be heard by the court that accepted the bankruptcy case), after Changsheng entered bankruptcy liquidation in 2019, the compensation amount of 500 million yuan was not included in the bankruptcy estate. Otherwise, the court would not have dismissed the plaintiff's claims and asked them to claim their rights against China Life Insurance.

According to article 2 of the Implementation Plan on Compensation for Changchun Changsheng's Faulty Rabies Vaccine, the special compensation should be used to pay for any subsequent and supplementary vaccination damages, civil lawsuit compensation, damage determination, consultation services, clinical observation, and so on, occasioned by the faulty rabies vaccine. Therefore, the tort creditors could no longer claim rights against the tort debtor but against China Life Insurance. Further referring to article 5 of the Implementation Plan:

According to the characteristics of rabies that its incubation period is usually 1–3 months and rarely longer than 1 year, the inoculated people that suffer the damage listed in article 3 within 1 year from the date of inoculation should apply for determination and be compensated according to this plan; those who suffer damage after 1 year from the date of inoculation may file a civil lawsuit for compensation before the people's court according to law.

In this case, the tort debtor is Changsheng, and according to the principle of privity of contract (i.e., the contract cannot be an obligation for third parties here), the Entrusted Management Agreement between Changsheng and China Life Insurance only bound the contracting parties. So how could the tort creditors claim rights against China Life Insurance for the damages they suffered?

The challenges that the Chinese government's approach encountered in handling the public health incident by setting up a special fund can be split into two groups: (a) the predicament of legitimacy; and (b) the predicament of effectiveness. The former is expressed as the conflict between the Chinese government's approach and the Enterprise Bankruptcy Law of China and other laws, while the latter concerns whether the approach adopted by the Chinese government could effectively protect the interests of the tort creditor and achieve the expected effect—according to the Enterprise Bankruptcy Law—after the Changsheng entered bankruptcy proceedings.

The approach faced legitimacy and effectiveness predicaments given that the special fund did not fall within the debtor's property

According to article 2 of the Implementation Plan, with respect to the entrustment relationship between Changsheng and China Life Insurance for the compensation of 500 million yuan, China Life Insurance was only the trustee rather than the owner. In other words, Changsheng was still the owner of the 500 million yuan. According to article 17 of the Enterprise Bankruptcy Law of China, after a debtor enters bankruptcy, the debtor's property holders should deliver the property to the bankruptcy administrator. In addition, article 2 of Judicial Interpretations (II) of the Enterprise Bankruptcy Law of China provides that whatever is not recognized as the debtor's property in accordance with the law and administrative regulations shall not be identified as the debtor's property. (i.e., laws and administrative regulations here refer to laws enacted by the National People's Congress of China and regulations enacted by The State Council of China) The Implementation Plan jointly formulated by relevant government departments in China is obviously not a law or an administrative regulation; therefore, it cannot be held as the basis for determining that the 500 million yuan was not the debtor's property. Nevertheless, the Chinese court ruled the opposite.

Moreover, according to an overview of provisions of the Enterprise Bankruptcy Law of China, Chinese legislators have strictly followed the rules that "property-secured creditor rights are paid first" and "unsecured creditors' rights are paid equally." According to the Enterprise Bankruptcy Law, compensation, including medical expenses and damages, can only be listed as unsecured claims equivalent to general contractual obligations behind general priority. Debtor is not allowed to make any individual settlements on specific creditors when debtor close to bankruptcy (12). The decision of the Chinese court clearly contradicted the basic principles of the Enterprise Bankruptcy Law.

In addition, according to article 54 of the Enterprise Bankruptcy Law, after the principal (i.e., Changsheng, in this case) enters bankruptcy proceedings, if the entrusted party (i.e., China Life Insurance, in this case) has no knowledge of the aforesaid facts and continues to deal with the entrusted

business, the entrusted party shall file their claim as a unsecured creditor in bankruptcy law. According to a reverse interpretation of this provision, if the entrusted party knows the facts, they should cease handling the entrusted matters, and the bankruptcy administrator should instead handle the same in accordance with article 25 of the Enterprise Bankruptcy Law. However, article 2 of the Implementation Plan stipulated that the compensation fund would be managed by China Life Insurance and specified that the management work would be supervised by the China Banking and Insurance Regulatory Commission. But if the compensation fund of 500 million yuan was not the debtor's property, what would be the legal relationship between the bankruptcy administrator and China Life Insurance and the China Banking and Insurance Regulatory Commission? According to article 25 of the Enterprise Bankruptcy Law, the responsibility of the bankruptcy administrator includes representing debtors in litigation, arbitration, and any other legal proceedings. If the 500 million yuan was not the debtor's property, the bankruptcy administrator would have no right to exercise any rights, including management and supervision, over the fund or to assume responsibility in order to participate in litigation, arbitration, or any other legal proceedings on behalf of the debtor. However, after the debtor entered the bankruptcy proceedings, the law did not authorize subjects other than the bankruptcy administrator to participate in the litigation, arbitration, or any other legal procedures involving the debtor. If the bankruptcy administrator was required to handle the litigation, arbitration, or any other legal proceedings involving the 500 million yuan, would the administrator be entitled to receive the corresponding remuneration? If so, what is the legal basis?

In sum, according to the provisions of the Implementation Plan, the bankruptcy administrator does not have the right to dispose of the compensation fund or to exercise supervision over the use of the fund, but this conflicts with the basic principles of the Enterprise Bankruptcy Law.

The effectiveness predicament facing solving the assumption of liability for endangering public health in bankruptcy proceedings by setting up special funds

Returning to the case itself, the special fund for compensation was set up to avoid sudden management difficulties or any excessively speculative behavior on the part of Changsheng that would go against the protection of the rights and interests of the tort creditor. This approach may serve as a point of reference for future instances in which the tort debtor does not enter bankruptcy proceedings. However, once the tort debtor enters bankruptcy proceedings, it may become another situation altogether.

According to the Chinese government's policy and the judgment of the Chinese court, even though Changsheng entered bankruptcy proceedings, the tort creditor could still claim compensation from China Life Insurance rather than the debtor. The court ruled that Changsheng enter bankruptcy liquidation in June 2019. According to the Enterprise Bankruptcy Law, the debtor cannot be transferred to bankruptcy reorganization proceedings after being ruled to enter bankruptcy liquidation proceedings since such a debtor will cease to exist after the bankruptcy liquidation proceedings. Therefore, if the compensation fund of 500 million yuan that was set up by the debtor was not enough to compensate all the tort creditors, the tort creditor would not be able to claim any more compensation from the debtor. Consequently, the question that needs to be answered is of whether there is a better approach to remedying such situation.

China's logic: Closing loopholes in legislation with power

The existing Chinese Enterprise Bankruptcy Law was promulgated in 2006 and implemented in 2007. Over the next decade, China's economy witnessed rapid growth, resulting in a very limited application of the Enterprise Bankruptcy Law. In this period, there were only a few hundred bankruptcy cases in China each year, to which academics paid little attention. In recent years, along with the supply-side structural reform (i.e., improve the quality of supply, advance structural adjustment through reform, correct distortions in the allocation of factors of production, and expand effective supply. It means inefficient firms will go into bankruptcy) proposed by the Chinese government and the spread of the COVID-19 epidemic, the number of bankruptcy cases has surged to tens of thousands (in 2015, 3,568 bankruptcy cases were accepted and heard in China; the number increased to 4,076 in 2016, 7,306 in 2019, and 13,369 in 2020). In this new context, legislators and scholars have begun to attach more importance to the Enterprise Bankruptcy Law (14). However, the lack of attention paid to the Enterprise Bankruptcy Law by legislators and scholars in China in the past has led to insufficient legislative efforts and limited theoretical research on bankruptcy law in China. For example, the Enterprise Bankruptcy Law does not offer a clear definition of the liquidation status of the tort creditor in bankruptcy proceedings, not to mention the protection of the rights and interests of the tort creditor after the tort debtor enters bankruptcy proceedings in cases of large-scale public health incidents. This means that the tort creditor in bankruptcy proceedings in public health incidents in China has the same status as the tort creditor in U.S. bankruptcy proceedings—they only receive partial compensation as unsecured creditors and have no room for bargaining (15). Some scholars have proposed that

the claims to claim compensation for infringement of personal rights should be granted the same order of liquidation as labor claims in bankruptcy claims by offering judicial interpretations (16). However, legislators have not adopted this view. Therefore, it is unrealistic for the Chinese government to give the tort creditor priority in compensation after entering bankruptcy proceedings, and this may not necessarily achieve the objectives of the Chinese government. Considering all these factors, requiring (by administrative means) the debtor to set up a special fund to compensate the tort creditor seems to be the only viable solution.

We must admit that the approach of the Chinese government in the Changsheng case was, in its nature, a strategy adopted by the Chinese government and the judicial body to close the legislative loopholes in Enterprise Bankruptcy Law. What this strategy can be successful? This was possible because, according to the Enterprise Bankruptcy Law, the acceptance of a bankruptcy case and the handling of related derivative actions should fall under the jurisdiction of the same court. Therefore, once the Chinese government and the bankruptcy court reach a consensus, even if the tort creditor lodged a derivative lawsuit, the judge handling the relevant derivative actions would not make a judgment inconsistent with the Chinese government and the bankruptcy judge. In the meantime, considering the Chinese public's general recognition of priority compensation for infringement of the right to life and health, the public would not raise any objections to the handling of relevant bankruptcy cases (for instance, in the Sanlu milk powder incident, the Chinese government also skipped the provisions of the Enterprise Bankruptcy Law to guarantee compensation for the tort creditor) (12).

In addition, asking the debtor to set up a special fund to compensate the tort creditor helps maintain social order and appease the tort creditor. In the real world, people facing similar social instances in China often exert pressure on the government through non-legal means or even hold the government accountable, although they know that the tort debtor, not the government, is liable. The Chinese people act this way mainly because since ancient times they have believed that the government has an obligation to protect the rights and interests of its people, even if it is not the perpetrator of the illegal acts.

Finally, the requirement directing the debtor to set up a special fund enhances the convenience of the tort creditor and minimizes the social cost. Those affected by the Changsheng vaccine were found in many provinces and cities in China. Tens of thousands of people were inoculated with the faulty vaccine. If each tort creditor claimed rights against the tort debtor on their own, the tort debtor would be exhausted in fund and time, and the social cost would be enormous. The approach adopted by the Chinese government not only freed the debtor from the burden of litigation but also reduced the litigation cost for the tort creditor.

Furthermore, a special fund set up by the debtor—as ordered by the government, with the amount of the special fund determined by the government—is also conducive to solve the problem of protecting the infringed in the future. Such issue have always been challenging for legislators and jurists; whether in China or the United States, the theoretical field has not yet reached a consensus on how to solve it. Tort debtors are inherently profit seeking, and as a result, they will inevitably minimize the compensation provided to the tort creditors. Here, tort creditors include possible future tort creditors. Nevertheless, the government will naturally strive to protect the rights and interests of the tort creditors to preserve social stability and protect the interests of the people; here again, tort creditors include possible future tort creditors. Therefore, the government should be the one to decide whether to set up a special fund and also set the size of the fund, thereby protecting the interests of possible future tort creditors as much as possible. In conclusion, I do not think there is a solution that can completely solve the problem of protecting the infringed in the future, and the Chinese government's approach can solve the problem to the greatest extent.

Reference value of China's approach to handling public health hazards: *Changsheng v. Johnson & Johnson*

As explained by Stacy L. Rahl, the United States has not specified enough rules to control the unethical behavior of companies, and social welfare could hardly compensate the tort creditors in full in mass tort cases; therefore, to resolve complex conflicts of interest and protect the rights of tort creditors, it would be more appropriate to give the courts considerable discretion. (17) In the United States, the assumption of liability for endangering public health in bankruptcy proceedings may conflict with not only the pursuit of the bankruptcy law for debtor relief, but also the protection of other creditors' rights and interests; moreover, it lacks a relevant legislative basis for government to intervene in such cases, for which the courts have most of the decision-making power over the handling of relevant cases.

Still, China's Changsheng vaccine incident is quite like the Johnson & Johnson baby powder incident in the United States, the latter of which began in 2017, when a Los Angeles, California, court ordered the company to pay $417 million in damages to a 63-year-old woman who developed ovarian cancer after years of using their talc-containing baby powder on her genital area. Talc is known to be susceptible to asbestos contamination, and asbestos, a natural mineral fiber, is considered a Class 1 carcinogen by the World Health Organization, so talc containing asbestos impurities can cause cancer. Johnson & Johnson has been facing allegations that its products cause cancer since 2016. On October 18, 2019, the Food and Drug Administration

(FDA) found small amounts of asbestos in Johnson & Johnson's talc products, forcing the company to recall a batch of more than 33,000 bottles from the market. Johnson & Johnson paid more than $34.4 billion in compensation to consumers from 2016 to 2019 alone. In May 2020, the company said it would stop selling talc-containing baby powder in the U.S. and Canada. As of April 2021, there were nearly 30,000 pending lawsuits against Johnson & Johnson and its subsidiaries in U.S. courts. There is still controversy over whether the company's talcum powder contains asbestos, but there have been numerous lawsuits and huge payouts. On October 14, 2021, LTL, a new company spun off from Johnson & Johnson, filed for bankruptcy reorganization proceedings in the Federal Bankruptcy Court for the Western District of North Carolina. According to bankruptcy court records, Johnson & Johnson faced more than 38,000 cancer-causing lawsuits and $3.5 billion in awards and settlements before it filed for reorganization (15, 18).

Under the burden of lawsuits, Johnson & Johnson first created a new legal entity and transferred its infringement liability to it. In the meantime, a relatively small portion of the original company's assets was also transferred so that the company was divided into a new company with assets and a new company with liabilities, LTL Management ("LTL" in short). Later, the newly established subsidiary with liabilities filed for bankruptcy, thus effectively protecting Johnson & Johnson from the impact of the infringement liability. (16) The maneuver used by Johnson & Johnson was called the "Texas Two-Step." This case is like the Changsheng vaccine case in that the tort debtor divested some independent assets from the original company to compensate the tort creditor, and the tort creditor could only claim rights against the divested assets. This way, the burden of lawsuits on the tort debtor was reduced and the overall social benefits improved. Moreover, in both the Johnson & Johnson case and the Changsheng case, the part separated from the debtor's property to compensate the tort creditors was working fund or unsecured property from the debtor; this is different from the viewpoint held by some scholars, which is that China should secure more protection for the tort creditors by reducing the interests of the secured creditor (12, 13). In both cases, the interests of the secured creditor in the bankruptcy proceedings were not compromised by the special protection for the tort creditors (18). The two cases are different in that the independent assets divested by Johnson & Johnson were injected into an all-new company, which then entered bankruptcy proceedings, whereas in the case of Changsheng, a special fund independent of the tort debtor was set up instead. According to Chinese law, the special fund could neither become an independent legal entity nor go through bankruptcy liquidation (19).

Johnson & Johnson's approach is similar to that of the Chinese government in terms of the intended purpose or social effect, which is why Judge Michael Kaplan of the Federal Bankruptcy Court for New Jersey approved LTL's bankruptcy reorganization plan on February 25, 2022. However, Johnson & Johnson's approach was more costly than the Chinese government's approach because LTL had to pay some fees, including the bankruptcy administrator fees, after entering bankruptcy proceedings, which in turn reduced the property used to compensate the tort creditors (The high cost of bankruptcy has long been criticized by not only American scholars but also Chinese scholars). The approach of the Chinese government, on the other hand, avoided fees such as high remuneration for the bankruptcy administrator.

How the Chinese government dealt with the Changsheng vaccine incident was also better than how Johnson & Johnson dealt with the baby powder incident since LTL's assets may were insufficient to compensate all the tort creditors. That is why it can be argued that Johnson & Johnson evaded some of its liability and deprived the rights of the tort creditors by what is known as the "Texas Two-Step" (20). To prevent latecomers from following the example of Johnson & Johnson, the House Judiciary Committee chaired by Representative Jerrold Nadler (D-NY) conducted a Mark-up Session and passed H.R. 4777, the Non-debtor Release Prohibition Act of 2021, out of committee for consideration by the full House of Representatives. H.R. 4777 would prohibit or severely limit the maneuver recently used by Johnson & Johnson (21). However, this problem is not associated with the approach adopted by the Chinese government because Johnson & Johnson, as a profit-making entity, certainly wanted to minimize the compensation it paid out, while on the other hand, Chinese government wanted to make sure that all the tort creditors were compensated so that the cost and pressure to maintain social order could be reduced. The tort debtor has an incentive to use bankruptcy proceedings to achieve what non-bankruptcy proceedings could not, thereby harming the interests of the tort creditors (22).

Legal basis for solving the problem of attribution of liability for endangering public health in bankruptcy proceedings by setting up a special compensation fund according to a government decision

In the United States, many scholars believe that bankruptcy reorganization is an effective solution to mass torts; on top of this, they have proposed legislative optimizations (23). However, the current literature offers justifications from the perspective of the debtor (i.e., by focusing on how to better solve the problem of liability for the tort debtor rather than on how to better address the problem of public health accountability). Of

course, if the tort debtor has going-concern value, legislators and judges should try to maintain its social value as much as possible; however, regardless of whether the tort debtor has going-concern value, the protection for the debtor should never override the liability for public health. Unfortunately, in both China and the United States, scholars in related fields have not attached due importance to the maintenance of public health. From the author's point of view, when an incident endangers public health, legislation should prioritize the solution to the problem of liability for endangering public health over relief for the debtor based on bankruptcy theory and legislation concerning debtor rescue. The government has always been the best candidate for maintaining public health; the debtor or the debtor's other creditors and shareholders cannot be the best candidates. During the process, it is still doubtful whether the court will prioritize the resolution of attribution of liability for endangering public health. This is because if the debtor chooses bankruptcy reorganization, the court should also consider the debtor's relief at the same time—after all, the debtor's relief is the core objective of the bankruptcy reorganization system.

Cases of bankruptcy involving the endangerment of public health also concern how to resolve the uncertainties in the assumption of liability for mass torts. Roe suggested that reorganization proceedings against the debtor should be adopted in mass torts case. During the reorganization, claims can be pooled and centrally administered in a manner analogous to the central administration by trustees of bond indentures or pension funds. Compensation methods similar to the variable annuity would reduce disparity in compensation among future tort claimants (24). Meanwhile, Roe also put forth that part of the future profits of the debtor should be included in the special fund. However, this approach risks tort creditors not receiving full compensation in the end. The profitability of the debtor is often difficult to calculate. If the debtor faces continued losses in the end, the legislator will have to make more-complex and less-operable regulations. In the bankruptcy cases of Changsheng in China and Johnson & Johnson in the United States, the set special funds came from the existing assets of the debtors (not including part of their future profits). In this way, the difficulty of handling relevant cases and the risk of the tort creditor not receiving full compensation in the end will both be reduced.

Admittedly, in both Changsheng's and Johnson & Johnson's bankruptcy cases, the tort creditor took a settlement status higher than other claims' (except for secured creditors, because in both cases, the property for paying off the tort creditor did not include the secured property), at least in terms of the separated special funds. This is why the author believes that the approach of the Chinese government lacks a basis in the Enterprise Bankruptcy Law of China. Theoretically, the tort creditors should have priority, mainly because such creditors are "passive creditors" (12). The attribution of liability for endangering public health in bankruptcy proceedings involves not only important human rights, such as the right to life and health, but also social stability. Therefore, it should be under special protection in law. That is, based on the point of view that rights, including the right to life and health, should be given a higher status than other rights and interests, the approach taken by the Chinese government in the bankruptcy case of Changsheng and the court judgment in the bankruptcy case of Johnson & Johnson are reasonable; in the future, targeted improvements should be made to the legislation.

It should also be explained in theory whether the proposed thinking for problem-solving applies to other types of mass torts. Here, the author's answer is no. This paper studies the attribution of liability for endangering public health in bankruptcy proceedings; the views and legislative suggestions put forward herein aim at the same. In the author's opinion, the legislation should distinguish mass torts that endanger public health from other types of mass torts. Chen Xiahong, a renowned expert in bankruptcy law in China, proposes that mass torts should be divided into those in traditional domains and those in emerging domains, with the former mainly involving mass torts endangering public health (25). However, Chen does not describe in detail how to handle them differently, nor does he elaborate, based on concrete cases, why they should be handled differently. According to Chen, the practice of the Chinese government in the bankruptcy case of Changsheng was similar to setting up bailout funds or trust funds under the leadership of the government (25). However, the actual practice of the Chinese government differed significantly from Chen's description. The biggest difference lies in the fact that the fund was set up by the Chinese government before Changsheng entered bankruptcy proceedings, not afterward through negotiation with the court and all interested parties, including other creditors (As we all know, any disposition of the debtor's property after the debtor enters bankruptcy proceedings is subject to a vote of all creditors). As a result, the practice of the Chinese government in this case conflicted with the provisions of the Enterprise Bankruptcy Law of China. In addition, debtors who enter bankruptcy proceedings for mass torts in traditional domains (mostly mass torts endangering public health) should be treated differently from those who enter bankruptcy proceedings for mass torts in emerging domains (for example, in the bankruptcy case of Kangmei Pharmaceutical, the debtor faced high compensation for false statements) for the following reason. In mass torts in traditional domains, there are many future creditors, and the tort creditors are often diversified, involving many people who know little about the law. In mass torts in emerging domains, however, the tort creditors often have relatively rich knowledge reserves and high risk-resistance. Therefore, the latter type of tort creditors should assume a higher duty of care: such creditors should bear certain commercial risks for their investment behaviors

and be treated differently from creditors in mass torts in traditional domains.

Even if debtors in bankruptcy proceedings are allowed to solve the problem of attribution of liability for endangering public health by setting up a trust, they may find the problem trickier later, because if at some point the claims against the trust exceed the amount of money that the corporation must contribute to it, numerous plaintiffs may go either uncompensated or grossly undercompensated. If the trust cannot be restructured to alleviate the shortage, the corporation may need to increase its contributions. Such an increase in contribution may require a modification of the reorganized corporation's Chapter 11 plan, a matter governed by the Bankruptcy Code (17). Furthermore, bankruptcy proceedings mostly adopt the settlement program of the majoritarian institution; that is, in bankruptcy proceedings, the tort debtor and most of the other creditors, including the non-tort creditors, have most of the right to decide the attribution of liability for endangering public health by setting up a trust. This is apparently disadvantageous for the tort creditor, because in public health incidents, the more compensation the tort creditor receives, the fewer the benefits enjoyed by the tort debtor and other rights holders.

When addressing the attribution of liability for endangering public health, both bankruptcy liquidation and bankruptcy reorganization proceedings should adopt the solution of setting up special funds, as decided by the government. Indeed, the repayment for creditors in reorganization proceedings is generally higher than that in liquidation proceedings. However, when it comes to liability for endangering public health, the question is no longer of which can enhance the repayment rate of the creditors but of how to ensure that the tort creditors can be repaid in full. We learn from these two cases that both the approach adopted by the Chinese government and that adopted by Johnson & Johnson were based on fully compensating the tort creditors, even though this may not have been realized in the end. This paper aims to determine how to better ensure that the tort creditors receive full compensation using the approach of setting up a special fund. Of course, there could be circumstances in which the special fund set up after a public health incident cannot guarantee that the tort creditors will all be paid off in full. Only in such cases will the government or other public welfare organizations be needed to compensate the tort creditors for the losses suffered. However, the approach proposed herein—that the government decides whether to set up a special fund and sets its size—minimizes the possibility that the special fund will be unable to guarantee full compensation for all tort creditors. Naturally, whether the debtor goes into bankruptcy reorganization or bankruptcy liquidation, the remaining special fund (if any) may be distributed to other creditors according to the provision on the additional distribution of article 123 in the Enterprise Bankruptcy Law of China.

Actionable recommendations: Codification of the approach for handling cases of incidents endangering public health in China

Some Chinese scholars believe that the claims of personal infringement should be given liquidation status second only to bankruptcy costs and public debt (According to the Enterprise Bankruptcy Law of China, bankruptcy costs and public debt have the first order of discharge), and they argue that if the establishment of the secured claims occurs after the claims of personal infringement, the latter should have priority over the former (26). This view is bound to increase transaction costs and count against the development of business innovation. Although there are many theoretical discussions on giving priority to the tort creditor in cases of incidents endangering public health, this priority is not actually given in either China or the United States because it might discourage the entrepreneurial spirit or prejudice the status of other priority holders, including the secured parties in bankruptcy proceedings, thus increasing the economic costs. Moreover, if the Enterprise Bankruptcy Law of China adopts the above scheme, relevant legislation in China would find it hard to prevent a Chinese version of Purdue Pharma's bankruptcy, thus damaging the procedural choice of the tort creditor (27).

In commercial bankruptcy practice, many creditors do not have the ability to negotiate with the debtor (28). The best way to solve incidents endangering public health is to take part of the property of the tort debtor to compensate the tort creditor. Legislators should also realize that if the right to divest compensation funds from the property of the tort debtor is given to the tort creditor, this is likely to damage the rights and interests of the tort creditor. The tort debtor, as a profit-seeking entity, would naturally seek to protect its own interests, and this can only be solved by giving right to a public body like government. What needs to be addressed in legislation is how the relevant practices can be codified and harmonized with the Enterprise Bankruptcy Law of China and other laws.

To solve the predicaments of legislation and effectiveness facing the Chinese government when dealing with incidents endangering public health, the Chinese legislature should specify that in the face of such incidents, relevant government departments will have the right to require the tort debtor to set up a special compensation fund based on the severity of the incident, and the management and supervision of such a fund would then be handed over to a third-party organization. In the meantime, relevant legislation should be clear about the criteria for determining the amount of the special compensation fund in incidents endangering public health in anticipation of a situation in which the special fund is insufficient to compensate the tort creditor. To further protect the rights and interests of

the tort creditor, the Enterprise Bankruptcy Law of China should also clearly state that the special funds set up for compensation in incidents endangering public health are not the debtor's property; otherwise, the provisions made by the legislators on setting up special compensation funds will be meaningless. In addition, the Enterprise Bankruptcy Law of China should allow the tort creditor to file a lawsuit against the tort debtor after the tort debtor enters bankruptcy proceedings and ensure that the bankruptcy administrator remains the representative of the tort creditor. At the same time bankruptcy administrator should be entitled to receive remuneration from the special fund rather than the debtor's property; otherwise, it will be unfair to the debtor's other creditors.

Discussion: Different reasons for same choices in China and the United States

It should be noted that the purpose of this paper was not to compare the relevant legislation in China and the United States, but to compare the bankruptcy cases of Changsheng to that of Johnson & Johnson. The United States is a country of case law, where court judgments, especially the reasoning therein, have an important influence on relevant future judgments. As such, in this paper the court judgment in the bankruptcy case of Johnson & Johnson was studied. China, on the other hand, is a country of statutory law. Moreover, this paper focused on the attribution of liability for endangering public health in bankruptcy proceedings in China, for which the discussion on related issues must be closely centered on the relevant legislation in China and policy documents promulgated by the Chinese government. More importantly, the reason that the bankruptcy case of Johnson & Johnson attracted broad attention is that the judge made a judgment at odds with public understanding and the core content of the judgment was not the interpretation and application of relevant provisions in the current U.S. law, but the reasoning of the judge.

In light of the political institutions and social environment of China, the Chinese government highly values social stability. As a result, the Chinese government becomes deeply involved in the handling of public health incidents to avoid shortfalls of funds for compensating tort creditors. By contrast, in terms of factors such as the political institution and social environment, the U.S. government will not, and has no sufficient legal basis to, become overly involved in cases to be decided by the court based on social stability and other considerations. Therefore, in cases in which bankruptcy proceedings are initiated for liability for endangering public health, the rights and interests of tort creditors in U.S. bankruptcy proceedings may be less protected than those in China. In bankruptcy cases, the court must consider not only the protection of the rights and interests of the tort creditors if the debtor chooses reorganization (in practice and as supported by many scholars in the United States, such cases should adopt reorganization proceedings instead of liquidation proceedings, because according to the bankruptcy law, the creditors' rights to repayment in reorganization will be greater than that in liquidation), but also debtor relief. Although the rights and interests of tort creditors in U.S. bankruptcy proceedings may receive insufficient protection when compared with Chinese bankruptcy proceedings, we must admit that the sound social security system in the United States can solve this problem to a large extent. In China, on the other hand, the emerging social security system means that the Chinese government must intervene early and strongly in bankruptcy cases involving liability for endangering public health. However, in practice, such intervention has no basis in bankruptcy law. Therefore, this paper recommends improving the relevant legislation in China in the future.

Many Chinese and U.S. bankruptcy law scholars call for tort creditor priority in bankruptcy proceedings, but neither Chinese nor U.S. legislators have adopted this philosophy. Although both Chinese and U.S. legislators hold the same opinion on this, it does not mean they make this decision for the same reason. Given the legal system and social condition of China, Chinese legislators' decision not to adopt tort creditor priority is based on the consideration of social stability (29). Even if tort creditor priority was adopted in China, for example, giving the tort creditor the same priority as the employee in bankruptcy proceedings (30), the tort creditor may also not get a full settlement, which may encourage the tort debtor to leverage the bankruptcy procedure to shrink from liability and force the tort creditor to impose pressure on the government through illegal means. The United States does not adopt tort creditor priority out of concern for the stability, but to maintain the stability and predictability of business activities, and few scholars consider social stability when suggesting tort creditor priority. Few U.S. bankruptcy law scholars consider social stability a factor mainly because people will not "seek the government for help in everything" in the United States, but in China, this is not the case (31).

The approach the Chinese government adopted in the Changsheng vaccine incident was mainly aimed at maintaining social stability while lowering the total social cost. As a result, the decisions of the Chinese government have not caused any social controversies because their primary goal is to protect the interests of individuals and maintain social stability, while reducing the total social cost is only a secondary goal and may not even be an expected outcome.

Author contributions

The author confirms being the sole contributor of this work and has approved it for publication.

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Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Baby food industry interference with infant feeding international regulation—A case study on the standard for follow-up formula

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Introduction: Globally, first-food systems have changed and breastfeeding has decreased due to the increased growth in commercial breast milk substitute (BMS) consumption, which includes both follow-up and toddler formulas. These products are manufactured by a small number of corporate leaders in international BMS sales. Discussions for global regulation of these products take place in the Codex Alimentarius and are permeated by the strong participation of these corporations in the Codex committees.

Objective: In the present study, the participation of the baby food industry in the review of the follow-up formula standard in the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was analyzed.

Methods: The analysis of the CCNFSDU documents was based on the period from 2009 to 2019 and used quantitative and qualitative approaches. Compositional and participation data from country delegations and observer organizations on the representative profiles of the involved institutions and the baby food industry's involvement in this process were established systematically.

Results: In total, 134 out of the 189 Codex Alimentarius member countries engaged in the standard review process, of which 28% were involved in the entire process. The private sector was present in 81% of the most assiduous member state delegations to the meetings. Furthermore, ~60% of the observer organizations involved in the review process were business associations representing industry interests. Moreover, the International Special Dietary Foods Industries was the only business association with observer status in the CCNFSDU that was specifically dedicated to representing the baby food industryduring the review process.

Conclusion: These research results expand the body of evidence confirming the expressive and disproportionate participation of baby food industries and their representatives in the discussion processes within the scope of the CCNFSDU. However, studies investigating the Codex and the public documents of its respective committees are limited. Thus, this was the first

study to analyze the influence of the baby food industry on BMS global regulatory compliance.

KEYWORDS

conflict of interest, commercial determinants of health, infants and young children feeding, breastmilk substitutes, baby food industry, infant formula

Introduction

"Codex Alimentarius" refers to a set of rules, guidelines, and codes of practice coordinated by the Codex Alimentarius Commission (CAC). The CAC is responsible for all matters regarding the implementation of the Joint Food and Agricultural Organization (FAO)/World Health Organization (WHO) Food Standard Program. All member countries and FAO/WHO affiliate members are eligible to join the Commission, in addition to scientific association observers, industries, food businesses, and consumers. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade (1). While the process to establish standards and guidelines is complex, it is designed to enable access to a wide range of stakeholders (2). Countries are allowed to create their own standards for public health, food security, and nutrition. Thus, the Codex regulations influence the national regulatory processes to ensure global food safety. However, evidence shows that standards facilitate business, prioritize trade concerns, and align with the interests of agri-food companies and the food industry, rather than adhering to health and food security (3–11).

Several studies have reported the influence of the food industry on the Codex (5, 7–13), primarily concerning committees for infant formulas, labeling, and additives. All of these committees benefit from the active involvement of observer organizations, including business associations from several pharmaceutical and food industries. In the context of products for infant feeding, particularly follow-up formulas, the first global standard for product compliance was adopted in 1987. The draft proposal for the follow-up milk standard by the Swiss delegation was submitted in 1975 and the Codex Commission approved it 12 years later in 1987. Thereafter, changes in product amendments and nomenclature were implemented until a consensus was reached for the name of the follow-up formula in 1987 (14).

Following the publication of the follow-up formula standard, a considerable amount of evidence regarding baby food and nutrition found widespread changes in the global food system, such as steep declines in breastfeeding and the normalization of formula feeding in many countries. In 2010, the New Zealand delegation proposed the preparation of a discussion article for the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to review the standard for follow-up formula. To date (i.e., November 2022), the review process has begun but is yet to be finalized.

"Non-government organizations that represented the baby food industry and other business interests attended and presented their perspectives throughout all the steps of the standard definition process with the CCNFSDU. According to Baker et al. (13), the "baby food industry" compasses Big Formula, the dairy industry as well as other input suppliers, retailers, advertising companies, and several other commercial entities profiting from the breast milk substitute (BMS).

Big Formula includes a limited number of corporations originating from food and pharmaceutical industries in Europe and the United States of America (USA) that dominate infant formulas. Furthermore, they manufacture major brands available on the market (13, 15). Big Formula comprises a network of trade associations and other influential organizations with corporate funding (e.g., lobbying groups and advertising associations). These organizations safeguard the interests of Big Formula on a global level and promote favorable regulatory environments for the expansion of their products (13). Moreover, some of these groups and associations have observer organization status on the Codex.

A coordinated network of commercial associations and Big Formula actively engages in political scenarios and regulatory arenas concerning baby and early childhood foods that influence the sales of these industries at a global level, such as the WHO, Codex Alimentarius, and the World Trade Organization (WTO) (13). In the context of debates about commercial determinants of health are strategies and approaches used by the private sector to promote products and alternative options. Thus, a special investigation into the commercial determinants of maternal, infant, and young child health has been conducted (13, 16). Investigating the corporate activities of the commercial actors specific to this context is pertinent to understand the corporate power that shapes first-food systems, fosters infant formula use and promotion, and jeopardizes breastfeeding on a global scale (8, 13, 15, 17–26). Participation in decision-making processes is one of these corporate actions. This study analyzed the participation of the baby food industry in the decision-making process regarding the revision of the standard for follow-up formula at the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

TABLE 1 Description of the methods adopted to analyze CCNFSDU[a] participation.

Analysis	Method
Participation percentage by group[b]	Number of participants in each group divided by the total number of participants
Participation percentage by group and by the *Codex Alimentarius* Regions	Countries were grouped according to the *Codex* geographic regions (Africa, Asia, Europe, Latin America and Caribbean, North America and South West Pacific, and the Middle East), and each region percentage was calculated based on the group
Private interest participants' percentage in member countries delegations	Private interest participants' rate per year was calculated for each country. Moreover, the average ratio for the years analyzed and aggregate private interest rates for participants were calculated, considering each country investigated during the second year
Total participants by interest group	Private interest (commercial associations participants and food industry) and public interest (government sectors representatives, universities, scientific associations, defense of rights associations, humanitarian organizations, and intergovernmental and consumer organizations) participants were categorized. Absolute and relative frequencies were calculated for each of the groups per year studied. These values were also averaged for the total number of years studied
Actors' participation percentage by group[b]	Each actor's group percentage was calculated according to the four group categories of attendance at the 11 sessions that took place during the period. The software Adobe® Illustrator version 25.2.3 was used for figure development. The figure was constructed in a circle layout, where each frame represented one group according to the attendance at the 11 sessions that took place during the period. Each color represented the actors involved in the process. Frames were introduced to display the number of actors in each meeting's attendance grouping

[a]Codex Committee on Nutrition and Foods for Special Dietary Uses.
[b]Group A: Members attending at least nine sessions.
Group B: Members attending 6–8 sessions.
Group C: Members attending 3–5 sessions.
Group D: Members attending two sessions.

Materials and methods

In this study, an exploratory analysis was performed by conducting a case study of the standard for the follow-up formula review process from 2009 to 2019. According to Yin (27), the strategy of implementing a case study is applicable when the researcher has no control of the events and focus is placed on facts concerning a specific real-life context, aiming to understand complex social phenomena.

This study systematized the composition of the delegations of member states and observer organizations and their attendance at meetings, the profiles of the participants from these institutions, and the extent of participation of the baby food industry and other industry groups in the revision process of the Codex standard for follow-up formula. Documents on the subject were collected from the Codex Alimentarius website on the CCNFSDU-specific page, where all documents available for public access can be found (https://www.fao.org/fao-who-codexalimentarius/en/). Data collection was performed in January 2020.

Collected documents included (a) CCNFSDU session reports, called ALINORM and REP (Commission, Committees, and Work Groups reports, as well as work documents for CAC session periods) and (b) Electronic Working Groups (EWG) and Physical Working Group (PWG) and Committee (referred to as CX) work documents, and Conference Room Documents (CRD). The collected and analyzed documents are listed in Supplementary material.

Data extraction and organization

A list of participants by member state delegation and observer organization is at the end of each ALINORM and REP, where the individual information of each session participant is entered. Information regarding session number and year, representative delegation, and the representative institution, industry, or country was collected and organized. All types of observer organizations and the participant's country of origin were registered. Participants from member state delegations and observer organizations were categorized into government, business associations, scientific organizations, human rights protection organizations (i.e., maternal and children's rights and breastfeeding), as well as consumer, humanitarian, and intergovernmental organizations.

Analysis of participating members

In total, 11 sessions were held during the study period and an Excel spreadsheet was used to count each session attendance of the participating member states. Based on these data, four group categories were created. That is, Group A comprised member states attending at least nine sessions; Group B comprised member states attending six to eight sessions; Group C comprised members states attending three to five sessions; and Group D comprised member states attending up to two sessions. Table 1 presents a description of the analysis

TABLE 2 Variables applied in private interest participants analysis, CCNFSDU[a], 2009–2019.

Variable	Description
Actors	Participant name initials
Origin	Participant country of origin
Total years	Total number of participants attending CCNFSDU sessions from 2009 to 2019
Delegation Country industry	The participant is part of the member state delegation, but represents a specific company
Delegation Country business association	The participant is part of the member country delegation, but represents an association that defends the interests of industries
Delegation Country University	It is part of member state delegation as specialized support
Observer *Codex*	It is part of an observer organization accredited by the *Codex*
Observer Codex_Industry	It is part of the observer organization delegation accredited by the *Codex*, but communicated that it represents food industry interests

[a]The Codex Committee on Nutrition and Foods for Special Dietary Uses.

methods used to measure delegation participation from member countries and observer organizations.

Analysis of participating private interest representatives

Table 2 presents the variables used in the analysis of private interest participants, including representatives from business associations and the baby food industry. Data from participants attending at least seven sessions were used (i.e., members who attended more than half of the sessions held). The private interest of each participant is shown using a line that indicates the representative institution or industry, country of origin, total years of attendance, and the delegation that the member was representing each year.

Link analysis between International Special Dietary Foods Industries and the baby food industry

The International Special Dietary Foods Industries (ISDI) website was analyzed to assess the links between this observer organization and the baby food industry. Thereafter, information was collected on the constituting associations. Data were extracted in November 2020 and were systematized using an Excel worksheet.

These links are expressed in figures exhibiting the four main Big Formula companies which include the transnational formula manufacturers that account for 55% of the formulas for infants and young children in the global market, namely, Nestlé, Danone, MeadJohnson, and Abbott (15). The links between transnational corporations that control the global production and distribution of ultra-processed products have also been presented. Furthermore, each business association member of the ISDI as well as the accompanying industry was identified. Each circle represents a transactional formula manufacturer with a color assigned to each circle. Lines with the same circle color were used to indicate links between business associations and the Big Formula, and each business association was represented by its acronym and country of origin. Big food is represented by orange circles with link lines of the same color. The software Adobe Illustrator version 25.2.3 was used for developing the figures.

Results

Composition and attendance of member state delegations and observer delegations in codex standard for follow-up formula review

In 2021, the Codex Alimentarius Commission comprised 189 members, namely, 188 member states and one member organization [i.e., European Union (EU)] (28). Among these, 134 members (71%) attended at least one of the CCNFSDU sessions during the investigated period, indicating heterogeneous country attendance during this period. Notably, 28% of the member countries regularly attended the meetings (Group A), while 37% attended <3 of the 11 meetings during the investigated period (Group D; Table 3).

Participation in the review of the Codex was analyzed according to region. The countries in the standard review were divided into regions according to the Codex. Upon observation, it was found that 57.2% of North America and southwest Pacific as well as 47.4% of Asian countries engaged in most parts of the investigated process (Group A). Furthermore, 47.2% of the African countries, 42.4% of the Near Eastern countries, and 33.4% Latin American and Caribbean countries attended <3 sessions (Group D; Figure 1). On the contrary, 58.7% of European countries participated in at least six of the 11 meetings. Table 4 shows private interest participants percentages (associations, business organizations, and food industry) according to the delegate composition of member countries. Only seven of the 37 Group A members (i.e., South Africa, Belgium, Sweden, Finland, Singapore, Zimbabwe, and the EU) showed a delegation composition with no private sector participation (i.e., private sector accounted for 81% of the delegation members). In the aforementioned group, the French delegation exhibited the highest participation average ratio in the private sector (72.8%), followed by the German (68.2%), the

TABLE 3 Member countries attending CCNFSDU[1] according to number of sessions 2009–2019.

Group A[a]		Group B[b]		Group C[c]		Group D[d]	
n = 37 (28%)		*n* = 20 (15%)		*n* = 28 (21%)		*n* = 49 (37%)	
Member country	***N*# sessions**	**Member country**	***N*# sessions**	**Member country**	***N*# sessions**	**Member country**	***N*# sessions**
South Africa	11	Saudi Arabia	8	Bangladesh	5	Angola	2
Germany	11	Spain	8	Cameroon	5	Antigua and Barbuda	2
Australia	11	Hungary	8	Cambodia	5	Bulgaria	2
Belgium	11	Ireland	8	Ivory Coast	5	Kazakhstan	2
Brazil	11	Russia	8	Cuba	5	Gambia	2
Canada	11	Turkey	8	Ecuador	5	Yemen	2
China	11	Vietnam	8	Mali	5	Jamaica	2
Colombia	11	Algeria	7	Paraguay	5	Jordan	2
South Korea	11	Denmark	7	Peru	5	Libya	2
United States of America	11	Estonia	7	Uganda	5	Luxembourg	2
France	11	Iran	7	Burkina Faso	4	Mauritania	2
Netherlands	11	Lithuania	7	Qatar	4	Moldavia	2
India	11	Morocco	7	Tanzania	4	Burma	2
Indonesia	11	Senegal	7	Uruguay	4	Nicaragua	2
Italy	11	Togo	7	Benin	3	Rwanda	2
Japan	11	Argentina	6	Bolivia	3	Samoa	2
Kenya	11	Slovakia	6	Botswana	3	Trinidad and Tobago	2
Malaysia	11	Kuwait	6	Croatia	3	Tunisia	2
Norway	11	Nepal	6	Ethiopia	3	Armenia	1
New Zealand	11	United Kingdom	6	Greece	3	Azerbaijan	1
Sweden	11			Iraq	3	Belarus	1
Switzerland	11			Israel	3	Comoros	1
Thailand	11			Laos	3	Congo	1
European Union	11			Lesotho	3	North Korea	1
Austria	10			Niger	3	Djibouti	1
Chile	10			Panama	3	El Salvador	1
Egypt	10			Dominican Republic	3	Eritrea	1
Philippines	10			Sri Lanka	3	Gabon	1
Finland	10					Georgia	1
Ghana	10					Guatemala	1
Mexico	10					Guinea-Bissau	1
Nigeria	10					Equatorial Guinea	1
Poland	10					Kiribati	1
Singapore	10					Latvia	1
Sudan	10					Lebanon	1
Zimbabwe	10					Macedonia	1
Costa Rica	9					Malawi	1
						Mozambique	1
						Mongolia	1
						Oman	1
						Papua New Guinea	1
						Pakistan	1
						Central African Republic	1

(Continued)

TABLE 3 (Continued)

Group A[a]		Group B[b]		Group C[c]		Group D[d]	
n = 37 (28%)		*n* = 20 (15%)		*n* = 28 (21%)		*n* = 49 (37%)	
Member country	***N*# sessions**	**Member country**	***N*# sessions**	**Member country**	***N*# sessions**	**Member country**	***N*# sessions**
						Czech Republic	1
						Saint Kitts and Nevis	1
						Sierra Leone	1
						Swaziland	1
						South Sudan	1
						Uzbekistan	1

[1]The Codex Committee on Nutrition and Foods for Special Dietary Uses.
[a]Members attending at least nine sessions.
[b]Members attending 6–8 sessions.
[c]Members attending 3–5 sessions.
[d]Members attending two sessions.

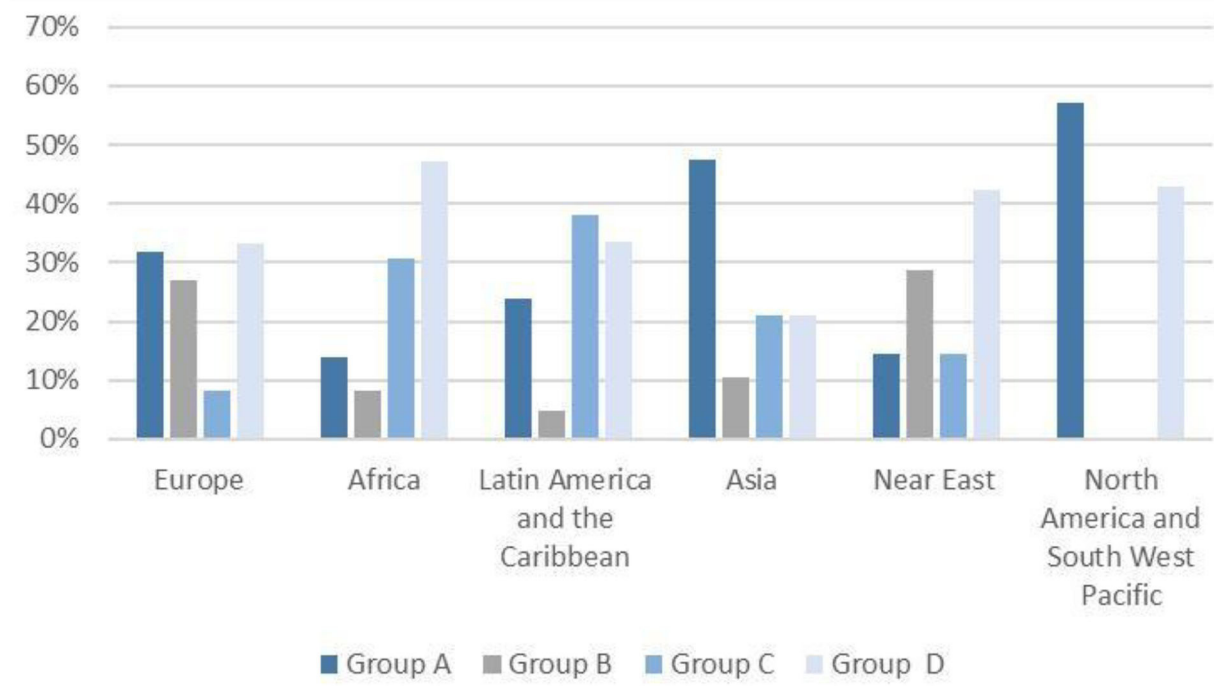

FIGURE 1
Percentage of participants attending CCNFSDU[a] sessions by region, 2009–2019. [a]The Codex Committee on Nutrition and Foods for Special Dietary Uses.

Colombian (63.9%), and the Swiss (59.4%) delegation. Group D did not have any private sector representatives, except for the Congo delegation participating in 2009.

After observing the total CCNFSDU participants based on the type of interest (including country delegations and observer members), this study found that, in every year, the proportion of public interest institution representatives was greater than the proportion of private interest institution representatives. During the period investigated, the participant average for private interests was 42%, while the average for public interest was 58% (Table 5).

Figure 2 presents relative participation according to the interest group type and the meeting attendance categories. A lower attendance of the member country in meetings was directly correlated with lower relative participation of representatives of private interests and greater relative

TABLE 4 Private interest participants rate in member countries delegations attending CCNFSDU[a], 2009–2019.

Member states	Years											
	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	2019 (%)	Average (%)
Group A												
South Africa	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Germany	66.7	60.0	76.9	71.4	78.6	60.0	77.8	66.7	57.1	63.6	71.4	68.2
Australia	0.0	0.0	0.0	50.0	33.3	66.7	66.7	75.0	50.0	50.0	25.0	52.1
Belgium	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Brazil	50.0	42.9	60.0	50.0	50.0	50.0	20.0	20.0	16.7	16.7	40.0	37.8
Canada	0.0	0.0	0.0	0.0	0.0	0.0	33.3	40.0	0.0	0.0	0.0	36.7
China	27.3	41.2	47.1	38.9	50.0	45.0	5.9	5.5	13.3	38.0	58.3	33.7
Colombia	50.0	33.3	100	0.0	0.0	100.0	50.0	0.0	50.0	0.0	0.0	63.9
South Korea	0.0	16.7	16.7	20.0	16.7	20.0	0.0	0.0	0.0	0.0	0.0	18.0
United States of America	33.3	36.4	30.8	30.8	33.3	28.6	33.3	23.1	23.5	29.4	26.7	29.9
France	75.0	80.0	75.0	80.0	66.7	50.0	80.0	75.0	75.0	71.4	0.0	72.8
Netherlands	50.0	50.0	50.0	50.0	50.0	0.0	0.0	0.0	0.0	0.0	0.0	50.0
India	33.3	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	29.2
Indonesia	0.0	0.0	0.0	14.3	33.3	4.9	57.1	60.0	75.0	42.9	50.0	42.2
Italy	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0
Japan	33.3	16.7	14.3	16.7	16.7	16.7	14.3	0.0	16.7	0.0	0.0	18.2
Kenya	0.0	0.0	0.0	0.0	0.0	50.0	50.0	50.0	33.3	16.7	33.3	38.9
Malaysia	0.0	0.0	50.0	0.0	0.0	72.7	25.0	50.0	25.0	25.0	42.9	41.5
Norway	33.3	33.3	33.3	33.3	0.0	33.3	33.3	0.0	0.0	0.0	0.0	33.3
New Zealand	0.0	0.0	0.0	33.3	50.0	50.0	60.0	60.0	50.0	60.0	50.0	51.7
Sweden	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Switzerland	75.0	75.0	66.7	50.0	40.0	50.0	33.3	33.3	80.0	75.0	75.0	59.4
Thailand	40.0	25.0	33.3	33.3	16.7	33.3	50.0	50.0	20.0	50.0	50.0	36.5
European Union	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Austria	50.0	0.0	0.0	0.0	0.0	0.0	–	0.0	0.0	0.0	0.0	50.0
Chile	33.3	61.5	0.0	–	0.0	0.0	0.0	50.0	50.0	33.3	0.0	45.6
Egypt	66.7	–	25.0	25.0	0.0	0.0	66.7	60.0	50.0	83.3	75.0	56.5
Philippines	0.0	0.0	0.0	0.0	0.0	–	0.0	50.0	50.0	33.3	33.3	41.7
Finland	0.0	0.0	0.0	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Ghana	0.0	0.0	14.3	0.0	0.0	0.0	0.0	–	0.0	0.0	0.0	14.3
Mexico	66.7	85.7	100.0	33.3	33.3	33.3	40.0	28.6	85.7	57.1	–	56.4
Nigeria	0.0	0.0	20.0	0.0	–	14.3	0.0	0.0	0.0	20.0	0.0	18.1
Poland	0.0	0.0	0.0	0.0	0.0	–	0.0	0.0	33.3	0.0	0.0	33.3
Singapore	0.0	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Sudan	0.0	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100.0	0.0	100.0
Zimbabwe	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Costa Rica	0.0	50.0	0.0	–	0.0	–	0.0	0.0	0.0	0.0	0.0	50.0
Group B												
Saudi Arabia	0.0	–	–	0.0	0.0	0.0	0.0	–	0.0	0.0	0.0	0.0
Spain	0.0	0.0	0.0	0.0	0.0	0.0	0.0	–	–	–	0.0	0.0
Hungary	0.0	–	0.0	0.0	0.0	–	0.0	0.0	0.0	–	0.0	0.0
Ireland	–	–	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Russia	–	–	–	80.0	66.7	80	83.3	80.0	50.0	33.3	60.0	66.7

(Continued)

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TABLE 4 (Continued)

Member states	Years											
	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	2019 (%)	Average (%)
Turkey	0.0	–	33.3	0.0	–	0.0	0.0	50.0	0.0	–	25.0	36.1
Vietnam	–	–	–	25.0	0.0	14.3	0.0	33.3	77.7	75.0	35.0	43.4
Algeria	–	0.0	–	0.0	–	0.0	0.0	0.0	0.0	–	0.0	0.0
Denmark	–	0	–	20.0	–	–	33.3	50.0	33.3	50.0	50.0	39.4
Estonia	0.0	–	–	0.0	0.0	–	–	0.0	0.0	0.0	0.0	0.0
Iran	0.0	–	–	0.0	0.0	0.0	0.0	–	–	0.0	0.0	0.0
Lithuania	0.0	–	0.0	0.0	0.0	–	–	–	0.0	0.0	0.0	0.0
Morocco	–	–	0.0	–	–	33.3	0.0	40.0	42.9	40.0	14.3	34.1
Senegal	–	–	–	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Togo	–	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0	–	–	0.0
Argentina	0.0	33.3	–	–	0.0	–	–	–	0.0	25.0	50.0	36.1
Slovakia	–	–	–	–	–	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Kuwait	0.0	–	–	–	0.0	–	0.0	–	0.0	0.0	0.0	0.0
Nepal	–	–	0.0	–	–	–	0.0	0.0	0.0	0.0	0.0	0.0
United Kingdom	0.0	–	0.0	–	–	–	–	0.0	0.0	0.0	0.0	0.0
Group C												
Bangladesh	0.0	–	–	–	–	0.0	66.7	–	–	0.0	0.0	66.7
Cameroon	–	–	0.0	0.0	0.0	–	–	–	–	0.0	0.0	0.0
Cambodia	0.0	–	–	–	–	–	0.0	–	0.0	0.0	0.0	0.0
Ivory Coast	0.0	–	–	0.0	0.0	–	–	–	0.0	33.3	–	33.3
Cuba	–	–	–	0.0	–	–	0.0	–	0.0	0.0	0.0	0.0
Ecuador	–	–	–	–	–	–	0.0	100.0	0.0	0.0	0.0	100.0
Mali	–	–	0.0	–	–	–	0.0	–	0.0	0.0	0.0	0.0
Paraguay	0.0	–	–	–	–	–	0.0	0.0	–	0.0	0.0	0.0
Peru	–	0.0	–	–	–	–	0.0	0.0	–	0.0	33.3	33.3
Uganda	–	–	–	–	0.0	–	0.0	0.0	50.0	50.0	–	50.0
Burkina Faso	0.0	–	–	–	–	–	–	–	0.0	0.0	0.0	0.0
Qatar	–	–	0.0	0.0	0.0	–	–	–	0.0	–	–	0.0
Tanzania	–	–	–	–	0.0	0.0	–	–	–	0.0	0.0	0.0
Uruguay	–	0.0	–	–	–	–	0.0	0.0	–	0.0	–	0.0
Benin	0.0	–	0.0	0.0	–	–	–	–	–	–	–	0.0
Bolivia	0.0	0.0	0.0	–	–	–	–	–	–	–	–	0.0
Botswana	–	–	0.0	0.0	–	–	–	–	–	–	0.0	0.0
Croatia	0.0	–	–	–	–	–	–	–	–	0.0	0.0	0.0
Ethiopia	0.0	0.0	0.0	–	–	–	–	–	–	–	–	0.0
Greece	0.0	–	–	–	–	–	–	–	0.0	0.0	–	0.0
Iraq	0.0	–	0.0	–	0.0	–	–	–	–	–	–	0.0
Israel	0.0	–	0.0	–	0.0	–	–	–	–	–	–	0.0
Laos	–	–	–	–	–	33.3	–	–	–	0.0	0.0	33.3
Lesotho	–	–	0.0	0.0	–	–	–	0.0	–	–	–	0.0
Niger	0.0	–	–	–	–	–	–	–	–	0.0	0.0	0.0
Panama	–	0.0	–	–	–	–	–	0.0	–	–	0.0	0.0
Dominican Republic	–	0.0	0.0	–	0.0	–	–	–	–	–	–	0.0

(Continued)

TABLE 4 (Continued)

Member states	Years											
	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	2019 (%)	Average (%)
Sri Lanka	–	–	50.0	–	–	–	–	–	0.0	0.0	–	50.0
Group D												
Angola	–	–	–	–	–	0.0	–	–	0.0	–	–	0.0
Antigua and Barbuda	–	0.0	–	0.0	–	–	–	–	–	–	–	0.0
Bulgaria	–	0.0	–	–	–	–	–	–	0.0	–	–	0.0
Kazakhstan	–	–	–	–	–	–	–	–	–	0.0	0.0	0.0
Gambia	–	–	0.0	–	–	–	–	–	–	–	0.0	0.0
Yemen	–	–	–	–	0.0	0.0	–	–	–	–	–	0.0
Jamaica	–	0.0	–	–	–	–	–	–	–	0.0	–	0.0
Jordan	–	–	0.0	–	–	–	–	–	–	–	0.0	0.0
Libya	0.0	–	–	0.0	–	–	–	–	–	–	–	0.0
Luxembourg	–	–	–	–	–	0.0	0.0	–	–	–	–	0.0
Mauritania	–	–	0.0	–	0.0	–	–	–	–	–	–	0.0
Moldavia	–	–	0.0	0.0	–	–	–	–	–	–	–	0.0
Burma	–	–	0.0	0.0	–	–	–	–	–	–	–	0.0
Nicaragua	–	–	0.0	–	0.0	–	–	–	–	–	–	0.0
Rwanda	–	–	0.0	–	–	0.0	–	–	–	–	–	0.0
Samoa	0.0	–	0.0	–	–	–	–	–	–	–	–	0.0
Trinidad and Tobago	–	0.0	–	–	0.0	–	–	–	–	–	–	0.0
Tunisia	–	–	–	0.0	0.0	–	–	–	–	–	–	0.0
Armenia	–	–	–	0.0	–	–	–	–	–	–	–	0.0
Azerbaijan	–	–	–	–	–	–	–	–	–	0.0	–	0.0
Belarus	–	–	–	–	–	–	0.0	–	–	–	–	0.0
Comoros	–	0.0	–	–	–	–	–	–	–	–	–	0.0
Congo	100.0	–	–	–	–	–	–	–	–	–	–	100.0
North Korea	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Djibouti	–	–	–	–	–	–	0.0	–	–	–	–	0.0
El Salvador	–	–	–	–	0.0	–	–	–	–	–	–	0.0
Eritrea	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Gabon	–	–	–	0.0	–	–	–	–	–	–	–	0.0
Georgia	–	–	–	–	–	–	–	–	–	0.0	–	0.0
Guatemala	–	–	–	–	–	–	–	–	–	0.0	–	0.0
Guinea-Bissau	–	–	0.0	–	–	–	–	–	–	–	–	0.0
Equatorial Guinea	–	–	–	–	–	–	0.0	–	–	–	–	0.0
Kiribati	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Latvia	–	–	–	–	–	–	0.0	–	–	–	–	0.0
Lebanon	–	–	–	–	–	–	–	–	0.0	–	–	0.0
Macedonia	–	–	–	–	0.0	–	–	–	–	–	–	0.0
Malawi	–	0.0	–	–	–	–	–	–	–	–	–	0.0
Mozambique	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Mongolia	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Oman	–	–	0.0	–	–	–	–	–	–	–	–	0.0
Papua New Guinea	–	–	–	–	–	–	–	–	–	–	–	0.0
Pakistan	–	–	–	0.0	–	–	–	–	–	–	–	0.0

(Continued)

TABLE 4 (Continued)

Member states	Years											
	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	2019 (%)	Average (%)
Central African Republic	–	–	–	0.0	–	–	–	–	–	–	–	0.0
Czech Republic	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Saint Kitts and Nevis	–	0.0	–	–	–	–	–	–	–	–	–	0.0
Sierra Leone	0.0	–	–	–	–	–	–	–	–	–	–	0.0
Swaziland	–	–	–	–	0.0	–	–	–	–	–	–	0.0
South Sudan	–	–	–	–	–	–	–	–	–	–	0.0	0.0
Uzbekistan	–	–	–	–	0.0	–	–	–	–	–	–	0.0
Private interest participants rate	37.3	44.0	40.3	42.1	43.1	40.9	43.1	42.7	43.6	42.7	41.8	42.0

[a]The Codex Committee on Nutrition and Foods for Special Dietary Uses.
–, Member state has not attended the meeting.

TABLE 5 Total number of participants (including member state delegations and observer delegations) by interest type attending CCNFSDU[1], 2009–2019.

Years	Participants				Total
	Public interest[a]		Private interest[b]		
	n	%	*n*	%	
2009	158	63	94	37	252
2010	131	56	103	44	234
2011	160	60	108	40	268
2012	158	58	115	42	273
2013	148	57	112	43	260
2014	176	59	122	41	298
2015	164	57	124	43	288
2016	168	57	125	43	293
2017	177	56	137	44	314
2018	220	57	164	43	384
2019	213	58	153	42	366
Average	170	58	123	42	294

[1]The Codex Committee on Nutrition and Foods for Special Dietary Uses.
[a]Government representatives, universities, scientific organizations, defense of rights organizations, humanitarian organizations, intergovernmental organizations, and consumer organizations.
[b]Business associations and food industry representatives.

participation of government representatives. However, this results in increased relative participation of government representatives. More than half of the participants in the member state delegations in Group A represented business associations and the food industry and 37% were government representatives, while in Group D these proportions were 36 and 61%, respectively.

The various participations of the baby food industry

Figure 3 shows the private interest participants and the respective annual representative institutions for Groups A, B, and C. In terms of delegation countries, a trend has been observed of representatives remaining within the same industry or business association, in contrast to representatives of observer organizations, which, in several cases, switch organizations and industries. These participants often change sides, and they sometimes serve as participants for country delegations in the food industry or as an observer organization. In this figure, we can see that three out of the five private interest actors who attended the entire review process represented supply manufacturing industries, such as vitamins, artificial flavors, and nutraceuticals for food industry formulations, as well as analytical and instrumental tests for food safety analysis, such as DSM and Merck.

During the investigated period, the participation of 67 observer organizations was analyzed. Based on the analysis of these organizations, 59.7% ($n = 40$) were business associations advocating food industry interests, 19.4% ($n = 13$) were scientific organizations, 6.0% ($n = 4$) were human rights-based organizations (human and breastfeeding), 4.5% ($n = 4$) were consumer organizations, 7.5% ($n = 5$) were humanitarian organizations, and 3.0% ($n = 2$) were intergovernmental organizations (Table 6).

Considering that the ISDI was the only observer organization that spoke for the interests of the baby food industry during the process of revising the Standard, it was considered important to identify the members of this organization. The study found that Big Formula was an active partner of the ISDI member associations. Nestlé was identified

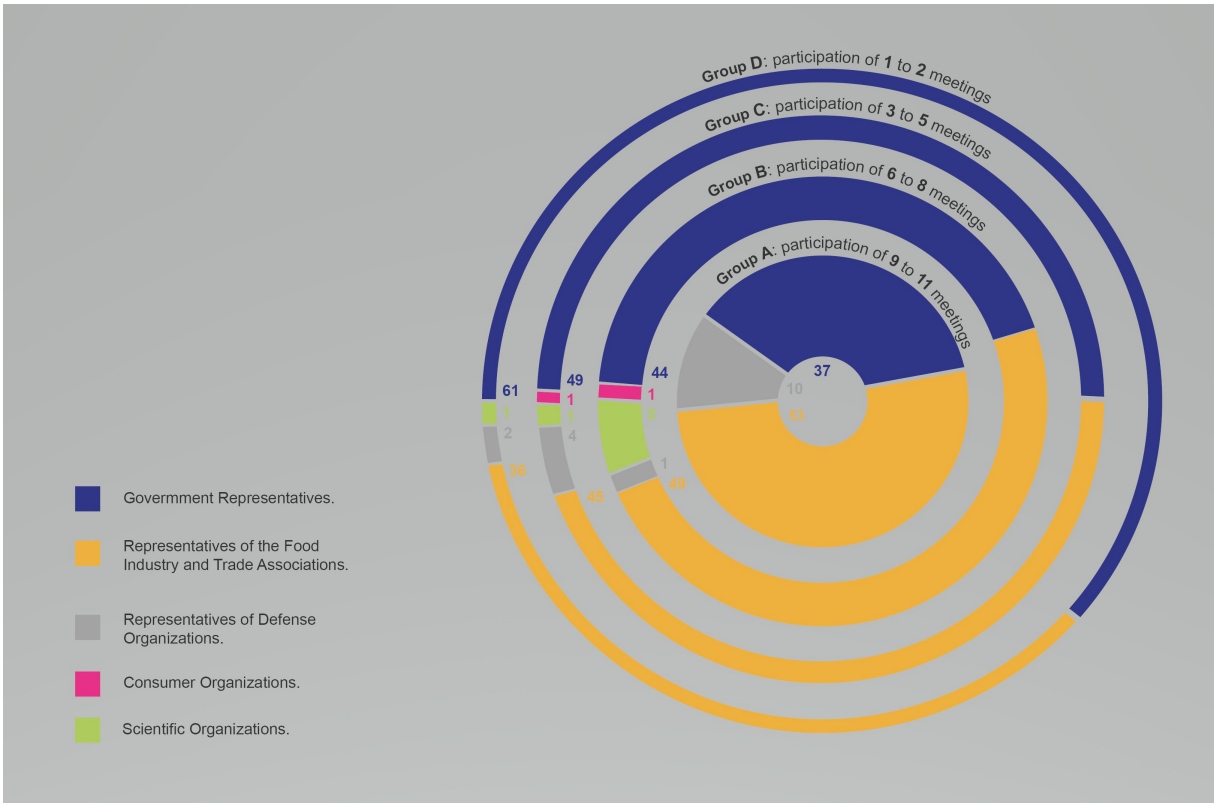

FIGURE 2
The relative participation of actors according to interest group, attending CCNFSDU[a], 2009–2019. [a]The Codex Committee on Nutrition and Foods for Special Dietary Uses.

as a member of all ISDI 22 associations, followed by Abbott, with 19 associations, Danone with 17 associations, and MeadJohnson with 13 associations (Figure 4). These results corroborate the literature (13), which indicates that these corporations are structured in a global influence network to protect their interests and promote regulatory environments that benefit their product expansion.

Discussion

This study identified that 134 of the 189 Codex Alimentarius Commission members (71%) attended the CCNFSDU sessions during the study period (2009–2019). Thus, this indicates different levels of attendance in the countries during the reference period. Smythe (5) underscored that national participation has been relatively unbalanced among the Codex committees despite the recent increase in adhesion among the countries. Furthermore, this unbalance remains despite the WTO's encouragement to its members to standardize their regulations according to the Codex rules and guidelines. Previously, low-income countries experienced challenges attending sessions. Thus, the Codex established a trust fund in 2003 to increase participation in 2004, which financed ~90 representatives from these countries (5). Despite efforts to enhance support, it was found that the participation among middle- and high-income countries was higher. In this sense, understanding the low adherence of these countries to the CCNFSDU is essential to verify whether the Codex norms and guidelines are reflected or not in public policies on infant feeding at the local level.

Industry participation in national delegations was another highlight of the present study which is seemingly common practice in the working processes associated with the Codex. Furthermore, industry participation can serve as a means through which the industry seeks to influence the internal decisions of the delegations. According to Thow et al. (10), this influence results from local lobbyists impacting committees, decision-making authorities, as well as national and global forums (10). However, the inclusion of industry representatives in national delegations led to a further imbalance favoring the industry because observer organizations linked to industry interests are formed exclusively by industry members.

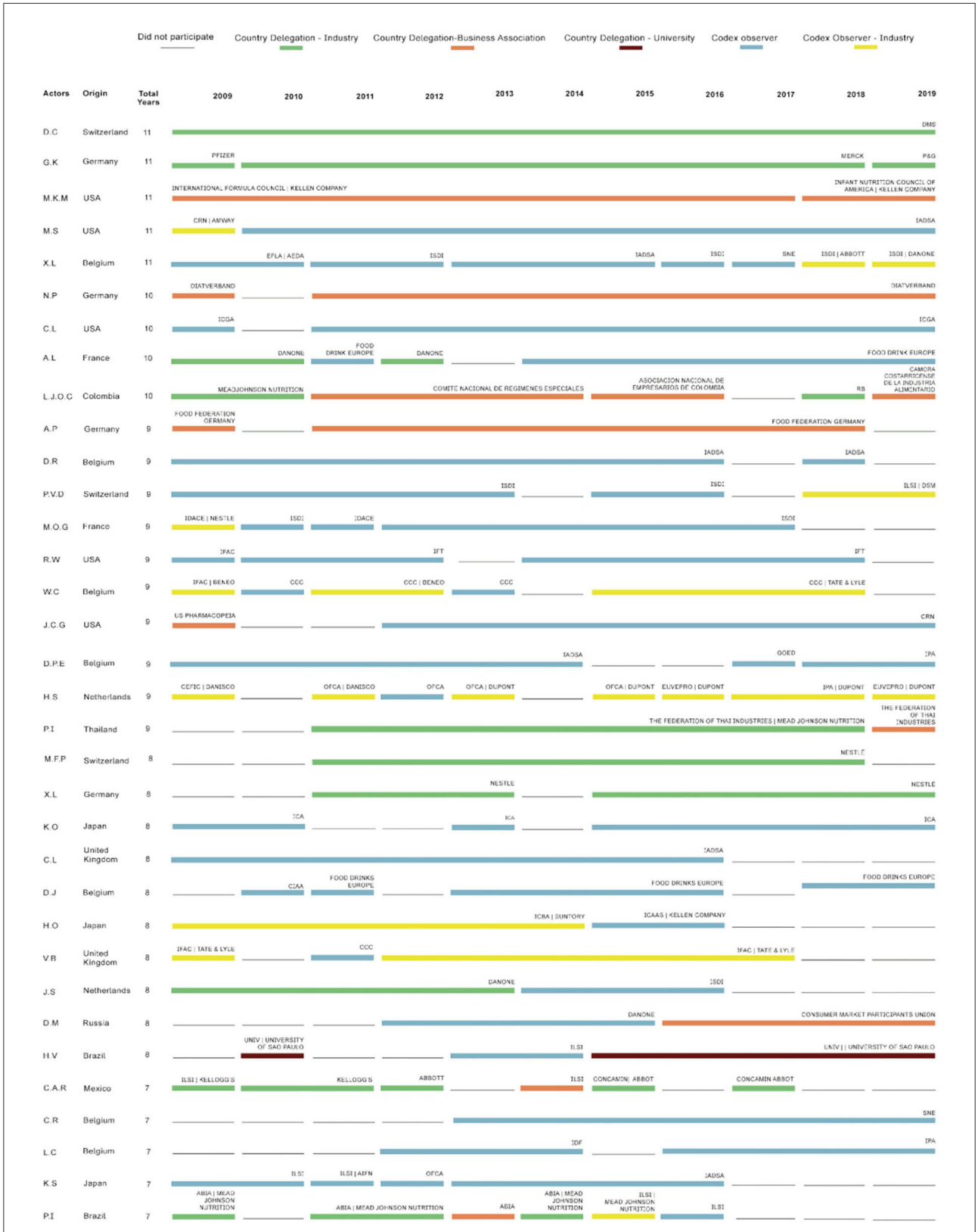

FIGURE 3
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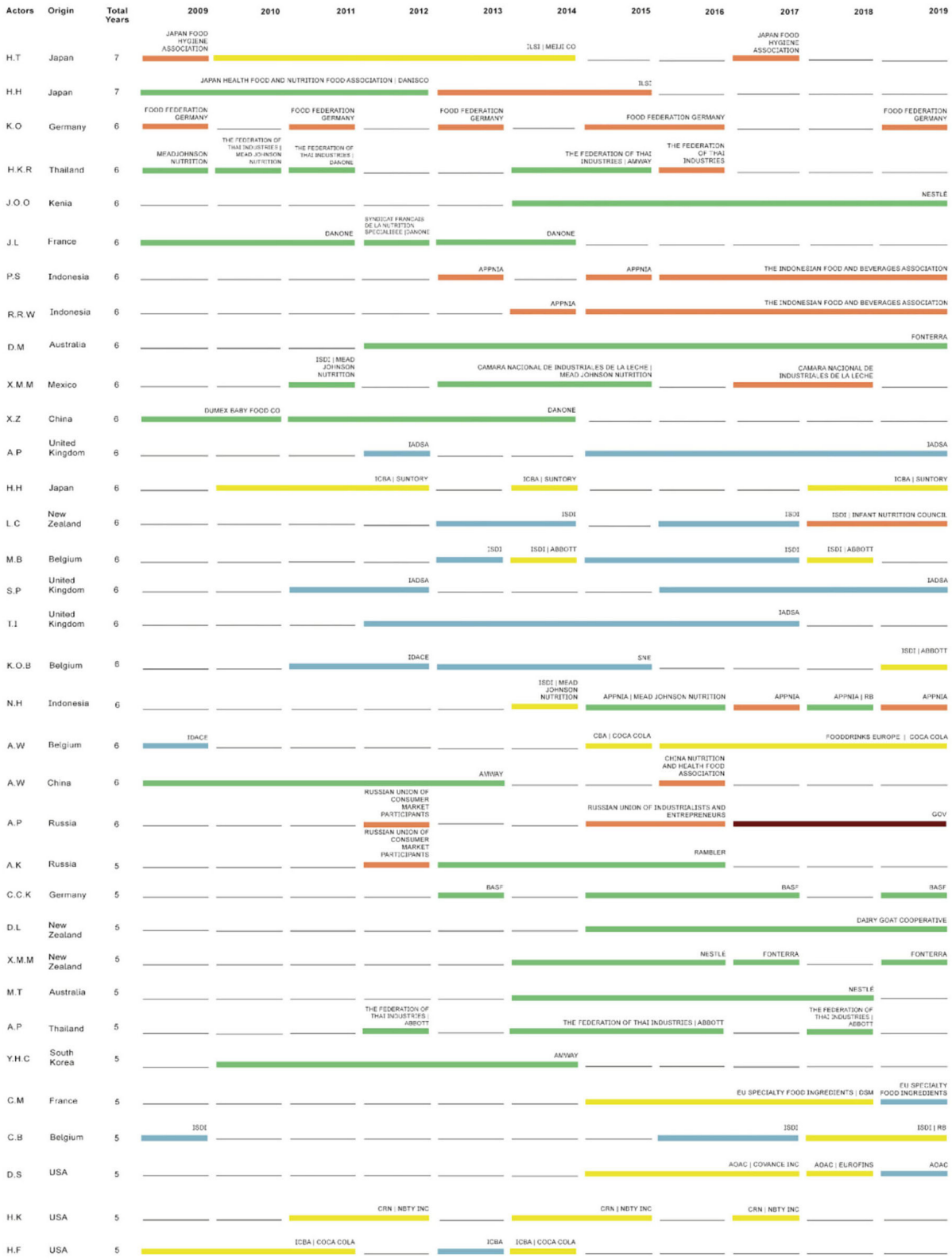

FIGURE 3
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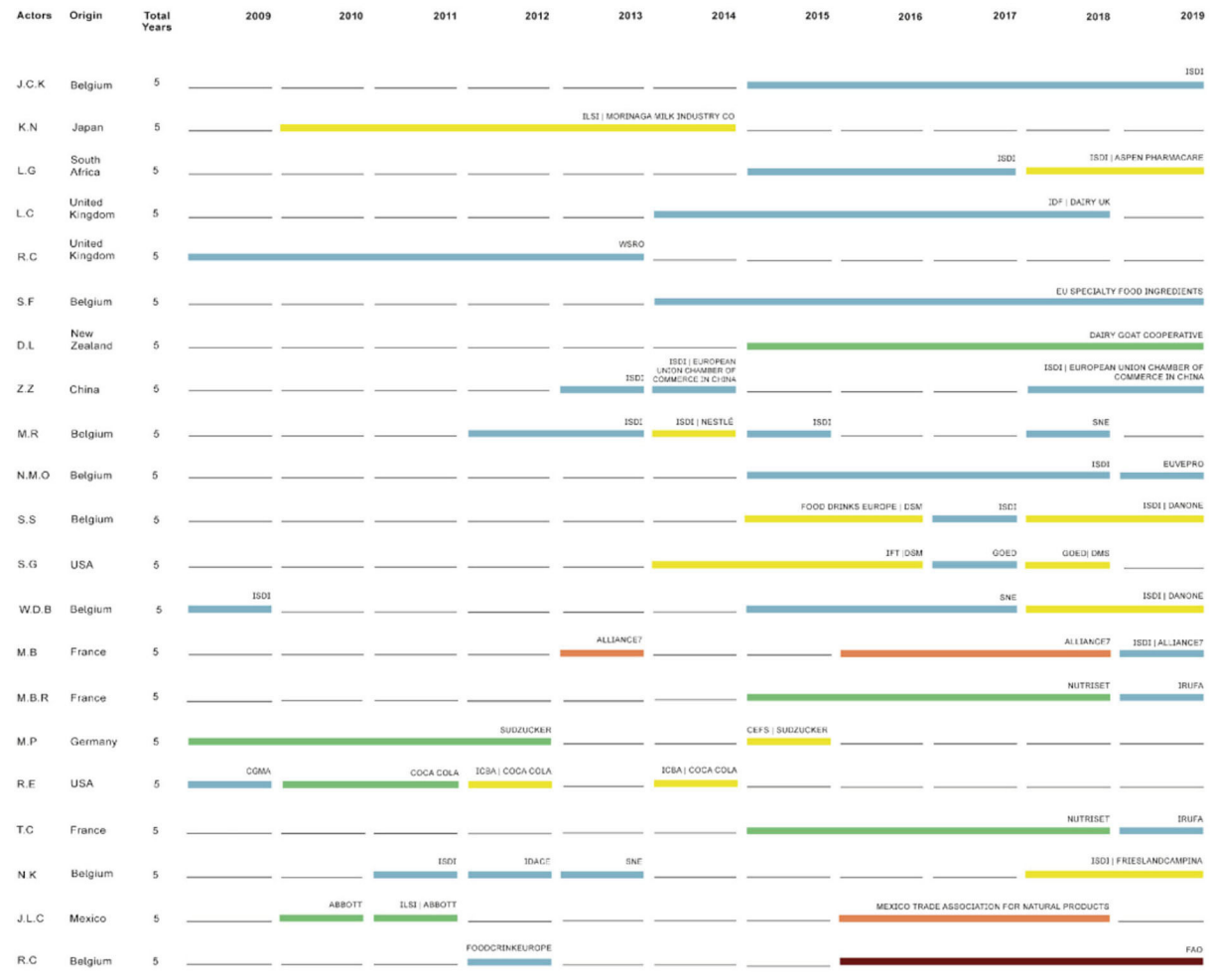

FIGURE 3
Private interest participants and participating institutions according to the origin and total years attending CCNFSDU[a], 2009–2019. [a]Codex Committee on Nutrition and Foods for Special Dietary Uses.

Several authors (5, 7–10) have also registered private interest participants which have compounded member country delegations. Furthermore, non-state actors from corporations and NGOs have played a significant role in the establishment of rules and guidelines through the direct involvement of the Codex Commission and their Committees as well as enhancing national efforts to influence the trading positions of state actors (28). Lee (6) observed an increase in industry participation between 1989 and 1991 on committees dealing with controversial issues, such as the Codex Committee on Food Additives (CCFA), handling additives, and CCNFSDU, handling special foods. The composition of industry actors attending the committee meetings that occurred between 1989 and 1991 was 41 and 47%, respectively (6). These findings are relatively similar to the attendance rates presented in this study (42%). However, the relative participation of the defense of rights, consumers, and scientific organizations was considered insignificant in this study. This participation may have been even smaller, as it was not possible to discern the source of funding for some of the scientific and humanitarian organizations that participated in the process. Some of them may have been financed by industries and actually defend their interests. Previous research (29, 30) has underscored that business groups are repeatedly overrepresented in decision-making politics. In contrast, public interest groups face difficulties in organizing themselves and enabling their participation and thus are underrepresented.

The imbalance observed in this study is consistent with previous literature in terms of the representation of several interest groups. This has resulted in the criticism of the Codex, considering that, in the private sector, this participation can influence food standards to benefit commercial interests (6, 7, 9) instead of public health interests. Throughout the

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TABLE 6 Observer organizations attending CCNFSDU[a] 2009–2019.

Observer organizations ($n = 67$)	*N#* Meetings
Business associations ($n = 40$; 59.7% of observer organizations)	
Council for Responsible Nutrition—CRN	11
International Alliance of Dietary/Food Supplement Associations—IADSA	11
International Council of Beverages Associations—ICBA	11
International Dairy Federation—IDF	11
International Life Sciences Institute—ILSI	11
International Special Dietary Foods Industries—ISDI	11
International Chewing Gum Association—ICGA	10
International Council of Grocery Manufacturers Associations—ICGMA	10
European Dietetic Food Industry Association—IDACE[b] (currently Specialized Nutrition Europe—SNE)	10
Calorie Control Council—CCC	9
European Food and Drink Industry—Food Drink Europe	9
Institute of Food Technologists—IFT	9
Federation of European Specialty Food Ingredients Industries—EU Specialty Food Ingredients	8
International Council on Amino Acid Science—ICAAS	8
European Association of Sugar Manufacturers—CEFS	7
International Co-operative Alliance—ICA	7
International Food Additives Council—IFAC	7
Association Européenne pour le Droit de L'alimentation/European Food Law Association—EFLA_AEDA	6
International Fruit and Vegetable Juice Association—IFU	6
European Vegetable Protein Association—EUVEPRO	5
International Probiotics Association—IPA	5
Global Organization for EPA and DHA omega-3—GOED	4
Organization des Fabricants de produits Cellulosiques Alimentaires—OFCA	4
Association of the European Self-Medication Industry—AESGP	3
Association for International Promotion of Gums—AIPG	3
International Federation of Margarine Associations—IFMA (currently IMACE)	3
European Chemical Industry Council—CEFIC	2
Confederation of the Food and Drink Industries of the EU—CIAA	2
European Federation of Associations of Health Product Manufacturers—EHPM	2
Food Industry Asia—FIA	2
Association of Yogurts & Live Fermented Milks—YLFA	2
Association des Amidonniers et Féculiers—AAF	1
Association of Manufacturers and Formulators of Enzyme Products—AMFEP	1
European Committee for Umami—ECU	1
European Food and Feed Cultures Association—EFFCA	1
European Association of Polyol Producers—EPA	1
European Salt Producers' Association—EUSALT	1
International Glutamate Technical Committee—IGTC	1
International Wheat Gluten Association—IWGA	1
International Ready-to-Use Foods Association[c] (NUTRISET)—IRUFA	1
Scientific associations[d] ($n = 13$; 19.4% of participating organizations)	7
European Society for Pediatric Gastroenterology Hepatology and Nutrition—ESPGHAN	
International Food Policy Research Institute—IFPRI	7
Association of Official Analytical Collaboration International—AOAC	5
Early Nutrition Academy—ENA	5

(Continued)

TABLE 6 (Continued)

Observer organizations ($n = 67$)	*N#* Meetings
World Sugar Research Organization—WSRO	5
International Association for the Development of Natural Gums—AIDGUM	4
American Oil Chemists' Society—AOCS	3
American Society for Nutrition—ASN	2
United States Pharmacopeial Convention—USP	2
World Public Health Nutrition Association—WPHNA	2
International Association for Cereal Science and Technology—IACST	1
International Organization for Standardization—ISO	1
World Obesity Federation—WOF	1
Defense of rights associations (n= 4; 6.0% of participating organizations)	11
International Baby Food Action Network—IBFAN	
International Lactation Consultant Association—ILCA	10
European Network of Childbirth Associations—ENCA	8
Association of European Coeliac Societies—AOECS	7
Humanitarian associations[d] ($n = 5$; 7.5% of participating organizations)	7
Helen Keller International—HKI	
United Nations Children's Fund—UNICEF	6
Global Alliance for Improved Nutrition—GAIN	4
Médecins Sans Frontières International—MSF	4
Action Contre la Faim—ACF	1
Consumer associations ($n = 3$; 4.5% of participating organizations)	11
National Health Federation—NHF	
International Association of Consumer Food Organizations—IACFO	10
Consumers International—CI	1
Intergovernmental associations ($n = 2$; 3.0% of participating organizations)	5
Inter-American Institute for Cooperation on Agriculture—IICA	
União Africana—UA	5

[a]The Codex Committee on Nutrition and Foods for Special Dietary Uses.
[b]IDACE had its name replaced with SNE in October 1, 2013.
[c]ONG IRUFA is registered in the Codex Website as a NGO, but presented data are from Nutriset, responsible for manufacturing Ready-to-Use Therapeutic Food (RUTF) Plumpy'Nut®.
[d]It was not possible to discern the source of funding for some of the scientific and humanitarian organizations that participated in the process. Some of them may have been financed by industries and actually defend their interests.

years, representatives of supply manufacturing industries as well as analytical and instrumental tests for food safety analysis integrated Swiss and German national delegations, potentially enhancing technical support and participating in all internal processes. The International Alliance of Dietary/Food Supplement Associations (IADSA) has also participated in the process, representing the interests of dietary and food supplement industries (e.g., Amway, DSM, Merck, Danisco, and Dupont). However, the participation of micronutrient industries only reinforces the debate on nutritional reductionism, which focuses exclusively on nutrients, disregarding the quality of food and the combination of foods that form a dietary pattern (31).

The investigation of participants representing different sectors found that the same participant from the Russian delegation representing the government from 2017 to 2019 also represented the Russian Union of Industrialists and Entrepreneurs in 2016. This union is a non-governmental organization that promotes Russian business community interests. Furthermore, a participant from the Brazilian delegation represented the University of São Paulo in 2010 and from 2015 to 2019. However, from 2012 to 2014, the participant joined the International Life Sciences Institute (ILSI) observer organization delegation. After analyzing this participant's curriculum, it was found that the participant had been an ILSI member since 2012, occupying the position of the Scientific Coordinator at the supposed ILSI Task Force Supplements and Food fortification.

The ILSI was created in 1978 by a former Coca-Cola chief executive officer to prioritize the work of the organization in the scientific and political context. Evidence suggests that the ILSI influences scientific integrity principles through a set of political practices adopted by industry actors to influence public policies,

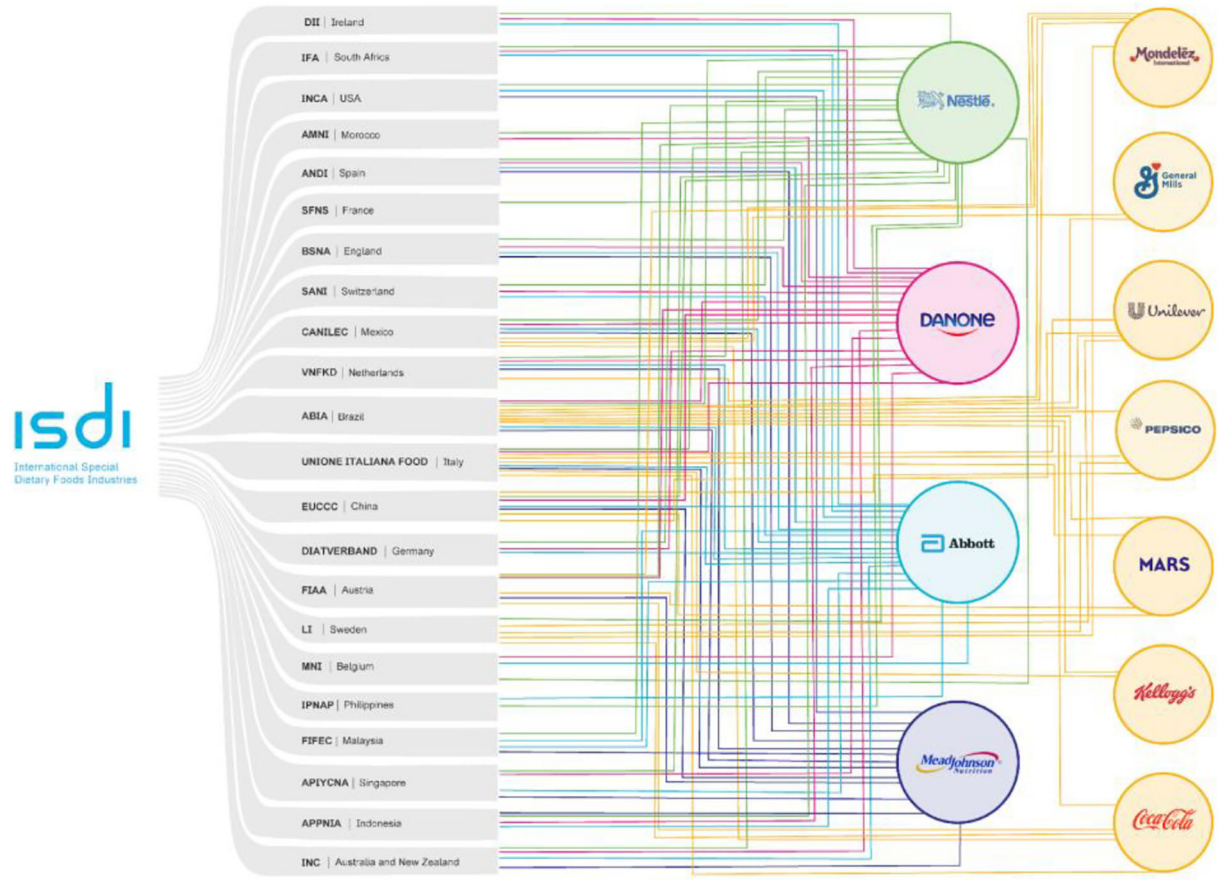

FIGURE 4
Commercial associations members of International Special Dietary Foods Industries and links with Big Formula.

research, and public health practice (32). Several representatives from the ILSI can be identified in state member delegations, such as the Japanese delegation from 2013 to 2015 and the Mexican delegation in 2009, 2011, and 2013, even though this is an observer organization. The same phenomenon is recognized at the ISDI, with participants in the New Zealand delegation in 2018 and 2019 and in the Mexican delegation in 2011.

Upon analyzing the baby food industries in the national delegation, it was found that these industries actively participated in the follow-up formula review. Representatives from Danone were identified in the French, Dutch, Thai, and Chinese delegations. Furthermore, representatives from Nestlé were identified in the Swiss, German, Kenyan, New Zealand, and Australian delegations. Representatives from MeadJohnson were in the Thai, Brazilian, Mexican, Indonesian, and Colombian delegations, while representatives from Abbott were found in the Mexican and Thai delegations. Corporations from the food and pharmaceutical industries of Europe and the USA dominate infant formula manufacturing and account for the major product brands. Moreover, only five of these corporations controlled 57% of the global market share, namely, Nestlé (Switzerland), Danone (France), Reckitt Benckiser (United Kingdom; in 2017 acquired MeadJohnson Nutrition), Abbott Laboratories (USA), and Royal Friesland Campina (Netherlands) (15).

The result of a higher proportion of participation of business associations representing the interests of the food industries among the observer organizations was also reported by Smythe (5). This author noted that there has been an increase in the number of industry-related observer organizations on the Codex over the years. In 1993, 660 out of the 2,578 participants from various Codex Committees represented the industry. Moreover, 140 and 157 observer organizations linked to the industry attended CAC sessions in 1993 and 2007, respectively. In addition, 70% of observer organizations in 2000 and 2002 represented industry interests (5).

Among the 67 observer organizations that attended the CCNFSDU during the evaluation period, only 11 organizations participated in the review of the follow-up formula standard beyond attendance at meetings. Participation comprised

performing written comments in response to requests included on Letter Circular (LC) at every review step. Future publications ought to provide detailed information about the documents and the respective observer organizations submitting these documents.

Lauber et al. (33) found that one of the food industry strategies involved in public consultation regulations and specialized agency documents, such as FAO and WHO, is related to business associations. Furthermore, increasing evidence suggests coordination between associations, even though some industry actors are competitors in their respective markets (33). This strategy was also used in this study. All 11 observer organizations effectively involved in standard review through official statements on each consulting document submitted by the CCNFSDU represent a different sector of the baby food industry. Consequently, seven organizations represented specific industries or supply manufacturing industries for formula preparation [e.g., sugar, cow milk, vitamins, minerals, and docosahexaenoic acid (DHA)], namely, the European Association of Sugar Manufacturers (CEFS), American Oil Chemists' Society (AOCS), Institute of Food Technologists (IFT), European Vegetable Protein Association (EUVEPRO), Global Organization for eicosapentaenoic acid (EPA) and DHA omega-3 (GOED), International Dairy Federation (IDF), and Federation of European Specialty Food Ingredients Industries, which is currently referred to as EU Specialty Food Ingredients. Moreover, two organizations, i.e., the International Council of Beverages Associations (ICBA) and ISDI, represented the main food industries on a global scale, while the ISDI was the only organization representing the baby food industry.

The ISDI is a non-profit business association composed of 22 national and local associations that share common goals. Each national association includes various industries. The ISDI comprises the main expert international association representing the special dietary food sector and performs as an industry platform promoting discussion about regulatory, technical, and scientific questions related to special dietary foods. The mission outlined by the ISDI is to support members by ensuring consistent policies based on science (34). Furthermore, the ISDI highlights its role as the Codex "partner," working as an "official observer at the Codex Alimentarius Commission," the joint FAO–WHO food standards-setting body (https://www.isdi.org/about). This structure positions the food industry as a legitimate political actor and partner in infant food promotion (33).

An important aspect to be highlighted is the capillarity of the ISDI and the presence of Big Formula industries in almost all associations. In addition to manufacturing and trading various types of both infant and follow-up formula, the industries have economic and political influence and act as a special interest group with the aim of impacting food and nutrition public policies to their benefit. This finding corresponds to the description of Mariah and Martins (30), which states that corporations' organizational capacity and high resource availability provide them a privileged position in relation to public interest groups advocating for collective rights. This is consistent with the case in this study regarding adequate food and health for infants and young children (30).

The results of this study support Baker's et al. (13) hypothesis that Big Formula operates in a global network of business associations and influences organizations. Particularly, Nestlé is a member of most organizations, followed by Danone, MeadJohnson, Abbott, and Friesland Campina (13). This study found that the ISDI business associations' members are located across six continents and are mostly national associations representing the baby food industry and dairy industry interests. Some of these associations gather information about breastfeeding and supplementary food for the general population and healthcare providers, identifying as technical supporters of local governments. In many cases, they pose as civil society organizations of the public interest despite representing corporate interests (35).

Finally, this study observed that food industry interest associations as well as associations focused on infant food are also ISDI members. These include organizations such as Associação Brasileira da Indústria de Alimentos (ABIA) from Brazil, Unione Italiana Food from Italy, Swedish Food Federation from Sweden, European Union Chamber of Commerce from China (EUCCC), and Food Industry Association of Austria (FIAA) from Austria. The largest transnational manufacturers of ultra-processed foods, such as Coca-Cola, Kelloggs, Mars, Pepsico, Unilever, General Mills, and Mondelez, are members of these associations. Representatives from these transnational companies were also identified in the observed delegations, namely, Coca-Cola in the ICBA and Food Drinks Europe, and Kellogs in the ILSI. Moreover, Coca-Cola was part of the US delegation in 2010 and 2011.

This study was limited due to the lack of interviews conducted with participants during the standard follow-up formula review process. This work is exclusively based on official data. Thus, the evidence examined does not provide an in-depth analysis of power discrepancies between participants representing corporations and participants representing public interests. However, this study clearly suggests a predominance of corporations over public interest actors.

The lack of official data on the conflicts of interest of the participants called for the investigation of the profile of each organization, imposing a challenge due to some actors' lack of transparency. Significant efforts have been made to identify the relationship between these organizations and the baby food industries and to overcome underlying limitations. Nevertheless, this relationship may not have been identified in some cases, which may have led to the underestimation of the participation of industries in the analyzed process. The strengths of the study are the thorough examination of all the materials available on each meeting of the CCNFSDU to regulate standards for infant

formulas and the synthesis of the findings through infographics, offering the reader a didactic communication resource.

The findings presented here expand the body of evidence confirming the expressive and disproportionate participation of industries and their representatives in the discussion processes within the scope of the CCNFSDU. Few studies have analyzed the Codex and the public documents of their respective committees. Thus, further studies are required to evaluate the internal processes of the Codex and the possible implications for the current regulations. Furthermore, an analysis of empirical data resulting from this study will provide evidence about corporative political action strategies implemented by infant formula industries and associated supplies in the standard for follow-up formula process that adheres to the CCNFSDU. Notably, prior to attending the Codex sessions, there is a preparation of the country's position, for which the articulation of all the actors in the delegation is necessary. As these local articulations are not transparent, we do not know which public interests are compromised and which private interests are benefited in this process. Thus, further studies are required to investigate these processes.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

KS participated in the study conception, design, data collection, analysis, interpretation, writing, critical revision, and approval of the final version. IC participated in the conception, design, supervision of data collection, analysis, interpretation, writing, critical revision, and approval of the final version. CC participated in the analysis and interpretation, writing, critical revision, and approval of the final version. KC participated in the conception, design, analysis, interpretation, writing, critical revision, and approval of the final version. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.984385/full#supplementary-material

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The interface between international trade and investment agreements and food environment policymaking: A conceptual framework

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Addressing the global challenge of malnutrition in all its forms will require policy measures to improve food environments, yet progress has been patchy and often slow, particularly for regulatory measures. International trade and investment agreements (TIAs) may limit governments' "policy space" for public health regulation. Constraints have been particularly apparent for public health measures targeting unhealthy commodities, including ultra-processed foods. Challenges and disputes regarding food environment regulation under TIAs (even if successfully defended) can entail significant drain of human and financial resources, and political capital. Lack of awareness or understanding of the implication of TIAs on policy space for regulation can contribute to regulatory chill and policy inertia. Governments lacking capacity to interpret their "legally available" policy space may want to err on the side of caution when there is perceived risk of a formal dispute—even if such threats are unfounded. This paper draws on analysis of literature, trade and investment dispute documentation, and data from inter-disciplinary expert interviews ($n = 22$) to present a new conceptual framework for the potential impacts of TIAs on policy space for regulating food environments. The analysis that underpins the framework focusses on the key policy domains of fiscal policies, front-of-pack nutrition labeling, restrictions on marketing to children, nutrient limits, and product bans. Analysis indicates that regulatory context and stakeholder influence, policy design, and mechanisms associated with TIA rules and provisions intersect in ways contributing to policy space outcomes. This new framework can provide a basis for rapidly assessing policy coherence between TIAs and food environment regulations in these domains. It can also be used to identify areas where further legal analysis would strengthen the development and defense of regulatory proposals. The framework may be applied to nutrition regulation more broadly, given the common themes that emerged across the different domains due to common interests of stakeholders, notably the food industry. It thus provides a basis for analyzing the political economy of regulation to address the commercial determinants of health in relation to unhealthy food and beverages.

KEYWORDS

policy space, food environment interventions, trade and investment agreements, political economy, public health

Introduction

There is an urgent need for research to address policy inertia in the regulation of food environments. Nutrition policy makers have the World Health Organization (WHO)'s "best-buys" and best-practice recommendations to refer to, yet uptake has been too slow to address the rising global burden of malnutrition. Most countries have failed to halt the rise in prevalence of obesity and reduce premature mortality from dietary non-communicable diseases (NCDs) (Lin et al., 2020) An emerging body of research indicates that binding constraints on nutrition policy space arising from international trade and investment agreements (TIAs) may hamper governments' efforts to address the growing burden of diet-related NCDs through food environment regulation, thereby contributing to policy inertia (Koivusalo et al., 2009; Friel et al., 2013a,b; von Tigerstrom, 2013; Thow and McGrady, 2014; Thow et al., 2015, 2017a,b; Kelsey, 2016; Ruckert et al., 2017; Barlow et al., 2018; Schram et al., 2019; Milsom et al., 2020; Garton et al., 2021a). However, such constraints are difficult to study empirically, and therefore the scholarship on this issue is largely theoretical.

Regulatory and policy space (hereafter simply referred to as "policy space") refers to "the freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfill their aims" (Koivusalo et al., 2009; p. 105). This concept thus includes the ability or right of states to regulate, the range of content and restrictions that policies can cover, as well as the processes through which policy can be chosen, designed, and implemented. National policy space encompasses both internal and external factors, pressures and priorities. TIAs are one contributing component, along with domestic laws and structures, that determine what governments can and cannot do. Under the purview of promoting freer flows of trade and investment, binding commitments made under TIAs may constrain the way countries can regulate goods, services, and investments to promote public interests (including public health) (Rodrik, 2018; Thow et al., 2022).

In this paper, TIAs refer to trade agreements and/or investment agreements. Trade agreements can be multilateral, involving most parties (e.g., the World Trade Organization, WTO, agreements); plurilateral involving many parties; regional, with membership confined to a specific region; or bilateral between two parties. Investment agreements are mainly bilateral, while combined trade and investment agreements are typically regional or bilateral. Agreements are negotiated between countries, signed, implemented, administered and ultimately enforced through agreed dispute settlement procedures and bodies. There are also informal forums for surveillance of compliance and management of disagreements outside of formal dispute settlement (e.g., the discussion of specific trade concerns at the WTO Technical Barriers to Trade, or TBT, Committee). Finally, there are external bodies that establish international standards and reference points that are referenced in TIAs (such as the Codex Alimentarius Commission, hereafter Codex, which establishes trade-relevant standards related to food and beverages, e.g., food safety and labeling). Trade disputes are most often arbitrated between states, i.e., Parties to the agreements. In state-state dispute settlement (SSDS), although companies cannot themselves challenge or initiate a formal dispute, they can encourage and support states to do so on their behalf, as has been documented in the challenges of tobacco packaging regulation in Australia and Uruguay (Crosbie et al., 2018; Jarman, 2019). More than 2000 bilateral investment treaties and several important regional TIAs include investor-state dispute settlement (ISDS), wherein companies can challenge government regulations directly (UNCTAD, 2022).

TIAs and the decisions of dispute settlement bodies are binding in a way that global health and human rights covenants are not, as consequences for non-compliance can be enforced through binding disupute settlement processes. These binding TIA rules include, *inter alia*, commitments not to discriminate between locally produced goods and "like" products from other nations, not to adopt regulatory measures that are more restrictive than necessary to promote public interests (including public health), to protect intellectual property rights, and also not to expropriate the property of foreign investors either directly (which is rare) *or* indirectly by enacting measures that have "equivalent" effects (Labonte and Sanger, 2006a,b). TIAs can also govern who must be consulted in policymaking processes, the adherence to agreed international standards, and an emerging codified understaning of "good regulatory practice" (Labonte and Sanger, 2006a,b; McNamara et al., 2021). These rules are meant to separate *bona fide* regulatory measures (i.e., made "in good faith" to achieve legitimate policy objectives) from those that constitute hidden forms of discrimination, protectionism or expropriation.

However, as indicated by several examples of WTO disputes (World Trade Organization, 2010a,b,c,d, 2014), investment disputes (UNCTAD, 2013a,b,c), and processes in informal trade fora (Kelsey, 2017; Thow et al., 2017a,b; Barlow et al., 2018; Barlow and Thow, 2021), these constraints on policy space can restrict governments' autonomy to enact policies to achieve public health, environmental and social development objectives, including mitigating the negative impacts of trade liberalization in harmful commodities. This has sparked a wave of critique from international legal, development, public health, environmental, and political science scholars (Wade, 2003; Page, 2007; Rodrik, 2011, 2018; Chan, 2013; UNCTAD, 2014; Fukuda-Parr and Treanor, 2018). Critics have long raised concerns regarding the WTO agreements—in particular, the General Agreement on Tariffs and Trade (GATT), the General Agreement on Trade in Services (GATS), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)—as constraining low- and middle-income countries' (LMICs)' ability to autonomously pursue development policies (Wade,

2003; Page, 2007). More recently, scholarship has revealed how the international trade and investment regime, especially through the proliferation of "WTO plus" bilateral and regional investment treaties and free trade agreements, has evolved into a system that often reaches behind borders into domestic policy arenas in ways that threaten the post-2015 development agenda (Chan, 2013; UNCTAD, 2014; Fukuda-Parr and Treanor, 2018; Rodrik, 2018; Labonte et al., 2019; Labonté et al., 2020; McNamara et al., 2021). Critically, disputes do not actually have to occur to influence policy making; the mere threat of a TIA challenge or dispute is often enough to discourage governments from pursuing a policy, in what is known as "regulatory chill".

In a normative sense, decisions made by dispute panels or other influential actors/institutions (e.g., about food environment or other public health policies in a trade context) may also shape future negotiations and interpretations of agreements. These all have an impact on policy and regulatory decisions at the national level, which may play out at different points in the domestic policy cycle (i.e., agenda setting, policy design, decision making, implementation, evaluation).

Regulating unhealthy foods to address the commercial determinants of health undeniably has impacts on industry. As unhealthy foods are a common product of trade and investment, these industry impacts can effectively trigger the use of TIAs, either by industry or trade partner governments, with arguments linked to economic concerns. As such, international trade law and international investment law introduce constraints on policy making that may not reflect domestic policy priorities, but those of other states and the private sector (Wagner, 2014). The critiques and challenges to the primacy of these agreements, and to interpretations of their various provisions, are part of a contested dynamic between actor-stakeholders in various related policy systems.

Constraints on food environment policy space have already occurred (Larios, 2005; Thow et al., 2017a,b; Barlow et al., 2018), and studies suggest future risks to health and food environment policy space posed by emerging international trade agreements and investment treaties (McGrady and Jones, 2013; Friel et al., 2013a,b; von Tigerstrom, 2013; Thow and McGrady, 2014; Marquez, 2015; Thow et al., 2015; Hirono et al., 2016; Schram et al., 2018a,b). A few examples help to illustrate different types of policy space constriction in the context of food environment regulations. There are certain policies that simply cannot be pursued within the bounds of TIA commitments, for example an increase in tariffs beyond agreed rates, or import bans of goods where there are domestic "like" products. Such constriction was seen when a population nutrition measure to prevent NCDs in the form of an import ban on turkey tails (a high-fat off-cut) to Samoa was required to be lifted when the country acceded to the WTO in 2011 (Thow et al., 2017b).

Front-of-pack nutrition labeling (FOPL) regulations for unhealthy food products is an example of a food environment measure for which Member states have raised specific trade concerns (STCs) in the WTO's TBT Committee, prompting the Member states behind the regulations to provide clarification, additional supporting evidence, or further justification (Friel et al., 2013b; Thow et al., 2017a). Though it is not a formal challenge or dispute, this process has the potential to cause regulatory chill, leading to delayed policy implementation, and/or weakening or abandonment of proposed regulations (Schram et al., 2018a).

Although there have been strong contributions from legal scholarship and public health nutrition literature, no framework exists specifically to assess policy space for food environment interventions at a national level, taking into account variable contextual factors and specific binding trade and investment commitments. Developing a better understanding of the potential constraints TIAs pose for policy space to address poor nutrition and diet-related NCDs through food environment regulation will assist in both the design of more robust nutrition policy interventions, and inform the negotiation of future TIAs that preserve food environment policy space. Such understanding may also help government policy makers to identify, critically assess and/or resist attempts by trade partners or commercial actors to restrict their policy space for food environment regulation through TIAs.

Research questions

The conceptual framework presented in this paper arose from the research undertaken for the lead author's doctoral thesis, supervised by the co-authors. Our hypothesis was that TIAs constrain policy space for food environment regulations, in a way that limits uptake of "best practice" nutrition policy. Our aim was to examine how these constraints occur (through what mechanisms, in what contexts), and what can be done to preserve this policy space. The investigation had three underlying lines of inquiry:

Global experience: How have TIAs been found to impact policy space for regulating unhealthy foods and beverages? What aspects of TIAs (e.g., specific chapters, rules, provisions) are relevant to governments' policy space for priority food environment interventions?

Policy design and context: How do different policy formulations result in different levels of vulnerability to policy space constraint? What aspects of the policies themselves are likely to be affected by binding TIAs, and what are the pressure points? How might contextual factors, such as actors and institutions, influence the mechanisms of TIAs' influence on policy space?

Preserving policy space: What are the key leverage points or strategies to increase/preserve policy space to achieve public health nutrition objectives via best practice in food environment regulation?

Methodological approach

This research was carried out through a critical realist inquiry with a political economy lens, using three qualitative methodologies: realist review, policy scenario analysis, and stakeholder analysis. The approach to analysis was underpinned by previous conceptualisations of health policy space constraints arising from TIAs and theories of power, blending and expanding upon these existing theories to arrive at a new conceptual framework.

Previous conceptualisations of health policy space constraints arising from TIAs

Fidler et al. described three mechanisms through which trade agreements could encroach on policy space, in their legal review of the WTO General Agreement on Trade in Services (GATS) from a health policy perspective (Fidler et al., 2006).

- Substantive constriction (i.e., direct limits on the range of policy instruments available to governments),
- Procedural constriction (i.e., the process of policymaking is limited or influenced), and
- Structural constriction (i.e., a shift from public to private provision of goods and services such that the economic and regulatory power of private sector actors is expanded)[1] (Fidler et al., 2006).

This framework was subsequently applied by Baker et al. (2014) and Hawkes (2015) in describing the nature of the threats trade and investment liberalization pose for governance in nutrition and NCD prevention.

In addition to these three mechanisms, the fourth mechanism relevant to food environment regulation is regulatory chill, as mentioned previously (Schram et al., 2018a). This refers to "government's response to a high (perceived) threat of [a trade dispute or] investment arbitration by failing to enact or enforce *bona fide* regulatory measures, or by modifying measures to such an extent that their original intent is undermined or their effectiveness is severely diminished" (Tienhaara, 2011; p. 5–6). Regulatory chill can occur in response to a real or perceived direct threat of challenge under TIAs, but its definition also includes internal institutional and systemic influences on domestic policymaking, resulting in internalized regulatory chill (Van Harten and Scott, 2016; Kelsey, 2017).

Schram et al. distinguish specific "response chill" through corporate influence or threat (e.g., through investor-state dispute settlement, ISDS), from "precedential chill" (based on past arbitral decisions), and "anticipatory chill" (internalized by policy makers based on uncertainty of policy (in)coherence with trade/investment, and therefore moderated by policy maker knowledge) (Schram et al., 2018a). Potential outcomes include policy being preserved and implemented "as is" or in modified form (which may or may not result in a challenge), or policy being delayed, compromised, or abandoned in response to perceived risk of a challenge. Other costs of pursuing a policy with potential for challenge may include reputational risk, expenditure of political capital, and the opportunity cost of diversion of efforts/human resources and budgets in order to confront or avoid a challenge (Van Harten and Scott, 2016). Contributing factors include the treaty context (i.e., specific content and dispute settlement mechanisms), the award context (relating to arbitral decisions), and the arbitration context (including e.g., a lack of precedent, means of appeal, potential arbitrator conflicts of interest, and legal fees and compensation). Political and economic factors, such as country resources, level of risk tolerance, political will/public support, political ideology, and the economic power of relevant actors/sectors may also influence the policy response (Schram et al., 2018a).

Theories of power

Political economy is concerned with how power and resources are distributed and contested in different contexts, and the implications for outcomes (e.g., in relation to development, health, and social justice). Political economy analysis looks beneath formal structures to reveal the interests, incentives and institutions that enable or constrain change. Within this lens, we drew upon theories of power from Lukes (1974/2005) and further elaborated by Gaventa (2003), including three dimensions:

- Decision making/formal authority (most visible) (Lukes, 1974). This involves direct, empirically observable, openly-contested public issues (Gaventa, 2003).
- Design of institutions, norms, and "rules of the game" that operate systematically and consistently to the benefit of certain interests (persons, groups) at the expense of others (Lukes, 1974). This is also referred to as "mobilization of bias" present in institutions (Gaventa, 2003).
- Ideological (invisible) influence, whose role is suppressing latent conflicts within society (Lukes, 1974). This may, for example, keep certain policy issues off the agenda,

1 From a general public health perspective, this could be relevant to the privatization of health care or health insurance. However, in the context of food environments, this is not a shift we would expect to see, aside from possibly in the procurement of food and beverage services in institutional settings. Even then, these tend to be small contracts that do not fall under the scope of procurement commitments in TIAs. This definition of structural policy space constriction was not deemed particularly relevant in the context of policy space for food environment regulation.

or influence expectations, so that inequities become non-issues (Gaventa, 2003).

We also drew upon the concept of "policy space analysis" put forward by Grindle and Thomas (1991) in relation to development policy, and as applied by Crichton (2008) and Thow et al. (2016, 2018, 2021) in answering public health and nutrition policy space questions, respectively. Grindle and Thomas (1991) policy space analysis framework highlights the interplay between context (e.g., actor characteristics and environment), policy characteristics (including public and bureaucratic impact and potential conflict, resources and political support for implementation and sustainability), and agenda-setting circumstances (e.g., the nature of problem, advocacy, and decision-making concerns) in policy change. Importantly, the framework characterizes policy space as being fluid, responding to the dynamics between forces that either support, or constrain policy space.

Realist review

Initially, a realist review examined the mechanisms through which policy space has been affected by TIAs in different contexts, through global experience in regulation of unhealthy foods and non-alcoholic beverages. The process served to begin identifying which factors (organized into contexts, mechanisms, and outcomes) are important to include in a framework of policy space for food environment regulation with respect to trade and investment. The review focused on published evidence and interpretations of the relevance of existing TIA rules to a sample of priority food policy domains. These included fiscal policy, FOPL, food standards and product bans relating to nutrient composition, public procurement[2], and restrictions on marketing and advertising to children. Methods and results for this study are published elsewhere (Garton et al., 2021a).

Policy scenario analysis through vignette interviews

Our next objective was to conduct a close examination of how policy design and context contribute to the mechanisms of policy space constraint, through perceptions of expert informants. Due to the complexity of assessing policy space with respect to dynamic contextual factors and variable policy formulations, a method was needed that was flexible to conditions of uncertainty, human choice and complexity. We therefore drew upon the concept of *scenario analysis* which explores implications of plausible alternative futures in a manner that reflects a normative dimension and incorporates different perspectives (Swart et al., 2004; p. 138). Qualitative scenario analysis in particular gives voice to the important intangible factors shaping decision making such as values, behaviors and institutional structures (Swart et al., 2004). This next phase of the research therefore involved a series of expert stakeholder interviews examining in depth the range of potential interactions with TIAs for various different policy scenarios, for a selection of policy instruments. We opted to focus these interviews on the policy areas of FOPL, restriction of marketing to children, and nutrient composition standards, based on the greater potential for TIA-related challenges identified in the realist review. Policy scenarios reflected changing policy settings, i.e., the adjustable specifications of a policy instrument, the modification of which can range from incremental shifts in policy to more radical transformations (Hall, 1993). Policy settings explored included degrees of compulsion (i.e., voluntary or mandatory), inclusion/coverage (i.e., products or services within remit), regulatory definitions and targets, implementation factors, policy design (process) factors, *et cetera*. These policy scenario interviews were carried out through a qualitative "vignette" exercise.

Each structured vignette was designed to shift incrementally, by changing a mix of policy settings, based on the variables that were hypothesized to influence regulatory space for the given policy according to the literature (Table 1).

Participants ($N = 22$) included experts in international trade and investment law, public health researchers, government bureaucrats working in public health and trade policy, and representatives from inter-governmental organizations concerned with global health, nutrition, and trade and investment (Table 2).

After talking through each variant of the policy scenario with the participant, we asked them to discuss their perception of challenges, threats or opportunities with regards to international trade and investment law for that particular situation, repeating this process through each variation. Through discussion of the various policy settings, the interviews also endeavored to define the perceived potential legal risk of each policy option (with respect to TIAs) in the given context, as well as what would need to change in order to reduce the potential legal tension with international trade and investment commitments. The same vignettes and variations were presented to each participant, allowing for comparison of responses between participants for a given policy action. This analysis was carried out for a hypothetical country context, incorporating discussions of how different contextual factors might influence policy space outcomes. The methods of the policy scenario analysis vignette study are further elaborated in a separate publication (Garton et al., 2021b).

2 It was anticipated that the area of public procurement to improve food environments would yield little evidence, as it is not widely applied and therefore largely untested; there are no known international trade- or investment-related challenges to food procurement policies as yet.

TABLE 1 Policy scenario variations for labeling, marketing restriction, and nutrient composition regulations.

Scenarios	FOP labeling	Marketing restrictions	Nutrient composition
0.0 Baseline	Voluntary Guideline Daily Amount thumbnails	Mandatory ban of television advertising using persuasive techniques during children's programming	Quasi-regulatory reformulation of targeted nutrients
1.0	1.1 Degree of compulsion: mandatory (after voluntary) 1.2 Degree of compulsion: mandatory (skip voluntary)	1.0 Content restricted: persuasive vs. all unhealthy food advertising	Nutrient: sodium Degree of compulsion: mandatory Products within remit: 1.1 Select food categories 1.2 Broad reduction 1.3 Exemptions (e.g., for traditional foods) Degree of compulsion: 1.4 Skip voluntary
2.0	2.1 Format: interpretive 2.2 Format: size increase 2.3 Format: warnings	2.0 Definition: time of day, peak viewing times	Venue: out-of-home meals 2.1 chains (>20 outlets) 2.2 all food service including informal sector
3.0	3.0 Nutrient profile: national vs. regional or international	3.0 Target audience: children under 12 vs. under 18	3.0 Nutrient: Trans-fatty acids
4.0	4.0 Due process: no consultation of industry	4.1 Medium: include non-broadcast 4.2 Medium: all marketing	4.0 Nutrient: Sodium
5.0	5.1 Implementation: short time frame 5.2 Implementation: no stickers	5.0 Targeted commodity: include Brands	5.0 Nutrient: Sugar
6.0	6.0 Evidence: international vs. local	6.0 Evidence: international vs. local	6.0 Evidence: international vs. local

TABLE 2 Expert interview participant characteristics.

Participant characteristics (N = 22)			
Policy area (n)	**Geographic region (n)**	**Sector (n)**	**Discipline (n)**
Labeling (9)	Australasia (9)	NGO (10)	Trade law (12)
Marketing (9)	Latin America and Caribbean (7)	Academic (16)	Investment law (7)
Nutrient composition (4)	Europe and UK (3)	Public sector (2)	Public health nutrition (8)
	North America (2)	Private sector (1)	
	Sub-Saharan Africa (1)	IGO (1)	

Stakeholder analysis: Actors, institutions, and global advocacy coalitions

Finally, we drew upon methods for stakeholder analysis to further analyse the data collected in the 22 vignette interviews and the documentary data from the realist review. The objective was to determine the roles and interests of actors and institutions that factor into food environment policy space, and the ways in which they exert influence. Drawing upon Varvasovsky and Brugha (2000), we conducted a thematic analysis of the realist review data and interview transcripts to describe and categorize the interests of different actors and institutions that factor into trade- or investment-related nutrition policy space, the terms of their involvement and the ways in which they exert influence in global trade policy, with reference to national policy making processes (Varvasovsky and Brugha, 2000). Our analysis was underpinned by Sabatier (1988) Advocacy Coalition Framework (ACF), which conceptualizes coalitions of actors, brought together by shared beliefs, as being influential in shaping policy outcomes for a given policy subsystem (Sabatier, 1988; Sabatier and Weible, 2007; Jenkins-Smith et al., 2014), which in this case was defined as the food environment regulation policy sphere. This framework is particularly relevant because the issue of TIAs constraining nutrition policy space is complex, international and intersectoral, with evidently competing key beliefs and interests between sectors as well as unequal distribution of resources between them. The lead author systematically coded each of the interviews and literature review sources according to themes in line with the ACF, in NVivo[3]. The methods used and findings of this phase of the study are described in detail elsewhere (Garton et al., 2021c).

3 QSR International Pty Ltd. NVivo qualitative data analysis software.

Integrated analysis: Retroduction

Through a process of "retroduction", within and between these studies, we developed a theoretical framework for the potential influence of TIAs on policy space/policy inertia for food environment regulation. Retroduction is a key feature of critical realist analysis; it is an iterative process, moving beteen induction and deduction, and continuous interaction between theory and observation (Halperin and Heath, 2012). In practice, "the compiling of evidence (induction) leads the researcher to theory (deduction); and once a hypothesis is formed, the researcher brings it "backward" for readjustment or redefinition" (Halperin and Heath, 2012; p. 32). Previous theories identified in an initial scoping review (e.g., Fidler et al. on TIA constraints to health policy space, Schram et al. on regulatory chill, and theories of power from Lukes and Gaventa) informed a preliminary conceptual framework, which in turn informed, and was subsequently revised after, each stage of research (see Figure 1). As such, it is an "evolving, dynamic process of discovery and hypothesis formation" (Halperin and Heath, 2012; p. 32).

Results: Elements of a new conceptual framework

In this section, we present how the findings from our research advance the previously described existing theories.

TIA mechanisms of policy space constraint

The realist review suggested that there are potential TIA contributors to policy inertia in food environment regulation, but that strategic policy design could avoid most of the substantive constraints, indicating a certain degree of policy coherence between public health nutrition and trade goals. The main substantive constraints are similar across food policy domains, but not identical; for instance, intellectual property protections are most relevant in marketing restrictions that touch brands and branded images. Process constraints, however, in the name of good regulatory practice (e.g., in the form of the "necessity test," transparency, fair and equitable treatment, regulatory coherence, and harmonization) appeared to pose more serious threats to policy space for food environment regulation. Such constraints tend to be consistent across the food policy domains assessed.

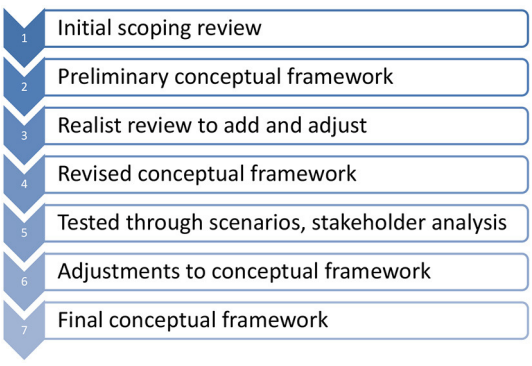

FIGURE 1
Steps followed in the research process.

In terms of **Contexts-Mechanisms-Outcomes:** TIAs and certain associated rules or processes (including non-discrimination, necessity test, harmonization/international standards, transparency, intellectual property protections, fair and equitable treatment, regulatory coherence, and investor-state dispute settlement) are Mechanisms of potential policy space constraint, which are activated (or not) depending on many different factors related to policy design, actors & institutions, and regulatory contexts (all of which can broadly be considered part of Context) (Garton et al., 2021a). These contextual factors, which influence how the TIA Mechanisms are used and interpreted, will be discussed in the section that follows. Outcomes (in terms of preserved or constricted policy space) therefore depend upon the interplay of contextual factors (policy design, actors and institutions, and regulatory contexts) with these TIA mechanisms. This conceptualization suggests that food environment policy space is a system of *competing forces*, or pressures. It also asserts that TIA rules are *constructs*, subject to a certain degree of interpretation.

Our analysis of the combined studies indicated that, on the surface, existing TIA rules for the most part are unlikely to pose "substantive" constraints to *well-designed* food environment policies made in good faith. Robust food environment regulations (e.g., informed by evidence, with strategically framed objectives, backed with nutrient profile models, and part of a comprehensive effort rather than "stand-alone" initiatives) should be coherent with basic TIA principles, under a "liberal" interpretation which implicitly prioritizes States' prerogative to regulate for the public interest. However, our analyses also revealed how TIAs *are* likely to pose constraints to food environment policy insofar as they are *used and interpreted* by different actors—which at present is underpinned by a dominant neoliberal ideology implicitly prioritizing corporate interests over the public good.

This is where the "procedural" constraints arise. This includes:

- Evidence generation that is more burdensome than would be considered acceptable for "good regulatory practice" in public health, to prove necessity or justify measures: how much evidence is "enough" depends upon the evidence

that will be brought *against* the regulation (by opposing industry groups);
- Pressure to harmonize regulations according to international standards (i.e., Codex), or justify deviation from this "standard" (which is often interpreted in trade forums as a regulatory "ceiling" rather than a regulatory "floor" or baseline): companies will purposely use their interpretations of international standards to undermine public health policy proposals;
- Transparency requirements (requiring early public notification of regulatory proposals) used by powerful countries, supported by their industry stakeholders, to raise specific trade concerns in the TBT Committee that may stall or chill policy;
- Investors taking advantage of ambiguity in the definitions of fair and equitable treatment to threaten or pursue claims against regulatory measures through ISDS; and
- Regulatory coherence/regulatory impact assessment (RIA) processes wherein internal vetting of regulatory proposals is influenced by industry and domestic economic actors.

In terms of trends over time, the data indicated a tendency toward TIA content that is potentially more procedurally restrictive of health and food environment policy space in recent agreements (for instance the evolution of regulatory coherence rules in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, CPTPP, and the United States-Mexico-Canada Agreement, USMCA). Though there have been some positive developments for health policy space (e.g., a partial tobacco carve-out from ISDS in the CPTPP[4], followed by a broader health carve-out from ISDS in the Peru-Australia Free Trade Agreement), this trend implies that there is a need for public health nutrition (and other health-related) actors to monitor and stay active in this international trade and investment sphere if policy space is to be preserved.

Having identified substantive constraints and procedural constraints TIAs pose to nutrition policy space, we found that Fidler et al. (2006) definition of "structural" constriction did not apply to the findings on constraints to food environment policy space. Moreover, several of the mechanisms of constraint we observed (e.g., some of the "industry and economic growth" coalition strategies to be described below) did not fit easily within that framework. We therefore contend that Fidler et al. (2006) definition of structural constriction should be expanded, for the purpose of examining policy space for food environment regulation. In the context of global nutrition policy, "structural" constriction is more relevant with reference to the trends in global trade and investment governance toward increased private sector engagement in governing institutions and influence in decision making. We identified the following structural constraints to nutrition policy space posed by TIAs:

- SSDS mechanisms wherein corporations may encourage and support nation states to challenge other nation states.
- ISDS provisions allowing investors to pursue challenges to regulatory measures against governments directly.
- Private sector participation in Codex/standards setting.
- Transparency and consultation requirements for regulatory measures allowing for food and beverage industry input into nutrition policymaking.
- Lack of public transparency regarding TIA negotiation but established processes for food and beverage sector input into TIA negotiation.
- Regulatory coherence provisions requiring RIA processes wherein internal vetting of regulatory proposals is influenced by industry and domestic economic actors.

This added focus on private sector engagement in governance is in line with literature concerned with the new generation of regional and bilateral trade agreements—frequently negotiated "behind closed doors"—assigning further power to industry actors through ISDS mechanisms and transparency provisions (Friel et al., 2013b, 2016; Thow and McGrady, 2014; Hawkes, 2015; Thow et al., 2015; Ruckert et al., 2017). An assessment of leaked Regional Comprehensive Economic Partnership (RCEP) chapters on services and investment exposed similar dangers, especially for the developing and least-developed countries involved (Kelsey, 2016). This focus also aligns with research on power imbalances and governance structures within Codex (Jones et al., 2019; Thow et al., 2019, 2020), and analyses of the USMCA regulatory coherence chapter (Jones et al., 2019; Labonte et al., 2019; Labonté et al., 2020; Thow et al., 2019, 2020).

Regulatory context and policy design

As stated previously, contextual factors influence how TIA mechanisms (i.e., their associated rules and processes) are used and interpreted; policy space outcomes (in terms of preserved or constricted policy space) therefore depend upon the interplay of contextual factors (policy design, actors and institutions, and regulatory contexts) with these TIA mechanisms.

Four cross-cutting findings stood out in the policy scenario interviews between the three policy areas of FOPL, restricting the marketing of unhealthy food and beverages to children, and regulating nutrient content limits in the food supply, in terms of the interaction of TIA mechanisms with the regulatory context and policy design.

4 This was only a "partial" carve-out as the CPTPP did not exclude tobacco from tariff reductions, or ISDS tobacco challenges explicitly, as governments still had to "elect to deny the benefits"; thereby placing the onus on the Member State to initiate a refusal of ISDS instead of it being fully carved out (Crosbie et al., 2014).

First, a key consideration regarding food environment regulations' trade-restrictiveness and incompatibility with TIAs and whether they have the potential to be discriminatory (either in intent or in effect) is what products or services fall within their remit, and how this selection is determined. The use of evidence-based, ideally WHO-endorsed, nutrient profile models can help justify such regulatory distinctions, though these are often contested. The growing acceptance of nutrient profile models underpinning food and beverage regulations is a significant supportive factor for preserving nutrition policy space, with potential for cascading normative effects. Participant responses also indicated the benefit of comprehensive regulatory design for policy coherence (i.e., applying across most or all food categories, rather than a select few). Comprehensive coverage was perceived to be less discriminatory, while having a greater potential for public health impact.

Second, participants stressed the importance of having evidence to justify the "necessity" of proposed food environment regulations with respect to their potential trade-restrictiveness. This implies establishing that there is no reasonably available alternative measure that is less burdensome or trade restrictive to achieve the stated objective. The strategic framing of regulatory objectives is therefore critical, as these directly relate to the evidence required to demonstrate a measure's expected effectiveness in achieving said objectives and in relation to available alternatives. It was noted that evidence generation is inherently imbued with power dynamics, and may present a considerable burden for some low-resourced countries.

Third, participants perceived that the internal government decision-making process is just as important to policy space as external bilateral or investor-state conflict, and this is often a matter of competing ideologies within the political system. Moreover, an internal bias toward minimal intervention in food system regulation may be codified into TIAs, for instance in the form of mandatory Regulatory Impact Assessment processes as regulatory coherence mechanisms, and contribute to systemic regulatory chill.

Finally, it has been noted that LMICs may be more prone to regulatory chill than HICs due to disparities in financial and human resources, and global political and economic power (Bernasconi-Osterwalder et al., 2012). Several interview participants acknowledged that the procedural and structural constraints posed by TIAs to nutrition policy space may be more acutely experienced by LMIC governments. One key example was having the resources to collect a body of evidence (i.e., to establish necessity) that would be perceived to be sufficient justification should the policy encounter any formal trade or investment challenges (bearing in mind the need to outweigh any counter-evidence generated by well-resourced food industry stakeholders and presented by HIC trade partners). In addition, capacity constraints within (and siloes between) government departments of trade and health may contribute to (mis)understandings around policy (in)coherence between health and trade objectives, and resulting food environment policy space; this could increase the potential for regulatory chill and, thus, policy inertia.

Actors, institutions, and coalitions

The evidence collected in the realist review indicated that the capacity and resources of relevant actors has a moderating effect on whether such policy space constriction occurs or does not, and that there are opportunities for strategic action to mitigate potential negative impacts in terms of TIA-related conflict. The stakeholder analysis highlighted the power and influence of certain actors and institutions in TIA-related policy space for food environment regulation, categorizing them into two competing "advocacy coalitions." There was a clear imbalance of power in favor of the group of stakeholders with common interests and beliefs associated with "industry and economic growth" as compared to the "public health nutrition" stakeholders trying to enact policy change. We also noted institutional bias toward "industry and economic growth" coalition stakeholders, for instance in the governance structure of Codex as an international standard-setting institution. In addition, there is evidence of power dynamics influencing the production of evidence, for example through the many industry-funded studies meant to confuse the evidence for food environment regulation.

Our stakeholder analysis (combining the realist review and interview data), identified five strategies used by industry and economic growth coalitions to constrict policy space through TIAs: (1) influencing government trade ministries' internal vetting of regulatory proposals; (2) convincing and supporting host governments to raise specific trade concerns and trade disputes, or raising own disputes in ISDS; (3) influencing TIA negotiations; (4) participation in Codex standards-setting; and (5) using transparency and consultation rules to influence food environment policymaking processes (Garton et al., 2021c).

We also identified three strategies used by public health nutrition coalitions to preserve policy space: (1) civil society organizations and key influencers pressure governments for transparency and accountability, including in TIA negotiation; (2) civil society organizations and other actors collaborate for greater collective influence; and (3) academics and other experts, including inter-governmental organizations (e.g., WHO, PAHO), provide technical support and evidence to legitimize advocacy and food environment policy development (Garton et al., 2021c). However, broader health advocacy literature describes additional strategies used by health coalitions confronting corporate influence on policy space through TIAs, such as in access to pharmaceuticals and tobacco control. Advocates have sought collective influence with those in other sectors (e.g., environmental, human rights, labor groups) and other jurisdictions on points of shared interest,

which may even include the occasional "unusual bedfellow" (Friel, 2021). Health policy advocates and governments have also received legal advice or other financial support from philanthropic donors or international civil society organizations to prevent or defend TIA challenges (e.g., the Anti-Tobacco Trade Litigation Fund, and the McCabe Centre for Law & Cancer's training programme) (Bloomberg Philanthropies, 2022; McCabe Centre for Law Cancer, 2022). Finally, health policy proponents have consciously borrowed language familiar to trade policy practitioners in a way that seeks to integrate the norms of health and trade (Drope and Lencucha, 2014).

Conceptual framework

In synthesis of the analyses conducted, we developed a novel framework to conceptualize how TIAs may constrain nutrition policy space, and how this policy space is preserved (Figure 2). This draws upon the initial realist review framework which outlined the key contexts, mechanisms, and oucomes (C-M-O) (Garton et al., 2021a). It incorporates TIA mechanisms representing potential substantive, procedural or structural food environment policy space constraints (adapted from Fidler et al.) examined in policy scenario vignette interviews (Fidler et al., 2006; Garton et al., 2021b). It adds elements of the Advocacy Coalition Framework of competing advocacy coalitions in the policy subsystem (and their respective interests, beliefs, power/resources, and strategies) (Sabatier and Weible, 2007; Garton et al., 2021c). Finally, it features a conceptualization of opportunities and constraints to policy space (support vs. opposition), embedded in policy context, adapted from Grindle & Thomas' policy space analysis framework (Grindle and Thomas, 1991).

As shown in the framework, food environment policy space involves an interplay of pressures and power in the policy subsystem. Contexts, whose influence pervades throughout the diagram, include national regulatory contexts and agenda setting circumstances, policy characteristics/design, and actors and institutions. The "ring" in the figure represents TIA mechanisms that may be used to constrict policy space (i.e., they are one-directional, designed to constrain policy space when maximally applied). The center of the figure represents food environment policy space outcomes (regulations may be preserved, modified, delayed, compromised, abandoned; through substantive, procedural, and/or structural policy space constraints).

Outside the ring/circle is the realm of the industry and economic growth coalition (including other governments/trade partners, companies, and internal government institutions) concerned with economic (e.g., export industry) interests, acting to constrict food environment policy space (i.e., to maintain the status quo of limited regulation or to further deregulate). Their interests are predominantly in economic growth and private profit, and belief in a minimal role of government in regulating markets. Sources of power or resources include substantial financial resources, a "revolving door" between regulatory agencies and the private sector, submissions to regulatory committees, lobbying, and technical expertise. Strategies to influence food environment policy space through TIAs include: (1) influencing government trade ministries' internal vetting of regulatory proposals, (2) convincing and supporting host governments to raise STCs and trade disputes (or raising on their own in cases of ISDS), (3) influencing TIA negotiations, (4) participation in Codex standards-setting, and (5) using transparency and consultation rules to influence food environment policymaking processes.

Inside the ring/circle is where the public health nutrition coalition operates (including government Ministries of Health, and public interest organizations), acting to preserve food environment policy space and seeking policy change in food environment regulation. Their common interests are in public health protection and promotion, and belief that the proliferation and overconsumption of unhealthy commodities implies a need for government intervention. Sources of power and resources include strong technical expertise in the science of nutrition policy (though low capacity in the technical TIA aspects), but fewer avenues for influence, and fewer financial resources than the industry and economic growth coalition. Strategies to preserve policy space include: (1) civil society organizations and key influencers pressure governments for transparency and accountability, (2) civil society and other actors within the nutrition sector collaborate for greater collective influence, (3) civil society and other actors in nutrition collaborate outside the sector for greater leverage on points of common interest, (4) academics and other experts provide technical support and evidence to "legitimize" advocacy and policy development, and (5) coalitions receive legal advice and/or financial support from philanthropic donors or international civil society organizations to prevent or defend TIA challenges.

This framework illustrates the power imbalances the international trade and investment regime imposes on the food environment policy subsystem, which can contribute to policy inertia. The industry and economic growth coalition seeking to deregulate or maintain the status quo by constraining food environment policy space have greater resources and influence than the public health nutrition coalition seeking to preserve policy space and enact food environment policy change. In addition, the *default* direction of the TIA mechanisms (rules, processes) is policy space constraint; the stronger they are implemented, the more policy space is constrained.

Discussion

This framework updates our understanding of how factors related to regulatory context and stakeholder influence, policy design settings, and mechanisms associated with TIA rules

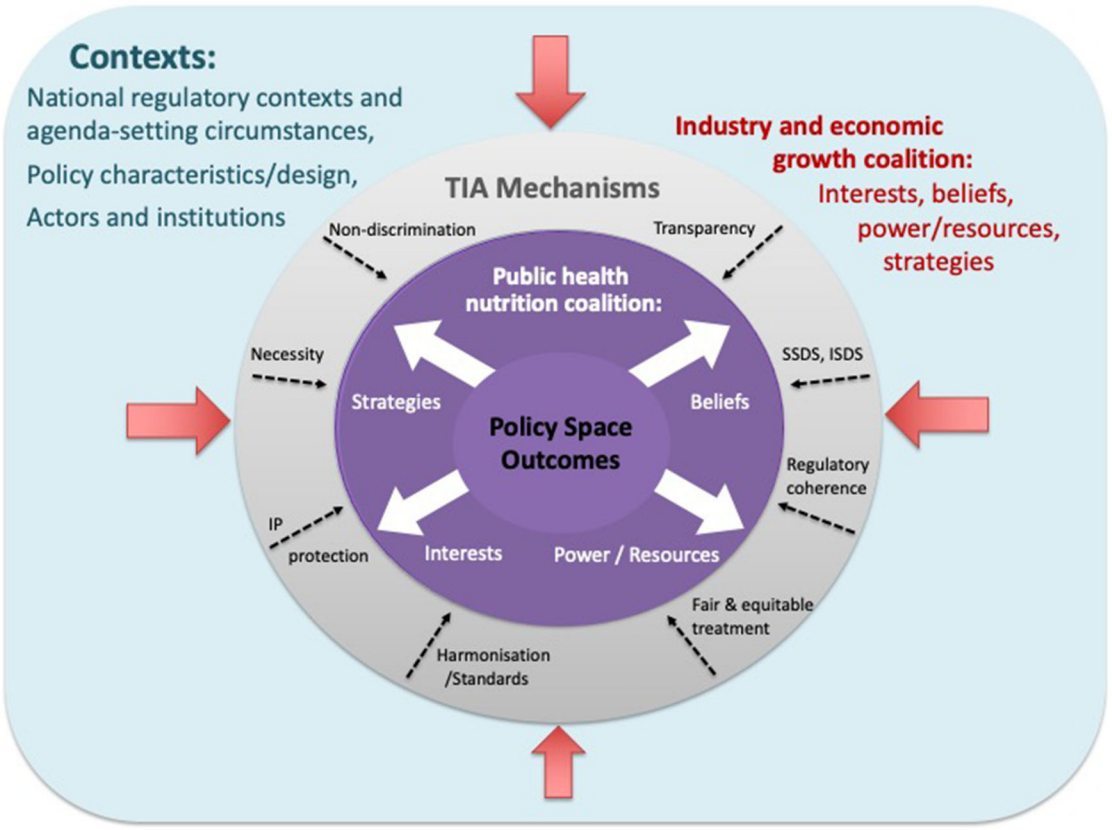

FIGURE 2
Conceptual framework for analyzing food environment policy space in the context of TIAs: Competing forces acting upon policy space (through TIAs) in the food environment policy subsystem within national contexts. Red arrows represent forces acting to constrict policy space; White arrows represent forces acting to increase/preserve policy space; Black dotted arrows represent TIA constraint mechanisms (default direction is food environment policy space constraint).

and provisions intersect in ways contributing to policy space outcomes, in the domains of fiscal policies, front-of-pack nutrition labeling, restrictions on marketing to children, and nutrient limits and product bans. In particular, it expands the definition of "structural" constriction of policy space used by Fidler et al. (2006) to include shifts from public to private governance of international trade in goods and services, such that the economic and regulatory power of private sector actors is expanded. In addition, this framework highlights the competing systemic forces and pressures influencing food environment policy space through TIA mechanisms within national policy subsystem contexts (Figure 2).

This framework can be applied as a discussion tool to enable capacity building, for policy makers in nutrition, health and food as well as in economic sectors, toward greater inter-sectoral collaboration and coherence in population nutrition and international economic policy making. It can also serve as a baseline to guide future research examining strategies to recalibrate power within the international trade and investment regime for increased food environment policy space. Alternatively, it may be useful as a template to guide policy space analysis for public health nutrition in a specific country context. It can provide a basis for rapidly assessing policy coherence between international economic policy (TIAs) and food environment regulations in these domains, and to identify areas where further legal analysis would strengthen the development of food regulatory proposals, in terms of robustness against international trade or investment challenges.

It has been said that trade and health objectives are not mutually exclusive, though they are often (and over-simplistically) perceived as such (Thow et al., 2022). Our analyses found that TIAs are likely to impose procedural constraints to food environment regulation through how they are used and (mis)interpreted by powerful stakeholders. Recent case studies have shown that transnational food and beverage company threats to pursue TIA challenges to food environment regulations in Latin America (food warning labels and advertising restrictions in Chile, and FOPL in Mexico)

were largely unfounded, using interpretive practices to influence regulators' understanding of their "legally available" policy space, and relying on governments' aversion to a challenge to delay or disrupt policy implementation (Dorlach and Mertenskotter, 2020; Crosbie et al., 2022). Similarly, Barlow and Thow (2021) analysis of STCs challenging health regulations in the TBT Committee highlighted the extent to which ideological arguments (outside the remit of the TBT Agreement) featured in the concerns raised, rather than focusing exclusively on the technical (substantive) aspects of TBT Agreement rules, thereby shaping the domestic policy understanding and/or interpretation of the implications of the Agreement. Governments seeking to regulate food environments with comprehensive FOPL, restriction of marketing of unhealthy food to children, and/or nutrient content limits will therefore need to understand the potential TIA-related legal issues, as well as the *limitations* to how they may be interpreted, and be willing to weather the inevitable storm of opposition from those who will readily use TIAs (among other means) to block or dilute regulation.

This framework, and discussion thereof, may be used as a tool to facilitate cross-sectoral capacity building for policy makers as part of a whole-of-government approach to improve policy coherence between health and trade. For instance, our analyses revealed that political will and capacity to understand the nutrition problem and legal parameters of the agreements are important parts in the equation of food environment policy space. It also indicates where institutional bias and structural power imbalances need to be addressed in order to preserve regulatory autonomy for implementation of "best practice" nutrition policies and other social development objectives. Suggested strategies to rebalance public and private interests in the trade-health nexus have included moving away from ISDS in future agreements, as well as increasing public health stakeholder participation and engagement in key trade-relevant forums like Codex (Schram et al., 2019; Thow et al., 2020; UNCTAD, 2021).

Thow and Nisbett (2019), assert that "public health actors need to recognize the fundamental and front-line nature of trade policy as both a barrier and potential catalyst for health." Recent scholarship has turned to how TIAs could be used to preserve, or even promote, policy space for NCD prevention (Delany et al., 2018; Thow et al., 2022). Thow et al. (2022) highlight how such policy space might be explicitly protected, e.g., in preambles to agreements, exceptions, exclusions, and limiting the scope/definition of key provisions. However, it is clear that more work is needed in this area to extract practical recommendations for policy makers. Moreover, as this conceptual framework demonstrates, without examining the agency, structures and power dynamics underlying the nexus between trade, health and food, an analysis misses the root causes of policy space constraint. Therefore, work on the technical aspects of trade/investment and health policy coherence needs to be coupled with attention to the underlying political economy aspects of regulation, in order to see any real change in the commercial determinants of health (Reich and Balarajan, 2014; Balarajan and Reich, 2016; Thow et al., 2016, 2018, 2019; Kaldor et al., 2018; Baker et al., 2019; Friel et al., 2019, 2020).

Strengths and limitations

One major strength of this analysis was its inter-disciplinary approach. We drew data from public health, legal, and political science literature, and the experts interviewed spanned all of these disciplines. Each of these fields of scholarship brought a different perspective to the research question. For instance, the public health discipline is grounded in concepts of health equity and "moral imperatives" but can be criticized for being idealistic or unrealistic, and policy inertia is a significant enduring challenge. A political economy lens introduced concepts of power and production, interests and belief systems that influence political behavior. A legal perspective highlighted the importance of specific language used in international treaty text, and the normative debates around its interpretation. This work therefore offers a more balanced and holistic view of what is a complex policy problem.

The new framework presented draws upon existing theory and expert knowledge to fill gaps in what we know about TIAs and policy space for public health nutrition. We have built upon the existing public health literature on this issue, which was largely speculative, through empirical research with global experts. In particular, use of vignette interviews based on policy scenarios was a novel method of understanding the nuances in the intersection between TIAs and policy settings, whose adaptation from social psychology and business applications presents an innovative repurposing of an analytical tool with promising potential in the field of nutrition policy research. Finally, the underlying philosophy of critical realism and associated process of "retroduction" in data analysis meant we could engage with both political economy and technical legal aspects based on real-world experiences. By iteratively moving between theory development and theory testing, with constant critique of our own interpretations, this allowed us to develop conclusions that are robust, policy-relevant, social-change oriented, applicable to different contexts, but fallible (i.e., open to change with new information).

In terms of limitations, this analysis was restricted by what is a relatively nascent field and small pool of expert knowledge. Most participants and literature reviewed were most familiar with WTO agreements, and thus there was limited discussion of "new generation" WTO-plus agreements and their influence on food environment policy space, including emerging areas of trade such as e-commerce. In addition, for some of the policy

areas of focus (such as marketing restrictions) there are few global "best practice" examples that can be studied empirically.

This work is also limited as a relatively point-in-time analysis of opportunities and constraints for nutrition policy space in a constantly changing international trade and investment (and geo-political) environment. For instance, the data was collected before COVID-19 appeared on the world stage; given the resurgence of issues around TRIPS and access to vaccines, diagnostics and therapeutics, some have speculated that COVID-19 may prompt a shift in global discourse toward greater attention to health consequences of TIAs (Barlow, 2022). Reportedly, nutrition featured more prominently in UK-US trade discussions following the British Prime Minister's admission that his personal COVID-19 complications were linked to being overweight (Barlow, 2022). On the other hand, the economic impact of the COVID-19 pandemic has been used by the food and beverage industry as another reason not to pursue health regulations such as FOPL that are argued will exacerbate the uncertainties and costs wrought by the pandemic (Barlow, 2022). More recently, the Russian invasion of Ukraine has shifted geopolitical alignments and disrupted global supply chains and trade partner relationships in ways that continue to unfold.

Finally, there was no participation of food and beverage industry stakeholders, nor trade or investment policy makers (e.g., negotiators), in the underpinning studies as these proved difficult to access. Therefore, the views expressed in the interviews, and thus their secondary analysis, may be skewed toward a public health nutrition stakeholder perspective.

Conclusion

Our analysis indicates that existing TIA rules, for the most part, are unlikely to pose "substantive" constraints to *well-designed* food environment policies made in good faith. Robust policy design, in this regard, includes strategically framed objectives and being informed by evidence, underpinned by nutrient profile models, and part of a comprehensive policy effort. TIAs are, however, more likely to pose constraints to food environment regulation insofar as they are *used and interpreted* by different actors, in what we have broadly referred to as "procedural" constraints. These constraints may appear the form of requiring justification regarding non-discrimination, necessity and intellectual property protections, harmonization and international standards, transparency requirements, fair and equitable treatment, and regulatory coherence processes over-and-above what would be undertaken/considered adequate in the domestic policy sphere.

This study highlighted the power imbalance within the food and beverage trade and investment system between public health nutrition actors and those primarily interested in industry and economic growth, particularly regarding participation in TIA governance institutions and processes. This unequal distribution of power and resources in favor of the industry and economic growth coalition of stakeholders poses "structural" constraints to nutrition policy space, in the form of state-state and investor-state dispute settlement mechanisms, transparency requirements, regulatory coherence, and standards-setting processes.

The conceptual framework we have presented provides a better understanding of the potential constraints TIAs pose for policy space to address the commercial determinants of poor nutrition and diet-related NCDs through food environment regulation. This framework may assist in both the design of more robust food environment policy interventions, and inform the negotiation of future TIAs that preserve food environment policy space. Such understanding may also help government policy makers to identify, critically assess and/or resist attempts by trade partners or commercial actors to restrict their policy space for food environment regulation through TIAs.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors upon request, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by University of Auckland Human Participants Ethics Committee. The patients/participants provided their written informed consent to participate in this study.

Author contributions

The research presented in this paper was undertaken as part of the lead author's KG doctoral thesis, supervised by the co-authors BS and AMT. KG carried out all data collection and analysis, with significant input from BS and AMT. All authors contributed to conceptual development and writing this manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Barriers and enablers in designing regulations to restrict the exposure of children to unhealthy food and beverage marketing

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Background: The insidious and pervasive nature of marketing of unhealthy food and beverages has been identified as one of several strategies the unhealthy food and beverage industry uses to exert their influence on population food choices and diet. Regulating the food and beverage industry's marketing practices is one mechanism to mitigate this commercial determinant of health. This paper seeks to understand the main barriers and enablers that governments face when attempting to design an appropriate regulatory system.

Methods: 14 semi-structured expert interviews were undertaken with participants across different jurisdictions (Ireland, United Kingdom, Chile, Canada, Norway, Portugal and Brazil) who were involved in introducing marketing restrictions; and a purposive documentary analysis was carried out. A thematic analysis of this data was conducted informed by the Health Policy Triangle.

Results: Multiple common technical and political issues were experienced by governments regarding the form and substance of the policy design regardless of the jurisdictional context. Such issues included: whether to introduce a mandatory approach; what age group to protect; what nutrient classification system to use; how to define "marketing to children"; and what mediums, settings and techniques to cover. The actors opposing regulation challenged the form and substance of each design element. However, having a strong political mandate to introduce regulation; multiple actors working together, including multiple government ministries, academics and civil society actors; and a strong evidence base supporting the policy design helped policymakers navigate the technical and political challenges faced when designing the regulatory approach.

Conclusion: Despite the different political contexts and actors involved in different jurisdictions internationally, there are many commonalities in the challenges and enabling factors faced by governments. Understanding the technical and political challenges experienced by governments and how these governments overcame those challenges is critical to improve capacity around designing more effective regulations to improve population's diets, and therefore NCDs.

KEYWORDS

marketing and advertising, child health, food marketing, non-communicable disease (NCD), regulation

Introduction

The insidious and pervasive nature of marketing of unhealthy food and beverages has been identified as one of the major channels that the food and beverage industry use to exert their influence and is a key "strategy used by the private sector to promote products and choices that are detrimental to health" and as such is defined as a key commercial determinant of health (Kickbusch et al., 2016; Mialon, 2020). Marketing of unhealthy products impacts on the preferences, purchases, brand awareness and consumption patterns of children which tracks into adulthood (Cairns et al., 2013; Kelly et al., 2015; World Cancer Research Fund International, 2020). Across the life course this leads to weight gain and an increased risk of overweight and obesity, cognitive impairments, reduced quality of life and non-communicable diseases (Chen et al., 2012; Telford et al., 2012; Black et al., 2015). One example of the health outcomes is the global prevalence of childhood overweight and obesity with 38.2 million children under 5 years of age with overweight or obesity as at 2019 and over 340 million children and adolescents aged 5–19 with overweight or obesity as at 2016 (Afshin et al., 2017; Bennett et al., 2018; World Health Organization *Obesity Overweight.*, 2021).

In addition, the World Health Organization (WHO) published a Set of Recommendations on the Marketing of Foods and Non-alcoholic Beverages (WHO Recommendations) in 2010 that called for a robust response to marketing to children from Member States (World Health Organization, 2012). Ten years on, very few governments have introduced a regulatory approach that fully operationalizes the WHO Recommendations despite a decade of further calls for action and research to support this action in this area (Magnusson and Patterson, 2014; World Health Organization Regional Office for Europe, 2018). There is therefore a high level of policy inertia to address the food and beverage industry's marketing practices.

This research explores the policy design processes of seven governments who have attempted to address the exposure of children to unhealthy food and beverage marketing. It aims to contribute to the call for capacity building in NCD prevention to aid governments in addressing the commercial determinants of health through regulation (McKee and Stuckler, 2018; Magnusson and Patterson, 2019, 2021; Magnusson et al., 2019; Mialon, 2020; Lee and Freudenberg, 2022). Regulating the exposure of children to unhealthy food and beverage marketing is a key area where governments can learn from other governments about designing robust policy interventions (Magnusson and Patterson, 2019, 2021; Magnusson et al., 2019). The aim of this paper was to answer the research question: what are the main barriers and enablers that governments face when attempting to design a regulatory system restricting unhealthy food and beverage marketing to children?

The research focuses on the policy design stage of policy development, namely what barriers and enablers governments faced when deciding on the form (what type of regulation) and substance (the scope of the regulatory response) of the regulatory system. It is acknowledged that the policy process is not linear, and therefore other stages of the process such as agenda setting, legitimation and implementation may be important factors that impact or occur alongside the policy formulation stage (Brewer and DeLeon, 1983).

However, the literature identifies a research gap in NCD prevention policy studies around understanding how to design effective regulatory approaches in order to meet the demand by governments for capacity building globally (Magnusson and Patterson, 2014, 2019, 2021; Magnusson et al., 2019). The call for evidence focuses primarily on establishing the policy problem rather than on the policy interventions to address those problems. Legal capacity-building requires scholarly consideration because NCD prevention policies will likely require legislative or regulatory responses to implement them (Magnusson and Patterson, 2019, 2021; Magnusson et al., 2019). Proponents argue that capacity building helps the actors involved understand how to design, and ultimately implement, effective and robust policies (Thow et al., 2010; Baker et al., 2018; Magnusson et al., 2019). Sharing government experiences is a key tenet to building capacity, particularly around designing regulatory approaches, as it will generate a clearer understanding of the technical and legal capacities required to introduce a restriction (Thow et al., 2011; Baker et al., 2018; McKee and Stuckler, 2018; Magnusson et al., 2019).

However, when policymakers formulate the form and substance of a policy intervention to restrict marketing, a complex mix of factors, including the actors involved and the political and economic context, shape the policy content and outcomes (Shiffman and Smith, 2007; Walt et al., 2008; Buse et al., 2012). Therefore, this research outlines a descriptive qualitative analysis of the technical issues policymakers grappled with, with the aim of increasing legal capacity building but also places the technical issues within the political economy context of policymaking.

Methods

Framework

Walt and Gilson's Health Policy Triangle framework (HPT framework) was used to inform the study, including the interview guide and thematic analysis (Walt et al., 2008; WHO, 2017). The HPT framework outlines four intersecting elements of healthy policy making; the content, the actors, the process and the context. In the context of policies to restrict food marketing, the use of the framework meant that several aspects of the policy design could be explored; for example, recognizing that the actors involved, the policy process those actors engage in, and the political and economic context the actors are operating in can influence the policy content and outcomes (Buse et al., 2012; WHO, 2017; Reeve et al., 2018).

This framework outlines the basic elements of a comprehensive approach to understanding the dynamics of policy issues. The framework was chosen as it exhibited key aspects that were relevant to the study of the global health policy process, particularly because it was grounded in the political economy perspective and had been used in similar research (Thow et al., 2010; Buse et al., 2012; Saito et al., 2015; WHO, 2017; Reeve et al., 2018).

Country selection

Countries were selected purposively from the World Cancer Research Fund International NOURISHING Policy Database. The inclusion criteria were first, that all of the potential interviewees were able to speak English or Spanish, and that the majority of the country's documents were available either in English or Spanish. Second, we selected countries that had a government-led regulatory approach, either mandatory (Chile, Portugal) or a mixed regulatory approach (Norway, Brazil, Ireland, UK) and a representative spread across multiple regions. Canada and the UK were included because both governments were attempting to design mandatory legislative approaches at the time of the research.

Data collection

Document analysis

A scoping review methodology was applied to identify relevant literature. Peer reviewed journal articles and gray literature, including WHO publications, were identified that discussed any of the selected country's experience with designing and implementing a marketing restriction. In particular, literature that aided in elucidating the challenges and enabling factors governments faced during the policy design process was selected for analysis. The document analysis was carried out ahead of the interviews to inform the interview guide and in a later stage during the iterative thematic analysis process. Undertaking a document analysis was also chosen to triangulate the interview data.

Interview data

Fourteen semi-structured expert interviews were undertaken in 2019. Ten interviews were with policymakers, civil society public health advocates and academics who were directly involved in the introduction of a marketing restriction in the selected countries. Four international experts on regulating unhealthy food and beverage marketing were also interviewed about their experience advising, monitoring or advocating for national level marketing restrictions across various countries, including the selected countries.

The participants were identified through the networks of the World Cancer Research Fund International Policy and Public Affairs team where FS and AC were employed at the time of data collection. Participants included international experts on unhealthy food marketing restriction policy design, and national policymakers, academics or civil society advocates who had worked closely on the design or introduction of a marketing restriction in their countries. In some instances, we identified further interviewees through snowball sampling. The interviews were conducted in English or Spanish which allowed for a broader range of participants to be included. Interviews were conducted with four policymakers; three academics; and three civil society advocates from the seven countries studied, and four international experts who knew about the barriers and enablers in more than one country. There was one interviewee from each country studied, with the exception of Norway, Brazil and Canada where there were two.

The interview guide was informed by each of the four elements of policymaking outlined in the Walt and Gilson policy triangle framework and by the key findings of the initial document analysis. This helped interviewees to identify not only the main barriers and enablers around establishing the policy content, but also the impact the context, process and actors had on the policy design and main outcome of its design. A copy of the interview guide is provided in Supplementary material 1 that lists each question asked under the headings agenda setting; policy design; policy process; legal and trade issues and lessons learned. Interviews were conducted by audio only and the participants were provided with the questions ahead of the interview.

The combination of methods allowed the authors to triangulate the data, to improve validity and reliability of the information obtained.

Analysis

A deductive reflexive thematic analysis was carried out using the interview data informed by the HPT Framework to answer the research question—what are the main barriers and enablers that governments face when attempting to design a regulatory system restricting unhealthy food and beverage marketing to children? (Saito et al., 2015; Reeve et al., 2018; Braun and Clarke, 2019). Using Braun and Clarke's approach to reflexive thematic analysis, the lead author (FS) coded the data and undertook the analysis independently because of the inherent subjectivity of the researcher's interpretation of the data (Braun and Clarke, 2006a,b, 2019). As inter-rater reliability was considered inconsistent with a reflexive approach (Braun and Clarke, 2006a,b, 2019), other co-authors reviewed the codebook but did not undertake a full coding analysis.

After an iterative coding process was undertaken the findings relating to how the actors involved; the policy process itself; and the decisions relating to the policy content were extracted and divided into whether they were barriers or enablers faced by governments. The results were then structured in alignment with this analysis with barriers to policy design addressed first followed by the enablers. A series of sub-headings address the relevant aspect of the HPT framework with a focus on actors; content and process. In relation to policy content, the findings were split into themes around regulatory form (what regulatory approach would be taken) and regulatory substance (the substantive content of the laws for example the policy scope). The results are a representation of the prevailing themes in the dataset, therefore were noted in more than one source.

Results

Barriers

Actors involved in the policy design

Every government faced opposition to their proposed policy during the policy design phase by actors whose commercial

interests were threatened. Such actors included: representatives of the food and beverage industry whose products would be restricted from being marketed; the advertising and media industries who would lose revenue from the reduction in advertising; and any other actors who supported those industries, including other Government ministries or parliamentarians. One of the main arguments around the opposition was the powerful position industry has in the policy space, both economic and discursive. The latter being more prominent in smaller countries. As several advocates pointed out:

> *"We're already seeing a huge amount of opposition from the media platforms, so in particular the TV broadcasters, the commercial channels. They're pushing back. Originally, their pushback was all around the cost to them and that it would prevent them from making original interesting programming, because it would cost them so much money. They've moved away from that argument now and are just trying to undermine the policy and say, Look. This isn't going to work." (Civil Society advocate participant, United Kingdom, Interview 1)*
>
> *"The industry really spent their time well pushing constantly while the non-governmental organizations largely lacked the resources to really follow up and it, kind of, disappeared from the horizon. It became clear how effective the industry can be in advocacy work because they have the resources to really stay in there and argue their case." (Academic participant, Norway, Interview 2)*

The different arguments put forward by the actors who opposed the regulation touched on all aspects of the form and substance of the policy design and policy process. The distinct arguments made in relation to the form and substance of the policy design are noted in the subsequent sections.

> *"I think the reality is that governments talk at a very early stage with the industry, [it] is my impression, and that they, especially some of the weaker governments, almost seek permission to move forward on this agenda from the industry. I think that's really slowing things down. I'm not talking about some of our bigger governments, who are a bit braver, but I'm talking about smaller governments that may want to do something but feel they don't have capacity." (International Expert participant, Interview 12).*

Process of policy design

One challenge noted by participants was how to engage with those actors who were opposed to any regulatory response to unhealthy food and beverage marketing when designing the policy. While all stakeholders did need to be consulted in accordance with good governance principles, a decision had to be made about how much to engage with those actors who opposed the policy. The outcome of those decisions on engagement were linked to the type of relationship the Government, particularly the Ministries of Health, had with those actors and their position on whether they were considered "experts" in the technical aspects of food marketing or whether they were considered to be conflicted because of their commercial interests. Increased engagement with actors opposed to regulation did not always result in the policy design weakening to account for their views.

In Canada, certain aspects of the policy design process (around evidence collation and policy development) were protected from engagement with external actors however during later stages of the regulatory development, the Government more closely consulted with industry actors. In Norway, consecutive Governments (opposing political parties) set up a high-level private sector advisory group to advise the Government on policy issues that met regularly. In Chile, officials from the Ministry of Health met with industry every month to talk through the proposed regulations, where drafts were presented and their opinions were sought. However, key informants stated that their opinions were not always adopted into the regulation because industry's position on the regulation differed from the Government's.

Content of policy design

Regulatory form—Mandatory or voluntary approach

Deciding whether to adopt a mandatory legislative or voluntary regulatory approach was a challenge for some health government agencies. Actors opposed to the policy argued that a self-regulatory approach was the most appropriate course of action to take because a mandatory approach would be an unjustified government action when weighed against the impacts it would have on industry's right to trade and their economic viability. Some participants also expressed that it was difficult to influence other non-health government ministries of the need to regulate unhealthy food and beverage marketing. This was particularly challenging if other non-health government ministries preferred to regulate industry as little as possible.

> *"Based on the resistance from the industry, the government actually pulled back and decided that they wouldn't go forward with the written legislative proposal, but rather, invite the industry to come up with a self-regulative version that would be equally strong or effective." "So right now, public health is being managed by the most conservative segments of our political spectrum, and they are very much in favor of private sector and want as few pieces of legislation on the table as possible." (Academic participant, Norway, Interview 2)*

Other governments were able to address opposition to a mandatory approach. The Portuguese government chose to introduce a mandatory legislative response after recognizing the weakness of the EU Pledge, an industry code adopted by several food and beverage companies in European countries.

> *"Our national association of the food industry subscribes to the EU Pledge. Often many problems, regarding these self-regulation codes, are related to the nutrition criteria because the nutrition criteria for the EU Pledge is less restricted when you compare, for example, with the WHO nutrient profile model. This is a problem because many, many, many food products that should be restricted for marketing to children, according to the*

> *EU Pledge criteria, they pass. This is one of the main problems. We think that the self-regulation approach is not enough to protect children from the marketing." (Government participant, Portugal, Interview 14)*

Government agencies that pursued a mandatory approach expressed an awareness that their jurisdiction to legislate in the interests of public health on this issue would be challenged by industry both during the policy development process and after the legislation had passed. Many participants expressed it was therefore imperative for governments taking a mandatory approach to have a robust legislative design that was backed by research and justified in the interests of public health or child rights.

> *"We know [the government department] have been very clear with us. They are preparing and ready for legal challenges on this. Yes. I think we all think that there will be. It's not going to be smooth sailing." (Civil society advocate participant, United Kingdom, Interview 1)*

Some experts, pointed at the challenges mandatory approaches might face, such as litigation on the basis of breaching corporation's interests and rights, and in many cases, based on the barriers such regulations present to trade. (World Health Organization Regional Office for Europe, 2018) As an expert mentioned:

> *"The risk of litigation is certainly on the minds of states. [..] the risk of litigation is strong. The question is, the risk of losing your case. That's what you should be concerned with as a government, not whether you're going to be challenged. If your marketing restrictions are going to be effective, if they're broad in scope, the chances are you will have a challenge, and probably several. The question is, how prepared are you to defend your challenge and make sure that it fails?" (International Expert participant, Interview 5)*

Regulatory form—Legislative framework

When choosing a legislative approach, the main challenge for countries was to identify the correct legislative framework under which the legislation would fit. For example, because of the mechanisms of the Canadian Food and Drug legislation, Health Canada had to work within a criminal law framework as opposed to a civil law framework, like consumer protection law, which had different requirements and thresholds. This had an impact on the way the key terms of the legislation could be defined, as the criminal law framework required the purpose of the legislation to be about harm reduction as opposed to health promotion. The legislative framework used also impacted on the enforcement powers available to the enforcing agency, for example, depending on the jurisdiction, a criminal law framework could possibly include different penalties such as a jail sentence compared to a civil law framework that could include injunctive powers.

Some participants stated the child-rights based framing, to protect children's right to health under the United Nations Convention on the Rights of the Child, was sometimes used by actors advocating in support of the policy, but that practically speaking, it couldn't have been used as the sole legislative framework. This was because the mandate of child's rights sat with another government ministry not the ministry charged with introducing the laws, which was typically the health ministry. Or because the health research underpinned the policy objectives not child-rights research and therefore a health-based legislative framework was needed.

Notwithstanding this, many participants expressed they would have liked to have used a child-rights based legislative framework, that would have utilized and protected the child's right to health. Others indicated that the child-rights based rhetoric had not been prominent at the time their regulatory approach was being developed, for example Chile and Norway in 2012, and those participants considered that if those regulatory approaches were being designed in the current day, that framing would have strengthened their policy process.

Regulatory substance—What marketing mediums and techniques are covered

Capturing the full extent of the marketing mediums and techniques to which children are exposed was a challenge for governments when deciding which mediums, settings or techniques the regulations would cover. Traditionally, governments have chosen to regulate broadcast marketing (World Health Organization Regional Office for Europe, 2018; Taillie et al., 2019) but decisions had to be made about whether to also cover school settings, digital marketing, sponsorship, retail outlets, and public spaces for example. Depending on the political will of the government, and the legislative and political mandate the government was working under, the scope varied. This was in part because industry challenged the scope of the legislation so governments had to justify the necessity of the wider scope using evidence of the means and level of exposure.

> *"I don't know of a country that has basically taken that [the WHO Set of Recommendations] definition and operationalised that in policy, because they always, as you just gave an example, they always exempt—well, almost always exempt—packaging, for example. (International Expert participant, Interview 12)*

As seen from tobacco advertising restrictions, when one medium, setting or technique was regulated, the advertising spend of the large tobacco companies moved into the unregulated areas creating a balloon effect. World Health Organization (2004, 2008), Munafò (2016) Governments had to balance this phenomenon with what was politically feasible to introduce into the scope of the legislation.

> *"The concern there is that if you shut off the ability of junk food to advertise on certain channels, that they just displace onto other types of channels, so we'd see more advertising on radio, we'd see more advertising on roadsides if they can't advertise on TV." (Civil Society Advocate participant, United Kingdom, Interview 1)*

Typically, important elements of the marketing landscape, like brand marketing and sponsorship, were not included in the scope of the legislation. Brand marketing was a particular challenge for governments. Brand marketing techniques that focused on building brand loyalty didn't always target children in traditional ways with

a "hook" or content that appealed specifically to children, and often didn't include a food or beverage product. This made it hard to include in the scope of the law as it was difficult to prove it was targeted or directed at children but also because it couldn't be categorized as a breach under the nutrient classification system as no food or drink were present.

> *Brands are very, very difficult to work with and I think that legal people and legal teams were very important in this moment. A lawyer of the World Health Organization was very important in this moment, to work with our lawyers, to develop a document, that is in English and Spanish, to help us with the problems with the brands, brands that are marketing itself, marketing directed to children. I think that is very important in the last moment of the process, when the regulations were implemented. (Government policymaker participant, Chile, Interview 13)*

Governments also came up against challenges to restricting sponsorship because such restrictions would reduce a funding mechanism for certain activities, particularly in sports or school environments. Canada removed sponsorship from its proposed Bill after heavy pushback on the impact it might have on the funding of children's sports (Health Canada, 2017, 2018). In lower resourced countries, sponsorship in the school environment created issues for governments trying to reduce the exposure of advertising in schools.

> *"So, the in-school marketing, for example, where there's sponsorship of school materials and it's quite difficult to take away because there's no replacement funding." (International Expert participant, Interview 6)*

Codifying the list of marketing mediums and techniques was considered unfeasible by the Chilean government because of the rapidly changing marketing environment, especially the digital environment. Chile drafted the legislation's language with an open-ended definition of what could be caught by the legislation in order to allow for changes in marketing techniques and practices.

> *"Then the other part is, of course, that it is changing so rapidly, so how can you have measures in place that would cover different new technologies or developments so that you don't have to run after constantly what is the latest?" (Academic participant, Norway, Interview 2)*

Regulatory substance—What age group to protect

The age threshold is typically challenged by industry and creates an issue for governments, with many examples of governments reducing their age thresholds through the policy process, for example Chile, Canada, Norway. Discerning the age at which a child is cognitively able to recognize and appropriately process marketing like an adult can cause issues for governments. Defining the scope of the legislation as protecting children up to 18, as required by the United Nations Convention on the Rights of the Child, has not always been feasible. This was despite robust research from global academic researchers showing a child's cognitive ability up to the age of 18 was susceptible to marketing (Pechmann et al., 2005; Kickbusch et al., 2016; Savell et al., 2016; Murphy et al., 2020).

> *"Governments do get bogged down in this nonsensical argument around: "A child above the age of 11 is able to cognitively recognize advertisement. Therefore, they have some sort of protection." [..] Even the most strong-willed government, like the Norwegians, like the Canadians, that recognize… their experts in-house fully understand, to the same extent that any UN experts or any academic experts understand, that a teenager is vulnerable. A teenager needs protection. A teenager is targeted. Therefore, the protection should go up to 18. They haven't been able to get that through internal processes or it's been very difficult and has led to some sort of concessions elsewhere. I think that age to protect is really a big challenge." (International Expert Participant, Interview 12)*
>
> *"The age limit is a big issue, because now it's 12 and younger when then original proposal was up to 18. That was the main argument, the fact that it was 18 and also seen as more or less adults, the industry was able to argue successfully that it was impossible to separate what was targeting adults and then this older adolescent group and that it will be too invasive." (Civil Society Advocate participant, Norway, Interview 3)*

Regulatory substance—How to define "marketing directed at children"

Focusing the scope of the restrictions on marketing "targeted at" or "directed to" children was common, but it was difficult to define.

> *"Then the next point we make, around what level of marketing should be restricted, is a real quagmire that governments struggle with. I think the majority of policies that I know of talk about marketing to children, so that I think the industry has been able to convince governments, or lobby governments, that they should only be concerned around the marketing that is directly targeted to children. The way that they should assess that is by the content of the advertising, if it appeals to children, etc., and with appeal to children being very narrowly defined in a very classic understanding of what a child might like." (International Expert participant, Interview 12)*

Governments chose definitions that included audience thresholds where children need to make up a percentage of the audience (i.e., 25%) as well as obvious tactics that could reasonably be considered "child-directed"' like offers of toys or use of childlike marketing tactics such as cartoons or other features that would appeal solely to children. If settings were covered in the scope of the law, they often needed to be child settings such as schools.

The definition of "targeted at" or "directed to" children is difficult to apply in the digital marketing environment.

> *"There's good robust data about the age of children that are watching certain TV programmes. When it comes to online content, it's pretty much impossible to know for sure how old people are. That data isn't published independently anywhere, it's not verified. This is data that the likes of Google and Facebook and YouTube hold themselves. So if we challenge them with a*

> *complaint—which takes months for the [Complaints Board] to process—they can often come back and say, "Our data shows that less than 25% of the audience is children." We've got no way of challenging that, because we don't have that data. That has big implications for the types of regulation that we'd want to see in there." (Civil Society Advocate participant, United Kingdom, Interview 1)*

Some participants expressed that defining the scope of the legislation to focus on marketing that was targeted at children meant that it would be difficult to capture the full extent of the marketing mediums, tactics and settings that children are actually exposed to.

Regulatory substance—Nutrient profile model

While governments now have regional WHO nutrient profile models to adopt when deciding what classification system should underpin the legislation, many governments still struggled with how strict to make their chosen model. While the WHO nutrient profile models can provide a valuable starting point for countries, amending these models to take account of the national context can require certain resources and capacities that many governments do not have. In Chile, there was no nutrient profile model to draw on at the time of the regulation design, and they struggled early on to decide what foods would be subject to the restrictions and which should not.

The WHO models typically include blanket bans on certain categories of unhealthy products including biscuits, confectionary and cakes for example. Participants stated that industry actors argue this does not incentivize reformulation of these unhealthier products if there is not a nutrient threshold to work toward.

> *"The industry don't like the idea, the concept that their product will never be able to be marketed. They've bought into this thing that, "A nutrient profile model should permit reformulation. That should be an incentive to companies to improve their product, and then they'll be able to market." WHO were saying, "Yes, however good you make your chocolate, it shouldn't be marketed to children." Industry have not accepted that yet, and I think a number of governments struggle with that." (International Expert participant, Interview 12)*

Industry actors not only attack the strictness of the chosen model, they also seek amendments to the model to exempt certain food groups from the 'not permitted to market' category. For example, the dairy industries in Ireland and Canada have pushed for exemptions on dairy products.

> *"The weakness in the proposal at the moment that we're trying to get to grips with is the exemptions that are being proposed. I think what we know from every other type of policy that anyone has ever worked on that when you start to introduce exemptions, you start to introduce loopholes and weak points that can be exploited." (Civil Society Advocate participant, United Kingdom, Interview 1)*

Enablers

Actors

A network of key actors working collectively with the shared common goal to introduce regulations was noted as an influential feature of success in designing and passing a regulatory response. The trifecta of government officials, civil society advocates and academics working together to navigate the policy process and collating the evidence needed to frame the debate and challenge industry opposition was a key enabler when designing the regulatory response. The role of these actors included creating consistent messaging about the need for the policy and why the proposed scope was necessary, building the evidence base to support the defined scope, and garnering public support.

In some cases, policy entrepreneurs such as key politicians were central actors who enabled legislation to move forward. Examples include Chile where Senator Guido Girardi worked with lead academic Professor Ricardo Uauy to lead the political and technical teams that enabled the legislation to defend industry challenge and also to garner more political will amongst other government actors. In Canada, Senator Nancy Green Raine championed the policy and introduced a Bill in the Canadian Senate. Participants noted that these actors can build support for the policy inside parliament.

> *"Ricardo Uauy was very important in all of this process, because he is a very respected person in Chile. When we have many problems with industry or with academic groups or also with politics groups, we invite Ricardo Uauy to talk with them, to present evidence and to present his opinion. And, of course, no-one wants to go against Ricardo Uauy." (Government policymaker participant, Chile, Interview 13)*

Academics and expert advisors were key players in the policy process, helping to design the policy and work through the challenges posed by the definitions of marketing to children, the nutrient profile models, and what age threshold to set for example.

> *"The Marketing to Kids Coalition, this was a coalition—and continues to be a coalition—of health organizations, academics, and other interested parties. There are two co-chairs, and several signatories, and many, many who support the coalition in the country. I would say this was the organization that helped drive marketing for kids onto the political agenda." (Government policymaker participant, Canada, Interview 4)*
>
> *"I think it's also important to have the civil society involved. In Portugal, for example, the Portuguese National Association for Consumer Protection, they are very active. They made a lot of pressure on the government, it is important." (Government policymaker participant, Portugal, Interview 14)*

Process of design

Some governments had given their Ministries of Health strong mandates to introduce laws and regulations that allowed them

to not only draft strong laws but also to defend the law against industry opposition more confidently. In Canada, Portugal, UK and Chile there was a clear directive from the Government that a strong legislative approach could be pursued by the relevant health ministry. The laws proposed were the most comprehensive globally whereas other countries with a weaker mandate, such as Brazil and Peru, struggled to introduce a strong and comprehensive regulatory approach.

Norway started with a strong mandate, as a European leader on the issue at the WHO level but experienced a change in government during the process and ended up with a voluntary system rather than a mandatory legislative approach. Portugal had cross-party support for the law and strong support from the governing coalition parties which was noted as a key enabler for moving its nutrition policy agenda forward.

Most governments gave full mandate to their health ministries to lead the policy process and there was no mention that this delegation of authority to health ministries was contentious—it was where the jurisdiction to regulate this issue lay. However, some health ministries, such as the UK's health ministry, developed the policy with co-leads such as ministries in charge of consumer protection or digital regulation.

Multi-sectoral collaboration between government ministries also aided the policy process. While the health ministries were typically the lead ministry, working in collaboration with other government agencies, such as those responsible for the digital environment or education, enabled effective policy designed that could be properly implemented. Other government officials such as trade and legal experts helped the lead ministry navigate and mitigate any legal or trade threats.

Some countries chose to manage external stakeholders by attempting to keep the food and beverage industry at arm's length from the policy design process. In Canada, all meetings and correspondence between Health Canada and any industry actors had to be minuted and made available online. This reduced the industry's ability to lobby the government to reduce the scope of the policy, as they were less willing to have their correspondence to the government made public.

> *"Don't feel obliged to take on board all of their [food and beverage industry's] comments. You don't have to address all of their comments. You just take the ones that you feel are pertinent and key that you feel that you have to address. You don't have to address it in their opinion or their view. You can just say, "We've addressed this. We've considered this and we're not going to change that position."(International Expert participant, Interview 12)*
>
> *"Then, industry kind of said that they don't know nothing, that this is inside regulation with no information. We informed all of them, month by month, and we present a draft and they can give us their opinion. Of course, we not always can put their opinion in the regulation because they don't want the regulation. But, during all the process, they gave us their opinion." (Government policymaker participant, Chile, Interview 13)*

Content of the policy

A key enabler for governments that succeeded in passing regulations was having sufficient and robust research to support the need for, and scope of, the policy. This helped not only to bolster the framing and rhetoric politically, but also to strengthen the law against legal or trade threats.

When the policy's form or substance was challenged the governments could use research to show that the extent of the problem had been quantified and that the policy design necessitated the broad scope of the law to ensure the legitimate public health objective set out was met. For example, participants noted that Portugal had a strong mandate to restrict marketing because of a data set showing obesity rates were high and a national nutrition survey that showed nutrition patterns were poor. Likewise, participants stated that the Canadian and Irish governments were influenced by national reports on obesity that indicated the prevalence rates, that called on the government to act to reduce these health outcomes.

> *"I think it is very important to have data to show politicians and create awareness regarding this issue. I think it was very important for the Portuguese case." "I think this data that we have now for the Portuguese population was important to create this awareness in the political domain. I think that, nowadays, our Ministry of Health is becoming more committed to the need to have a strong policy to promote a healthy diet in the Portuguese population." (Government policymaker participant, Portugal, Interview 14)*

International and national research was also used to demonstrate that a reduction in the exposure and power of marketing over multiple mediums and platforms could reduce children's preferences, purchases, consumption of certain food and beverages as well as brand awareness. A reduction in those indicators would in turn impact on weight gain, obesity and diet-related NCDs.

Other governments found that by drawing on evaluations of existing regulatory approaches in their respective countries, which were typically self-regulatory systems, it could be shown that those systems had not been effective and a stricter approach was required.

Another enabler noted by those interviewed was the existence of both international consensus and international reports by global health actors such as the WHO calling on Member States to restrict unhealthy food and beverage marketing. This increased governments' legitimacy to act. The WHO's leadership, particularly the WHO Set of Recommendations and its regional nutrient profile models, which many participants cited as the basis for their government's policy, was critical. Chile and Canada looked to WHO and academic literature about controlling the advertising, promotion and sponsorship of tobacco products to learn how to navigate some of the technical challenges in designing the legislation.

Discussion

This study of the barriers and enablers governments face in designing the form and substance of marketing restrictions

found multiple, common areas of both technical and political challenges. The technical challenges observed in all countries include whether to introduce a mandatory approach; what age group to protect; what nutrient classification system to use; how to define "marketing to children"; and what mediums, settings and techniques to cover. Each of the technical aspects opened the government up to political vulnerability as the actors championing a limited regulatory response to the issue challenged both the form and substance of the regulation at every point.

In all contexts, political challenges were described. The actors opposing the governments approach to regulation challenged the mandatory nature of the regulation, preferring self-regulatory approaches. Actors that opposed regulation, specifically the food and beverage and advertising and media industries, applied pressure on the policy design process attempting to reduce the impact of the regulatory response on the core business function of those industries. The corporations' political activity during the policy design in all cases impacted the final design of the regulatory approaches studied.

In addition to corporate political activity, ministries of health are also operating within the political context of prevailing neosliberal ideologies that prefer to regulate markets as little as possible. Neoliberal policy paradigms have existed globally for four decades, leading to a disconnect in approaches to government intervention not only across political parties but within governments, impacting on policy coherence, particularly between the economic or agricultural sector and the health sector (Lencucha and Thow, 2019). Some academics argue that it is the underlying neoliberal policy paradigm that allows for such commercial interests to influence policy design, and that until this paradigm is addressed through wider structural changes, the attempts by governments to regulate harmful commodities, like unhealthy food, will always be fraught (Lencucha and Thow, 2019).

Some enablers identified related to how the political will for regulation was enabled by strong policy champions. Civil society actors and academics, particularly those that formed close coalitions, enabled the government to overcome many technical and political challenges by providing strategic advocacy, supporting the policy option and providing expert advice and evidence to support the need for the policy. To overcome these technical challenges, governments drew on experts in the area and used examples of regulation from other areas, particularly tobacco control.

This study illustrates the effect of corporate political activity such as lobbying on the policy design; and expands on the literature exposing corporate strategies in contemporary, comparable country case studies. The phenomenon of corporate influence in policy development for marketing restriction observed is similar to those from other harmful commodities such as alcohol and tobacco, which provide important precedents for the field of unhealthy food and beverage marketing (Brownell and Warner, 2009; Bakke and Endal, 2010; Miller and Harkins, 2010; Babor and Robaina, 2013; Mccambridge et al., 2014; Savell et al., 2016; Hiscock et al., 2020).

Analyzing the common barriers and enablers from other governments in relation to policy design for food marketing restriction, is not only necessary to aid with technical capacity building but also to address the challenges posed by powerful influences in opposition to the policy.

Strengths and limitations

The strength of this research is that it captured the experiences of key stakeholders involved in introducing unhealthy marketing restrictions from multiple jurisdictions. Little is understood about how governments design a regulatory response to unhealthy food and beverage marketing, what difficulties they face and how they overcome them. Using an HPT framework to direct the data collection and analysis also adds strength to the study to explore factors such as political context and actors that impact on the design of the policy.

A limitation of the study is that the breadth of the jurisdictions covered meant that findings are a more general overview of the issues faced, and overcome, by different governments. Interviewing additional government and policymaker participants would have added more insight into the challenges governments face. Therefore, a more in-depth case-study analysis of any of these jurisdictions is recommended to fully understand the policy process as a whole and its barriers and enablers at different phases.

More research capturing the full extent of the political nature of the food marketing policy development process would also provide greater insight into the political economy of regulating food and beverage marketing.

Policy implications

This research provides an in-depth understanding of how governments have attempted to address the marketing of unhealthy food and beverage marketing, a component of the commercial determinants of health. This will contribute to the need for capacity building in NCD prevention to aid governments to address the commercial determinants of health through regulation. Regulating the exposure of children to harmful food and beverage marketing is a key area where governments can learn from other governments about designing robust policy interventions, in particular, the common barriers and enablers faced by those governments who have attempted to design regulations to restrict unhealthy food marketing to children.

This research shows that designing and introducing marketing restrictions is politically and technically challenging when actors opposed to the regulations challenge the form and substance, preferring a limited regulatory response.

While a lot of the technical challenges are surmountable with robust research and experts guiding the design of the process, there are some key areas that would benefit from further research, where the technical guidance is currently limited. These areas include: how to incorporate brand marketing in the scope of the regulations when using a nutrient-based classification system; technical input to counter the argument that it is too hard to discern between a teenager and an adult so age thresholds must be reduced; and the definition of "directed to

children" not adequately protecting the full exposure of children to unhealthy food and beverage marketing particularly in the digital space.

Conclusions

The marketing of unhealthy food and beverage is a prolific and insidious commercial determinant of health. Regulating unhealthy food and beverage companies to reduce the exposure of children to their marketing practices is a critical regulatory response to a commercial interest interfering with children's health. The study found that designing the form and substance of polices for marketing restrictions is both technically and politically challenging but that the challenges are not insurmountable. Despite the different political contexts and actors involved in different jurisdictions internationally, there are many commonalities in the challenges and enabling factors faced by governments. Understanding the technical and political challenges experienced by governments and how they overcame those challenges is therefore an important study to contribute to capacity building in the NCD regulatory space.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by University of Auckland Human Participants Ethics Committee in July 2020, reference 024671. Written informed consent to participate was provided by all study participants.

Author contributions

FS was involved in all aspects of the study and drafted the manuscript. FS and AC undertook the interviews. AC informed the original thematic analysis work and edited and reviewed the manuscript. SM, TT, and BS provided supervision and review of the analysis and the manuscript. All authors read and approved the final manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpos.2023.945742/full#supplementary-material

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Qualitative analysis of front-of package labeling policy interactions between stakeholders and Health Canada

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Background: Front-of-package labelling regulations proposed by Health Canada in their Healthy Eating Strategy (2016) were finally passed in 2022, but remain unimplemented. This study analyzed interactions that occurred between stakeholders and government related to this policy proposal to identify key themes and policy implications.

Methods: A qualitative framework analysis was conducted on publicly available documents for stakeholder correspondences related to front-of-package that occurred between 2016 and 2019 in Health Canada's Meetings and Correspondence on Healthy Eating database. Five sequential steps were applied: familiarization, identifying a thematic framework, indexing, charting, and mapping and interpretation. A complex systems (i.e., a dynamic system with multiple interconnecting components) lens was incorporated in the final step to deepen the analysis.

Results: Hundred and seventy-three documents were included, the majority from industry stakeholders (n=108, 62.4%). Three overarching themes were identified: industry trying to control the agenda and resist regulation; questioning the evidence supporting the policy and its impact on the agri-food industry; and dismissing the need and effectiveness of the policy. Incorporating a complex system lens found industry and non-industry stakeholders held markedly different perspectives on how cohesive the system defined by the front-of-package labelling policy was, and the policy impact on its stability. Economic and opportunity costs were the main trade-offs, and symbol misinterpretation considered an unintended consequence by industry. Finally, some stakeholders argued for wider policy scope incorporating more products, while others requested a narrower approach through exemptions.

Conclusion: Interactions with industry stakeholders on health food policy proposals require careful consideration, given it may suit their interests to generate delays and policy discordance. Explicitly setting out the principles of engagement and actively encouraging non-industry stakeholder representation provides a more balanced approach to policy consultation and development.

KEYWORDS

front-of-package labeling, nutrition labeling, food labeling, nutrition policy, consultation, obesity, industry, lobbying

Introduction

Diet-related chronic non-communicable diseases continue to have a profound effect on health. Globally, dietary risks were responsible for 7.94 million deaths and 188 million disability-adjusted life-years among adults, as calculated by the Global Burden of Disease Study 2019 (1). In Canada 63.1% of adults (aged 18 or older) were classified as overweight or obese in 2018 (2) and high body mass index (BMI) was the most significant risk factor after tobacco for death and disability in Canada (3). Risk factors related to unhealthy diets and chronic disease are estimated to cost $26.7 billion in Canada annually (4).

Given the burden of disease generated by poor diets, a range of policy options have been deployed to mitigate them. The World Cancer Research Fund International NOURISHING database identifies a range of policies in place to promote healthy diets including nutritional labelling policies on foods such as front-of-package labelling (FOPL) (5, 6). It records this policy being implemented by over 50 governments globally including mandatory labelling in much of Latin America (6–8). FOPL provides visible nutritional information on the display surface of a product and can be presented as nutrient-specific systems focusing on a few key nutrients (such as fats, salt and sugar), or as summary systems that provide an overall nutritional score (9).

One aim of FOPL is to promote healthier choices by consumers. The literature on FOPL has assessed its role in outcomes such as healthier product identification, selection, purchasing, and consumption. One meta-analysis found that FOPL use resulted in easier identification of healthier foods and a smaller positive effect on consumer purchasing but limited evidence on consumption behaviours (10). Similarly, a second review found a significant overall effect of any FOPL compared to no-label for lower sugar and sodium content of purchases, but limited findings on consumption (11). Another aim of FOPL is to prompt the reformulation of products that would be required to display a FOPL to make their nutrition profile healthier, and there is evidence to show the impact of this both in Chile where a prospective study found a significant decrease in the proportion of products with any "high in" nutrient of concern from 51 to 44% (12), and in Australia and New Zealand where the Health Star Rating has prompted the reformulation of less healthy foods (i.e., with a lower number of stars) (13). Thus, the current evidence around FOPL leading manufacturers to reformulate is stronger than the evidence around the impact of FOPL on consumer behaviours, such as product identification and consumption. One limitation is that current national dietary intake survey methodology cannot assess the impacts of FOPL on consumption unless surveys capture brand specific data. Although recent data from Chile show significant reductions in sales of foods with the mandatory FOPL implementation (14).

The main challenge in reaching a consensus around any national FOPL policy - beyond getting the policy adopted at all - is the choice of the symbols to be used. Although research shows that interpretive symbols such as warning labels (rather than presenting guideline amounts) are most effective (11, 15–18), there remain many options. Furthermore, the majority of symbols currently in use are either voluntary or industry-led. Additionally, the effectiveness of symbols can be implicated by other health claims on the pack, with a FOPL symbol alone being more effective than FOPL in combination with other health claims (18, 19). There have therefore been calls to standardize the symbols used (16), and implement mandatory policies to increase overall effectiveness (6, 7, 17).

As the food industry has continued to grow, with large multinational corporations dominating the market, their obstruction of public health interventions that may threaten profits has become apparent (20). Additionally, the replication of tactics used by other unhealthy industries (such as tobacco and alcohol) to resist regulation has been well-documented (21).

Multiple frameworks to categorize tactics unhealthy industries use in lobbying have been published (22–25) and results have shown that frequently used industry tactics include: discrediting scientific evidence or formulating evidence through scientists and front groups (21–23, 26), using public relations to inform public opinion (21, 22, 24, 26), promoting alternatives to regulation such as voluntary schemes or pilots (22, 24, 25), amplifying economic importance and impact on industry (21, 22, 26), and threatening legislation (23, 24, 26). Furthermore, industry stakeholders have been found to invest in long term relationship building approaches to exert influence on policymaking (27) whilst silencing those who advocate for healthier diets by discrediting scientists (28).

Health Canada (HC) published the Healthy Eating Strategy (HES) in 2016 outlining a suite of nutrition policies aimed at increasing the healthiness of the Canadian food environment (29). Research on the strategy found that industry stakeholders initiated, and had a greater proportion of interactions with Health Canada (HC) than non-industry stakeholders (22, 30), and attempted to influence policy by framing the debate on diet, promoting deregulation, and promoting alternatives (22). One of the proposed policies included a mandatory FOPL approach (29) where the labelling requirements included a nutrient-specific interpretive symbol that would be required to be displayed on foods that met or exceeded the threshold of 15% of the daily value requirements for nutrients of public health concern (sodium, sugars, and saturated fat) (31).

As part of the strategy approach HC explicitly stated that "*the food environment is a complex and interconnected network of factors and public policy needs to affect multiple parts of the network to affect real change*" (29). The food system in particular has been widely recognized as a complex system (32–34). Complex systems are described as dynamic, with multiple interconnecting components that interact in often random ways (35). Such thinking recognizes that a linear approach – whereby an action results directly in a relatively predictable change may be limited. For example, FOPL policy would not result in everyone choosing to avoid products with FOPL, however it could result in reduced consumption of unhealthy products and lower obesity prevalence. FOPL is one shift in the system that helps it move in the desired direction, health-wise. Although the FOPL policy is intended by HC as one of a range of interventions, a criticism of the policy by some, is that it requires high levels of individual agency – to act on the information to eat healthier foods. By proposing FOPL as a mandatory scheme, the HC policy mitigates these criticisms to some extent, as evidenced by the impact of a similar policy in Chile (12, 36).

The proposed policy underwent two consultations in 2016 and 2018 detailing the FOPL approach and symbol to be used. HC committed to a Transparency and Openness policy (37) where all correspondence and meetings with stakeholders external to public consultations were published in an online database (38). The proposed regulations were published officially in the Canada Gazette, in

February 2018 (39), with plans for publication of the final regulations to follow later that year which did not occur, although publication of the final regulations were listed in the Forward Regulatory Plans for 2021–2023 (40) and eventually published in July 2022 (41).

As part of a range of policies to address the complex issue of unhealthy diets in Canada, the FOPL policy is an evidence-based, effective policy that had undergone extensive consultation with stakeholders, yet was stalled for several years. Interactions and consequently influence of stakeholders on policymakers can impact the progression and ultimate implementation of policies. The aim of this study was to analyze stakeholder interactions – through published correspondence and meeting notes – to identify narratives presented by industry and non-industry stakeholders, and their potential role in the policy's delay.

Materials and methods

This qualitative study employed framework analysis (42, 43) to analyze correspondence and meeting notes published by Health Canada related to the proposed FOPL policy. The analysis was deepened using a complex systems lens.

Data selection

Health Canada's Meetings and Correspondence on Healthy Eating (MCHE) database (44) was developed as part of the Government of Canada's Regulatory Transparency and Openness policy (45). The MCHE database contains detailed records (hereafter referred to as documents) of all the meetings and correspondence that were shared between stakeholders and Health Canada related to the Healthy Eating Strategy. Documents spanned a time period from 2016, when the Healthy Eating Strategy (HES) was introduced, until 2019 at which point the final regulations had not been introduced and a general election was held (46).

All documents labelled by HC with the subject 'Front-of-Package Labelling' were extracted in November 2019 (44); they included meeting notes, presentations, letters, and emails. Duplicate copies of documents (e.g., French versions of English documents or handwritten copies of digital documents), documents that did not refer to FOPL explicitly, and HC publications (e.g., HES report) were excluded from the sample for analysis.

Document date, stakeholder name, and type of meeting (stakeholder- or HC- initiated, as indicated in the MCHE database) were extracted from the database. Stakeholder types were categorised in line with previous research analysing the HES (22, 30) as: 'industry' (organisation with a commercial interest, e.g., food companies), 'non-industry' (organisation with no commercial interest, e.g., health bodies), or 'mixed' stakeholders from the former categories or other organisations.

Data analysis

Basic quantitative analysis of the documents was conducted in Microsoft Excel to show the quantity of documents submitted from each category and type of documents. Documents were then imported into NVivo 12 (47) to facilitate the framework analysis; this was followed by more in-depth analysis using a complex systems lens.

Framework analysis

Framework analysis is a systematic methodology commonly used in policy analysis (42, 43, 48). The methodology was developed for use in large-scale policy research, and since adapted for health research (48). It enables the condensation of large volumes of data into a matrix output comprising cells of summarized data (48). Strengths of this methodology in policy research include the use of pre-set aims and objectives identified from the outset, and the ability to include *a priori* issues while remaining grounded in the data (43). Additionally, the ease of collaboration during the analysis increases inter-rater reliability (42). The five steps of framework analysis include: familiarization, identification of the thematic framework, indexing, charting, and mapping and interpretation.

In the familiarization step, the first full read through of the dataset is used to generate a log of key ideas and themes in the data through an inductive approach. Next these themes are developed, and are incorporated with *a priori* themes, in an iterative process that results in the identification of the thematic framework. In the indexing step, the data is coded into the thematic framework topics, with relevant lines of texts being selected as a 'code' and assigned to a topic. In the charting steps these codes are grouped into the topics, collectively reflecting certain views and experiences. The final mapping and interpretation step involves creating a framework matrix with the thematic framework topics. During this process, the findings are analyzed and reviewed to identify the key themes in the data.

The first author completed the familiarization log, and then the thematic framework and resulting charts were presented to co-authors to validate the identified themes and interpret them collaboratively. *A priori* themes from the literature including industry tactics, economic and opportunity cost, and public health approaches were discussed and incorporated where appropriate (22, 23, 49, 50). The thematic framework charts provided a summary of the directly observable ideas (51), and overarching themes across all the thematic framework charts were found during their analysis. These findings are presented in the thematic analysis results. In the final stage of mapping and interpretation, the analysis was deepened by incorporating a complex system lens.

Complex systems analysis

Complex systems research has been widely used in other disciplines, but only more recently gained traction in health research (35). A complex system is a dynamic system of interacting components, including actors, who could be individuals, groups or organizations (52). The boundaries around the system are in themselves dynamic and changing (52). However, in order to make the system comprehensible they are artificially imposed, and hence must be placed appropriately to ensure the full impacts of a policy on the system are captured (53).

To describe the changes within a complex system, the guidance created by the United Kingdom's National Institute of Health Research School of Public Health Research (SPHR) summarized the

TABLE 1 Terms to describe changes in a complex system by Egan et al. (52) and a FOPL example to illustrate.

Terms for complex system (52)	Front-of-package labeling example
System cohesion	Are stakeholders aligned and in agreement that FOPL is an appropriate policy to improve nutritional choices?
Stable and unstable systems	Would the FOPL policy have any impact on the system or will the change be absorbed and lead to no overall change in food choices?
Non-linearity	Could introducing the FOPL lead to a significant change such as transforming consumer expectations of product composition and thus change the food system disproportionately?
Trade-offs and choices	By introducing FOPL, what other policy options were not introduced?
Unintended consequences	What unintended consequences occur? e.g. can the FOPL result in consumers picking less nutritious foods unintentionally?
Emergence (scope)	To what extent is the FOPL policy scope expanded to apply to a greater 'system map' such as digital innovations or restricted to limited products?
Adaptation	What changes will be made to how the system works as a result of the policy? Will industry adapt by reformulating to avoid having to apply FOPL to their products?
Spill-over/displacement	Could the policy move the issue to another area rather than resolving it, e.g., by applying FOPL to certain products will it result in the consumption of alternative unhealthy products?
Feedback	Could the policy result in an accelerated action where it creates a positive or negative feedback loop, e.g., can the FOPL change consumer taste demand for further reduced sugar products?

terminology used, and is presented in Table 1 with a FOPL specific example for each term (52).

The benefits of taking a complex systems approach allows easier conceptualization of the many factors at play in a given issue and better anticipation of unexpected and counterintuitive consequences (35). The majority of work around complex systems remains theoretical, with limited application in generating evidence or effective policy (32). In order to make a systems approach more accessible and effective, the SPHR created guidance on how to generate research that takes complexity into account and to evaluate interventions appropriately (52, 54). Given that FOPL is one intervention in the 'system' of diet-related poor health, and the explicit reference to complex systems in the HES (29), it is valuable to examine it with a complex systems lens.

A novel approach was employed by this study to adapt the Framework Analysis methodology by incorporating the SPHR systems terms (52) in the final mapping and interpretation stage of analysis. To create the framework matrix, the thematic framework topics were cross-tabulated with the complex systems terms (presented in Table 1). This resulted in the cells summarizing references in the data where complex system concepts were being directly or indirectly expressed. Further themes from this extended systems analysis are presented in framework analysis results.

Results

Overview

There were 317 documents labelled by Health Canada (HC) under the topic "Front-of-package labelling" extracted from the Meetings and Correspondence on Healthy Eating (MCHE) database. Hundred and seventy-three were included in the final analysis after exclusions (such as French or handwritten duplicates) as presented in Figure 1. Documents covered the time-period from December 2016 to June 2019.

Most documents were recorded by HC as being stakeholder-initiated interactions ($n = 144$, 83.2%); 6.9% ($n = 12$) were HC-initiated, and the remaining interactions were initiated by both HC and stakeholders ($n = 17$, 9.8%). When categorized by stakeholder type, almost two thirds of all documents ($n = 108$, 62.4%) were from industry stakeholders. A breakdown of documents by stakeholder type is presented in Table 2.

As per the framework analysis steps, after familiarization, eight topics were identified in the Thematic Framework (column one in Table 3) with three overarching themes emerging from analysis across the topics.

Thematic analysis

Familiarization with the data found no apparent changes in the narrative over time, thus all the documents were analyzed collectively. During this first step a log of ideas were kept and eight key topic groupings emerged. *A priori* issues such as industry tactics, economic and opportunity cost, and public health approaches were also incorporated as they were found to be relevant by the authors (22, 23, 49, 50), and the thematic framework was agreed by authors in an iterative process. A detailed breakdown of each the eight topics and the corresponding codes can be found in Supplementary Table S1. In the indexing step the codes were applied to all documents, and then the codes were pulled from the documents and charted under the applicable topic. Analysis of the codes across all the topics using inductive reasoning found three overarching themes that were present: (1) industry controlling the agenda, (2) Industry questioning the evidence base of the policy and impact on trade and competitiveness, and (3) Industry dismissing the policy. The three key themes are elaborated on below.

Theme 1: Industry controlling the agenda

Although industry actors refer to themselves in the FOPL consultation process as 'stakeholders', there is a clear sense of them attempting to lead the decision making: they appeared to expect to

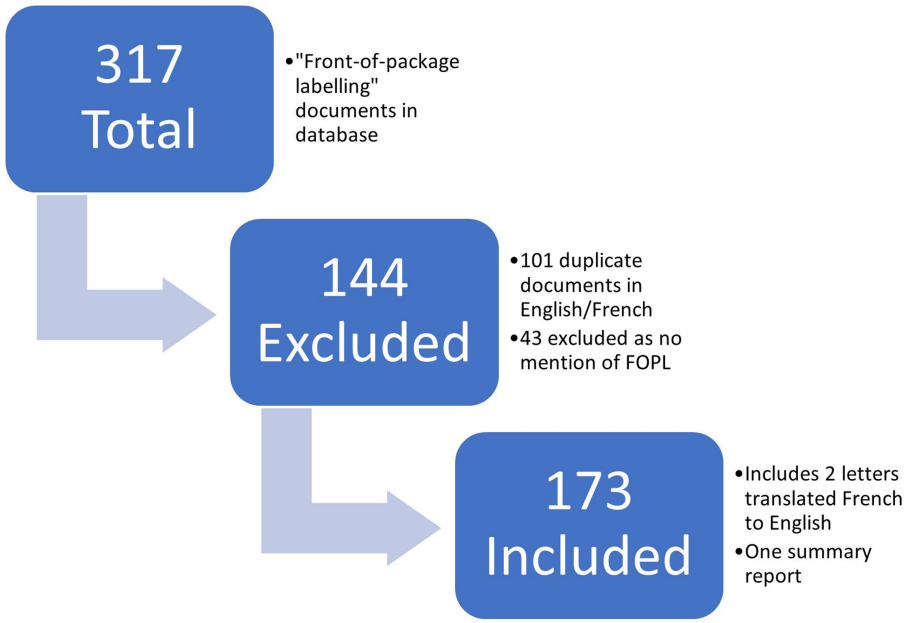

FIGURE 1
Flowchart to show documents included in the analysis.

TABLE 2 Stakeholder types.

Stakeholder type	Description	Total (%)
Industry	Organization with a commercial interest	108 (62.4%)
Non-industry	Organization with no commercial interest	37 (21.4%)
Mixed	Industry and non-industry stakeholders together Other organizations	28 (16.2%)
Total		173 (100%)

be able to change previous decisions taken in the policy development process. This was most apparent in discussions on the selected FOPL symbol, where even after being presented with the evidence base and criteria for the proposed symbol, industry stakeholders continued to reject it:

> *"During the Meeting food industry participants specifically stated for the record that there was no agreement to design principles and called for a robust and inclusive dialogue to take place to develop appropriate, scientific and evidence-based principles for FOP labelling. It is therefore inappropriate for Health Canada to impose the four design criteria outlined in the Letter."*

(Industry stakeholder, 04/10/2017)

Industry stakeholders implied they have a leadership role compared to other stakeholders in the decision making due to a perceived unique insight into the FOPL policy and its impacts. There were also many references to the benefits they provide to the economy and in employment.

> *"Food industry has an immense amount of knowledge and data that no other stakeholder can provide."*

(Industry stakeholder, 26/05/2017).

As an alternative to regulation, industry stakeholders promoted the use of their own FOPL symbols or labels and highlighted that some of the symbols were already in widespread use. Voluntary schemes and pilots were also promoted as an alternative.

> *"Pilot and evaluate the voluntary introduction of a neutral fact-based front-of-package system on a sample of foods and compare its results to existing programs."*

(Industry stakeholder, 26/05/2017)

Finally, rather than considering FOPL, some industry stakeholders focused elsewhere, and reported slow regulatory processes were the limiting factor in reformulating and improving products and should consequently be corrected first.

> *"The Canadian food and beverage industry continues to face challenges with timely regulatory approvals and costs for reformulation and innovation. Because of outdated regulations, it takes far longer to bring new and reformulated products to market in Canada than in other countries. Health Canada and the Canadian Food Inspection Agency must address lagging regulatory modernization quickly – before imposing new regulations."* (Industry stakeholder, 18/09/2017).

Theme 2: Industry questioning the evidence base of the policy and impact on trade and competitiveness

The policy was questioned by industry actors in terms of whether the evidence supporting FOPL was sufficient, and whether the economic impacts of the policy was justifiable. Discussions around

TABLE 3 Framework matrix.

		Complex system terms								
		System cohesion	Stable and unstable systems	Non-linearity	Trade-offs and choices	Unintended consequences	Emergence (scope)	Adaptation	Spill-over/ displacement	Feedback
Thematic Framework Topics	Industry's role as a stakeholder	**-Industry want FOPL aligned with trade partners**	**Unstable system where FOPL limits Canada's potential -Trade pressure on Canadian market**	**-FOPL can have disproportionate impact on Canada's potential**	**-Economic *vs.* societal costs -Regulatory *vs.* business cost**	**-Reformulation may not improve product**		-Business to adapt to healthier goals. -Motivate reformulation to avoid FOP		
	Industry's engagement in policy development	-All sectors have a role to play in food industry	-Uneven playing field for industry							
	Concerns about the policy		**-FOPL can have disproportionate impact on Canada's potential**			-Disproportionate targeting of nutrient dense products	-Widened to consider digital approach **-Widened to multi-factorial solutions and promotion of healthy diets rather than nutrients -Widen to apply to all foods**	-Move to digital interface **-Negative adaptation to additional calories in poorly reformulated products**	- Displacement from healthy diet to reduced healthy calories (e.g., less diary consumption) - Additional calories in poorly reformulated products	
	Consumers response to the policy	-Industry 'opposed to... Transparency'			-Deprioritize educating consumers	**-Consumers cannot distinguish healthier products** -Undermine public trust -Inappropriate use of safety symbol -Conflicting health claims -Health halo **-Uneven playing field for industry**	**-Narrowed to NFt**	-Positive adaptation where it leads to change in consumer behavior		-Positive loop where consumers and manufacturers improve products in a mutually reinforcing way
	Industry perception of a weak evidence base for the policy	**-FOPL does not align with agri-food industry system**			**-Business Investment *vs* health**	-Multiple clashing symbols on products -Widespread application leading to insensitivity	-Widened to say FOPL will not resolve obesity **-Widened to health rather than behavior change**	-Positive adaptation where it leads to change	-Discouraging nutritious foods	-Positive feedback loop where reduced beverage calories lead to further reductions

(Continued)

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TABLE 3 (Continued)

		Complex system terms								
		System cohesion	Stable and unstable systems	Non-linearity	Trade-offs and choices	Unintended consequences	Emergence (scope)	Adaptation	Spill-over/ displacement	Feedback
	Global policy comparisons	**-Industry want FOPL aligned with trade partners.** -Non-industry note a global move to improve food offering	**-Concerns about potential reputational damage to Canadian products and impact on trade**	**-Reputational damage to Canadian products -Undermine trust in food industry**						
	Practicalities of policy implementation	-Cohesive approach between FOP, serving size, and NFt			-Cost of delays in policy implementation on industry vs. health	**-Exemptions lead to uneven playing field** -Including HC name could be seen as endorsement. -Misleading nutritional health advice **-If threshold cannot be reached will disincentivize manufacturers** -Uneven playing field with negative brand power for pre-packaged foods	-Widened to future trends and retail environment -Widened to non-pre-packaged foods. **-Widened to apply to all packaged food and beverage** -Narrowed to serving size	**-Negative adaptation if cannot meet thresholds to reformulate may increase sugar/sodium/ fat to meet competitive and consumer taste preference**		
	The Front of package symbol	**-Using a current industry FOPL symbol promotes system cohesion**				-Confusion with a safety symbol				

Blank squares indicate there were no explicit/implicit reference between the thematic framework topic and system term within the data. Bold type indicates references from a greater number of stakeholders.

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the economic impact and potential impact on trade and competitiveness were from a trans-national corporation perspective, with little or no mention of small business. While many industry organizations stated they supported evidence-based policies to improve health outcomes, they did not acknowledge the evidence and consumer and market research summarized from the preceding consultation (55) that specifically documented the evidence and need for a FOPL, rather than the aim of this consultation which was to focus on the final form the FOPL would take.

> "*there is no defendable evidence which supports a positive correlation between a change in consumer choices and improved health resulting from warning labels on the front of pack*" (Industry stakeholder, 03/07/2018).

Although there was some opposition to the demand for further evidence and the validity of the FOPL policy by non-industry stakeholders, it was minimal compared to the industry stakeholder voice. In particular, the FOPL policy introduced in Chile (similar to the proposed HC FOPL) was mentioned by many, though only non-industry stakeholders referred to the positive impacts of the Chilean policy in changing consumer behavior and driving reformulation. Industry stakeholders argued the impact was short lived, and the evidence on its success was weak. Significant focus was paid to previous opposition of the scheme by a Canadian government official at trade meetings, and to the lack of longer-term evidence.

> "*Canada challenged Chile regarding their similar FOP initiative within WTO Technical Barrier to Trade (TBT) meetings in 2015 and 2016. Noting that Chile's requirements deviated from international standards… were not based on science and were more trade-restrictive than necessary. It is inexplicable that Health Canada would now forge ahead with its own divergent FOP initiative.*" (Industry stakeholder, 04/10/2017).

Industry stakeholders contributed to the evidence base by submitting industry-commissioned literature reviews describing specific nutrient evidence and arguing for exemptions. They also presented other industry-commissioned research, carried out to gage consumer opinions on the FOPL symbol, and its impact. However, non-industry stakeholders argued the methodology used in this research was poor, as there was only theoretical, and not functional testing of participants preferences, and hence was of low quality compared to the extensive market research conducted by Health Canada in their preceding consultation (55).

> *"Clarification is needed on the methodology used by* [redacted] *for their survey. There are important limitations inherent to public opinion research." (Mixed stakeholder summary report, 19/09/2017).*

Industry stakeholders also criticized the FOPL cost benefit analysis published by HC as "*lack[ing] balance and nuance*" (Industry stakeholder, 30/05/2018) by not accounting for future regulatory changes. Although the HC response to another industry stakeholder reported "*both costs and benefits were calculated using a conservative approach, with the intention of costs being overestimated and benefits underestimated.*" (Non-industry stakeholder, 04/06/2018).

Industry stakeholders reporting feeling "*initiatives unfairly target the food processing industry*" (*Mixed stakeholder summary report, 19/09/2017*) and had concerns about the impact the policy would have on their business and ability to trade. With regards to individual businesses, they reported concerns about the economic cost of the combined food policy changes proposed as part of the HES, with stakeholders arguing they would need to divest from other areas, such as innovation, to compensate.

> "*Given the magnitude of the costs associated with food labelling proposals, industry's ability to invest in equipment, R&D or new product development will be impacted as innovation capital is reassigned to regulatory compliance.*" (Industry stakeholder, 14/05/2018).

The FOPL policy was perceived by the industry sector to create "*an uncertain and onerous regulatory environment that will decrease investment in the food sector in Canada*" (Industry stakeholder, 04/10/2018) and risk changing the way the food industry was viewed: "*Label foods like foods, and not like drugs, alcohol or tobacco*" (Industry stakeholder, 24/05/2018).

Concerns about the impact on international trade were dominant among industry stakeholders. Using a different approach to trade partners, or using a different FOPL symbol to that used by many trans-national corporations, were perceived to cause a negative reputational impact on Canadian goods. Industry stakeholders reported the FOPL policy may "*be seen by other countries as a non-tariff barrier to trade for their imports into Canada*" (Industry stakeholder, 29/06/2018) and would subsequently have a significant effect on the economy.

There was limited discussion on the impact of the policy on behavior change and health outcomes, with the exception of one non-industry stakeholder:

> *"As you and your officials weigh the potential cost to industry of new FOP labelling regulations against the known costs associated with chronic over-consumption of these nutrients on Canada's already-fatigued health care system, we encourage you to place the emphasis on Canadian's health and wellbeing*" (Non-industry stakeholder, 11/12/2017).

Theme 3: Industry dismissing the policy

Industry stakeholders dismissed both the need for the policy and its effectiveness, if it were introduced. This theme also covered the technical aspects of the FOPL policy such as what products it applies to and the proposed nutrient thresholds for triggering a warning label.

Industry stakeholders denied the need for a regulated FOPL symbol by referring to initiatives they already had in place or were planning to introduce. Many industry stakeholders argued they already had a FOPL symbol on their products, and prompted HC to adopt an industry FOPL symbol, arguing that it would be less trade restrictive.

> "[Industry stakeholder] *indicated that fact-based FOP labelling has already been implemented, or proposed, in many countries on a voluntary basis…only Chile has a mandatory interpretive system.*" *(Mixed stakeholder summary report, 19/09/2017).*

Additionally, many industry stakeholders illustrated their commitment to health policies by referring to specific nutrient efforts such as work to reduce sodium in products, whilst others referred to broader campaigns to reduce calories in beverages or signing up to a global marketing to children code. Only one industry stakeholder referred to work to directly address the nutrients covered by the FOPL policy.

> "*I know one of the key objectives of the HES it to try and get industry to reformulate. As you know* [Industry stakeholder] *has been working for the past five years to decrease the amount of sugar, salt and fat in our products and has dedicated significant resources towards doing so*." (Industry stakeholder, 07/07/2017).

Industry stakeholders questioned the policy effectiveness at changing product offerings, encouraging manufacturers to reformulate, or at changing consumers purchasing patterns:

> *"How do you know that labels will be effective, given that there is no convincing evidence in the literature…What evidence was there that indicates that labels will change consumer behavior that leads to better health outcomes?"* (Industry stakeholder, 14/06/2018).

Many stakeholders (industry and non-industry) felt that the application of the FOPL policy only to products with Nutritional Facts tables (NFts), and not all food products in retail settings, would result in an unsuccessful policy. This was acknowledged by HC as a gap that they hoped to address in future. It was also argued by industry stakeholders that the proposed set thresholds of 50 g for the FOPL policy would disincentivize reformulation by manufacturers.

> "*A 50g threshold removes any relationship between FOP labelling, the NFt, and the serving size. It also removes incentive for companies to reformulate their products*" (Industry stakeholder, 04/10/2017).

They also argued that even if they were to reformulate, it would not necessarily improve the nutritional profile of the product.

> "*Reformulation to reduce or replace sugar content in foods may not improve their nutrition profiles or reduce caloric contents, as sugars will likely be replaced with refined starches and maltodextrins*" (Industry stakeholder, 30/05/2018).

Furthermore, the FOPL symbol was presented by industry stakeholders as being confusing for consumers, and that the focus should be on education instead. Ways in which the symbol was considered confusing included if it displayed other conflicting nutritional claims such as '*lower in*' alongside the FOPL warning, or was a symbol typically used in warning settings (e.g., hazard sign).

> *"As outlined in our original proposal, and further expanded upon in the attached, octagons, triangles and exclamation marks are regulated for the purposes of denoting a safety hazard. Their use on food products would inappropriately suggest a food safety risk, and their prevalence on foods could also undermine their effectiveness as safety warnings*." (Industry stakeholder, 18/09/2017).

Educating consumers was considered important by all stakeholders, although industry-stakeholders tended to prioritize this above the FOPL policy, rather than alongside it, which was the approach taken by most non-industry stakeholders. Additionally, industry stakeholders also offered to contribute to the organization and financing of such initiatives.

> *"Moreover, education is the first and most effective tool to change behavior — and that is exactly what the Government is not doing: educating the public*." (Industry stakeholder, 18/09/2017).

Framework analysis

The framework matrix was constructed by cross-tabulating the thematic framework with characteristics of a complex system. Where there was an implicit or explicit reference to a system term in each theme, it was recorded in the matrix and is presented in Table 3. Although there were some references to all the system terms, those cited more often and by a greater number of stakeholders are grouped and presented in the findings (highlighted in bold in Table 3). The groupings in order of dominance were as follows: (1) system cohesion, stable/unstable systems, and non-linearity (2) trade-offs and unintended consequences, (3) emergence and adaptation, and (4) spill-over/displacement and feedback. Due to the majority of interactions being from industry stakeholders, the majority of references to system terms are theirs.

System cohesion, stable/unstable systems, and non-linearity

Industry and non-industry stakeholders had markedly different perspectives on how cohesive, or aligned, the system was due to the fundamental antagonism between profiting from the sale of unhealthy products and the health benefits of minimizing consumption of such products. However, they both agreed that the policy has the potential to initiate change rather than just being absorbed without impact, hence the system was unstable.

Many industry stakeholders described the policy as specifically disadvantaging their interests, creating an uneven playing field in the sector, restricting potential sales and growth, and causing a loss of trade. In particular, they described the agri-food industry as non-cohesive and competitive internationally and that applying FOPL on Canadian products would have a detrimental impact on them. Additionally, changes in trade with the United States (US) through the impending North American Free Trade Agreement (NAFTA) negotiations, and tax and tariff differences also indicated the system was non-cohesive. They identified a non-linear, and disproportionate response to the FOPL symbol as having the potential to damage public trust, reputation of Canadian goods, and the agri-food industry's future potential. Contrastingly, the unanimous promotion of current industry FOPL policies to mitigate trade risk, depicts a comparatively more cohesive sector that can be aligned to achieve the policy aims.

> *"Putting stop signs on Canadian made food products will undermine confidence in our agriculture and food industry in Canada and abroad. This approach would most likely result in great harm to the industry's reputation, undermining public trust in Canadian food and industry's continued efforts to capture emerging markets, both domestically and internationally*" (Industry stakeholder, 09/03/2017).

Non-industry stakeholders' voices, including HC, were quieter in comparison, but described a cohesive system where stakeholders could work together to improve the food offering, of which FOPL is one part of the policy approach.

> *"The Healthy Eating Strategy provides an opportunity for the food industry to adapt business practices to align with healthy eating goals while being economically successful. This strategy, which is supported by regulations, will provide the agri-food sector an important opportunity to grow, develop, and market healthier foods."* (Non-industry stakeholder, 04/06/2018).

Trade-offs and unintended consequences

Trade-offs as a result of the policy were considered in terms of economic cost and opportunity cost. Regarding the economic impact of the policy, industry stakeholders felt the short-term costs to industry were underestimated and that the long-term costs would be substantial, due to the potential impact on trade. In comparison, non-industry stakeholders argued that the economic trade-off, whatever the extent, was limited compared to the opportunity cost of improving health outcomes.

> *"The truth of the matter is that while these spokespeople seem to be engaging in economic fearmongering and getting up in arms about logos intended to reveal more clearly the true nutritional value of many food products on the market, overweight and chronic diseases associated with unhealthy eating are taking a heavy toll on our society."* (non-industry stakeholder, 08/08/2017).

A second issue was in the timing of policy implementation where industry stakeholders requested a delay in enforcing the policy to allow industry time to absorb the costs more gradually. This was rejected by HC as a trade-off between delaying for industry benefit vs. delays to societal benefit.

> "*Giving industry an extra year to implement changes would delay the benefits to health, which also has significant economic implications.*" (non-industry stakeholder, 17/12/2017).

A third trade-off between the aims of educating consumers or changing behavior with FOPL was only explored by industry stakeholders, as non-industry stakeholder considered them complementary initiatives.

> *"If the goal is to influence consumer purchasing behavior, rather than education and information, Health Canada must demonstrate the efficacy of its approach in light of the trade-restrictive nature of its proposal compared to other equally effective approaches." (industry stakeholder, 18/09/2017).*

Industry stakeholders raised several potential unintended consequences. Varied reasons for the FOPL symbol being potentially misinterpreted were given, including whether exemptions can cause consumer confusion. As the policy proposed to include the FOPL symbol only on pre-packaged products with a Nutrition Fact tables (NFt), both stakeholder groups argued exempted foods not subject to the NFt policy, and hence exempted from FOPL, could be misinterpreted as healthier, by virtue of not displaying the symbol.

> *"Not only will the food industry have to bear the costs of the change alone, but many of its products will have a logo for those that exceed the standards, while retail and bulk foods are not subject to regulation... For example, consumers could estimate that lasagna prepared at retail and sold at the refrigerated counter is superior in terms of nutritional quality."* (Industry stakeholder, 29/11/2017).

Furthermore, industry stakeholders argued the policy may result in less healthy diets if nutrient dense products are included.

> "*A number of participants expressed concern that warning symbols do not discriminate between nutrient-dense foods and others. There could be unintended consequences, such as children under 2 years old being fed low fat milk.*" (Mixed stakeholder summary report, 18/08/2017).

Finally, unintended consequences of the symbol used included concerns by industry stakeholders about the use of common safety symbols as deeming food unsafe, or the inclusion of HC's name within the symbol as being considered an endorsement of the product rather than mark of authority.

Emergence (scope) and adaptation

The FOPL policy proposed by HC had clear goals that were set out in the consultation guidance. Using the FOPL policy proposed by HC to inform the scope of the system, however, it becomes apparent some stakeholders widened or narrowed the scope of the policy.

Proposed ways to narrow the policy by industry stakeholders included exempting certain products such as those with small serving sizes. Furthermore, there were calls for specific exemptions such as dairy, fruit juices, cranberries, and others.

> *"In addition, Health Canada is not giving adequate consideration to the impact FOPL will have on confections, which self-regulate via portion control. Many confections are offered in individually wrapped portions, which are consumed as occasional treats, rather than meal supplements or components. If Health Canada proceeds with FOPL, an exemption should be granted for confection products"* (Industry stakeholder, 30/05/2018).

Some industry and non-industry stakeholders promoted applying the FOPL policy to a wider range of foods, whilst other industry stakeholders argued this in itself would make it less effective.

> *"Consumers who will be asked to choose from a majority of products displaying logo could develop insensitivity and override these warnings"* (Industry stakeholder, 29/11/2017).

Other suggestions of widening the policy scope included considering larger health outcomes such as diets overall and obesity trends rather than quantifiable behavior changes such as selecting foods without FOPL labels. Future digital innovations and consumer demands were also suggested as a way the policy could be broadened.

> "*By the time the regulations come into force, our members anticipate significant technology driven changes to the way consumers shop for food*," (Industry stakeholder, 18/09/2017).

The HC FOPL policy's stated aims were to change consumer behavior and result in food industry adaption through reformulation. This positive adaptation was discussed exclusively by non-industry stakeholders, and one industry stakeholder who was an anomaly in the responses. In comparison, other industry stakeholders argued manufacturers who could not meet the thresholds would instead adapt by developing a less healthy products (e.g., with increased sugar content) to compete with other products and increase consumer demand.

> *"sugar, sodium, or saturated fat content of products could unfortunately increase to meet competitive and consumer taste preferences"* (Industry stakeholder, 20/04/2018).

Spill-over/displacement and feedback loops

There were much fewer references to displacement and feedback loops, and the few that were found related to other system terms too. Discussion of displacement focused on detrimental impact on nutritional intake if consumers shifted to low-fat dairy products or increased nutrient dense food consumption (which were also considered as unintended consequences of the policy). A further example given of displacement was increasing the use of sugar in reformulated products to improve taste when sodium and fat were reduced.

There were two references to positive feedback loops, the first referring to an ongoing reduction in beverage calories in Canada, and the second recognizing the intended policy outcome of reformulation and healthy product identification. Of note, the latter, depicted in the quote below, was an anomaly response and this view was not shared by other industry stakeholders.

> "*FOPL is a promising intervention that can make healthier food choices easier by nudging both consumers & manufacturers in a mutually reinforcing way*" (Industry stakeholder, 13/07/2017).

Discussion

Between 2016 to 2019, 173 individual documents were submitted to the MCHE database discussing Front-of-Package Labelling. The majority of documents were stakeholder-initiated, and almost two-thirds of all documents were from industry stakeholders, indicating that the discourse around this policy was dominated by industry viewpoints.

Using framework analysis to qualitatively analyze the documents, a thematic framework emerged with eight topics (detailed in Supplementary Table S1). Analysis of the thematic framework yielded three overarching themes: industry controlling the agenda and resisting regulation; questioning the evidence base of the policy evidence and impact on trade and competitiveness; and dismissing the policy and the need for it. The analysis was deepened using a complex systems lens, by cross-tabulating the thematic framework topics with characteristics of a complex system (see Table 3). This process highlighted that industry and non-industry stakeholders held markedly different perspectives on system cohesion, however, both agreed that it was an unstable system. Economic cost and opportunity cost of the policy were seen as the main trade-offs, and concerns of unintended consequences around misinterpretation of the symbol were reported. With regards to emergence, some stakeholders argued for a wider policy scope, whilst others requested a narrower approach through exemptions. Finally, limited discussion of adaptation and spill-over/displacement as a result of the policy was referred to.

Our study identified that industry stakeholders opposed the proposed FOPL policy whilst promoting multiple alternatives, including industry promoted FOPL initiatives. This is reflective of the global picture where the majority of FOPL policies are voluntarily applied, and in some cases may be FOPL symbols preferred by industry (8, 56). Globally, Latin America has had the most success at implementing mandatory policies, the majority of which are black and white octagonal 'warning or high in' symbols (8). In comparison, countries in the European continent and Australasia almost all have voluntary policies in place using summary systems, rather than nutrient specific systems (8).

The shift to individualist framing of the FOPL policy outcomes, where industry stakeholders anticipated that consumers will be confused and require education, detracted from the structural changes needed to respond to diet-related chronic diseases as a population health issue (57, 58). Employing complex system theory helps to interpret some of the industry claims and brings to the forefront the lack of cohesive vision on policies, due to misaligned goals between industry and non-industry stakeholders. The industry focus on less effective downstream interventions (50) and resistance to more effective interventions or regulation (59, 60) through juxtaposing narratives becomes more apparent through a complex system lens, enabling policymakers to address such arguments more promptly and robustly.

The 'policy cacophony' created by the multitude of policy options including industry-promoted symbols, or educational programs inhibits progress by drowning out concerted, coherent efforts (61) and delaying policy implementation (62). Our study reported multiple instances of competing policy recommendations, such as requests for exemptions, juxtaposed with requests for universal application of FOPL to all retail products. Similarly, research published by Health Canada was ignored, while calls for more market research were made simultaneously. Therefore, it is plausible that industry stakeholder's opposition resulted in delays, either directly through lack of agreement on the symbol to be used, or indirectly through a prolonged stakeholder consultation phase, in which the implementation of the HC policy remains to be implemented. The main findings of this analysis resonate with other studies conducted on stakeholder interactions in relation to the HES (22, 30), namely that a large proportion of interactions are industry-stakeholder driven, and that these stakeholders frame the narrative to fit their interests. The 'louder' industry voice which accounted for 62.4% of all documents further highlighted the limited, opposing public health voice. Food industry corporate political activity to influence policy has been documented in a range of countries (49), over long time periods (27), and more active lobbying has been found where there is a greater potential pay-off for the organization (63). In comparison, Stuckler et al. argue that public health professionals are slow to respond to nutritional threats due to discomfort in tackling powerful companies' vested interests (20, 64). Additionally, there tends to be a lack of coordinated effort and resource by health professionals

to proactively frame public health arguments to balance the food industry lobbying cacophony (61, 65).

Additionally, many previously documented industry tactics were prevalent in the material examined in this study. Tactics were wide ranging, including resisting regulation through the promotion of voluntary schemes and pilots (20, 22, 25, 62), and promoting industry FOPL policies over those proposed by HC (20, 22, 59). Additionally, there was one instance of industry stakeholders volunteering to fund educational campaigns as an alternative to regulation (59, 62). Industry stakeholders also discredited scientific evidence (23, 26) and denied the impact of FOPL policy on health outcomes, however, they promoted industry funded research of questionable rigor (23). The amplification of economic importance and impact was apparent in many documents when considering the impact on trade (21, 22). Of note, there was no mention of the impact on small businesses, indicating it was predominately the views of large trans-national corporations that were being represented.

Whilst this study embeds complex systems theory into the methodology, similarly to the majority of the literature on obesity as a complex system, the findings do not directly identify where solutions could be applied (66). However, unique insight into industry stakeholders' consultation responses gained through the complex systems lens allows policymakers to manage unrealistic linear arguments, whilst accounting for valid concerns about the impact of the policy on the system. The focus of industry stakeholders on the lack of cohesion in vision is fitting, as it demonstrates the inherent misalignment of goals between health policies and the processed food industry that is well documented. This mis-alignment has led to calls to manage industry stakeholders appropriately in the policy process (20, 23, 64).

Although HC's Transparency and Openness policy provides a unique insight into the disparity between industry and non-industry activity, the dominance of industry stakeholders shows a more structured engagement approach is needed by policymakers to ensure proportionate representation of all stakeholders in the policy process. A framework created by the World Health Organisation (WHO) with guidance on engagement of stakeholders (67) was criticized as insufficient (68, 69); however, the principles of engagement provide a starting point for policymakers to consider the need, and extent of engagement of industry stakeholders in specific aspects of policy development. Taking a nuanced approach relevant to the healthy food policy being discussed can promote transparency and reduce delays to the implementation of effective, evidence-based public health policies.

Strengths and limitations

Vast amounts of publicly available data were obtained and analyzed in this study as a result of the landmark Transparency and Openness Framework adopted by HC. The MCHE database provided a unique opportunity to access uncensored primary data from stakeholders discussing the development of the FOPL policy over a period of three consecutive years. The thorough database included copies of all emails and letters as well as notes from meetings. Whilst the letters and emails were very informative, one of the limitations was the variability in how detailed meeting notes were. Generally, while they adequately recorded the contents of the conversation, they did not tend to convey the views held by stakeholders, therefore the analysis and interpretation of meetings was limited to the contents of the meeting notes, that at times were very brief. The database only recorded direct stakeholder interactions with HC, and hence other lobbying activities (e.g., with politicians or other government departments) and other opportunities (e.g., donations or the use of third parties) were not explored. Additionally, interactions between HC and individuals representing themselves were excluded from the database, and this may have underestimated the number of non-industry stakeholder documents (e.g., academic experts), but the number of these interactions is likely to have been limited in comparison to the volume of industry documents.

A major strength of this work was the use of framework analysis, a validated qualitative method for use in policy analysis, which allowed for a systematic approach to manage the large dataset. The methodology allowed for an inductive discovery of the thematic framework, that was complemented by integrating *a priori* themes. Allowing researchers to develop the key themes collaboratively increased inter-rater reliability of the analysis. Additionally, the incorporation of a complex systems lens deepened the analysis by including implicit references made by stakeholders rather than just explicit references in the data. The analysis was limited to the data consultation period, and hence we are unable to analyze the impact of the lobbying on further policy development since this time. Although delayed, publication of the final regulations was listed in the Forward Regulatory Plans for 2021–2023, and were eventually finalized in Canada Gazette 2 in July 2022 (41), but we were unable to quantify what extent this was influenced by stakeholder lobbying or other political factors.

Conclusion

The Front-Of-Package Labelling policy (FOPL) proposed by Health Canada (HC) is an evidence-informed policy introduced as part of a range of policies in the Healthy Eating Strategy. Analyzing stakeholder interactions through the Meetings and Correspondence on the Healthy Eating database identified differing perspectives between industry and non-industry stakeholders due to misaligned goals. The Transparency and Openness policy by HC allowed greater insight to the consultation process and should be continued and more widely applied in future policies.

The insights of this study can be widely applied, as many of the industry stakeholders are global actors or have shared industry tactics globally. There was strong lobbing for voluntary FOPL policies that industry have chosen, or for the delay of mandatory policy implementation. Continuing to focus on the ever growing evidence-base of the effectiveness of mandatory FOPL and in selecting the symbol for the policy is key to ensuring an effective approach is applied more broadly in other jurisdictions. These data can also help support efforts to ensure the implementation of other healthy food policies.

Industry stakeholders with a vested interest against healthy food policies employed many tactics in an attempt to delay, alter, or prevent policy implementation and hence require careful consideration. Policymakers need to set out their principles of engagement in advance to identify appropriate engagement points for all stakeholders in the policy development process, and proactively ensure

proportional representation of all stakeholders (including active enablement of less well-resourced, non-industry stakeholders).

Ultimately, understanding delaying tactics in the policy process can provide lessons for future health-related policies and could ensure that evidence-based health policies such as FOPL are implemented.

Data availability statement

Source data is available on the Health Canada Meetings and Correspondence on Healthy Eating database. Data available at: https://www.canada.ca/en/services/health/food-nutrition/healthy-eating/meetings-correspondence.html

Author contributions

AJ and MRL conceptualized the study. AJ, MRL, and NS designed the methodology. AJ and CM completed the analysis with input from all authors. AJ drafted the manuscript. All authors reviewed, edited, and approved the final manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.982908/full#supplementary-material

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Corruption in healthcare: global perspectives and the recent escalation of violence in Ecuador's public medicine procurement system

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Corruption is a multifaceted phenomenon that involves dishonesty and criminal behavior perpetrated by individuals or organizations holding positions of authority. It encompasses the pursuit of unauthorized advantages and the exploitation of power for personal gain. This comprehensive definition, as outlined by UNODC's Action against Corruption and Economic Crime reflects a complex social, political, and economic issue with far-reaching implications for all nations (1, 2).

Corrupt practices have a significant impact in developing jurisdictions, such as Ecuador, as they undermine the integrity of institutions, hinder development, and harm society. In Ecuador, corruption can manifest itself in various forms, including bribery, embezzlement, and nepotism. The consequences of corruption are difficult to calculate and result in the erosion of public confidence in government and institutions. Corrupt practices distort the allocation of resources, diverting funds intended for essential public services such as healthcare, provision of medicines, education, and infrastructure (3). This disproportionately affects vulnerable populations, perpetuating inequality and hindering socioeconomic progress (4). Corrupt practices can severely compromise the justice system, preventing impartial trials and diminishing the rule of law. This environment can promote a culture where powerful figures avoid accountability. In the realm of healthcare corruption, several forms prevail. These encompass absenteeism, characterized by the persistent absence of healthcare professionals; informal payments, which are unrecorded contributions made by patients or their families in cash or kind; fraud, committed by various stakeholders such as providers, government inspectors, regulators, or payers; and finally, the misallocation of resources and pilferage of supplies (5).

This landscape becomes particularly complex in countries like Ecuador. The nation's healthcare system operates within a multifaceted and segmented structure, comprising multiple entities serving diverse population sectors. The Ministry of Public Health (Ministerio de Salud Pública), or MSP, is responsible for the healthcare of a vast number of citizens. Furthermore, specialized social security institutes like the Ecuadorian Social Security Institute (IESS) and those dedicated to police and army personnel (ISFFA and ISSPOL) also play crucial roles in healthcare delivery. Alongside these government-driven efforts, a significant portion of healthcare financing stems from out-of-pocket payments, mirroring trends seen in other Latin American nations (6).

In this context, Ecuador places significant emphasis on primary healthcare as the foundation of its healthcare system, focusing on community-based and preventive measures to enhance overall health outcomes and alleviate the demand for more specialized services (7). The country also acknowledges the significance of traditional and indigenous medicine, and efforts have been made to integrate these practices into the formal healthcare system, ensuring their safety and effectiveness. Moreover, out-of-pocket payments play a role in financing healthcare for a specific population segment (8). Additionally, a public-private partnership model is present, with the public sector aiming to provide healthcare services to all citizens and the private sector contributing to associated services and private healthcare. This partnership aims to ensure comprehensive healthcare coverage across the board. The National Agency for Regulation, Control, and Health Surveillance (ARCSA) holds the responsibility for regulating and supervising the quality, safety, and efficacy of drugs and pharmaceuticals. This pivotal role contributes to the maintenance of quality standards within the healthcare system (9).

The global healthcare landscape is increasingly tarnished by pervasive corruption, with severe repercussions on the quality and accessibility of health services, a situation acutely highlighted in developing nations. This widespread problem has been laid bare during the COVID-19 pandemic, where inflated prices, pervasive corrupt practices, and the proliferation of a black market for drugs and medical supplies have been starkly evident (10–12).

Globally, corruption in healthcare systems has far-reaching effects, extending beyond inflated costs to impact the availability and quality of essential drugs. The heavily regulated, complex, and often opaque nature of health systems provides ample opportunities for corruption to flourish at every point in the drug supply chain (10).

Pharmaceuticals, representing a significant portion of public health budgets, stand as the second-largest health sector expenditure following salaries, particularly pronounced in developing nations like Ecuador. In the context of Ecuador, the annual expenditure on medicine surpasses 1–1.5 billion dollars, with an overall spending of almost two billion dollars, predominantly within the public health sector (13). Despite this significant financial investment, the World Health Organization highlights a sobering fact: up to 50% of populations in low-income countries lack reliable access to quality essential medicines (14). This glaring deficiency finds its roots in the infiltration of fraud and corruption within the system, impeding access to safe and affordable medication. Notably, the countries most impacted by pandemics such as AIDS paradoxically stand as the most susceptible to corruption, owing to their fragile governance structures and lack of transparency (15).

The global healthcare landscape grapples with a pervasive challenge: corruption, fostered by inadequate government regulation, unrelenting bureaucratic pressures, and specific cultural contexts. This issue takes center stage, particularly pronounced in Latin American nations where a concerning inverse relationship exists between medication quality and corruption level (16).

Transparency and public accountability emerge as critical safeguards against corruption and key drivers of citizen engagement within public administrations. Comprehensive research spanning healthcare centers across Chile, Colombia, Ecuador, and Spain reveals a compelling nexus between transparency and factors like healthcare system architecture, internet accessibility, and administrative hierarchy. This interplay underscores the indispensable role of State participation in fostering information accessibility and nurturing a culture of social responsibility (17).

In Ecuador, corruption has become a critical issue within public health services, primarily witnessed in the procurement of medicines and medical supplies (18). Unethical practices such as collusion within the reverse auction system, bribery, price manipulation, procurement fraud, embezzlement, and nepotism have insidiously entrenched themselves into the very fabric of our healthcare system (19–21). However, the problem transcends these practices; it has been found that political mafias and drug lords may be involved in these corruption schemes. Infamously known cases, such as the Israeli citizen murdered in prison and another individual killed during a prison mob incident after publicly selling biosimilars procured during the COVID-19 pandemic, only scratch the surface of this deep-seated issue (22).

These practices do more than merely inflate the cost of healthcare; they fundamentally jeopardize the delivery of essential services and threaten the safety and wellbeing of those involved. Consequently, the quality, accessibility, and integrity of healthcare for Ecuadorian citizens are severely compromised. Related to this, a troubling surge in violence against medical personnel has been witnessed. Last year, Rubén Hernández, the administrator of the "Delfina Torres Hospital" in Esmeraldas province, who was attacked while returning home on March 29 (23). More recently, the murder of Nathaly López, Financial Administrative Director of the "Teodoro Maldonado Hospital" in Guayas province, served as another chilling reminder of the escalating violence (24). These incidences are symptomatic of a more profound crisis and demonstrate the environment of fear in which our health professionals now operate. Many have been compelled to leave their positions, depriving our citizens of their valuable service year (25).

Those of us devoted to public health often find ourselves cornered into expressing our concerns and accusations through academic channels. The prevailing state of fear and violence in Ecuador has led to a reluctance to voice our opinions on social media platforms. This widespread fear is rapidly eroding the quality of our public health system, as many health professionals consider abandoning their posts in favor of the private sector, where they perceive fewer of these problems (26, 27).

Consequently, we find ourselves at a critical juncture where the escalation of these issues threatens to debilitate our healthcare infrastructure. It is imperative for our authorities and the global community to acknowledge this crisis for what it is—a public health emergency. Securing the safety of our healthcare workers, dismantling the mafias operating within the system, and implementing comprehensive, robust measures to prevent corruption are vital.

By confronting these issues head-on, we can aspire to restore integrity in our healthcare system, ensure the safety of our healthcare workers, and enhance healthcare delivery

for the Ecuadorian people. Potential solutions include stricter regulatory enforcement, increased transparency in procurement processes, establishment of more effective and participatory monitoring mechanisms, and rigorous prosecution of health-related corruption. Initiatives promoting transparency at all stages of the drug supply chain, especially concerning the quality, availability, and prices of medicines, can also make significant strides in combatting corruption. It is only by taking decisive action now that we can prevent further attrition of our healthcare workforce and safeguard the quality of our public health system.

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The causal configurations of provincial health policy innovation in China: an analysis of the food safety standard filing policy

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Introduction: According to China's Food Safety Law of 2015, the filing of food safety enterprise standards is a policy innovation led by p9rovincial governments in China. However, there are significant differences in the development of the "Food Safety Enterprise Standard Filing Policy" between provincial governments across the country. This study aims to explore the internal mechanisms driving autonomous innovation by provincial governments in the absence of administrative pressure from the central government, to better understand the policy innovation mechanism in the Chinese context.

Methods: Crispy Set Qualitative Comparative Analysis (csQCA) method is used to identify the innovation mechanism.

Results: This study found that provinces with good provincial economic resources and strong government capabilities are prone to policy innovation, and the influence of internal factors of provincial governments is stronger than that of external factors.

Discussion: When provincial economic resources and capacity are weak, endogenous factors in the province also help achieve proactive policy innovation by provincial governments. The research results reveal how provincial governments construct local policies in the absence of administrative pressure from the central government.

KEYWORDS

policy innovation, food safety, enterprise standards, filing system, qualitative comparison

1 Introduction

Food safety has long been an important issue of widespread concern in China society. Enterprise standards are tools for food production enterprises to guide production, process management, food safety, and other tasks to ensure food safety (1). Therefore, enterprise standards have been formulated by China's central government. After the implementation of China's Food Safety Law 2015, the standard preparation system for food safety enterprises changed, and the central government handed over the right to formulate the system to provincial health departments. Accordingly, provincial health departments implement the filing system on their own under the comprehensive lead of provincial governments. The change in policy preparation for food safety enterprises is an innovation of the government administration, which is conducive to enterprises paying attention to food health and safety and putting forward their own food safety standards in accordance with food safety requirements.

As a factor conditioning production and inspection in food businesses, food standards influence the health of the population (2). Food companies in China are required to produce products that meet the national quality standards. Currently, the health administrations of most provinces in China have completed procedures for filing food safety standards with food safety companies. Without the involvement of the central government, provinces are in the process of developing or amending local food safety standards filing systems. However, the development of this policy has progresses to different extents in different areas. From this perspective, there is a pressing need to identify the factors that influence the proliferation of provincial innovation and how they interact to create innovation in provincial government policies.

Policy innovation is understood as the creation or introduction of solutions to resolve problems, overcome challenges, or seize opportunities in political systems (3). While policy innovation is a more traditional research topic, decentralization reforms, in which the central government devolves economic and administrative authority to provincial governments, have been undertaken in recent years in a large part of the world (4), whereby provincial governments undertake policy innovations to facilitate governance transformation. Differences in political systems and cultural traditions mean that provincial governments in different nation-states form unique paths of policy innovation, resulting in enormous differences in their patterns of behavior and outcomes. Therefore, provincial governments in both democracies and authoritarian countries have an intrinsic drive to stimulate policy innovations, and their innovative reproduction has become one of the most important practices in countries around the world (5).

China's political system is characterized by a socialism with China top-down managerial characteristics, which leads provincial government officials to behave differently from their Western counterparts. Within this political structure, provincial officials select development strategies to their own advantage based on the available resources. China's local bureaucratic system is characterized by fiscal half-power, administrative half-independent, with the central government playing an important role in driving innovation in provincial governments (6). Given that much of the literature on innovation in provincial governments has been published in Western democracies (7), provincial government innovation should spread across countries to enrich the logic of policy innovation in provincial governments. However, the logic of provincial innovation has been ignored in many studies in China, with only a few case studies examining it (8–10). The Food Safety Enterprise Standard Filling Policy (FSes) is a health management policy that has been in place in China for 8 years, under which the central government has authorized provincial governments to develop provincial policies. FSes policy thus affords researchers the opportunity to examine provincial innovation in the Chinese context and further test the applicability of the policy proliferation theory in China.

2 Theoretical framework

Policy innovations can help identify and accumulate knowledge about the determinants of policy uptake, and numerous studies on the proliferation of policies have been published over recent decades (11) (10). The study of policy diffusion is of great theoretical and practical importance as government policies have been documented to be transmitted through either vertical or horizontal mechanisms (12–15). However, the factors influencing policy innovation are multifaceted, including both horizontal and vertical ones. Horizontal proliferation occurs between neighboring governments, whereby new policies are built through learning, mimicry, and competition. When the geographic proximity of the intergovernmental development environment at the same level is similar, the communication of information is more convenient, provides favorable conditions for horizontal policy diffusion, is more applicable to policy replication in neighboring provinces, and reduces the potential for trial and error. Vertical diffusion reflects the vertical relationship between two levels of government, with empirical replication at the bottom and mandates at the top.

In addition to horizontal and vertical diffusion models, internal and external models have been widely used to explain the mechanisms of policy innovation (16). It has become conventional to explain policy innovations as an interdependent policy making process shaped by both internal and external factors. Normally, the internal factors represent the capacity of the government itself (e.g., organizational structure and resource capacity), as well as factors related to jurisdiction (covering local social, political, economic, cultural, and natural aspects). External factors are primarily the aforementioned pattern of vertical and horizontal proliferation and domestic and foreign political, economic, environmental, and other factors.

The fact that China is very different from typical Western countries in terms of economic development, political uniqueness, and Confucianism makes it an excellent case study of the universality of political proliferation theory. In the context of China, the internal-external mechanism is very helpful to explain influencing factors for China's political innovations. Traditionally, China has been considered to be run by top-down structured governmental systems (6), and the activities of governmental policy innovations significantly depend on the non-western bureaucratic system. In China, main provincial government leaders have possibility to be promoted by the central government. Because neighboring provinces have many economic and demographic similarities, provincial government leaders may view peers in neighborhoods province as competitors (17). As a result, provincial political innovations partly depend on the political innovations of competitive provinces. Competition between neighboring provinces is a key external determinant of provincial political innovation.

Meanwhile, the internal factors of provincial innovation in China are more diverse. As a developing country with the world's largest population, China has measured government performance primarily by economic outcomes since ethe 1980s (18). Thus, the government has given strong incentives to support the companies under their regime and respond to companies' requirements for local policies. The abilities of provincial governments to enact political innovation include the economic ability to apply innovation, the professional ability to conceive local polices, and the leadership ability to develop innovation programs. Therefore, we consider government capacity, socioeconomic development, and professional authorities as internal factors for provincial policy innovations.

2.1 Government capacity

China's reform and opening-up process was initiated in 1978, aimed at unlocking the nation's growth potential through a dynamic socialist market economy (19). In addition to the development of the concept of socialism, the central government gradually reformed the

highly centralized management model inherited from the socialist planned economy. The central government accepted the need to devolve its economic power to the provincial governments, encourage policies that foster institutional innovation, and avoid the need for reformist leaps and bounds (20–22). Following improvements in the tax system in 1994, the central and provincial governments formed a shared tax distribution structure, and the central government secured the vast majority of fiscal resources for redistributing fiscal transfers, balancing regional economic differences among provincial governments. Relative autonomy has been granted to provincial governments to initiate innovative projects and build local financial capacities (23). As a result, provincial governments have a greater incentive to adopt innovative policies and measures to develop the local economy, raise revenue, and reduce financial expenditure according to the actual situation of the local economy.

When government finances run large surpluses, it is best to stimulate government innovation, which in turn drives government innovation policies (24). Studies have shown a clear positive correlation between provincial government revenue and provincial political innovations in China (25). Therefore, the actual implementation of policies depends on the level of government input. Without substantial financial support, provincial governments have little incentive to implement such projects. Simultaneously, the theory of resource relaxation posits that innovation is more likely to occur under conditions of excess organizational resources. In recent years, with the slowing economic growth of our country, provincial governments have faced unprecedented financial pressure. Even developed provinces and cities such as Beijing and Guangdong face funding shortfalls as revenue growth slows sharply. However, when the attention, time, and resources of lower levels of government are limited, the level of policy innovation varies from province to province.

The rule of law is one measure of the modernization of governance (26). Under strong rule of law, governments ensure quality, stability, and access to justice for all members of society. Thus, rule of law in good governance indicates that a legal framework is in place that empowers the government in governance (27). With a good legal system, provincial governments have accumulated a great deal of experience in building a system of rule of law, which is useful for tracking policy changes quickly at higher levels. On the other hand, strong experience in provincial government provides reformers with greater psychological security in that they can make mistakes or take risks, thus increasing the likelihood of another reform (28). Standard filing system for food safety companies is itself a legal system with the provincial government as the main body, as well as a system for managing businesses in the area. Food safety is a common concern in society that affects the health of all consumers (29), legal system for the regulation of food safety is highly technical and demanding. As a result, the greater the degree of rule-of-law, the more provincial governments enable to formulate laws and systems consistent with the current legal system to avoid food-safety-related loopholes.

2.2 Socioeconomic developments

Socioeconomic developments include the economic level of provinces, economic growth, industrial structure, and the number of foreign-owned enterprises (30–33) are also considered in this study. An example of the impact of socioeconomic development on policy innovation can be seen in the evaluation of provincial government leaders in China. Given that economic performance is a primary criterion for assessing and promoting local leaders in the past several decades in China, provincial governments have a strong incentive to support economic growth through market-driven innovation. Filing systems provide a legal basis for food safety companies to engage in their production and operations. The early establishment of a local legal system at the behest of a higher government can provide the corresponding direction and adaptation to the needs of society and ultimately foster the development of the local economy.

On the other hand, socioeconomic factors may have a "pressure valve effect" on innovation in provincial government, meaning that when an area is more economically active there is a lobbying presence. Lobbying involves efforts to deliver pressure on policy makers to secure desired political outcomes (34). In Western countries, interest groups lobby provincial governments for economic benefits to facilitate the passage of legislation and institutions that benefit them (35–37). Although there is no lobbying in China, companies work more closely with provincial governments. If the business is not only a major provincial tax payer but also the primary agency to absorb local jobs, food production, and operations companies, the provincial government should establish a closer symbiotic relationship. When the economy is active, firms work more closely and harmoniously with provincial governments. Thus, when the economy is active, provincial governments have incentives to engage in institutional innovation based on their business needs. As the main body for adjusting the standard filing policy of food safety firms, the amount and size of the food industry have an important influence on the requirements for standard filing policies and also constitute a source of pressure when supervisory authorities oversee them. As the number of food producers increases, so does the number of business activities (design, production, and technical marketing) that require provincial government regulation as a guide to facilitate governmental structures (38, 39).

2.3 Professional authorities in leadership

The capacity of provincial government to innovate as an agent of policy innovation is a product of organizational functioning (40). Decentralization between government departments, however, also makes cross-sectoral cooperation challenging and detrimental to the governance of social issues (41). Schick (42) argues that successful budgeting for government performance requires strong leadership; otherwise, the process will face a great deal of resistance and obstacles. Throughout the 1980s and 1990s, the US federal government took steps to decentralize the control of certain policy areas such as social assistance to the states and localities of the country. More than a dozen states do not employ a large number of lawmakers and legislatures meet for no more than a few months each year.

Consequently, legislators tend to address the most urgent tasks, and autonomous and innovative policies are not on the legislative agenda (35). This is one of the main reasons legislators must deal with the most pressing issues. China has launched a model of policy innovation and diffusion in the field of river pollution control in the name of "river chief." China's waterways have been polluted for years, and the economic effects of the rivers that flow through the provinces

have been marred by their commercial activities. Cooperative governance between provinces has always been an issue since provincial governments are reluctant to cooperate out of concern for the economic benefits of their local areas. China has adopted a multisectoral "river chief" policy to control river pollution, and a "river chief" should be appointed to oversee the protection of every river in the country. Therefore, each province has applied the "river chief" policy within its administration region since 2016. River chiefs are authorized to lead river protections against pollution, and the institution has been an effective policy for solving complex collaborative problems in river management. The water quality in China has improved significantly in the past several years because of the "river chief" policy, which indicates that organizations with authorized power contribute strongly to innovation in government management.

Under the Chinese bureaucratic system, the responsibility of provincial health departments to manage the standard filing policies of food safety enterprises is broken down into internal agencies that are specifically responsible for the standard filing of food safety enterprises. The internal agency must complete a series of studies and prepare the food safety company's standard filing policy, then report it to the provincial health department and, after consideration by the meeting, to the provincial legal department. The innovation agency's policy function is to exercise the power of its suggestions during this process. Reform efforts in China often require cooperation and coordination among multiple stakeholders from different sectors (such as audits, inspections, and personnel), comprehensive knowledge, prior experience with reform, and leadership in relevant professions (28). Thus, independent innovation agencies are professionalized and empowered institutions in the field of policy innovation, facilitating multi-stakeholder cooperation and policy innovation.

2.4 Neighborhood learning and competition

Horizontal diffusion is often driven by learning, imitation, and competition, whereby the government attempts to reduce the cost of trial and error and improve performance by mimicking other governmental practices. It has similar political and economic structures when combined in geographic clusters. In many cases, governments draw advice and lessons from other provinces, especially those with similar economic or political standing, which helps reduce the costs and risks that may be absorbed into the decision-making process (43). Through policy innovations between neighboring states, for example, the United States has shown that geographic proximity between governments improves the efficiency of information diffusion and facilitates the adoption of new policies by policy adopters.

China's central government has since devolved significant economic-related administrative functions and powers to the provincial government (44–45), which has been the focus of much of this research. Under China's political system, the central government enable to limit the direction or scope of reforms through the direct issuance of policy documents or by appointing and removing provincial government leaders via performance reviews (46). Provincial governments may view peers in similar economic situations as competitors, with limited funding or political support from higher governments. If certain policies are adopted by one province, other provinces with similar economic structures may be under competitive pressure to adopt the same policies in order to avoid becoming overwhelmed. Consequently, with most neighboring provincial governments adopting a food safety grading system, it is easy for provincial governments to adopt this innovation.

3 Method and data analysis

The political, economic, and social environments of different provinces vary, and the formulation of public policies in each province is unique. The uniqueness of the individual cases coincides with the coherent analytical idea of qualitative comparative analysis. This retrospective case review allowed the researchers to interpret specific cases as much as possible and gain inspiration. This article, based on the chronology of the review of the provisions of the Food Safety Law of the Twelfth National People's Congress Standing Committee on April 24, 2015, on the lodging of food safety standards for food safety companies, investigates the sequence of measures canceling and revising the filing system for food production firms in each province as measures of the diffusion of policy innovation, taking provinces as the basic unit of research and combining the cancelation and revision of the food safety company filing system in the 31 provinces (including provinces, autonomous regions, and municipalities).

Based on the explanation and statistics noted above, the newly revised provincial food safety enterprise standard filing systems implemented by the 31 provincial health administrative departments was used as the outcome variable in this study. Based on provincial health administration statistics on the timing of the implementation of the newly revised standard food safety business filing system, the implementation timing reflects provincial government uptake and perception of the policy and whether there is innovative policy proliferation. Given that the event observation endpoint for policy innovation in this study was the formal publication of normative documents (the abolition or a new filing system of food safety standards for enterprises), the production and filing of normative documents should be strictly in accordance with the degree of provincial rule-of-law, with a typical cycle of 60 days. When we assigned the time nodes in Table 1, we treated dates that differed by no more than 60 natural days as juxtaposed data.

Government capacity for food policy innovations includes the financial ability to stimulate innovations and the professional ability to create political innovations (47). Following Nan et al. (48), we measure provincial financial ability (PFA) from the China Statistical Yearbook (2016). The legal system for the innovation of food safety policy is highly technical and professional. As a result, the greater the degree of rule of law, the more provincial governments will be able to formulate legal and policy systems consistent with the current legal system. Following Cai and Wang (49), we measure the provincial degree of rule-of-law (DOR) based on data from Annual Assessment Report on China's Law-Abiding Government (50).

Since GDP (Gross Domestic Product) is a key indicator of market-related economic activities in a country, we use provincial GDP *per capita* to estimate provincial socioeconomic developments (51). Since business activities (design, production, and technical marketing) require provincial government regulation as a guide (38, 39), the food producers constitute a source of pressure upon government for

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TABLE 1 Values of explanatory variables.

CASEID	PFA	GDP	DOR	FISV	INP	IA
AH	2454.3	35,997	199.56	661.64	2/3	1
BJ	4723.86	106,497	224.18	281.77	1/2	1
FJ	2544.24	67,966	197.06	1258.45	1	0
GS	743.86	26,165	199.09	77.9	5/6	0
GD	9366.78	67,503	234.43	1751.52	1/5	1
GX	1515.16	35,190	198.18	363.58	1/5	0
GZ	1503.38	29,847	214.66	157.05	3/5	0
HAN	627.7	40,818	180.02	43.71	1	0
HEB	2649.18	40,255	171.18	1022.72	5/7	1
HEN	3016.05	39,123	194.18	2803.26	1/6	0
HLJ	1165.88	39,462	214.83	649.73	1	1
HUB	3005.53	50,654	184.98	1172.91	3/7	1
HUN	2515.43	42,752	207.87	1020.43	1	0
JL	1229.35	51,086	184.49	460.3	2/3	1
JS	8028.59	87,995	214.17	946.01	1/4	1
JX	2165.74	36,724	222.75	536.63	0	0
LN	2127.39	65,354	186.62	441.95	0	0
NMG	1964.48	71,101	171.1	680.96	1/2	0
NX	373.45	43,805	154.99	154.76	0	0
QH	267.13	41,252	172.23	32.68	0	1
SD	5529.33	64,168	202.56	2637.18	1	0
SX	1642.35	34,919	157.3	117.97	0	0
SAX	2059.95	47,626	168.5	487.94	1	0
SH	5519.5	103,796	230.44	598.65	1	1
SC	3355.44	36,755	221.14	971.35	3/7	1
TJ	2667.11	107,960	180.7	1347.53	0	1
XZ	137.13	31,999	125.76	5.92	1/2	0
XJ	1330.85	40,036	155.65	218.92	1/3	0
YN	1808.15	28,806	190.83	201.29	1	1
ZJ	4809.94	77,644	214.13	534.74	1/5	1
CQ	2154.83	52,321	212.19	232.13	0	1

impartial legal innovation of regulations. The business activities of food industries can be indicated by Food Industry Sales Value (FISV). We obtain the census data for FISV from the China Food Industry Yearbook (52). According to the Regulation of the People's Republic of China on the Disclosure of Government Information (53), the agencies of provincial governments are required to publicly disclose all bureau institutions. Thus, we counted the provinces that have built an independent agency (IA) for the management of the standard filing policy for food safety before 2015 on the website of each provincial government. We calculated the number of provinces that were the first to implement the policy as a percentage of the provinces that were adjacent to it; the order of time points at which provinces implemented the policy is examined. Following Singu (54), we measure INP (influence of neighboring provinces) by examining whether a policy innovation occurs in neighboring provinces before the time that a province proposes its own policy innovation. The values of the six variables chosen based on the research framework given above are illustrated in Table 1.

Variables are dichotomized according to the basic principles of partitioning, which makes the distribution of examples more meaningful and easier to align with existing theories, thereby supporting the correlation between variables and positive results. Results: When the variable was binomial, the optimal ratio of no cases (0 assignments) to cases (1 assignment) was 1:3. Therefore, we assigned zero values to 1 of the 23 positive cases and 1 of the 8 negative cases. This study concludes that the distribution of these two variables is the same across provinces, both in terms of the time taken to repeal the policy and the time it was revised. Therefore, for ease of description, the time at which the policy was repealed was selected as the outcome variable.

The time point at which the variables were observed was November 4, 2016; therefore, we classified them according to the time

point of November 4, 2016. The province ahead of the time node was considered to have an administrative pressure value of 0 at the upper level or 1 at the lower level. The establishment of a separate office with organizational characteristics caused us to assign the province a value of 1; if there was no separate office or organizational functions, it was assigned 0. Because of the large variances and variances in other precursor variables, the median rather than the mean was used as a mechanical cutoff point to spread the cases more evenly.

In all, 31 samples were selected as case analysis units from all provinces of mainland China. The Crispy Set Qualitative Comparative Analysis (csQCA) methods is used to explore the causal configurations in this study. The first step was to select cases supported by the theoretical identification of predictors and outcome variables. In the second step, each variable was dichotomized by fact and theory and described in a binary language. The third step was to set up the truth table, perform a standardized analysis, obtain the preset configuration, and impose the single-element or multi-element joint detection requirement according to the specific situation. In the fourth step, the combination path of each element was summarized and analyzed, and the discovery and revelation of each element were reviewed. On this basis, a binary distribution was created between one outcome variable and seven predictive variables, resulting in factual values for the 31 provincial cases (Appendix Table A1). To maximize the combination of key sufficient conditions and ensure that each antecedent variable is an indispensable and sufficient condition for the outcome, it is necessary to first analyze the necessity of each variable and then construct a table of true values and standardize the analysis (Table 2).

In all, 64 conditional combinations were obtained using two classification assignments based on the six interpretive variables. Path selection was based on the principle that case frequency must be no less than 1 and consistency must be no less than 0.8, yielding the following table of truth values. Subsequently, a table of truth values was provided to determine the solution of the path. In this study, we selected the three combination paths with the highest coverage (0.261, 0.217, and 0.174).

Path A1 = PFA × GDP × DOR × IA.

Path A2 = PFA × GDP × FISV × ~INP × IA.

Path B = ~PFA × ~DOR × ~FISV × ~INP × ~IA.

Variables that appear in concise and intermediate solutions are generally considered core factors (Appendix Tables A2–A4), whereas variables that do not appear in concise solutions are considered secondary factors. The path configurations are listed in Table 3.

The overall path consistency in Table 3 is 1, indicating a high correlation between the configuration combinations and results. The total coverage was 0.87 or greater, suggesting that the configuration may provide a more robust interpretation of the results. Path A1 had a coverage of 0.261 and a net coverage of 0.13 among the three paths chosen, while the Path A2 coverage was 0.217 and the Path B2 coverage was 0.174. The results for the A1 and A2 core conditions of the GDP agree with the

TABLE 2 Necessity analysis of explanatory variables.

Explanatory variables	Consistency	Coverage rate
PFA	0.608696	0.875000
GDP	0.608696	0.875000
DOR	0.478261	0.687500
FISV	0.608696	0.875000
INP	0.434783	0.625000
IA	0.565217	0.866667
APAP	1.000000	1.000000

Outcome variable: APAP.

TABLE 3 Configurations of paths.

	Path A1	Path A2	Path B
PFA	●	●	⊗
GDP	●	●	
DOR	●		⊗
FISV		●	⊗
INP			⊗
IA	●	●	⊗
Coverage	0.261	0.217	0.174
Unique coverage	0.13	0.087	0.087
Cases	Beijing, Shanghai, Jiangshu, Zhejiang, Guangdong, Chongqing	Hubei, Tianjin, Guangdong, Jiangsu, Zhejiang	Ningxia, Shanxi, Liaoning, Xinjiang
Total consistency	1		
Total coverage	0.87		

IA. Simultaneously, A1 and A2 had similar configurations, with representative instances having overlapping instances.

Three pathways cover 12 cases, or 39 per cent of the 31 cases. Paths A1 and A2 comprise Jiangsu, Zhejiang, and Guangdong Provinces, all of which are southeastern coastal provinces. Some Path A1 cases are Beijing, Shanghai, and Chongqing, all of which are municipalities directly under the Central Government of China, with better provincial economic resources and more rapid economic development. The cases in the Path A2 group include Hubei and Tianjin. These areas have good geographical locations, well-developed transport systems, and large food industries. Route B includes four provinces, Ningxia, Xinjiang, Liaoning, and Shanxi, which are located in the northern part of China, are relatively remote, and have a low degree of governmental rule-of-law.

These three paths contain four core conditions: GDP, IA, DOR, and INP. IA reflects the distribution of administrative resources in the organizational structure of the health sector in the provinces, DOR reflects the local legal system, and INP reflects the influence of neighboring provinces. Based on these four core conditions and cases, the path of provincial government policy innovation can be divided into the following two categories:

First, the path is driven by provincial economic resources and government capacity. It contains two sub-pathways, A1 and A2, with GDP and IA as its core factors. The cases received through this path were mainly from provinces and municipalities with developed economic and geographical advantages. At the same time, these provinces have better local legal systems, mature markets (e.g., Shanghai and Jiangsu), and strong government capacity (e.g., Beijing and Tianjin). In other words, they have advantages in terms of both fiscal capacity and responsiveness to the government, which makes them highly susceptible to policy innovations.

The second is the endogenous innovation path, or the B-configuration path. This path had two core factors: DOR and INP. As a result, the corresponding regions are not highly regulated by law, and dissemination policies at the level of neighboring provinces result in less inter-provincial competition and relatively remote geographical locations (e.g., Liaoning and Xinjiang). These findings suggest that when a province faces a vertical or horizontal combination of high administrative pressure and a high degree of government rule-of-law, it may be difficult for it to break through existing legal frameworks and achieve policy innovation during periods of ambiguity. In contrast, geographically isolated and less rule-of-law provinces can be protected from excessive external pressures, and policy innovation and contagion can be promoted.

4 Discussions and political insights

Provincial government discretion in particular policy areas is a key condition that underpins the existing research on policy innovation. Thus, innovation in provincial government policy is not confined to typical Western countries. This type of policy phenomenon exists in developing, nondemocratic, and authoritarian countries, where policy innovation by provincial governments can be achieved as long as provincial governments have ownership over policy formulation. However, in an economical developing socialist country, such as China, provincial government policy innovation has unique characteristics.

In China, the main political leaders, such as secretaries of party committees, of provincial governments are generally not elected by the citizens of the provinces under their jurisdiction with one person one vote. Rather, appointments of secretaries of party committees are chosen by the Communist Party's parent committee on the basis of economic performance, social stability, or political affiliation (55, 56). Local leaders are given carte blanche by the central government to determine their political careers, including evaluation, supervision, appointment, promotion, rotation, and demotion (57). Central policy signals must be given high importance by provincial governments. If the central government advocates a specific policy, it may be adopted by the provincial government in order to receive praise or attention from the central government. What are the factors that influence provincial government's attempts to innovate when they are not required by the central government to take a particular action? This is the focus of this study.

Based on the theory of policy innovation, this study selected five influencing factors: government fiscal capacity, provincial economic resources, policy needs, neighborhood influence, and organizational characteristics. Subsequently, a policy innovation impact model framework was built based on these influential factors. Second, beginning with the adjustment of the standard food safety company filing policy following the Food Safety Law 2015, the qualitative comparative analysis method of the clear set was used to discuss the combination of factors affecting the standard deposit policy of food safety firms (58). Following the dichotomy of assignment, necessity testing, truth table construction, and norm analysis, three types of pathways for promoting policy innovation were analyzed. In this study, we integrated various horizontal and vertical proliferation mechanisms and tested them based on the proliferation of provincial government policies. The results of our research show that it is of great theoretical and practical importance to select appropriate methods for determining the specific mechanism of the policy proliferation process outside the Western context.

4.1 Economically developed provinces with sufficient resource and governmental capacity to have healthy policy innovations

The two basic conditions in the first path, GDP and IA, represent good provincial economic resources and a good organizational structure. Combined with GDP and IA, this can have a significant positive impact on policy innovation outcomes. Moreover, the greater the government revenue, the greater the impact. Theoretically, to the extent that lower-level governments are politically or financially constrained by higher-level governments, the former may be responsive to the latter's policy preferences. The resource relaxation hypothesis suggests that policy innovation and diffusion activities are more likely to occur when the levels of government capacity are excessive relative to government resources (15, 59). Limited by the attention, time, and resources of lower-level governments, provinces with better resource endowments can respond more quickly to the demands of higher-level governments.

Turning to the mechanism of public policy innovation, there is a need to analyze China's institutional context. Unlike Western democratic elections, China has its own bureaucratic system (60). Provincial officers work around the Western electoral system to win

the support of voters and interest groups (61). Competition among provinces is strongly linked to elections. Under the Chinese bureaucratic system, the provincial government is more concerned with its performance and promotion, which are controlled by the central government. Innovation at the provincial government level demonstrates that provincial government leaders are loyal to the central government and are responsive to change, while economically developed provinces are more concerned about being perceived as inefficient. Regions with better resource endowments, such as Beijing and Shanghai, have higher levels of motivation and ability to respond to central policies in a timely manner. Beijing, for example, as China's capital and political hub, has a strong government capacity and is easier to recognize and promulgate policies. Shanghai is located at the leading edge of China's Yangtze River Delta region, where the economy is highly developed, transportation is convenient, and resources are relatively concentrated. In this respect, these two provinces had among the most innovative policies.

4.2 Less economically developed province with low legalized government and provincial competition are core determinants for political innovation

The empirical results of this study suggest that DOR and INP are fundamental determinants of endogenous innovation pathways, each of which represents a low level of regional case law and are less influenced by neighboring competition. The provinces of Xinjiang, Liaoning, and Ningxia have low levels of legalized governments and little interprovincial competition. All these provinces share the same characteristics, including being economically underdeveloped, relatively geographically remote, and having few policy innovations in neighboring provinces. In other words, the level of the legal system is not high, the lack of provincial competition in the less-developed sectors of the economy is the same, and political innovation occurs easily. Finally, in Section II, we mention that the levels of rule-of-law, competition from provinces, and economic development have positive impacts on political innovation. However, in the absence of these three fundamental factors, provincial governments can innovate more rapidly.

The degree of government rule-of-law is a central factor affecting the capacity of provincial governments to place greater emphasis on the local rule of law (62). However, this study finds that the degree of rule-of-law of a provincial government is not the core factor in its innovation measures. Conversely, provinces with low government rule-of-law are prone to policy innovation. This finding shows that there is a complex relationship between the level of rule-of-law of provincial governments and political innovation. The government, with its high degree of rule-of-law, strictly executes social governance according to the rule of law. The innovation of local policy involves reforming the existing system and improving the existing rules. The highly legalized government sets an example for government employees to enforce the law, which is not conducive to creating an administrative culture that improves existing laws and policies. Meanwhile, innovation in provincial government policies must be consistent with existing legal arrangements. Therefore, provincial governments with higher levels of rule-of-law are more willing to comply with the law. Where policy innovations conflict with existing legal arrangements, they must be pursued in conjunction with the relevant legislative branches. Provincial governments with higher levels of rule-of-law thus face greater challenges regarding policy innovation.

Geographical proximity is a frequently cited factor in innovative mechanisms (35). Many policy innovations confirm that geographical proximity promotes policy learning and that competition is a driver of mutual learning in adjacent regions (63). Where policy innovations do not occur in neighboring provinces, provincial governments typically lack learning opportunities and motivation, but when there is no policy innovation in neighboring provinces, it also affords provinces an opportunity to demonstrate the results of policy innovation under the policy and to be more easily recognized and supported by the central government (64). Although economic underdevelopment can hinder the economic basis of innovation, provincial governments in China have the opportunity to innovate through a cross-regional policy of peer support programs. In the 1970s, China began a policy of reciprocal support for ethnic minority areas and border regions. China supports Xinjiang and other locations through project assistance and the transfer of human resources, which also allows for the diffusion of new governance ideas and experiences in remote areas. For example, experience suggests that intergovernmental exchange fosters policy innovation in assisted areas (65). Counterpart aid has provided significant assistance to provincial governments in the remote parts of China in achieving policy innovation.

4.3 Internal factors play a more positive role in policy innovation than that of external factors

In the necessity test, we found the highest consistency and coverage of three variables: PFA (Local Public Finance Revenue), GDP (GDP *per capita*), and FISV (Food Industry Sales Value). Therefore, this study concludes that internal factors are more likely to lead to policy innovation than external factors. This finding can be explained in terms of China's political system.

In recent decades, decentralization reforms have largely been implemented between central and provincial governments (66). Although China's central government can still control the political mobility of provincial leaders through a crony-class personnel system, "Chinese federalism" (67) provides provincial governments with sufficient policy autonomy and protects their jurisdictions from political interference by the central government. Provincial governments support economic growth and social development by maintaining policy autonomy and formulating policies that are locally appropriate (68, 69). For provincial governments, enacting policies also has the important benefit of attracting the attention of the central government and ultimately indirectly preserving provincial autonomy by demonstrating their capacity.

Moreover, we found that IAs have a significant positive effect on policy innovation. Institutions with complex internal organizational structures find it difficult to coordinate with stakeholders, making policy innovation difficult (71, 72). According to China's hierarchical governance rules, named the "three fixes" (70), independent agencies have authorized responsibilities and assigned resources and are

empowered to perform their functions independently. Therefore, provincial governments that establish agencies with independent powers often break down organizational complexities, resulting in rapid professional innovation. The independent Food Safety Administration Office was established as the agency for this study and completed the strategic innovation of standard filing by food safety firms relatively quickly. This means that independent internal agencies with more defined roles are more focused on transforming new policies and may be supplemented by more administrative resources to absorb and transform relevant policies.

5 Conclusion

Over the past few decades, many countries have joined the global decentralization trend. Various economic and administrative powers have been devolved to provincial governments, many of which decide their own local policies on a case-by-case basis. Innovation in provincial government policies has become a popular topic. However, research on the diffusion of policy innovation in classical theory is generally based on a decentralized democracy. With sufficient discretion, provincial governments in non-democratic countries can also derive innovations.

Thus, in a socialist country such as China, the path of policy innovation by provincial governments is a meaningful research topic. We expect to conduct more research on policy innovation in various policy contexts. Provincial government innovation in China is not new, but has been a common phenomenon in China's provincial government policymaking process for many years. Prior studies have typically examined the existence of policy proliferation and its influencing factors but have rarely shown the means of achieving policy innovation. In this regard, this study incorporates a variety of horizontal proliferation mechanisms to test health policy diffusion by provincial governments in China. The cases considered in this study provide a typical example of the mechanism for the diffusion of policy innovation by provincial governments in China without guidance from the central government.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

LL: Formal analysis, Methodology, Project administration, Resources, Validation, Visualization, Writing – original draft. GH: Conceptualization, Investigation, Software, Supervision, Writing – original draft, Writing – review & editing. YC: Validation, Visualization, Writing – original draft, Writing – review & editing. ZZ: Data curation, Formal analysis, Investigation, Methodology, Software, Visualization, Writing – original draft. XF: Investigation, Funding acquisition, Formal analysis, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

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Research on the identification and evolution of health industry policy instruments in China

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The application of health industry policies could be discovered more quickly and comprehensively through the automated identification of policy tools, which could provide references for the formulation, implementation, and optimization of subsequent policies in each province. This study applies the Bidirectional Encoder Representation from Transformer (BERT) model to identify policy tools automatically, utilizes Focal Loss to reduce the unbalance of a dataset, and analyzes the evolution of policy tools in each province, which contains time, space, and topic. The research demonstrates that the BERT model can improve the accuracy of classification, that supply and environment policy tools are more prevalent than demand tools, and that policy instruments are organized similarly in four major economic regions. Moreover, the policy's attention to topics related to healthcare, medicine, and pollution has gradually shifted to other topics, and the extent of policy attention continues to be concentrated on the health service industry, with less attention paid to the manufacturing industry from the keywords of the various topics.

KEYWORDS

health industry policy, policy instrument, BERT, deep learning, multi-label classification

1 Introduction

In recent years, people have paid more and more attention to health, and the scale of the Chinese health industry has been continuously expanding. The policies introduced by the government have provided powerful assistance to the development of the health industry in various aspects. Each province, autonomous region, and municipality have formulated a successive policy according to the characteristics of the region, especially after the State Council issued the "Healthy China 2030" planning outline, which has greatly promoted the development of the health industry in each province. Policy instruments mean the government applies policies into effect and are actual means that the government selects in formulating for implementing policies (1). The policy instruments are the representation of the policy text and are relevant to policy design and policymaking (2). Therefore, the rational selection of policy instruments will have a positive and long-term influence on the development of the health industry.

Textual data are steadily paying more attention to researchers due to the diversification of data formats, and text mining is becoming increasingly prevalent in text analysis for tasks including sentiment analysis, information retrieval, and intelligent push. Most textual data originate from search engines, social platforms, media reports, and policy text, and policy text is normative and distinctive. Moreover, text-as-data research is rising in political science (3). Policy text has an alternative paragraph marker format, which is more challenging to segment

into separate paragraph statements and the length of the cut statements varies. Therefore, manual coding for policy tools is still the conventional research paradigm because policy instrument classification is distributed unevenly. Employing machine learning methods to classify policy instruments would improve the efficiency, due to highly costly manual labeling; however, the accuracy of classification methods for identifying unevenly distributed samples still needs to be ameliorated.

In this situation, this study aims to address the following questions (1): What is the more efficient method to identify the policy instruments from the health industry policy texts? (2) How can these classified policy instruments detect the change of different dimensions in the health industry? To answer these questions, this study utilizes the BERT deep learning algorithm to automatically quantify the policy text and aims to reduce the elevated labor costs. In addition, it applies the classification results to analyze the distribution and evolution of health industry policy instruments in time, space, and topic, and the latent dirichlet allocation (LDA) topic model is applied to detect the variation of industrial strategic initiatives. This framework for evolution and comparative analysis has significant policy implications.

2 Literature review

In 1964, the Western economist E. S. Kirschen classified the general type of policy instruments into 64 types, and subsequently, Rothwell and Zegveld (4, 5) elaborated three approaches to innovation policy in the context of reindustrialization, classifying policy instruments into supply, demand, and environmental types concerning the object of the policy or the focus of its operation. Afterward, based on existing theories of the effects of government action and the choice patterns of policymakers, McDonnell and Elmore (6) proposed a generalized framework for the analysis of policy instruments that translates essential policy goals into tangible action mechanisms and classified them into four types, which are mandates, inducements, capacity-building, and system-changing. Schneider and Ingram (7) proposed a set of policy analysis frameworks in 1990 to capture the behavioral attributes of policy content. These analytical frameworks for policy instruments that focus on behavioral characteristics are to be based on individual decisions and behaviors. As a result, based on the behavioral patterns of the target group, policy instruments are classified into five categories: authority, incentives, capacity-building, symbolic and hortatory, and learning. In 2003, Howlett and Ramesh (1) classified policy instruments into voluntary, coercive, and hybrid by focusing on the level of government provision of goods and services. In 2007, Hood and Margetts (8) summarized the basic resources that governments possess and classified them as information-based, authority-based, treasure-based, and organization-based, and these four attributes can then serve as the basis for policy instruments that play a role in detection and effects.

From the current point of view, the basis of the classification of policy instruments lies in coding, and manual coding is tedious and time-consuming (9). There have been many analytical studies based on the theory of policy instruments, and the main research paradigm has been studied by combining manual labeling of policy instruments with two or multiple-dimension labels and building an analytical framework for policy instruments. The number of policies might be a suitable measure, which can prescribe the current condition and goal; however, the sentences in the policy text could identify the policy measures and instruments (10). The provincial policy analysis should not be neglected due to local governments' distinctive measures, which might provide more samples to compare the differences (11). Policy instruments have been advocated by governments to address the structural determinants of health (12), but it is difficult to extend the research objects through a case study. States in America adopt a mix of policy instruments to regulate competitive food sold in schools to ameliorate the nutrition environment of the school, and policy instrument analysis with manual coding provides the reference for the effectiveness of the various policy instrument mixes (13). In addition, policy instrument study can be analyzed by study cases that are selected purposely (14). However, some policy instruments might take more than one category, and it is hard to distinguish the category clearly but choose the category with strength according to past experience (15). In medical device policymaking, the United Kingdom's active intervention with a variety of tools provides the environment of coordinative actions according to the expert interview, compared with the unbalanced German policy tools (16).

The quantity of policy releases accumulates over time, and in the era of big data, attempting to apply methods such as machine learning and deep learning can improve the efficiency of policy instrument classification, such as multi-classification (17) and multi-label learning (18). The application of a plain Bayesian algorithm for the classification of policy datasets shortens the distance between manual coding and computers and increases efficiency (19). Topic modeling could enhance the capacity of addressing larger sets of policy data, which might boost the efficiency of the policy study (20). A neural network and its improved methods are enabled to potentially boost the model accuracy in classification missions (21). The Transformer algorithm (22) was proposed in 2017 to provide a boost to text analysis, and later the BERT algorithm (23) improved it, which can significantly improve the accuracy of classification prediction. It is proved that the pre-training model could improve the efficiency of text classification in the policy content (24). Moreover, changing Chinese pre-training models could improve the accuracy of the multi-class model (25).

In summary, there is still space for ameliorating the method to identify and detect the policy instruments from the research on relevant studies. First, most research mainly applies manual coding and subsequently illustrates with dimensional combination, which generates higher labor costs or utilizes the smaller sample to analyze policy text. This approach is unable to compare the application of health policy from provincial and topic dimensions. Second, some studies apply multi-class models for policy instrument classification, but each policy statement could be relevant to multiple tools, and fewer studies apply the multi-label classification method in policy instrument identification. This study applies the BERT multi-label classification method with Focal Loss to identify the health industry policy instrument. Furthermore, the result of multi-label classification is utilized to discover the variation of health industry policy instruments in time, space, and topic dimensions.

3 Research design and methodology

The flowchart of this study for analyzing policy texts is displayed in Figure 1. First, health industry policy texts are collected automatically using crawler technology; second, policy semantic units

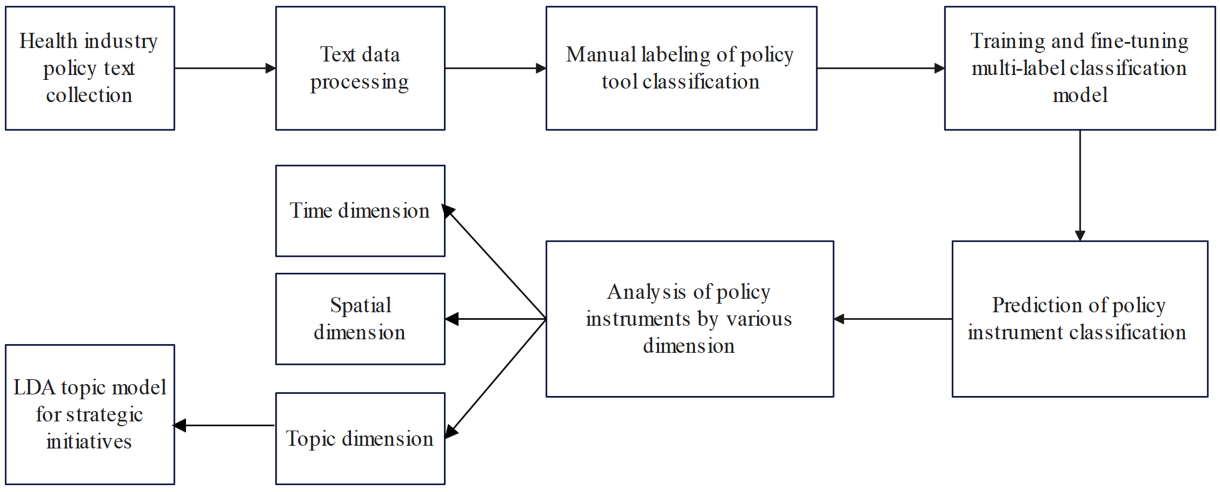

FIGURE 1
Policy instrument analysis flowchart.

are segmented through pre-processing of policy texts, and then, the parsed policy semantic units are classified into policy tools by utilizing the BERT deep learning algorithm; finally, the policy instruments were analyzed in multiple dimensions, and the themes of strategic initiatives instruments were identified through an LDA model with extracted keywords.

3.1 Establishing semantic units

This study applies the last level of subheadings as the segmentation method of semantic units considering policy text is composed in a more standardized manner, typically has different levels of headings, and retains all levels of headings up to the last level of subheadings. Policies usually have different structures, and they might not have the same level of subheadings as their last-level subheadings; therefore, the number of levels should be summarized first, and then, the last-level subheadings with their own policies text should be chosen. Additionally, policy information under the same heading has a more similar meaning to convey; therefore, the headings of each level are retained to ensure the continuity of information. The meaning to be expressed by the policy can be understood more rapidly by combining the headings at different levels to reinforce the model's comprehension of the context.

3.2 Model settings

This study applies the BERT model to encode the policy text and automatically classify the policy instrument categorization. The BERT model is built based on the Transformer model, which is divided into two parts, encoder and decoder. The basic architecture of the BERT model is built on the Transformer's encoder component, and it is a multilayer and bidirectional encoder design. The encoder part of the Transformer's algorithm maps the natural language sequence to the hidden layer, and the decoder part maps the hidden layer to the natural language sequence. The encoder part consists of positional encoding, multi-head attention mechanism, residual linking, and layer regularization. The positional encoding mechanism determines the positional information of each word to identify the sequential relationships in the language. The Transformer model can operate in parallel in comparison to other neural network models, such as LSTM, which requires sequential iteration, significantly boosting computational efficiency. The weights of each word in a sentence are determined by performing three linear transformations on the vectors of all the words in a sentence using three matrices. The results are subsequently output through residual connectivity and regularization of the self-attentive mechanism.

The BERT model contains pre-training and fine-tuning. There are two unsupervised tasks in the BERT pre-training model, which incorporate the language tasks of random masking (masked language model) and next sentence prediction (next sentence prediction) to the multilayer bidirectional transformer encoder-based architecture. In the random masked language task, any word is randomly hidden or substituted, and the model is permitted to predict based on context, which has the advantage that the model does not rely too much on the current word at the time of encoding, but corrects errors by context. In the task of next sentence prediction, the special token [CLS] and [SEP] will be employed as the identifier for the previous and next sentences to separate them, which is convenient to enable the model to locate the position of the sentences. The subheading in the policy text supports understanding the policy meaning to identify each semantic unit and to classify the policy instruments by applying context. For instance, if the subheading is a policy objective, the subsequent text should be categorized as a policy tool in the goal planning category. The parameters can be modified in the fine-tuning process according to the corpus of policy texts.

The structure of the BERT model is as follows:

(1) Embedding. BERT embedding contains token embeddings, segment embeddings, and position embeddings. The special token [CLS] is constantly positioned at the beginning of the sentence, and [SEP] is positioned at the end of sentences to differentiate the sentences. The segment embedding corresponding to each token in sentence A is E_A and that in sentence B is E_B, if there are two input sentences A and B, which are represented by the symbols E_A and E_B

as the segment embedding, respectively. Then, position embeddings can provide information about the order of words in a sentence. Finally, the input of [CLS] should consist of E_{CLS}, E_A, and E_0.

(2) Multi-head attention. The word vectors that are obtained from embedding are linearly transformed, and the results are packed together into the query matrix, key matrix, and value matrix. Each "head" of the multiheaded attention mechanism represents a scaled dot-product attention, which is computed by the dot products of the query with all keys in a softmax function multiply the value matrix. The multi-head attention mechanism's final output is the merging of each head's outputs.

(3) Feedforward. The feedforward network is composed of two linear transformations with an activation in between.

The multi-label classification model is a machine learning model that can assign multiple labels to a data point. The BERT model is utilized in the multi-label classification of policy instruments, and binary cross entropy loss is employed in the model for the multi-label classification task. In the classification layer, we apply the Sigmoid function to predict the multi-label of each sample, and 0.5 is set to be the threshold value for judging the multi-label classification. The RoBERTa model and MacBERT model have been tried, which were built by BERT. The RoBERTa model robustly optimizes the BERT model in dynamic masking and replacing next sentence prediction with full-sentence task (26); in addition, whole word masking (WWM) could be combined with RoBERTa to address the Chinese word specifically. The MacBERT model adopted the masked language model (MLM) as a correction to reduce the discrepancy between pre-training and fine-tuning (27).

3.3 LDA topic model

The LDA topic model is a document topic generation model, proposed by Blei et al. (28), which contains three structures: document, topic, and word. The distribution of documents with subjects and topics with words constitutes a representation of the complete text. Since the learning and inference difficulties associated with the LDA model cannot be directly solved, Gibbs sampling is utilized to estimate the parameters. In the theme evolution analysis, the LDA model is applied to analyze topic changes in the strategic initiatives instruments and the topic words with high weight.

The generative process of the LDA model in a given corpus is as follows:

1. Choose $\varphi_k \sim \mathrm{Dir}(\beta)$ as the word distribution $p(w|z_k)$ of the topic $1 \le k \le K$.
2. Choose $\theta_m \sim \mathrm{Dir}(\alpha)$ as the topic distribution $p(z|w_m)$ of the document $1 \le m \le M$.
3. For each of the N words in M documents $1 \le n \le N_m$:

   a. Choose a topic $z_{mn} \sim \mathrm{Multinomial}(\theta_m)$.
   b. Choose a word $w_{mn} \sim \mathrm{Multinomial}(\varphi_{z_{mn}})$.

The parameters α and β are given, and assuming the topic number K is known. The text generation process based on the LDA model is Formula (1):

$$p(w,z,\theta,\varphi|\alpha,\beta) = \prod_{k=1}^{K} p(\varphi_k|\beta) \prod_{m=1}^{M} p(\theta_m|\alpha) \prod_{n=1}^{N_m} p(z_{mn}|\theta_m)\, p(w_{mn}|z_{mn},\varphi) \quad (1)$$

Perplexity is usually used as an indicator to evaluate the effect of the model by Formula (2). A smaller perplexity means that the model has a better predictive ability for new datasets. The calculation method is as follows:

$$\mathrm{Perplexity}(D) = \exp\left\{ -\frac{\sum_{m=1}^{M} \log p(w_m)}{\sum_{m=1}^{M} N_m} \right\} \quad (2)$$

4 Data and process

4.1 Data collection

The data on the health industry policy came from the official websites of the provincial governments and the Beida law treasure platform which is a database managed by the School of Law of Peking University. The keywords, such as medical care, fitness, pollution, health insurance, medicine, doctor, medical education, medical-education collaboration, nutrition, healthy aging, drug safety, and health industry, that are applied to the search are extracted from "Statistical Classification of the Health Industry (2019)" that is introduced by National Bureau of Statistics. Employing a crawler to collect policy texts before February 2023, and filtering out policy texts with the Office of State Council or provincial government office, the health industry policies were collected from 31 provinces, autonomous regions, and municipalities across the country based on data availability. Policy texts related to the epidemic were removed since the epidemic policies are relatively special, and there were 3,226 policy texts in total.

4.2 Policy text processing

To improve data quality and provide structured data for subsequent manual labeling and model prediction, it is indispensable to unify the format of the collected health industry policy texts, which mainly includes the following:

1. In the crawling process, most of the policy texts have structured formats; however, some policies do not have paragraph marks by parsing the texts from different attachment files and websites. Therefore, regular expressions are used to locate titles at all levels, such as chapter one, section one, and first-class subject, to perform paragraph marking and segmentation to standardize the text structure. Considering that after coding the policy texts, the connections between the contexts would be weak, which is not conducive to text recognition, and the automatic labeling is carried out in the form of subtitles at all levels, that is, each policy statement is preceded by subtitles of policies at all levels, totaling 78,343 policy statements.

2. Due to the non-standard format of the policies' appendix, it is likely to cause misplacement when segmenting titles at all levels, so that the policy texts cannot be trained by the model and the classification results might be interfered with. Therefore, appendixes, schedules, annexes with company names, factory names, and place names in the policy texts are eliminated, and appendixes and annexes on specific policy initiatives are retained as the policy texts.

4.3 Trainset encoding

Rothwell and Zegveld's method of classifying policy tools is applied to categorize them into supply, demand, and environment tools because this method could be regarded as more suitable in an industrialization background than other methods that consider government action or behavioral characteristics. The supply policy instruments provide funds, talented human resources, and scientific and technological support to the development of the health industry by the government, which can promote the development of the industry directly; the demand policy instruments are meant to drive the development of the industry by pulling the market demand; the environment policy instruments are intended to indirectly impact the development of the health industry by creating the conducive policy environment. These three types are further divided into 13 subcategories following the characteristics of health industry policies, as shown in Table 1. The category "Others" is established, totaling 14 categories, because some of the words in policy texts, including policy background or notices, do not involve specific policy initiatives. In total, 10% of the policy texts were randomly selected for manual labeling, and 8,362 labeled policy statements were acquired. We randomly select 500 policy texts from the labeled dataset to examine the consistency of the sample, and the consistency is 95.4% after relabeling the policy texts. The training set, test set, and verification set are then divided into 8:1:1 to build the model.

4.4 Model parameter setting

This study implements the PyTorch structural framework for model building. Other parameters of BERT are fine-tuned as model parameters. The maximum text length is set to 512, the maximum number of characters that BERT can process, with truncating the portions of policy statements larger than 512 characters because the proportion of policy statements exceeding 512 words is relatively small, which could maintain the main semantics, as shown in Table 2. Batch_size is set to 12, utilizing AdamW as the model optimizer, and the learning rate and weight decay rate are 1e−5 and 1e−4, respectively. The number of model training iterations is set to 5.

We select BERT and RoBERTa to compare the effect of the model and apply binary cross entropy loss as the loss function (BCE Loss). y_i is the binary label of the i's sample, and $p(y_i = 1)$ is the prediction of the i's sample by the model. The BCE Loss function is Formula (3):

$$\text{BCE Loss} = -\frac{1}{n}\sum_{i=1}^{n}\left[y_i * \log p(y_i = 1) + (1 - y_i)\log\left(1 - p(y_i = 1)\right)\right] \quad (3)$$

We also try the Focal Loss as the loss function (29) to increase the weight of samples with a smaller proportion. The form without α would be selected in multi-classification, γ is set to 2, and the expression of the Focal Loss Formula (4) is as follows:

$$\text{FL}(P_t) = -(1 - P_t)^{\gamma}\log(P_t) \quad (4)$$

5 Results and analysis

5.1 Research results

This study employs precision, recall, and $F1$ as the evaluation metrics for the model performance. In the multi-label classification, the recall rate can assess the proportion of the correctness predicted by the model in the actual samples, while the precision rate can assess the proportion of the correctness predicted by the model in the predicted samples. However, there would be sample imbalance in the multi-label classification of policy instruments, and the demand policy instruments have relatively few subcategories from the policy instrument distribution. The $F1$-value could give average weights to the proportion of precision and recall to reduce the negative effect of an unbalanced sample.

The BERT model has a better performance in the multi-label classification of policy instruments (30). The BERT model is finally applied after comparing BERT with other related BERT models, such as RoBERTa and MacBERT, as shown in Table 3, and the pre-training model of RoBERTa and MacBERT is Chinese-roberta-wwm-ext and Chinese-macbert-base from HFL. The performance of the Focal Loss function is only a little higher than the BCE Loss function in the $F1$-value to process an imbalanced sample problem. Therefore, this study continues to employ Bert-base-Chinese as the pre-training model and Focal Loss as the loss function of BERT, and the $F1$-value achieves 79.5%. The precision, recall, and $F1$ in each instrument type are displayed in Table 4.

5.2 Evolution analysis of policy instruments

The quantity of health industry policies released varies from year to year; therefore, the proportion of each type of policy instrument is applied to illustrate the changes in health industry policy instruments in China. The proportion of supply-side instruments gradually rises, the proportion of environmental instruments steadily declines, and after 2015, the proportion of supply-side policy instruments exceeds that of environment side, indicating that governments have gradually shifted their policy priorities for the development of the health industry from regulating the environment for industrial development to promoting industrial development, displayed in Figure 2. The demand-side policy

TABLE 1 Health industry policy instrument citation and interpretation.

Instrument types	Instrument subtypes	The interpretation of instrument types
Supply	Technology support	The government provides support for various scientific innovations and the application of internet technologies, such as improving database systems and encouraging the development of medicines and medical devices
	Fund support	Government supports the development of the health industry and increased financial investment, such as direct government investment
	Talent support	Strengthen the training of talents and improve the education and training system, such as the training of general practitioners and the introduction of talents
	Infrastructure support	Enhance the investment in infrastructure construction, improve infrastructure configuration by building hospitals and laboratories, introducing advanced equipment, and creating campus bases
	Public service	Measures formulated to enhance public services for the health industry and provide corresponding supporting public services, such as improving the service system and strengthening publicity and guidance
Environment	Goal planning	The government sets specific goals and plans to be achieved
	Regulations	Ensure an organized healthcare sector by enacting laws and regulations
	Financial support	Support companies such as concessions, tax breaks, financing, loans, and other means of financial deregulation to facilitate the development of the health industry
	Strategic Initiatives	The government formulates industrial layout and adjustment and forward-looking industrial planning to cultivate industrial growth points
Demand	Public purchasing	Utilize financial funds to purchase service products from third parties, including enterprises and non-profit organizations
	Demonstration projects	Conducting pilot projects and supporting leading enterprises
	Market shaping	The introduction of third-party forces to increase market dynamics, as well as the use of market-based approaches to price adjustments, such as the introduction of social forces to run hospitals, regulate drug prices, and cooperation with overseas institutions
	Fiscal subsidy	Subsidize the purchase of health service products by the general public to drive consumer and business demand for health
Others	Others	Other policy content that is not related to the policy tool, such as background information

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TABLE 2 Percentage of length interval in policy statements.

Length interval	Word count	Percentage	Cumulative percentage
0–49	1,347	1.7%	1.7%
50–99	10,837	13.8%	15.6%
100–149	12,800	16.3%	31.9%
150–199	13,580	17.3%	49.2%
200–249	11,207	14.3%	63.5%
250–299	8,238	10.5%	74.0%
300–349	5,870	7.5%	81.5%
350–399	3,919	5.0%	86.5%
400–449	3,285	4.2%	90.7%
450–500	1,679	2.1%	92.9%
>500	5,581	7.1%	100.0%

Data were obtained from the authors' calculations.

TABLE 3 Comparative experimental results.

Model	Loss	Precision	Recall	*F*1
BERT	BCE Loss	0.7929	0.7885	0.785
	Focal Loss	0.7979	0.8057	0.795
RoBERTa_wwm	BCE Loss	0.8035	0.7879	0.7885
	Focal Loss	0.7685	0.8107	0.7821
MacBERT	BCE Loss	0.7943	0.7786	0.7793
	Focal Loss	0.7693	0.805	0.7807

Data were obtained from the authors' calculations.

TABLE 4 Precision, recall, and *F*1 in each instrument type by the BERT model with Focal Loss.

Instrument types	Precision	Recall	*F*1
Technology support	0.75	0.79	0.77
Fund support	0.76	1	0.86
Talent support	0.81	0.86	0.83
Infrastructure support	0.75	0.72	0.73
Public service	0.9	0.67	0.77
Goal planning	0.92	0.77	0.84
Regulations	0.81	0.77	0.79
Financial support	0.63	0.75	0.68
Strategic initiatives	0.97	0.7	0.81
Public purchasing	0.67	0.78	0.72
Demonstration projects	0.81	0.84	0.83
Market shaping	0.58	0.8	0.68
Fiscal subsidy	0.82	0.88	0.85
Others	0.99	0.95	0.97
Average	0.7978	0.8057	0.795

Data were obtained from the authors' calculations.

instruments fluctuate, but they generally decline. At the same time, it also demonstrates that governments tend to employ supply-side and environment-side policy instruments in formulating policies for the health industry, and the demand-side policy instruments are fewer in quantity.

Table 5 displays the evolution and proportion analysis of several types of policy instrument subcategories, which could be adopted to further investigate the variations in policy instruments. The Chinese five-year plan represents the future policy priorities and development plans of various industries; thus, the period should be in line with it. Before 2001, the proportion of market-shaping tools on demand was relatively high, mainly because each province successively overhauled its urban medical and health systems by supporting market-driven adjustments to medical service prices and strengthening drug price management, and then, the percentage of market-shaping tools declined due to the lack of relevant policies. After 2010, it subsequently increased primarily to facilitate the accession of social capital, loosen market restrictions, and accelerate market expansion. The proportion of fiscal subsidy tools has steadily declined over time, particularly after 2015. The main reason is that, before 2005, the policy concentration was on enhancing health insurance coverage for people's fundamental medical security. With the incremental enhancement of the medical security system, the proportion of fiscal subsidy tools has gradually decreased. Public purchasing tools have not previously taken up an enormous percentage to vary the current tendency of the demand-side instruments. Demonstration project tools have increased slightly, indicating that the government is continually implementing pilot policy innovations, but it still cannot transform the overall trend of demand-side instruments due to its low share. The proportion of supply policy instruments gradually increased above that of environmental policy instruments from 2006 to 2010, with 2009 serving as the turning point. Public service tools account for a larger proportion and display a growing trend, while regulation tools are gradually reduced, so supply instruments are more prevalent than environmental policy instruments. The rising proportion of goal planning and strategic initiatives among environmental policy instruments illustrates that the government is constantly enhancing and adjusting the planning and industrial layout of the health industry, which proves that the health industry has tremendous potential for development in the future. Financial support tools are gradually improved, which is conducive to the development of enterprises and provides a more favorable environment for enterprises in terms of tax incentives, financial credit, and financing. The percentage of infrastructure support tools in supply policy instruments continued to rise throughout the five-year plan from 2006 to 2010, and talent support tools would gradually increase in the following five-year plan. During this period, the country began to focus on the impact of technology and information on industrial development support.

5.3 Evolution analysis of provincial policy tools

The quantities of various types of policy tools utilized are slightly different, but the proportion of policy tools employed in each province is generally similar. Considering that there would be enormous dimensions by adding provinces and years, the release of health industry policies has gradually increased after 2010, and the policy system of each province is relatively complete; therefore, the "Five-Year Plan" was applied as the boundary and the provinces are divided into four major economic regions, namely, the eastern, central, western, and northeastern regions, which could helpfully analyze the

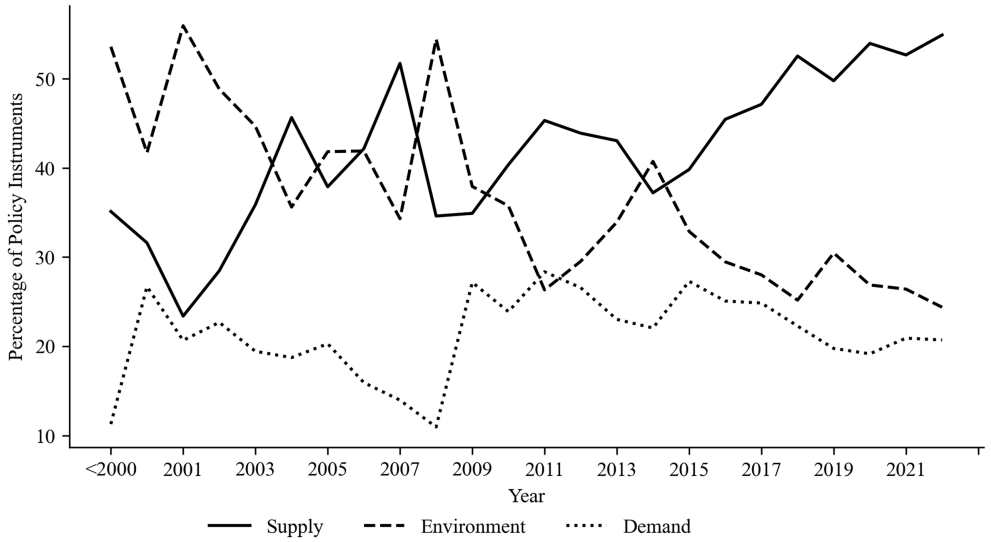

FIGURE 2
Trends of each type of health industry policy instrument.

TABLE 5 Percentage of the column of policy instruments subcategories (%).

Instrument types	<2001	2001–2005	2006–2010	2011–2015	2016–2020	>2021
Supply	**33.76**	**33.21**	**40.73**	**41.64**	**48.77**	**53.44**
Public service	27.73	24.87	26.15	20.63	23.21	21.64
Infrastructure support	1.95	3.77	5.76	7.78	7.98	12.04
Technology support	1.00	1.29	2.45	4.10	7.56	8.21
Talent support	1.73	1.24	4.08	7.26	7.90	9.80
Fund support	1.34	2.04	2.28	1.86	2.11	1.76
Environment	**49.00**	**46.38**	**39.89**	**32.48**	**28.12**	**25.71**
Strategic initiatives	0.84	1.15	1.82	2.68	3.40	2.40
Regulations	35.04	34.26	24.19	15.00	12.14	11.74
Financial support	4.63	3.07	2.91	3.58	3.29	4.03
Goal planning	8.48	7.90	10.97	11.22	9.29	7.53
Demand	**17.24**	**20.41**	**19.38**	**25.88**	**23.11**	**20.85**
Fiscal subsidy	10.21	12.96	10.53	8.68	3.86	4.16
Demonstration projects	1.67	3.30	4.15	5.72	6.97	7.07
Market shaping	4.69	3.73	3.21	8.40	10.25	7.77
Public purchasing	0.67	0.42	1.49	3.08	2.03	1.85

Data were obtained from the authors' calculations. The bold values are first level class, and the others are the second level class.

proportion of policy tools used in the four major regions from 2011 to 2023 and conduct in-depth analysis on typical regions, such as the Beijing-Tianjin-Hebei region, the Yangtze River Delta, and the southeast coast, detecting the similarities and discrepancies in the health industry policy distribution.

In the health industry-related policies issued by the State Council from 2011 to 2015, supply policy tools accounted for 32.04%, environmental tools accounted for 42.04%, and demand tools accounted for 25.92%. The demand-side tool percentage of the four major economic regions is close to that of the central government, the supply-side tool percentage of the four major economic regions is higher than central government, and the environment-side tool percentage of the four major economic regions is lower than the central government, as displayed in Table 6, which illustrates provincial government focus on motivating health industry directly. From the composition of policy instruments in the Beijing-Tianjin-Hebei region, Table 7 displays that Hebei province has a higher proportion of supply-side tools and a relatively lower proportion of environment tools, and Hebei has stronger policy support which presents a rapid development of industry, especially in talent support. The policy similarity between Beijing and Tianjin is relatively high. Beijing, as the technology and innovation center in China, has paid

TABLE 6 Percentage of policy instruments' column in four major economic regions (%).

Time interval	Instrument types	Northeastern	Eastern	Western	Central	State Council
2011–2015	Supply	44.02	42.74	41.56	40.95	32.04
	Environment	29.62	32.76	33.09	30.14	42.04
	Demand	26.36	24.50	25.35	28.91	25.92
2016–2020	Supply	51.15	47.22	49.33	50.20	42.15
	Environment	25.90	29.69	26.82	27.93	33.41
	Demand	22.95	23.09	23.84	21.87	24.44
After 2020	Supply	56.84	55.51	53.42	51.01	35.83
	Environment	25.42	23.25	25.04	28.72	46.06
	Demand	17.73	21.24	21.55	20.27	18.11

Data were obtained from the authors' calculations.

TABLE 7 Percentage of policy instruments' columns in typical regions from 2011 to 2023 (%).

Time interval	Instrument types	Yangtze River Delta			Southeast coastal area			Beijing-Tianjin-Hebei		
		Jiangsu	Zhejiang	Shanghai	Fujian	Guangdong	Hainan	Hebei	Beijing	Tianjin
2011–2015	Supply	44.58	38.82	42.44	43.84	44.80	45.58	42.82	37.64	40.19
	Environment	28.32	37.76	39.53	32.27	31.52	33.88	22.36	33.95	36.14
	Demand	27.10	23.41	18.02	23.89	23.68	20.54	34.82	28.41	23.68
2016–2020	Supply	47.12	52.39	50.22	43.11	49.09	42.37	50.48	46.64	44.43
	Environment	27.25	24.44	27.36	28.86	22.38	36.77	25.52	35.78	33.99
	Demand	25.63	23.17	22.42	28.03	28.53	20.86	24.01	17.58	21.58
After 2020	Supply	51.41	62.50	54.63	58.16	51.96	57.51	59.81	51.37	58.24
	Environment	24.73	23.21	22.45	12.77	26.26	20.47	22.12	28.63	27.65
	Demand	23.85	14.29	22.92	29.08	21.79	22.02	18.08	20.00	14.12

Data were obtained from the authors' calculations.

more attention to science and technology, and the proportion of technology tools is 6.64%, which is higher than Hebei and Tianjin. In the Yangtze River Delta region, Jiangsu and Zhejiang have resembled the distribution of policy tools, while Shanghai displays certain distinctions, with a lower share of supply tools and a higher share of environment tools. The Southeast coastal region, mainly including Fujian, Guangdong, and Hainan, has a roughly similar distribution of policy instruments between each other.

The supply policy tools accounted for 42.15%, environment tools accounted for 33.41%, and demand tools accounted for 24.44% from 2016 to 2020, issued by the State Council. There would be an increased proportion of supply policy tools and a decreased proportion of environment policy tools compared to the last five-year plan. In the four economic regions, the proportion of supply policy tools has been rising slightly in general. Hebei has partially stimulated its investment in infrastructure and technology in the Beijing-Tianjin-Hebei region. Jiangsu sustains a higher proportion of fund support in the Yangtze River Delta region. Guangdong has boosted the proportion of supply policy tools and begun to raise the proportion of talent support policy tools; furthermore, Fujian has paid more attention to the demand policies to build a conducive market environment for enterprise in the Southeast coastal region.

Central government relatively focuses on environmental policy instruments after 2021, even though the quantity of policies is small due to the unterminated five-year plan; however, other provinces prefer to supply policy tools. Hebei has seen greater growth in infrastructure development and technology, while Beijing still places emphasis on science and technology support, and Tianjin is prominent in the financial subsidy category. In the Yangtze River Delta region, Zhejiang has a significant increase in the proportion of talent support, resulting in an increased percentage of supply policy instruments. In the Southeast Coast region, Guangdong's proportion of supply policies declined, but talent support policies remained relatively high.

5.4 Evolution analysis of policy tools' topic

5.4.1 Topic analysis of policy classification

The health industry contains more subcategories, and categorizing the policies can more clearly determine the proportion of policy instruments implemented and dissect the development direction of the health industry. Due to the large number of policy-searching words, classifying the policy-searching words in the policy collection can reduce the analysis dimension. There are nine topics acquired, which are insurance, health industry, rehabilitation, sports, pollution, medical services, medical education, medicine, and nutrition. The 16 keywords from the title of policies are discovered and extracted to complement the topic classification after using search words as topic

categories when we read and label the training samples of policy texts manually. The method of topic classification is shown in Table 8. From 2011 to 2015, the percentage of pollution policy tools gradually fell, illustrating that environmental problems had begun to ameliorate and that the policy's attention was beginning to shift in other directions. Medical and pharmaceutical policies remained the top priority of health industry policies. The proportion of sports and fitness policies gradually grew in 2020, illustrating that China's health industry gradually began to move from medical to health maintenance, sports, and commercial health insurance. From the subcategories of policy instruments in Table 9, the balanced expansion further indicates that the share of the health services industry is gradually rising.

It is evident that, in the medical service theme, the proportion of fiscal subsidy tools in demand-side policy instruments gradually decreased from 26.48% to 5.88% between 2011 and 2023, and the proportion of infrastructure tools in supply-side policy instruments gradually increased from 5% to 8.09%, and the proportion of technology support also grew from 4.57% to 5.05% at the same time. The basic medical insurance system was not impeccable in the early stage, and the government's fiscal support was indispensable to promote it. Then, infrastructure and technology research and development turned out to be the focused investment target with the improvement of the medical insurance system. In the medicine theme, the percentage of technological support grew from 1.23% to 4.56% between 2011 and 2023, and the proportion of market tools in demand-side policy instruments gradually increased from 2.93% to 10.55% at the same time. Since pharmaceutical innovation plays an essential part in disease control, an open research environment is indispensable for attracting third-party power and achieving continuous innovation, which could stimulate market demand and expand the scale of the health industry.

TABLE 8 Method of topic classification by search words and keywords of policies' titles.

Topic	Search words	Keywords of policies' title
Insurance	Health insurance	Insurance
Health industry	Health industry	Health
Health maintenance	Healthy ageing	Older individuals' care
		Health maintenance
		Tourism
Sports	Fitness	Sports
Nutrition	Nutrition	Food safety
		Reasonable diet
Pollution	Pollution	
Medical services	Doctor	Social medical care
	Medical care	Hospitals
		Chronic diseases
		Hygiene
		Medical care
Medical education	Medical education	
	Medical-education collaboration	
Medicine	Medicine	Essential medicines
	Drug safety	Drugs
		Generic drugs

5.4.2 Evolution analysis of policy texts' topics

The development of the health industry is inseparable from policy support. In 2013, the State Council issued "Several Opinions of the State Council on Promoting the Development of Health Service Industry," releasing the signal to foster the mainly related industries for supporting the health service industry and to support the development of diversified health services. Subsequently, the central and provincial governments have begun releasing planning policies for the health industry and health service industry. The strategic initiatives are primarily based on government planning and the industrial layout of the industry; therefore, they are screened as the primary analysis target in the theme analysis of the policy tool. Building a health industry dictionary is indispensable, which has been expanded with proper nouns, such as medical association, general practitioner, and fitness circle, to combine with Jieba subscripts, and then it has been employed as the tool to cut the policy text. The segmented policy text is vectorized by word frequency matrix representation, and the lda package in Python is employed to construct an LDA topic model. The perplexity trend figure's turning point indicates that 4, 5, and 4 are the optimal number of topics for each period. Figure 3 displays this by generating some of the top 10 keywords under each topic to investigate the changes in strategic initiatives focused on the "health industry" topic among the five-year plans.

The policies that are related to industrial planning apply more strategic initiatives. In 2013, the State Council issued "Several Opinions of the State Council on Promoting the Development of Health Service Industry" to accelerate the development of diversified health services such as healthy older individuals services, Chinese medicine, and healthcare services. The "General Office of Zhejiang Provincial People's Government on Opinions on Accelerating the Development of Chinese Medicine Health Services" document, published by Zhejiang Province in 2015, emphasized the criticality of developing the Chinese medicine healthcare industry in addition to the health tourism and Chinese medicine equipment industries. As indicated in Figure 4, the themes of the strategic initiatives are primarily concerned with "Chinese medicine," "rehabilitation," and "nursing care," etc. by choosing the higher weight of words, which may represent the policy tendency from 2011 to 2015. In 2016–2020, the weight of keywords, such as "agglomeration," "clustering," and "data," increased, and the main reason is that in 2016, the State Council issued the "General Office of the State Council on promoting and regulating the development of healthcare big data application guidance" to comprehensively deepen the application of healthcare with big data in various aspects of healthcare industry governance, medical clinical, scientific research innovation, public health, medical intelligent equipment, etc. The State Council published the Opinions of the General Office of the State Council on Promoting the Development of "Internet Medical Health" in 2018. This document involves telemedicine services, health management, medication management, doctor appointments and consultations, and medical insurance payment, among other topics. It will incorporate Internet technology in numerous ways to accomplish interconnection, boost the process of the medical association, enhance the efficiency of medical services by integrating Internet medical resources, and achieve effective business collaboration. On the other hand, the

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TABLE 9 Percentage of rows of policy instruments in each topic (%).

Time interval	Instrument types	Insurance	Health industry	Health maintenance	Sports	Pollution	Medical services	Medical education	Medicine	Nutrition
2011–2015	Supply	2.53	2.53	0.50	4.96	29.71	45.46	0.00	9.90	4.42
	Environment	5.84	2.38	0.77	2.80	44.42	32.08	0.00	8.45	3.28
	Demand	3.62	4.11	0.45	1.30	17.06	63.46	0.00	7.11	2.89
2016–2020	Supply	4.21	14.28	0.80	7.19	17.60	35.58	3.78	13.17	3.39
	Environment	7.22	10.81	1.25	8.14	26.76	29.82	0.56	13.07	2.36
	Demand	3.84	14.78	1.02	12.97	10.41	41.15	1.97	11.54	2.30
After 2020	Supply	9.01	1.34	3.90	13.65	7.85	33.01	9.87	20.65	0.72
	Environment	18.09	2.21	4.58	7.43	13.36	32.57	1.58	18.84	1.35
	Demand	10.87	2.96	5.46	14.95	5.51	32.86	6.20	21.15	0.05

Data were obtained from the authors' calculations.

prominence of industrial innovation additionally keeps gradually expanding, relying on industrial centers and enterprise resources to promote the agglomeration of biomedical industries, support enterprise innovation, such as research and development in biopharmaceuticals and other domains, and improve the industrial chain. From 2020 onward, keywords such as "innovation," "high-end," and "chengdu-chongqing" have more significance in the theme of industrial transformation and industrial innovation. It demonstrates that the integration of industry within the region and the development of industrial refinement have been given more emphasis, and the development of the health industry would be guided to become high-end through industry innovation, which also confirms the direction of the Chinese economy's high-quality development from another perspective.

6 Discussion

In this study, the deep learning algorithm is linked to the multi-label classification of policy instruments, which enhances the classification precision of policy instruments, and the average precision is nearly 80%, after the addition of the Focal Loss function. Moreover, enlarging the research sample to explore the evolution analysis in multiple dimensions could be possible by knowing the research results. In some traditional research methods, manual coding is relatively subjective, time-consuming, and hard to replicate, especially, for very large datasets. The deep learning method could improve the efficiency of the policy analysis. Some study proves that combining rigorous manual labeling methods with machine learning approaches could offer a good performance to reduce the time cost (31). In addition, some study also demonstrates that there is a good performance in less classification and short sentences (32). In policy analysis, due to the different data sources, sentences and paragraphs are often used as analysis units in most policy texts, but some studies are not (33). The last-level subheadings for establishing semantic units are applied, which can reinforce the coherence of context, and process the large datasets with uniform specifications automatically.

Qualitative analysis and content analysis are often applied to policy instrument studies by manually coding the policy text. However, some research just explores the industry plan of each province, which involves 19 provinces and 57 policy texts (34). This study presents an application of deep learning in health industry policy instruments based on the characteristics of the policy texts. Applying the multi-label classification method could provide a more detailed class and detect more information than the multi-class classification method in long paragraphs. Considering the unbalanced sample of policy instruments, this study combines the Focal Loss function to increase the weights of smaller samples and detects the rationality of the policy instruments' collocation to increase the rationality of the model. There is not enough sample in the whole industry policy, and comparing the policy instruments in sub-sectors could be difficult with a small policy dataset. Therefore, expanding the study sample might be more tangible for comparing the instrument distribution among provinces and topics. As shown in Tables 7, 8, some key regions' governments prefer the policy instruments mix that is suitable for local development, but there are still some similarities among the policy instruments mix of the four major economic regions. The topic of medical service and medicine

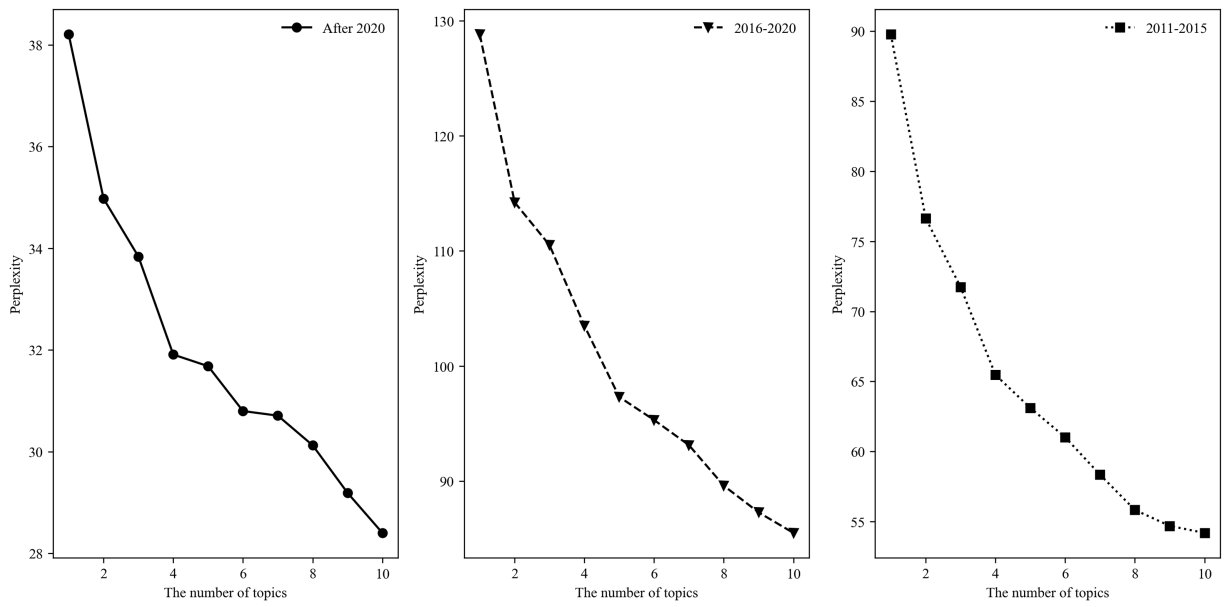

FIGURE 3
Perplexity trends of strategic initiatives instruments under different topic numbers in each period.

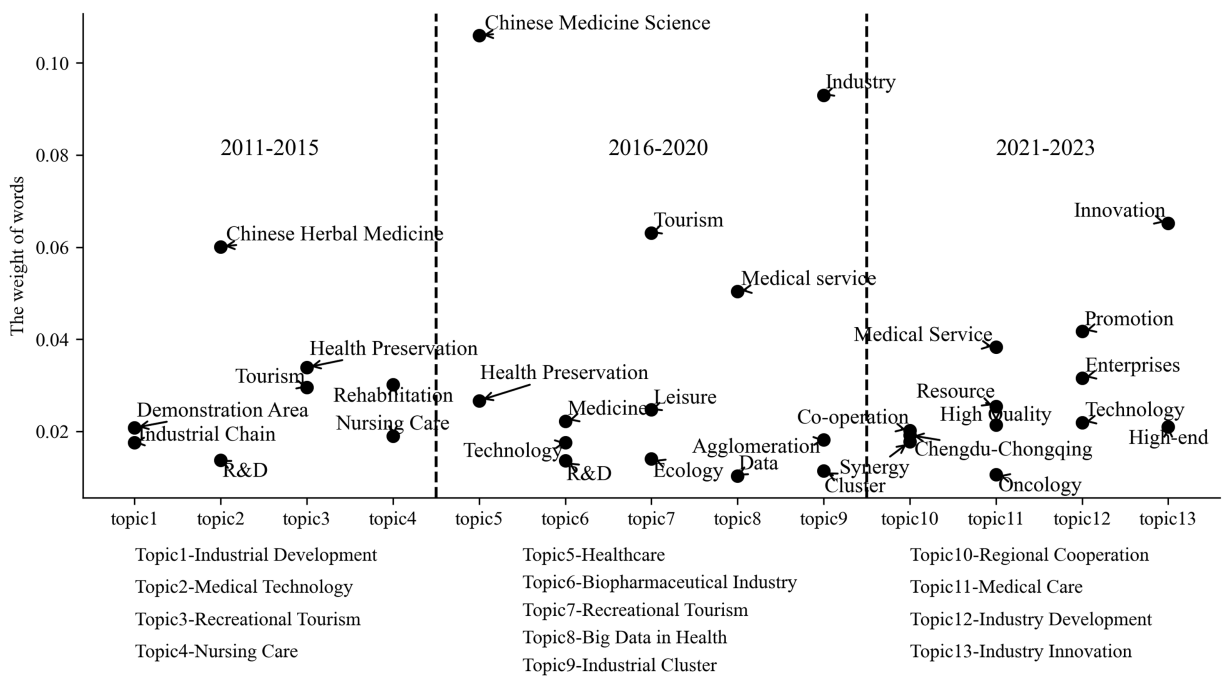

FIGURE 4
Topic change of health industry strategic initiatives based on LDA topic words' weight.

has nearly 50% in the health industry, which is not realized by the small samples. The BERT multi-label method enlarges the sample dataset in the health industry that involves many industry sectors. The monitoring system of policy instruments should be in a long-term and efficient way, and applying a relatively comprehensive dataset of policy text is beneficial to the development of China's health industry.

7 Conclusion

This study proposes a framework for classifying health industry policy instruments and analyzing the evolution of the policy instruments. First, the BERT model with Focal Loss is employed for policy instruments' multi-label classification, which enhances the accuracy and provides a boost to analyze the policy instruments more efficiently.

Second, in the temporal dimension, the proportion of supply policy instruments has increased since 2008, the proportion of environment policy instruments has gradually decreased, and the proportion of demand policy instruments has fluctuated and has slightly declined. The supply and environment policy instruments are predominant, while the demand instruments are neglected relatively. The government is paying more attention to the health industry by offering many direct supports to accelerate industry development, and marketization still needs to be improved. Regulations and public service have a large percentage, which illustrates the environment of the health industry has been gradually normalized; however, the low percentage of public purchasing may affect the order volumes of pharmaceutical companies and medical institutions, which would limit the growth of health industry, and the absence of market-shaping instruments might cause unequal distribution within the health industry and discourage social capital from getting involved in the market, both of which are unfavorable to the formation of a diversified market and a healthy competitive environment.

Third, multi-label classification makes the expansion of the sample, and the composition of regional policy instruments could be compared by the model predicted result. In the spatial dimension, the proportion of policy instruments among the four major economic regions is similar, with provincial governments having a higher proportion of supply policy instruments than the central government and a slightly lower proportion of environment ones; among the key regions, Beijing and Tianjin have similar policy instrument combinations and an increased level of synergy, while Hebei is vigorously catching up in terms of policy support; the Yangtze River Delta region's Jiangsu and Zhejiang have resembling distributions, while Shanghai illustrates some variations, and the southeast coastal region has similar instrument compositions. A similar mix of policy tools could make governments learn the successful experience easier, but this might leave governments with limited space for creativity and flexibility to promote local characteristic industries and confront the special challenge. Moreover, it may not be conducive to the effective allocation of resources according to the actual local situation without considering its own resource endowment and economic structure.

Finally, the three issues of healthcare, medicine, and pollution continue to be the focus of policy instruments in the thematic dimension, but the proportion of health maintenance, sports, and insurance is increasing, indicating a trend of shifting policy focus. The policy emphasizes the themes of fitness, healthcare, and health tourism between 2011 and 2015, as can be seen from the primary phrases extracted for the strategic initiatives of the health industry theme, the weight of data and information has increased with the introduction of the Internet and big data concepts during the years 2015–2020, and, after 2020, industrial development will focus a greater deal on innovation and improvement to propel the sector toward high-end development.

This framework could improve the efficiency of refining the health industry policy instruments based on the deep learning method. In addition, it can reduce the time cost of manual coding and detect more labels in the policy paragraph by applying a multi-label classification method. The health industry includes several subfields, such as medical service, health education, and pollution control, which contain plenty of policies year by year. This framework could process a very large dataset that is suitable for the complex health industry, and comparing the difference between provincial and topic dimensions could be possible. The policy text can be transferred into valuable information to help policymakers master the health industry policy instrument system.

Health policy instrument analysis can only judge the development of the provincial health industry from macro-level policy application, but it cannot evaluate the effect of a specific policy. Due to the limited space, the evolution analysis of policy instruments by province and topic is in a segregated manner. Each province has its priorities, and the order of policy instruments should be considered according to the particular situation. Cross-analysis in multi-dimension will be considered in the future. In addition, due to the different writing preferences of governments' policy texts, different levels of policy texts would exist. Therefore, calculating the proportion of sections below each level for a better segment of each semantic unit will be considered in further study.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

JJ: Conceptualization, Funding acquisition, Investigation, Project administration, Supervision, Writing – review & editing. HD: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Software, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Capture and corporate cooptation: the role of the Mexican Foundation for Health in public health policy

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Introduction: Corporate capture responds to efforts to strengthen regulation or prohibition of commercial determinants of health [tobacco, alcohol, sugar-sweetened beverages, ultra-processed products (UPFs), commercial milk formula, and pharmaceuticals], in an attempt to interfere with public health policies that threaten the commercial, economic, and political interests of major industries. This manuscript proposes the characterization of the corporate capture of public health in Mexico, exercised through the Mexican Foundation for Health (FUNSALUD).

Methodology: An analysis of FUNSALUD and its stakeholders was carried out under the framework of commercial determinants of health, using a qualitative methodology, and executed in five stages: document analysis from 1985 to 2021; identification and characterization of stakeholders; semi-structured interviews; classification of corporate strategies; and relationship mapping.

Results: Actors in the pharmaceutical, food, tobacco, alcohol, commercial milk formula, and sugar-sweetened beverage industries were identified as corporate members of FUNSALUD. We identify six corporate strategies used to interfere in public health and food policies, highlighting the role of a revolving door bureaucracy in the case of the Ministry of Health.

Conclusion: The Mexican Foundation for Health has functioned as a front organization created by the private sector to influence public policy decision-making, protect corporate interests, and oppose international recommendations to combat non-communicable diseases.

KEYWORDS

commercial determinants of health, corporate practices, conflict of interest, health policy, nutrition policy

Introduction

The capture of public policy is the process whereby political decisions respond to the particular interests of an individual, a group of people, or a private organization, to the detriment of the public interest, through the intentional actions of such private agents. The consequence is unfair regulation or a lack of regulation when it is needed to protect the common good, which is harmed as a result (OECD, 2017). When public policy initiatives seek to regulate products that harm health such as alcohol, tobacco, sugar-sweetened beverages, UPFs, and commercial milk formula (Pérez-Escamilla et al., 2023), corporations become interest groups that take on outsized relevance in public policy debates.

According to Royo et al., corporate capture is exercised through various strategies that were first implemented by the tobacco industry and have since been imitated by the industries of sugar-sweetened beverages, UPFs, alcohol, tobacco, and commercial milk formula (Royo-Bordonada, 2019) in an effort to protect their economic, commercial, and political interests (Carpenter, 1936). According to Duran, corporate capture focuses on processes or situations where an influential elite, develops a collusive relationship with political elites at various levels (local, regional, and national) and in various state instances (regulatory agencies, ministries, and main economic bureaucratic instances; Durand, 2019). These strategies have marked the history of corporate influence on potentially harmful regulation of their products, and they have demonstrated the purchasing economic and political power they have acquired; as well as the impact and aspect it has on the formulation of public policies.

The legitimacy of the state is threatened by the corporate capture of political spaces and a development narrative that assigns a leading role to external private investment (McKeon, 2018). Multiple corporate practices aimed at capturing the state, science, and decision-makers have been documented, specifically, public health agencies are particularly susceptible to corporate capture, a process by which an institution promotes the commercial interests of industries and of other stakeholders, above public interests (Mindell et al., 2012; Wiist, 2016); for this, one of the mechanisms that can potentially lead to the capture of health is the capture of science, whose purpose is to distort the scientific evidence that links the consumption of certain products with health damage; through the financing of research, researchers, and the creation of institutes or front organizations, they tend to divert the narrative about the risk factors that lead to non-communicable diseases (Mialon et al., 2020a,b,c; Scrinis, 2020).

Another corporate aspect is the approach with decision makers to influence policy formulation mechanisms, in legislative and deliberative processes of public health initiatives (Savell et al., 2014); as well as, exercising influence through the revolving door as a way to penetrate the highest government spheres, whose intention is to favor the corporate interests by improving the internal knowledge, increasing the access of corporations to decision making and influencing policy outcomes (Robertson et al., 2019; Miller et al., 2021).

On the other hand, the industry has permeated the public health community by training human resources, creating institutional forums, using public relations or supposed social responsibility, and discrediting organizations, groups, or individuals who promote public health regulations; this has positioned the industry as leaders in public health (Mialon et al., 2015; Mialon and Mialon, 2018), this has been a strategic key for the private sector to lead a narrative on health problems; in addition to influencing public opinion and positioning their interests on the public agenda (Carriedo et al., 2022).

Thus, close relations between corporations and public bodies can result in a lack of transparency and independence of regulatory bodies, which in turn can lessen the effectiveness of the State's efforts to combat non-communicable diseases linked to poor diet (Laswell, 1958). For example, international instruments speak of "institutional corruption," which is the normalization of conduct that endangers transparency and gives rise to the formation of networks of perverse incentives, in which health agents take advantage of their position in an organization to influence institutional processes and actions. Considering that the risk of undue corporate influence or capture is generated especially by multinationals, trade associations, consortia, and philanthropic foundations, our analysis is especially concerned with these actors, to which we refer as the corporate sector.

At a global level, different corporate practices of advocacy in public health policy have been identified, which have been called commercial determinants of health (CDoH), a term that Gilmore et al. define as "the systems, practices, and pathways through which commercial actors drive health and equity (Gilmore et al., 2023). This definition aims to convey four key issues, (1) encompasses all commercial entities rather than just corporations because we recognize their diversity; (2) goes beyond a simple focus on unhealthy commodities and profits as the sole driver; (3) aims to recognize positive and negative contributions and the potential for change; and (4) focus the definition on health (both human and planetary health, which are interlinked and codependent.

Corporate influence is exerted through seven practices, political, scientific, financial, marketing, supply chain and waste, labor and employment, and reputational management. The extent to which each business entity engages in these practices, and whether they cause harm, depends on that entity's product, business model, and growth strategy. Practices vary according to the context in which the entities operate, with transnational companies having the most power and influence in decision-making; it has also been shown that in low- and middle-income countries they start all their machinery running through gaps in the regulations (Gilmore et al., 2023; Lacy-Nichols et al., 2023).

The concept of commercial determinants of health encompasses different levels, from the micro or individual to the macro or structural. Baron mentions that the structural level is made up of the market and non-market components, which are shaped by corporations to position, market, and promote their products, in this sense, through the market and non-market strategies, they can influence decision-making, in the stakeholders, institutions, and initiatives that seek to regulate corporate action (Baron, 1995). Among the policies that the industry seeks to interfere with are fiscal (tax), regulatory (labeling and advertising), commercial (sale of UPFs), and prohibitive (UPFs in the school environment).

In Mexico there is an institution that has established the country's health agenda for more than 30 years; the Mexican Health Foundation, better known as FUNSALUD, was founded in 1985, with the support of then-Minister of Health, Guillermo Soberon Acevedo, with the aim of "promoting the development of high-level human resources [and] supporting health research, in a framework of collaboration and respect with the federal government" (FUNSALUD, 1985).

In 1985 FUNSALUD had the participation of 22 entities and commercial actors that constituted the assembly of the organization at that time, and that belonged to the financial, ultra-process food, automotive, food and baby products, department stores, construction, pharmaceutical, and hospital sectors. However, with time, various commercial entities have joined the ranks of the

organization; in 2021 a total of 56 people from the board of directors; 61 people from the general assembly of associates (founders, active and honorary); and 26 commercial organizations (commercial associates), these represent shareholders and directors of the main companies in the food, pharmaceutical, health, and financial sectors at a national and international level.

FUNSALUD has been involved in public policy decision-making through varied strategies, among them the strategic placement of its former officers in the federal government. The most documented initiatives the foundation has spearheaded include the modification of the Mexican public health system, with proposals such as universal health service, decentralization, and the creation of popular insurance (Loera, 2016).

In Mexico, various initiatives derived from FUNSALUD corporate capture in the health have been documented, including violations of the Framework Convention for Tobacco Control (Madrazo-Lajous and Zambrano-Porras, 2007; Burch et al., 2010; Guerrero et al., 2010), the Food and Beverage Advertising Self-Regulation Code (PABI Code; Instituto Nacional de Salud Pública, 2020), and Frontal Food Labeling (GDA Labeling; El Poder del Consumidor, 2014; Calvillo and Székely, 2018) and the implementation of the "designated driver" campaign by the alcohol industry (Robaina et al., 2020).

We use a dynamic-relational approach to understand this agreement, identifying the structural and institutional factors that generate or facilitate more marked situations of capture, and the networks used by corporate elites to protect their interest and take advantage. This manuscript proposes the characterization of the corporate capture of public health in Mexico that has been exercised through the Mexican Foundation for Health (FUNSALUD), with emphasis on the commercial determinants of health as well as the influence of members of the foundation and its relationship with the corporations of ultra-processed industries, sweetened beverages, tobacco, alcohol, and commercial milk formula and its influence on government policy agendas for harm prevention.

Materials and methods

An analysis of FUNSALUD and its stakeholders was carried out in the framework of the commercial determinants of health, using a qualitative methodology, and executed in three dimensions: (1) document analysis from 1985 to 2021, (2) stakeholder identification in high command positions in government; and (3) characterization of the corporate capture of the state through the foundation.

Document analysis

For the search of scientific literature, databases such as Pubmed and Scielo were reviewed, using the search terms "FUNSALUD" AND "conflict of interest" "Pharmaceutical" AND "Popular Insurance" AND "Health Policy;" AND "Mexico." For the review of gray literature, documents from FUNSALUD and the organization's website, news articles, online books, reports from civil society organizations, congressional minutes, and professional profiles were consulted. For this search, search engines such as Google, and LinkedIn were chosen, with keywords such as "FUNSALUD" OR "Mexican Foundation for Health" AND "interference" AND "conflict of interest" AND "public policy" AND "tobacco" AND "alcohol" AND "sugar-sweetened beverages" AND "Nestlé" AND "corporations" AND "revolving doors" AND "incidence" AND "Ministry of Health." Information was collected for the period from 1985 (the year of FUNSALUD's creation) through 2021.

Stakeholder identification

Our analysis of the General Associates' Meeting (Spanish acronym AGA) of FUNSALUD helps form a perspective on the people who have held executive and management positions in FUNSALUD in recent years. To analyze FUNSALUD's AGA, we selected the period from October 2019 to October 2021. The reason for addressing this period is to observe changes in AGA membership under the current federal administration headed by Andres Manuel Lopez Obrador, which took office on December 1, 2018. However, although the analysis of AGA membership focuses on the last 2 years, at the same time we analyzed the positions its members have held in the public and private sectors since the Foundation was created in May 1985. To reconstruct the relationship mapping of AGA members, backward searches were conducted using public sources such as the Public Registry of Commerce (Spanish acronym RPC), reports of companies listed on the Mexican Stock Exchange [Spanish acronym BMV and those submitted by companies to the U.S. Securities and Exchange Commission (SEC)]. The positions of the AGA members in the business sector were defined by their membership status, taking into account if they held a position of high responsibility (general manager or CEO), served on the Board of Directors, or were shareholders or business owners. This way, in the AGA the business sector is linked in two ways: (a) through the owners or members of the founding families who act as active associates, honorary or founders, and (b) through directors with high responsibilities who participate as representatives of institutional partners.

In the case of AGA members who have formerly held positions of high responsibility in the public sector, such as federal cabinet secretaries and undersecretaries, and directors of organizations in charge of health in Mexico, their property declarations registered in the government portal *Declaranet* were consulted. In the case of members holding positions in the social sector, the annual reports of universities, research centers, foundations, and civil society organizations (CSOs) were reviewed.

Characterization of the corporate capture of the state through the foundation

To analyze corporate capture in public health in Mexico through FUNSALUD, we use the framework proposed by Marion Nestle, which focuses solely on the capture of science and public policies in food health; however, we apply it to characterize the strategies in FUNSALUD, which is an organization that in

TABLE 1 Actors who participated in the semi-structured interviews.

Sector	(*N* = 12)
	Número
Multilateral Organization (MO)	3
NGOs	4
Academics (ACA)	4
Media (MED)	1

Actors: We are referring to people who work in the mentioned sector, not groups of people.

its activities conducts research, finances institutions dedicated to science and exercises political power to influence public policies.

The classification of corporate capture proposed by Nestle (2018), focuses on political strategies such as (a) revolving doors, (b) financing of institutes dedicated to science, (c) use of front groups, (d) granting of monetary prizes or other incentives for research, (e) promoting self-regulation, (f) making use of "corporate responsibility." The advantage of using this framework is that it focuses solely on the characterization of the capture of science, through interference in institutions that generate scientific evidence, researchers, and decision-makers. The disadvantage is that the framework has only been used to characterize corporate capture in the ultra-processed and sugar-sweetened beverage industry, and has not been used to describe other corporations.

To complement and rectify the documentary information collected, we conducted 12 interviews with actors, who were aware of FUNSALUD's influence on and interference in different public policies related to big industries (UPFs, sweetened beverages, tobacco, alcohol, and commercial milk formula); and actors who hold or held positions within some government and private agency. The selection of informants was carried out through documentary analysis and the snowball technique (Table 1). For their selection, their relevance and participation in the study topic were considered, as well as their knowledge of public health policies, corporate strategies, and interference in health initiatives by FUNSALUD.

Initially, permission to participate was obtained by signing the informed consent letter for each participant. An interview guide previously piloted with experts in the field was applied, which was made up of four sections. (1) General information of the informant, (2) General knowledge about the incidence of FUNSALUD in the Health System in Mexico, (3) Direct or indirect strategies for corporate capture of public health in Mexico, and (4) Experience in incidence processes in public policies (tax policies, tobacco control, alcohol regulation, food labeling, and infant formula regulation). The interviews lasted ∼45 min; a Jitsi meet platform was used for communications, which is an encrypted program to make video calls, the research was carried out in the context of the COVID-19 pandemic, so there were restrictions on face-to-face meetings, which is why it was decided to use Jitsi platform to hold virtual meetings. The semi-verbatim interviews were transcribed, and the information was collected in content matrices; also, participants' confidentiality and anonymity were ensured.

The analysis of the qualitative information was carried out under the theoretical scheme used, that is, we carried out selective coding according to the Marion Nestle Framework, and the complementarity of the data with the literature survey was assessed (Busetto et al., 2020; Tenny et al., 2024). The key information we identified in our data was (1) interactions between key leaders of FUNSALUD and corporations; (2) corporate participation in FUNSALUD; (3) use of revolving doors between FUNSALUD directors with government positions; (4) narrative review of our results in the form of mechanisms we identified in which corporations might exert their influence in and through FUNSALUD; (5) corporations funding to institutes dedicated to science; and (6) promoting self-regulation. However, the data not found was the granting of incentives (financial, material, or other), which is contemplated within the Marion Nestlé framework.

Results

Identification of actors

Through the documentary analysis of FUNSALUD we were able to identify 22 partners including Guillermo Soberon (former secretary of health—Government sector), who included department store owners such as Jeronimo Arango (Waltmart Mexico), and Nicolas Madahuar (Super Maz); directors of banks such as Carlos Abedrop Davila (bank of the Atlantic); Jose Carral Escalante (Bank of America); and Ruben Aguilar (Banamex), as well as owners and representatives of industrial companies, pharmaceutical firms, and hospitals, and even actors and artists. In Figure 1 we can see a proportion of 21 commercial actors summoned by Guillermo Soberón from his position as minister of health in Mexico. So after finishing his position in the public sector, he became president of the organization.

FUNSALUD's organizational structure is divided into (1) a general associates' meeting (FUNSALUD, 2021a,b), (2) a board of directors (FUNSALUD, 2021a,b), and (3) its human resources (FUNSALUD, 2021a,b). The associates' meeting is divided into (a) founding associates; (b) active associates, who are representatives of corporations, leaders of commercial chambers, lobbyists, and corporate CEOs; (c) honorary associates, many of them former public officials (health sector), directors of foundations, and representatives civil society and (d) institutional associates, mainly from pharmaceutical companies, commercial chambers, and manufacturers of processed foods (Bimbo, Nestlé; see Supplementary material 1). Our sources maintain that FUNSALUD protects the interests of its associates and does not concern itself with the real problem of chronic non-communicable diseases.

> *"It is necessary to review the historic agenda FUNSALUD has adopted, with minimal commitment to risk factors and no meaningful action on recommendations made by institutions such as WHO, PAHO, and FAO, or even the United Nations program against drugs and crime. They seem to serve only the interests of [manufacturers of] junk food, sugar-sweetened beverages, tobacco, and alcohol…" (NGO 1).*

According to FUNSALUD's bylaws, its "governing body" is the General Associates' Meeting, which has four types of partners:

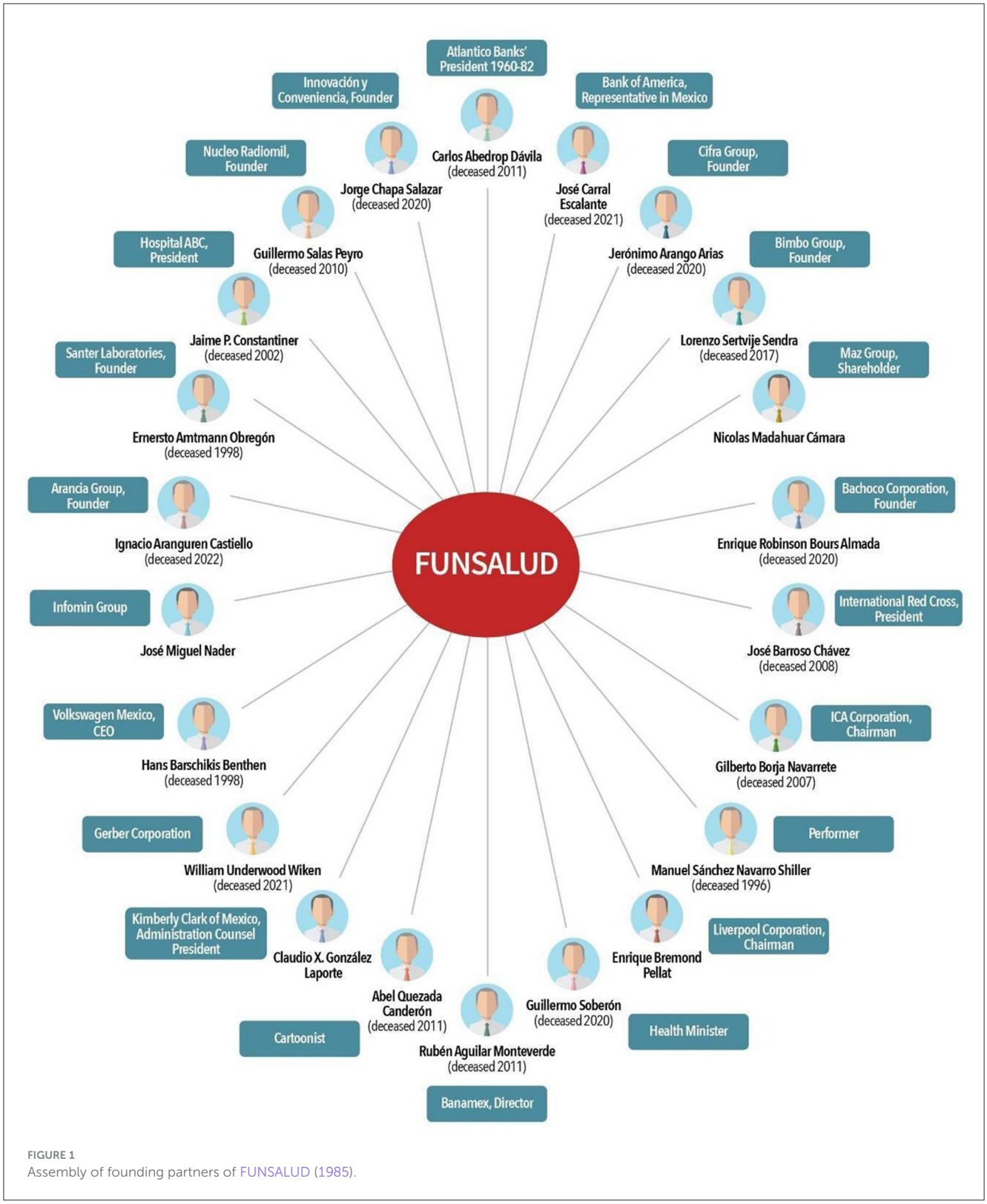

FIGURE 1
Assembly of founding partners of FUNSALUD (1985).

founding, active, honorary, and institutional. From October 2019 to October 2021, the AGA was made up of 79 people who act as founding, active and honorary associates, with 22 companies and 6 chambers and commercial organizations as institutional associates, for a total of 107 members. The existence of the figures of the executive president and chairman of the board explains the relationship between the public and private sectors in FUNSALUD.

Although FUNSALUD has employed 19 high-profile former public servants (revolving doors) since its founding, including five former Ministers of Health named to positions in the AGA, as

president and executive vice-president, or on the Foundation's technical committees, none of the former public officials has been named chairman of the Board of Directors. In addition to being former public officials, the individuals appointed to the AGA are shareholders or hold high-ranking positions in large domestic and international companies in the food, pharmaceutical, health, and financial sectors (see Figure 2). All of these actors were in FUNSALUD before taking a position in the federal or state government; in some cases, like Mercedes Juan, they held positions in both the public and private sectors.

López, held the executive presidency of FUNSALUD from 2009 to 2012, which she resigned to join as secretary of health. The interests of FUNSALUD were immediately placed on the agenda with the proposal for universality of health services. This proposal included having a single fund; financing via general taxes; capitation principle; competition between providers, including the private sector; subrogation of services; and freedom of choice and prioritization of interventions and conditions "in packages" (Ocaranza and Escamilla, 2023).

The reform also initiated the process of decentralizing public health services, delegating functions, authority, and resources to the states. However, at the same time, these changes opened the door for private businesses to get involved in efforts to improve the efficiency and quality of services to expand eligibility to members of the population who lacked social security benefits (Cardozo, 1993; Jaramillo-Cardona, 2007; López and Blanco-Gil, 2017).

Corporate strategies

Revolving doors

FUNSALUD's relevance within the Political System in Mexico is rooted in the roles its members have held in government institutions: 19 high-profile former public officials have joined the Foundation after leaving their posts or have left the government to serve on the AGA or the Board of Directors. Likewise, owners and shareholders of large companies in the domestic and international pharmaceutical, food, and financial sectors have held positions in the country's main public health institutions. Such former officials include three former governors, three former CEOs of Petroleos Mexicanos (Pemex), six former federal cabinet members, five former Ministers of Health, and several heads of major public health organizations (Figure 3).

Of the most emblematic cases, the position of Minister of Health stands out, with five of the last 10 health ministers having passed through FUNSALUD. Guillermo Soberon, who headed the Ministry of Health (Spanish acronym SSA) between 1982 and 1988, and just a year after leaving the SSA, became FUNSALUD's executive president and president emeritus. During his tenure in FUNSALUD, Soberon reached an agreement with Nestlé, to create the Nestlé Fund for Nutrition (Spanish acronym FNN), that is, the Nestlé body to generate scientific evidence in favor of its products. Jesus Kumate Rodriguez, Minister of Health in the period 1988–1994, also joined FUNSALUD years later (2002), holding the position of an honorary member until 2017.

Julio Frenk Mora, who headed the SSA from 2000 to 2006, is another example. Unlike Soberon and Kumate, Frenk Mora passed through the Foundation first, having been invited by Soberon to serve on its Technical Council and as executive vice-president between 1989 and 1995. During his tenure as Health Minister, the Center for Genomic Medicine was created, under the terms of an agreement signed between the SSA, FUNSALUD, the National Autonomous University of Mexico (UNAM), and the National Council on Science and Technology (CONACyT). In addition, as Minister, Frenk implemented the *Seguro Popular* program based on his "Economy and Health" study, which was financed by FUNSALUD.

The next head of the SSA was Mercedes Juan Lopez, who was executive president of FUNSALUD from 2009 to 2012, resigning to take office as Minister of Health for the period 2012–2016. FUNSALUD's interests were embraced almost immediately by Juan Lopez, in proposals such as universal health services, an issue that FUNSALUD had supported for more than 15 years. Jose Narro Robles, Juan Lopez's successor in the SSA, also joined FUNSALUD as an advisor to the Technical Committee in early 2016, even though he was Minister of Health, and held this position until October 2019.

> *"...the decisive influence FUNSALUD has exercised on the appointment of Ministers of Health represents a clear conflict of interest; and if clearer mechanisms were established, I am sure that those functionaries would not have assumed the position of the Ministry of Health..." (Activist).*

From the position of health ministers, they interfered in public health policies such as the anti-tobacco law, the prohibition of advertising aimed at children and adolescents, frontal labeling of food, tax on sugary drinks, among others, they also opened the government to other personalities in the private sphere to protect economic and commercial interests of large corporations.

According to our informants, one of the reasons why FUNSALUD has influenced or interfered in health policies in Mexico is due to the interests of its associates. One of the policies in which FUNSALUD has a significant interest is the reform of the health system; some of our interviewees mentioned that the main commercial entities benefiting from these reforms are pharmaceutical companies, private hospitals, and insurance companies that are part of the organization's network of associates.

On the other hand, some policies such as tobacco control, regulation of alcohol or ultra-processed products, FUNSALUD has had a position against these measures given that at the time industries such as Cigarrera La Moderna (now British American Tobacoo) and Bacardi had an important presence within the organization; However, other corporations, such as Coca-Cola and Nestlé, continue to be represented within FUNSALUD, and these last two examples have been the entities with the greatest interference in regulations such as taxes on sugar-sweetened beverages, front warning labeling; and regulation of advertising.

> *"Instead, there is the interest of corporations to generate an economic benefit and on the other hand there is the intention and obligation as a right, so very frequently we have been able to observe actions and omissions of FUNSALUD that are related to the industry and its representative on different points of the agenda in advance of health protection" (ACA 2).*

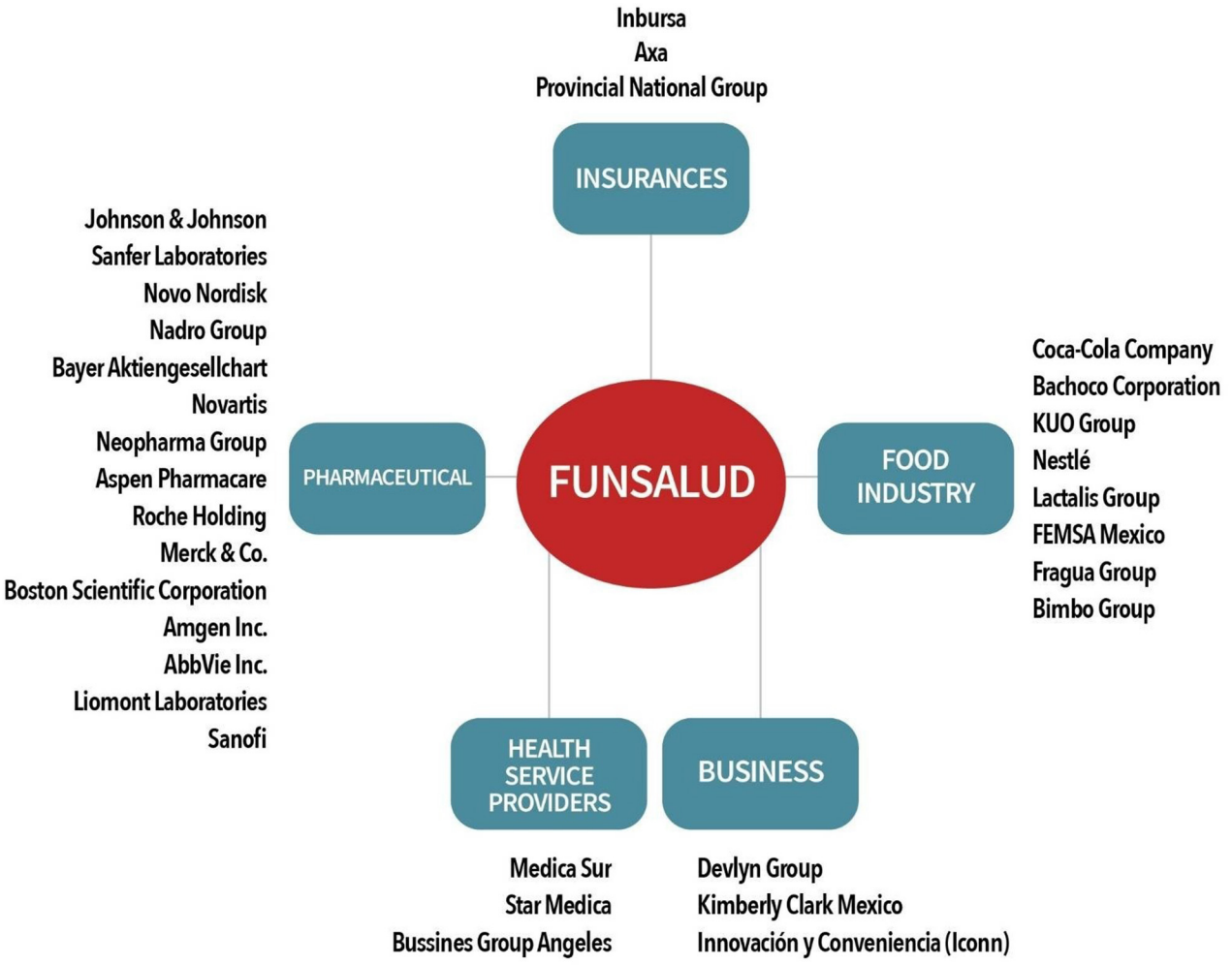

FIGURE 2
Map of corporate relationship in AGA of FUNSALUD (2020, 2021a,b).

Financing of institutes dedicated to science

FUNSALUD has allocated funding to public institutions dedicated to research, specialized publications, academic forums, and collaborative projects. Through access to information requests, we were able to identify 28 agreements between Nestlé and FUNSALUD with INMEGEN between 2005 and 2020 (Supplementary material 2), which underscore the intrinsic relationship between the three entities; agreements signed between INMEGEN and FUNSALUD in March 2010 established that the Foundation would be in charge of managing funds allocated by Nestlé to three programs: Nestlé Scholarships in Nutrigenomics, a research project for the treatment of fermented dairy food, and the administration of the Nestlé Chair in Nutrigenomics.

Nestlé has also actively participated in various public health policies in Mexico, such as the National Crusade against Hunger; the National Strategy for the Prevention of Overweight, Obesity, and Diabetes; and the National Strategy for Breastfeeding. Many of them were designed by FUNSALUD and implemented by key actors aligned with the interests of big corporations, such as Julio Frenk Mora and Mercedes Juan Lopez.

Use of front groups

One of the most widely reported cases involving a front group was the Mexican Observatory of Non-Communicable Diseases (Spanish acronym OMENT), which was created in 2014 to support decision-making on the performance of the National Strategy for the Prevention and Control of Overweight, Obesity, and Diabetes (Spanish acronym ENPCSOD) by Dr. Mercedes Juan, at the time Minister of Health, and Under-minister of Prevention and Health Promotion Dr. Pablo Kuri. This observatory had as its stated purpose the surveillance, monitoring, and implementation of public policy against obesity. However, more than half of its members were representatives of the UPFs industry or financed by organizations including the National Chamber of the Transformation Industry (CANACINTRA), the Confederation of Industrial Chambers (CONCAMIN), the Mexican Council of the Industry of Consumer products (ConMéxico); the Mexican Diabetes Federation (Nestlé, Coca-Cola, Bimbo), We Want Active Mexicans (Femsa Coca-Cola, Bimbo, PepsiCo, Qualitas), the Mexican Academy of Pediatrics (Nestlé); the Mexican Foundation for Health (Nestlé), the Mexican Institute for Competitiveness

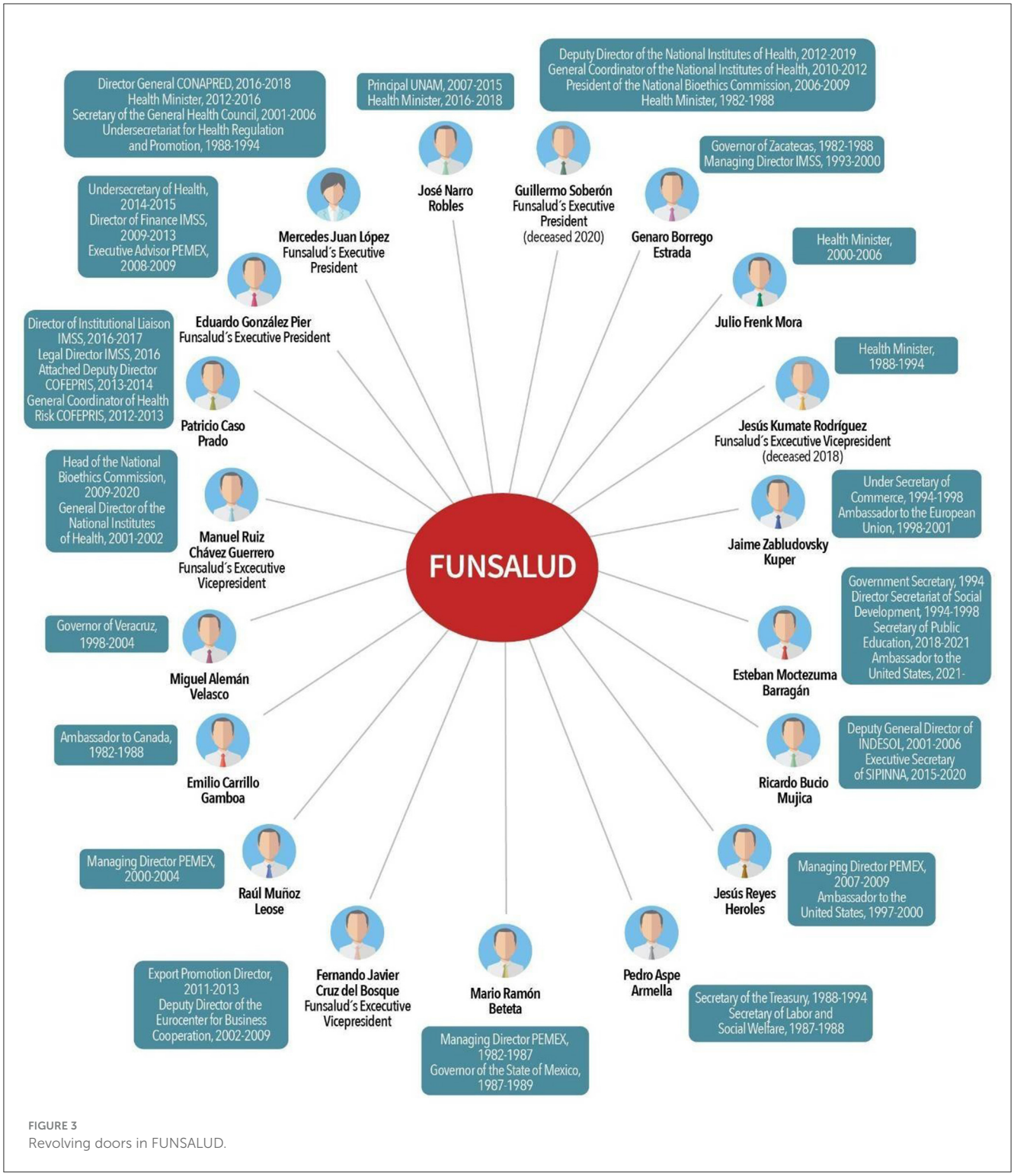

FIGURE 3
Revolving doors in FUNSALUD.

(with Bimbo and ConMéxico represented on its Board of Directors), [and] the Aspen Institute (with representatives of Coca-Cola on its board of directors).

> *"…let us not forget that Dr. Mercedes Juan herself never wanted to make a public commitment in favor of fiscal policies and front labeling of foods to advance in regulation of these products, and even Dr. Jose Narro himself, who sometimes employed rhetoric ostensibly in favor of such policies, in practical terms did absolutely nothing" (Multilateral organization).*

Within the OMENT, FUNSALUD had a space as an advisor, forming a coalition with the industry to block regulatory initiatives such as the front labeling of foods and the regulation of advertising

aimed at children and adolescents. According to a civil society representative free of conflict of interest who was at the OMENT working tables, she mentions:

> *"I highlight my participation in the OMENT, I joined at the time when the possibility of implementing new labeling was being discussed, and the industry did not recognize the term 'ultra-process' which is an interference tactic, these groups opposed labeling included commercial chambers such as ConMexico, and CONCAMIN; and as 'representatives' of civil society were FUNSALUD and the Mexican Diabetes Federation (NGO 3)."*

OMENT lobbied in favor of corporations, and public health initiatives that sought to regulate UPFs and sugar-sweetened beverages were blocked. From this observatory, organizations free of conflict of interest such as the National Institute of Public Health were excluded.

Granting of monetary prizes or other incentives for research

Each year, the Nestlé Fund for Nutrition (FNN), the Salvador Zubirán National Institute of Medical Sciences and Nutrition (INCMNSZ), and the Association of Members of Faculties and Schools of Nutrition (AMFEN) sponsor the "Nutrition Research Awards," which has as its stated aim to "recognize and promote scientific research carried out in Mexico in different areas of nutrition, with emphasis on research aimed at solving health and nutrition problems." From 2015 to 2021, the awards supported 30 research projects in applied science, basic science, and social and cultural environment, in areas including epigenetics, metabolic changes, and individual eating habits as risk factors for the problem of NCDs.

Promoting self-regulation

Starting in 2010, Mexico adopted the use of daily nutritional guidelines (Spanish acronym GDA), a labeling system designed by the food and beverage industry, which was not based on scientific evidence and was difficult to understand even for students of nutrition. Despite widespread criticism and pressure from CSOs to regulate front labeling of food, in 2014 it was declared mandatory by the Federal Commission Against Sanitary Risks (Spanish acronym COFEPRIS), led by Mikel Arriola Peñalosa, and with support from Dr. Mercedes Juan in the SSA. At this time, Patricio Caso Prado was the Counterpart Director-General in COFEPRIS and was responsible for establishing mandatory criteria for GDA labeling (driven by the industry), in collaboration with Matiana Ramirez Aguilar and Juan Leonardo Menes Solis.

The implementation of the GDA label in Mexico was in complicity between Patricio Caso Homologous Director General of COFEPRIS and Coca-Cola; this was documented thanks to an email exchange between both parties; and once Patricio Caso finished his work within COFEPRIS, he joined the ranks of Coca-Cola as Senior Director of Government Affairs. Currently, Patricio Caso represents Coca-Cola in FUNSALUD as a member of the General Assembly of Associates.

During the presidency of Vicente Fox Quesada, with Julio Frenk Mora heading the SSA, Mexico would ratify the Framework Convention for Tobacco Control. However, weeks before, Health Minister Julio Frenk signed an agreement with the tobacco companies (known as the Frenk Agreement) that established guidelines for advertising and imposed a ban on sales of cigarettes to minors, mandating warning labels and barring companies from making investments in products aimed at children. The Frenk agreement did not adhere to the international recommendations of the Framework Convention for Tobacco Control, contained in Article 5.3, which states that no decision-maker should negotiate with the tobacco industry, but instead forced the tobacco companies to contribute to the SSA's Fund for Protection against Catastrophic Expenses (FPGC), stipulating a contribution of "one peso per pack." Such contributions did not continue and were maintained only until 2007 when Julio Frenk resigned from the SSA. Once Frenk finished his administration as head of the health ministry, he worked at the Carso Foundation, which received funds from tobacco companies (revolving doors), and according to our informants, this action cost him the WHO Directorate.

Use of corporate social responsibility

FUNSALUD has collaborated to award corporate social responsibility badges to its members through the Mexican Center for Philanthropy (Spanish acronym CEMEFI), of which FUNSALUD is a founding partner. CEMEFI's programs with the greatest impact include the Socially Responsible Company (Spanish acronym ESR) distinction, and in 2021 alone companies that obtained this certification were in the areas of mining, UPFs, pharmaceutical, automotive, alcoholic beverages, stock trading, health services, universities, convenience stores, gas stations, radio, television, [information] technologies, telecommunications, agrochemicals, hotels, etc. Regarding UPFs (production and distribution), corporations such as Grupo Bimbo, Walmart México, Jugos del Valle, Nestlé México, Oxxo, Grupo Lala, Unilever, FEMSA, and JUMEX, among others, have obtained this ESR distinction, despite evidence that Coca-Cola and Nestlé are the companies that generate the largest amount of plastic waste, in addition to the impact their products have on NCDs.

Discussion

Our literature review and interviews allow us to confirm that FUNSALUD and its associates have exercised a powerful influence on public health policy in the last three decades in Mexico. Through corporate strategies such as lobbying, revolving doors, creation of front groups, cooptation of science, and promotion of self-regulation, they have sought to protect products that are harmful to human health and are considered CDoH. Corporate capture has been a strategy widely used by the private sector in Mexico through FUNSALUD; in this way influences the public agenda, establishing priorities in public health, and interfering in those initiatives that seek to regulate unhealthy products.

FUNSALUD was founded and constituted as an organization of the corporate sector, where pharmaceutical companies; manufacturers of UPFs, sugar-sweetened beverages, commercial milk formula, and alcoholic beverages; insurers; hospitals; banks; laboratories; and medical service providers converge in space for advocacy and lobbying on health policies in Mexico. At a global

level, the ultra-processed and sugar-sweetened beverage industry has used the organization International Life Sciences Institute (ILSI) as a source of scientific evidence (Mialon et al., 2020a,b,c, 2021a,b) and lobbying to interfere in fiscal (tax), regulatory (labeling and advertising), commercial (sale of UPFs), and prohibitive (UPFs in the school context) policy (Pedroza-Tobias et al., 2021). This body has been singled out in cases of conflict of interest and putting commercial interests before public health at the global level (Jacobs, 2019). Recently, the conference on climate change (COP27) held in Egypt in 2022, was pointed out as being conducted with a conflict of interest, given that The Coca-Cola Company was the main sponsor to carry out the meeting, taking into account that the soda is the industry with the highest production of plastic pollution (Allen, 2022). In a recent study, Carriedo et al. (2022) evidenced that the Academy of Nutrition and Dietetics receives funds from corporations such as Nestlé, Pepsico, pharmaceuticals, and agribusiness corporations. This has had implications for DNA pro-corporate stances regardless of whether it goes against the global and public health agenda (Carriedo et al., 2022).

Our findings are consistent with other studies that show revolving doors as one of the many resources corporations use to protect their interests. In the case of FUNSALUD, it was shown that 19 high-level officials such as governors; officials in the areas of trade, social development, government, the oil industry, internal revenue, foreign service, and health have held positions in the foundation. It is worth highlighting the role of the last five Ministers of Health, who have played an important role in interfering with health policies such as tobacco control, front labeling of food, and the tax on sugar-sweetened beverages. An exemplary case of the revolving door phenomenon involves Vicente Fox, a former official of Coca-Cola's Latin America division who later was elected president and during his administration actively worked to help Coca-Cola expand its market (Gómez, 2019); an illustrative case has been Patricio Caso, who was deputy director of COFEPRIS, during the exercise of his work within the institution, allowed the intrusion of Coca Cola in COFEPRIS to influence the front-of-package labeling; and as of 2020, he joined as Senior Director of Government Affairs of the soda company (Velázquez and Rosales, 2021). In Colombia, Coca-Cola collaborated with the Ministry of Health to create education and food support programs for families with children under 2 years of age (Mialon et al., 2020a,b,c). In Brazil, Ecuador, Panama, and Venezuela, the tobacco industry has penetrated governments; and has influenced national policies such as tobacco production, illegal market policies, and economic revival through the marketing of tobacco products (Valdivieso et al., 2021).

Officials linked to FUNSALUD by having held positions such as president, vice president, or honorary adviser have promoted corporate self-regulation from the Ministry of Health. On the one hand, Dr. Julio Frenk was singled out for a conflict of interest with the tobacco industry for signing the "Frenk agreement," which cost him the leadership of the World Health Organization (Madrazo-Lajous and Zambrano-Porras, 2007; Burch et al., 2010). Dr. Mercedes Juan implemented mandatory GDA labeling, which was implemented by Coca-Cola and COFEPRIS (El Poder del Consumidor, 2014), and was instrumental in the creation of the OMENT as an initiative to combat CNCDs. Despite the denouncement that the OMENT represented a conflict of interest because it gave representation to industrial chambers (Ojeda et al., 2020); Jose Narro Robles continued this project notwithstanding the fact that in 2016 he issued a health alert for obesity and diabetes in Mexico (Secretaría de Salud, 2016). A literature review by Chimonas et al. (2021) found that the pharmaceutical industry uses health ministers, decision-makers, and regulatory entities to position their products and thus benefit from health reforms at the global level. Legg et al. (2021) have evidenced the corporate practices of the tobacco industry worldwide, characterized by the widespread use of influence in political circles and with government officials to evade and violate tobacco control legislation. Philip Morris International unsuccessfully sued the Australian and Uruguayan Governments to block the implementation of their laws requiring a series of regulations such as plain packaging and warning labels on tobacco products (Crosbie et al., 2018; MacKenzie et al., 2018).

Finally, we were able to show that FUNSALUD works as an agency that finances scientific organizations to produce evidence on health, in addition to granting financial incentives to researchers or institutions through the FNN through the "Nestlé Research Award" for genomic research projects on molecular, metabolic, and individual risk factors for NCDs. This practice has been documented globally as a strategy to divide the scientific consensus or alter the narrative on health issues. In the United States, it was shown that Coca-Cola financed the organization Global Energy Balance Network to emphasize physical inactivity as the major problem causing overweight, obesity, and diabetes in the country (O'Connor, 2015; Scrinis, 2020). On the other hand, Legg et al. (2021) have shown that Phillip Morris is the main donor of the Foundation for a Smoke-Free World (Legg et al., 2021), an organization with the stated objective of "helping to stop smoking traditional tobacco and focusing efforts on the promotion of vaping" (Foundation for a Smoke-Free World, 2022).

This study demonstrates how the Mexican Health Foundation has exercised outsized influence on health policy in Mexico, putting the commercial interests of its associates before public health. Through various strategies, it has hijacked the national health agenda by placing its operatives in the Ministry of Health, where they have worked to block various initiatives seeking to regulate products that are harmful to the Mexican population, such as tobacco, UPFs, and sugar-sweetened beverages.

We could not access the financial issues of the foundation, because the research was carried out during the pandemic, which made it difficult to access economic information. This is important since we do not know the contributions of corporations to FUNSALUD.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

CT carried out the corresponding research and participated in the design of the study and in the writing of the manuscript. AC

participated in the design of the study and in the writing and critical reading of the manuscript. JZ participated in the writing and critical reading of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

CT, AC, and JZ were employed by El Poder del Consumidor.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpos.2024.958854/full#supplementary-material

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The pharmaceutical suitcase trade and the need for multisectoral regulation-unproven COVID-19 (Ivermectin and HCQ remedies unmask an insidious health danger in a Caribbean Island)

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This article seeks to highlight an aspect of the illegal pharmaceutical trade in the Caribbean. With the advent of COVID-19 there has been a shortage of a number of drugs in the formal sector. This is largely due to restrictions on foreign exchange, importation delays and sensationalized reporting of unrecommended drugs having a curative effect on COVID-19 patients. This article examines the issue of "the informal suitcase trading" of these drugs. It posits a need for a collaborative and multi-sectoral approach to mitigate the negative effects of the practice on health, trade and national security.

KEYWORDS

suitcase trade, pharmaceutical regulation, health in all policy, public health, Ivermectin

Defining the issue

The volume of international trade in regulated pharmaceuticals has seen a substantial increase over the past two decades, making it one of the most profitable industries in the global economy. This trend is forecasted to grow exponentially making this industry increasingly attractive and lucrative. This is illustrated in Figure 1, taken from the S&P global trade website (1).

Suitcase trade: the unspoken component of pharmaceuticals

The International Monetary Fund recognizes suitcase trading as "a form of unrecorded or under-recorded international transaction in goods that is currently existent at the edges of formal trade." Suitcase traders benefit from avoidance of customs duties, tariffs, freight charges and regulatory oversight in the recipient country. The unrecorded items are entered and sold at

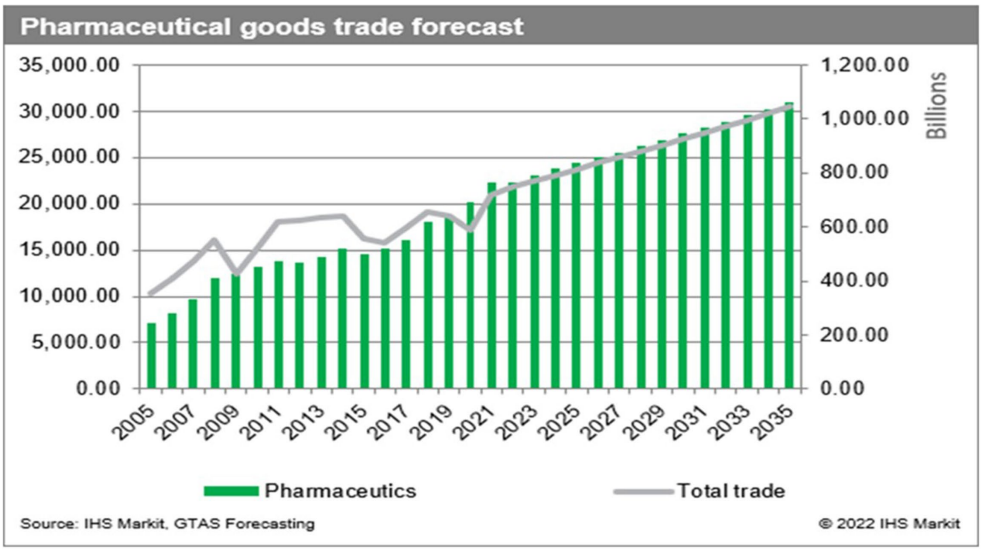

FIGURE 1
Pharaceutical goods trade forecast 2022.

market or above market prices and also evade imposts. Most importantly, they escape the oversight of regulatory processes (2). Compared to the established trade patterns illustrated in Figure 1, little is known about the volume of trade generated by this informal sector and only rough estimates can be discerned by assessing movement of counterfeit medication. Suitcase trading also includes authentic medications which enter by irregular and non-regulated means.

This form of trade is considered opportunistic since it is dependent on the rigidity of the receiving markets where a demand for the goods, coupled with anomalies in regulatory processes provide informal traders with an unfair economic advantage (2). The suitcase trading of pharmaceuticals takes advantage of loose regulatory and economic loopholes as well as gaps in enforcement. This phenomenon was highlighted in Trinidad and Tobago by the Minister of Health in recent years in the face of Ivermectin during the COVID-19 pandemic (3) but has been long recognized in the literature due to its potentiation of counterfeiting (4), illicit use (5) and illegal trade disruption (6). This issue came surging to the fore again in 2023 with news outlets reporting police exercises that seized hundreds of thousands of United States dollars (USD) worth of unregistered pharmaceuticals from the bonds and warehouses in Trinidad and Tobago (7, 8). From the health perspective, the use of unregistered medication poses a potential risk to patient safety since its effect may be unpredictable and even unsafe. Health systems therefore require a robust public health education thrust to sensitize potential buyers to the risks (9). Unregistered medication also results in a range of non-health effects extending to several sectors including trade and national security. A multi-sectoral approach is therefore required for mitigation (10).

Root causes of the problem

Ayduin et al. in a regional analysis of the economic impact of the suitcase trade on formal trade explore several reasons for its existence and propagation. While primarily taken in the context of its impact on foreign trade, the effect on the pharmaceutical industry, and by extension health, is noteworthy (11). The first context considers the suitcase trade as a by-product of global trade in an almost disruptive innovation to normal practices. This speaks to the change in consumption tendencies in populations and the evolution of providers who seek to fill new gaps between supply and demand (12). In the health context, this is manifested as drug shortages where regulated distributors are unable to keep pace with demand. This can result in disproportionate price differentials between regulated and unregulated products. It has also been noted that highly controlled pharmaceutical products potentially propagate unregulated trade making it highly illicit. The recent worldwide scourge of opiate addiction is one such example and has created another dimension of suitcase trade where products have been confiscated on their way from the Global South to the Global North (13, 14). The unregulated trade therefore is not restricted to developing and transition states. It provides a platform for pharmaceuticals to enter the more regulated markets in the metropolitan countries, as recently seen in the arrest and detention of two visiting British nationals for possession of hundreds of bottles of Codeine linctus stored at paid accommodation facilities. It highlights the two-way element of the trade and the entry of restricted pharmaceuticals into states with more advanced capacity and detection mechanisms (15).

The second context considers the evolution of suitcase trading in transition economies where countries with high expenditure on non-market items such as defense can create a gap in supply for routine products which ultimately drives up prices (16). In the health sectors of the Caribbean, halted or disrupted importation may decrease the availability of certain drugs to vulnerable groups. The Caribbean does not historically engage in high expenditures on defense and the regional Gross Domestic Expenditures are considerably less than partners in the Global North. The Island States nevertheless face growing fiscal restraints on health in the post pandemic era. Resultantly, health sectors are subject to declining budgetary allocations for some pharmaceuticals and medical devices leading to decreased supplies and disproportionate pricing in retail markets.

The third context is the cultural dynamic of the suitcase trade where the unregulated suppliers in communities are considered an integral part of the supply chain (17). The rampant and unrestricted influence of social media has had a significant impact on health matters in the Caribbean as was exemplified throughout the pandemic with vaccination (18). In the context of peddled misinformation, this is impactful since unregulated traders can be perceived as a panacea to gaps in health systems.

COVID-19: Ivermectin and hydroxychloroquine (HCQ)

Ivermectin, a drug traditionally utilized for parasitic infections, came into the spotlight in 2019 as the world sought an effective therapeutic for COVID-19. The Food and Drug Administration of the United States constantly rebutted claims that it was effective and repeatedly underscored that no approvals were granted for its use in the United States or the Caribbean (19, 20). Counterproductively, certain sectors of society held tightly to ill-founded and unscientific information regarding its efficacy which spurned its global demand. In this regard, the stage had been set, with legal barriers to importation and a demand in the local market to foster the suitcase trade of Ivermectin and Hydroxychloroquine (HCQ) in Trinidad and Tobago as demand outstripped market supply (21).

During the COVID-19 pandemic in Trinidad and Tobago, unethical practices in healthcare became rampant. Medications like Ivermectin, not officially available in the country, were smuggled and sold at inflated prices. Hydroxychloroquine, typically prescribed for autoimmune diseases, was hoarded for COVID-19 treatment, leaving regular patients without their necessary medication. A senior physician recounted a case where a colleague, despite having minimal COVID-19 symptoms, was prescribed an unnecessary array of drugs including Intravenous Meropenem, Azithromycin, Hydroxychloroquine, and Ivermectin, none of which were appropriate for treating COVID-19. These actions were fueled by misinformation spread through social and mainstream media, sidelining scientific evidence. The pandemic saw the rise of unqualified individuals presenting themselves as experts, promoting ineffective treatments like high-dose Vitamin C, unnecessary medications and discrediting vaccines. The integrity of journalism in reporting accurate information eroded, while financial motives further compromised healthcare providers' ethical standards (22).

Based on a newspaper report in 2020, the local lupus advocacy group expressed concerns about the unavailability of the drug. Due to rumors of its benefits in the treatment of COVID-19, pharmacy dealers engaged in price gouging and tripled the price from $3.20TTD to $10TTD.The result was predictable panic buying which led to an exhaustion of stock in the private sector. Patients afflicted with diseases for which HCQ was the recommended treatment, were unable to access it. There were also suspicions of illegal brands on the market which could not be verified (3, 23).

Based on Ayudin's review article, in the case of high demand for unproven remedies during the COVID-19 pandemic, the clear precipitants are demonstrated where an astronomical increase in demand well outstripped supply which allowed unregulated suppliers who had gained public trust, to flourish. This unregulated supply stream proved costly to buyers and disadvantaged some segments of the population who were unable to afford the drug and may have caused medical complications.

The surge in demand for medications like Hydroxychloroquine, driven by unsubstantiated claims of its effectiveness against the virus led to panic buying and stockpiling, causing shortages that affected patients who rely on the drug for conditions like rheumatoid arthritis and lupus. Global responses to these shortages included regulatory measures such as export bans by the NHS in the UK and restrictions in India to safeguard domestic supply, exacerbating shortages worldwide. Concerns also arose over the availability of active pharmaceutical ingredients (APIs) from China and India, crucial for global drug manufacturing. In Trinidad and Tobago, price hikes and hoarding of medications underscored fears of supply disruptions, particularly for chronic diseases. Regulatory bodies and health officials urged restraint and responsible prescribing to manage these challenges during the pandemic (24).

Hydroxychloroquine, Azithromycin, and Ivermectin gained widespread attention in Latin America and the Caribbean (LAC) during the early days of the pandemic. Social media played a significant role in disseminating misinformation and promoting these unproven treatments, contributing to a broader "infodemic" in the region. Countries like Peru and Costa Rica faced particularly high risks of misinformation spreading, correlating with increased COVID-19 mortality rates. This phenomenon highlighted the challenge of combating false narratives and maintaining adherence to proven public health strategies amidst a global health crisis (25).

The dangers and threats of the practice

The World Health Organization's 2022 publication on Therapeutics and COVID-19 recommended against the use of Ivermectin outside of research settings and also strongly against the use of HCQ for any treatment of COVID-19 (26). The result of acquisition of pharmaceuticals other than by regulated and registered mechanisms include the injection of counterfeit medications into markets, encouraging abuse and misuse of certain drug classes, together with the creation of anti-competitive behaviors. These factors are disadvantageous to market providers who operate within the legal remit (2). This is particularly relevant to the pharmacy markets in Trinidad and Tobago where the effects have been documented and placed in the public domain (3). These factors may have had the effect of suppressing growth of small and medium enterprises which act within the legal parameters of the healthcare trade, and by extension, block equity access to service providers who depend on these enterprises for economic activity.

According to the Food and Drug Administration (FDA) of the United States of America, the unregulated procurement of pharmaceuticals in a country, such as through online purchases, significantly increases the likelihood of the entry of counterfeit medications into the market. It notes that this potentially harmful activity should be counter-measured through monitoring and legal consequences for those found in breach of regulations (27). The potentially serious health effects are echoed by the European regulators who cite a wide spectrum of medication categories as being vulnerable to counterfeiting, but notes significant efforts by the European Police Agencies to curb this problem (28). The World Health Organization recognizes the significant global challenges posed by counterfeit medical products and medication and through its Member States Mechanism on Substandard and Falsified Medical Products, provides a forum for convention, coordination and active programs to allow multilateral mechanisms to counter what it calls a "pervasive problem" (29).

The unregulated presence of Ivermectin and Hydroxychloroquine through the suitcase trade in Trinidad & Tobago can pose potentially

serious public health risks which include counterfeit pharmaceuticals, drug interactions, adverse drug events and improper handling and disposal of medication. These clinical hazards support the need for strengthening pharmaceutical regulations and empowering professionals in the field (30). This is relevant in a global health environment where even drugs that have been legally imported sometimes fail medical standards with extreme detriment to consumers such as the case of contaminated cough syrups in India in 2023 (31). It is therefore imperative that all medical products and drugs be subject to quality assurance testing; the suitcase trade bypasses this step with potentially devastating effect.

The legislative landscape

As it stands, there is sufficient legislative teeth to address the scourge of the illicit entry of pharmaceutical drugs into Trinidad and Tobago. There is a wide spectrum of enforcement powers under the Food and Drugs Act and Customs Act of Trinidad and Tobago. The Food and Drugs Act grants the inspectors power to evaluate and examine imported pharmaceuticals at any time (32). The Customs Act confers the power to demand information and seize articles in circumstances where requisite legal protocols are violated (33). There are also like provisions in the Barbados Customs Act (34) and the Jamaica Customs Act (35). With adequate laws in place, the authors posit that the problem appears to be with the enforcement of the law and the absence of a collaborative multi-sectoral approach. With increased capacity of the regulatory bodies, proper training of Customs and Excise Officers and law enforcement agencies in national security, this problem can be effectively addressed and the negative effects mitigated.

The need for multisectoral regulation

To safeguard the public, there are some multi-sectoral actions that the policy makers and relevant regional bodies can consider.

1. Education – the public, healthcare professionals and officers at ports of entry need to be made aware of the existence of this trade and its potential for grave effects on public health. Public Health Education should continue to be a focus as a mitigation strategy.
2. Legal and regulatory frameworks –The capacity of the Drug Inspectorate needs strengthening to include ready attendance at points of entry and to conduct audits on pharmacies and doctors' offices to identify breaches. There should be a dedicated cadre of trained personnel to enforce the law and prosecute offenders.
3. Trade and Industry- Standardization of drug prices across the Caribbean may reduce the large differential which facilitates this trade. Multilateral organizations such as the Caribbean Community (CARICOM) with its harmonized trade regimen must play a greater role in the exercise of its trade regulatory functions. This would allow greater bargaining and advocacy power in the international political economy.
4. Finance- Governments to purchase drugs which, although not profitable, are required in small volumes in the market. This would allow the needs of vulnerable populations to be met, ensuring the provision of the required therapeutics.
5. Health- Drug registration processes need to be more efficient. Health ministries should continue to be the centralized governance overseer for pharmaceuticals. An expanded list of approved drugs would foster competition and is likely to drive down prices.
6. Information Technology- The recognition of prescribing, utilization and supply chains of pharmaceuticals should be driven and empowered by information technology. This allows the governing structures to have awareness of gaps and potential breaches.
7. National Security- With its suite of law enforcement and detection powers, there is need for scanning and detection equipment at points of entry and borders and greater on-the-spot capacity to conduct quality assurance of medication.

Conclusion

The examples of Ivermectin and HCQ during the pandemic are two of many in the informal and unregulated suitcase trade. The trade has the potential to cause serious harm to population health and as such requires a collaborative approach to mitigation. There must be sensitization of policy makers to the root causes of the problem and the necessity for multisectoral collaboration for mitigation. The over focus on third-party certification, verification and paper compliance without local capacity building, both in terms of equipment and human resource can do little to arrest the scourge. The authors believe that this is an underexplored topic that would benefit from further research involving pharmacists, the public and other stakeholders. It is only when this collaborative multisectoral approach is meaningfully undertaken that the deleterious effects of the suitcase trade in pharmaceuticals can be mitigated.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

SM: Conceptualization, Writing – original draft. DD: Writing – original draft. RH: Writing – review & editing. KR: Writing – review & editing. AR: Writing – original draft. DF: Writing – review & editing. SP: Writing – original draft.

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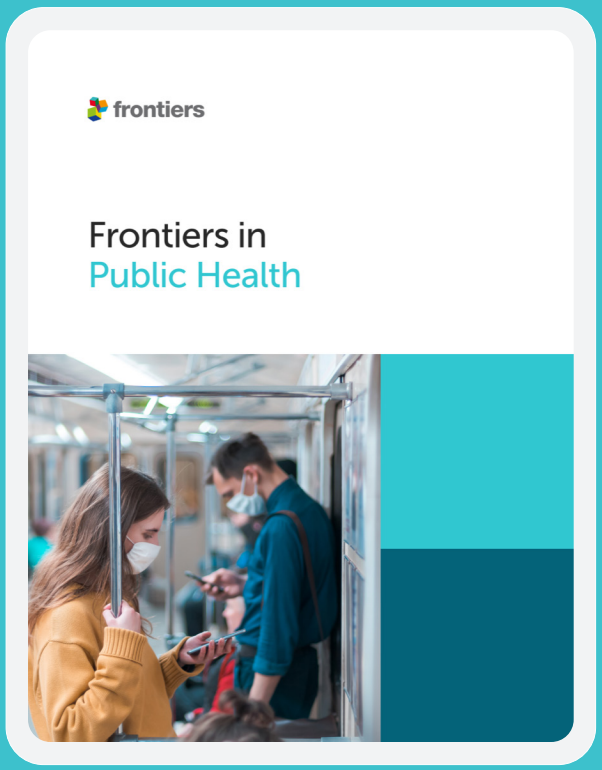

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