







REVIEW

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Outcomes of implementing the International Code of Marketing of Breast-milk Substitutes as national laws: a systematic review

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Abstract

Background The International Code of Marketing of Breast-milk Substitutes, or ‘the Code’, sets standards to regulate marketing of commercial milk formula (CMF) to protect breastfeeding. World Health Organization member states are advised to legislate the Code into national law, but understanding of its implementation outcomes is limited. This systematic review aimed to examine implementation outcomes in countries implementing the Code as national law.

Methods We systematically searched five academic databases in September 2022 for articles published in English from 1982 to 2022. We double-screened titles/abstracts and then full texts for eligible articles reporting implementation outcomes of the Code in 144 eligible countries. We used the Mixed Methods Appraisal Tool for quality assessment and synthesized data thematically. We applied the Proctor et al. framework to guide synthesis of implementation outcomes, organizing our findings according to its taxonomy.

Results We included 60 eligible articles of the 12,075 screened, spanning 28 countries. Fifty-seven articles focused on legal compliance, 5 on acceptability, and 1 on feasibility. Compliance was assessed across multiple sources, including mothers, health workers, media, points of sale, and product labels. Maternal exposure to CMF promotion remained widespread, with reports of mothers receiving free samples and coupons, and encountering media advertisements. Compliance of health workers varied across countries, with many reporting contact with CMF companies despite legal prohibitions. Public hospitals generally showed better adherence to the national law than private ones. While implementing the Code as national law effectively regulated the promotion of CMF for infants aged 0–12 months in public settings and in the media, it remains insufficient in addressing the promotion of unregulated products like growing-up milk, which are often marketed through emerging strategies such as cross-promotion and digital advertising. Point-of-sales compliance was inconsistent, with many countries reporting non-compliant price-related promotions.

Conclusion To enhance legal compliance, robust monitoring and reporting systems are necessary. Utilizing technology-assisted solutions for monitoring compliance can be an option for countries with limited human

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resources. Adequate training for health workers and communication strategies targeting shop managers about national law are also essential in enhancing their acceptability and compliance.

Keywords Breastfeeding, Commercial milk formula, Infant formula, International Code of Marketing of Breast-milk Substitutes, Implementation, Compliance, National legislation

Background

World Health Organization (WHO) and United Nations Children's Fund (UNICEF) recommend that all children should be optimally breastfed, initially within an hour of birth, exclusively to six months, and continually up to 2 years or beyond with appropriate complementary feeding [1]. Optimal breastfeeding offers incomparable short and long-term health benefits, socioeconomic return, and positive environmental impacts [2, 3]. However, despite the benefits, less than half of infants globally were optimally breastfed as of 2021 [1].

Commercial milk formula (CMF) marketing competes with breastfeeding and contributes to a low global breastfeeding rate [4–8], as CMF companies may use misleading and predatory marketing tactics targeting parents and health workers to alter social perceptions about infant and young child feeding and create conditions that facilitate CMF sales and consumption [3, 5, 9]. To protect breastfeeding from CMF marketing, the International Code of Marketing of Breast-milk Substitutes was adopted in 1981 with subsequent resolutions adopted in later years, referred to as 'the Code,' by the World Health Assembly [10]. The Code sets standards for restricting the promotion of CMF for children aged 0–36 months, feeding bottles, and teats, for the public and in health-care settings, and sets standards for product labeling to not discourage breastfeeding [11]. The Code extends to commercially produced complementary foods (CPCF) for children aged 6–36 months, recommending that their marketing messages always include statements advising against feeding them before 6 months and emphasizing the need for continued breastfeeding for 2 years [12].

Existing evidence suggests that implementation of the Code is necessary to improve breastfeeding practices, along with other interventions including the Baby-Friendly Hospital Initiative (BFHI) and maternity protection including paid maternity leave [8, 13, 14]. While CMF consumption has continually increased globally [8, 15], WHO and UNICEF recommended countries to legislate the Code into national laws and establish monitoring mechanisms to ensure compliance.

However, a study reported that the translation and implementation of the Code into national measures pose challenges in reality [16], so outcomes may not always align with the Code's intentions. Moreover, a scoping review conducted in 2022, four decades following the Code adoption, indicated that aggressive CMF

marketing, in violation of the Code, persists globally, even in countries with legal measures in place [17].

Currently, 144 countries have adopted the Code into national law, with 32 of them having laws that substantially align with the Code [18]. Yet, relatively little is known about the implementation outcomes of the Code in these countries. This systematic review therefore aimed to synthesize evidence on outcomes of the Code implementation in countries where the Code has been legislated as national law, hereinafter referred to as 'national law'.

Methods

Study design

We conducted a systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines [19]. Our research question was 'What are the outcomes of implementing the national law to regulate CMF promotions in countries where the Code was legislated into law?' We defined implementation outcomes using Proctor et al.'s eight-category conceptualization [20] (see Table 1). We selected the Proctor et al. framework for its comprehensive approach to evaluating implementation outcomes. Given the unique context of implementing national law at the country level, which requires rapid nationwide adoption post-enactment, we adapted the terminology to prioritize 'compliance' over original terms such as 'fidelity' or 'adherence'. This is because compliance in this context refers to adherence to specific legal requirements, whereas adherence encompasses both mandatory regulations and voluntary practices that align with guidelines or recommendations. Fidelity, on the other hand, involves faithfulness to the original design and intent of an intervention. Our exploration of compliance across different types was driven by the Code's regulatory complexity and the diverse stakeholders involved. This adaptation better reflects the regulatory nature of the Code as a national law.

Information sources and search strategy

In September 2022, we searched five academic literature databases, i.e., Medline via PubMed [21], Embase [22], CINAHL [23], Scopus [24], and Web of Science [25], using no filters and a search string based on the two core concepts: (1) 'The International Code of Marketing of Breast-milk Substitutes' using keywords i.e. milk substitutes, infant food, and infant formula; and

Table 1 Operational definition of each implementation outcome adapted from Proctor et al

Outcome	Operational Definition
Appropriateness	The perceived fit of the national law to address a problem of CMF marketing. Other terms: relevance.
Feasibility	The extent to which the national law or related policy can be successfully carried out within a particular setting or organization. Other terms: suitability for every use or practicality.
Adoption	Uptake or intention to employ actions required by a national law
Acceptability	The perception among implementation stakeholders that national law and related policy are agreeable, palatable, or satisfactory, is based on the stakeholder's knowledge of or direct experience with various dimensions of the national law to be implemented, such as its content, complexity, or comfort.
Compliance	The degree to which the national law was implemented according to its legal provisions or as intended by stakeholders. The original term is fidelity with alternative terms such as adherence.
Penetration	The integration of actions/practices required by the national law within a setting and its subsystem.
Sustainability	The extent to which a newly implemented national law is maintained, institutionalized, or integrated into a targeted setting's ongoing operation or culture.
Implementation cost	The cost impact of an implementation effort depends on three aspects: the costs of delivering a policy or intervention, the implementation strategies, and the location of setting delivered such policy.

Source: [20]

(2)'Implementation' using keywords i.e. implementation, enforcement and restriction. See Supplementary Table 1, Additional File 1 for details of the search strings.

Eligibility criteria

We included all articles describing the outcomes of implementing the national law, as of September 2022, following the PICOS framework (Table 2).

Selection

We imported 12,075 potential sources into EndNote and removed duplicates. CT and NC then independently screened titles and abstracts, using Covidence, with a Kappa statistic of agreement of 74% and disagreements resolved by reviewer discussion. CT and NC then double-screened the remaining 355 full texts against eligibility criteria, providing a total of 60. No automation tools were used.

Data extraction

We developed a metadata form in Excel to extract data on study characteristics (i.e. year, authors, country, type of study site, study design, methods, sample size, and participant characteristics) and the quantitative data (i.e. percentage of violation reported, and number of mothers exposed to CMF marketing). The qualitative data, i.e. details of national law, implementation process, and experiences or perspectives of participants, were captured narratively in Microsoft Word. CT and NC extracted data independently, with discrepancies resolved through discussion with YE and MC. After data extraction was completed, each article was deductively coded, based on its findings, into 1 of 8 implementation outcomes using Proctor and Colleagues' eight-category concepts.

Data synthesis

We synthesized the extracted data using two approaches, depending on data types. For quantitative data, we grouped similar reported data, presented it descriptively including counts, frequency, and percentages, and listed it in the tables. For qualitative data, we applied a thematic synthesis method [26], which involves the three steps as follows: (1) line-by-line coding of the extracted data from each article (2) organization of the coded data into descriptive themes to capture key issues, and (3) development of analytical themes to generate overarching insights. We choose thematic synthesis for its ability to systematically analyze and interpret qualitative data from multiple articles.

Quality assessment

CT and NC independently assessed the quality of included articles using the Mixed Methods Appraisal Tool (MMAT) version 2018 [27] which contains 15 questions with specific criteria for assessing qualitative, quantitative, and mixed method studies. Overall, we found a low to moderate risk of bias. Supplementary Table 2, Additional File 1 shows findings of quality assessment for each article by 15 questions.

Results

Article characteristics

Figure 1 shows the PRISMA flow diagram of 60 eligible articles of 12,075 potential sources identified in searches.

From a total of 60 articles, all were published between 1990 and 2022, with 53 (88%) published since 2011, three decades after the Code was adopted internationally in 1981. More than half (55%) were quantitative cross-sectional studies. These articles covered 28 countries across six WHO regions (see Supplementary Table 3, Additional File 1), with most countries from the African region, and 71% of them were middle-income countries. The

Table 2 Eligibility criteria for included articles

PICOS	Inclusion criteria	Exclusion criteria
Participants	General population	Populations with specific conditions for breastfeeding or Code implementation (e.g., women living with HIV; orphaned or sick children who require special formula use).
Intervention	National laws imposing restrictions on the marketing of commercial milk formula (CMF), commercially produced complementary foods (CPCF), bottles, and teats following the scope of the Code, including: <ol style="list-style-type: none"> 1) CMF advertisement, 2) CMF promotions in public, 3) CMF promotions in health facilities, 4) Engagement between CMF companies and the health sector, 5) CMF labeling, 6) Promotion of CPCF, bottles, and teats. 	National laws that regulate CMF products but are not specific to the Code, such as safety measures for CMF production and distribution, or ingredients requirement of CMF.
Comparators	Not applicable, as we aimed to summarize available evidence on national law implementation and thus included all study types primarily observational studies.	NA
Outcomes	The implementation outcomes of the national law adopted from the Code.	Other aspects that are relevant to the Code i.e. the Code's history and interpretation, the formulation or adoption of the Code as national policy or law at the country level, or the progress of the Code implementation at the regional/global level
Settings	Any of 144 countries, as listed by WHO in 2022 [18], with national law adopted from the Code	50 countries, as listed by WHO in 2022, with no legal measures adopted from the Code.
Language	Published in English	Published in any other languages.
Year	Published from 1982, as the Code was first adopted in May 1981.	Published before 1982.
Publication type	All study designs and publication types for which full texts were accessible.	Studies that did not include full texts (e.g., conference abstracts, posters), or for which they were unobtainable, or that did not include primary data collection (e.g. commentaries, editorials).

Note: NA means Not applicable

distribution of articles across countries with different levels of legal provisions was fairly even (Table 3).

Implementation outcomes

Most articles (95%) reported on compliance with 5 focusing on acceptability and 1 on feasibility, but none covered the other 5 implementation outcomes (i.e. adoption, sustainability, appropriateness, penetration, and implementation cost), see Supplementary Table 4, Additional File 1. We synthesized the findings under these three implementation outcomes: (1) compliance; (2) acceptability; and (3) feasibility.

Compliance

Fifty-seven articles reported compliance with the national law and/or the Code, primarily using quantitative methods, from five sources: mothers ($n=25$), health workers ($n=22$), media ($n=22$), point-of-sale ($n=15$), and product labels ($n=13$), see Supplementary Table 5, Additional File 1. Articles published since 2018, tended to assess compliance using the NetCode protocol recommended by WHO, UNICEF, and global partners in 2017 [28]. Overall findings indicated good compliance with the national law for the promotion of regulated products, particularly the promotion of CMF for infants aged 0–12 months in the media [29–37]. However, promotions for

unregulated products, especially growing-up milk, were observed in the media and by mothers across countries [29, 31, 32, 34, 35, 38, 39]. Some degree of non-compliance with the law was observed at the point of sale [39–43], and in healthcare settings where the engagement of CMF industries with health workers was reported [44, 45]. Moreover, product labels with at least one non-compliance with the Code were reported across countries [29, 30, 33, 43, 46–48]. Further elaboration of compliance from each source is described below.

Compliance assessed through mothers

Most articles ($n=25$) mentioning compliance with national law described the assessment of maternal exposure to CMF promotions, indicating the percentage of mothers exposed to various CMF marketing strategies [29, 30, 33, 43, 46, 47, 49–67]. Widespread exposure was reported, with the most common experiences being receipt of free samples and coupons and exposure to CMF advertising in media. Maternal exposure to advice to use CMF for infants or young children from health workers, friends, and others was also commonly observed and reported, although this kind of exposure is not in violation of the law/the Code. While most articles did not provide a specific percentage of non-compliant promotions with national law, the level of maternal exposure

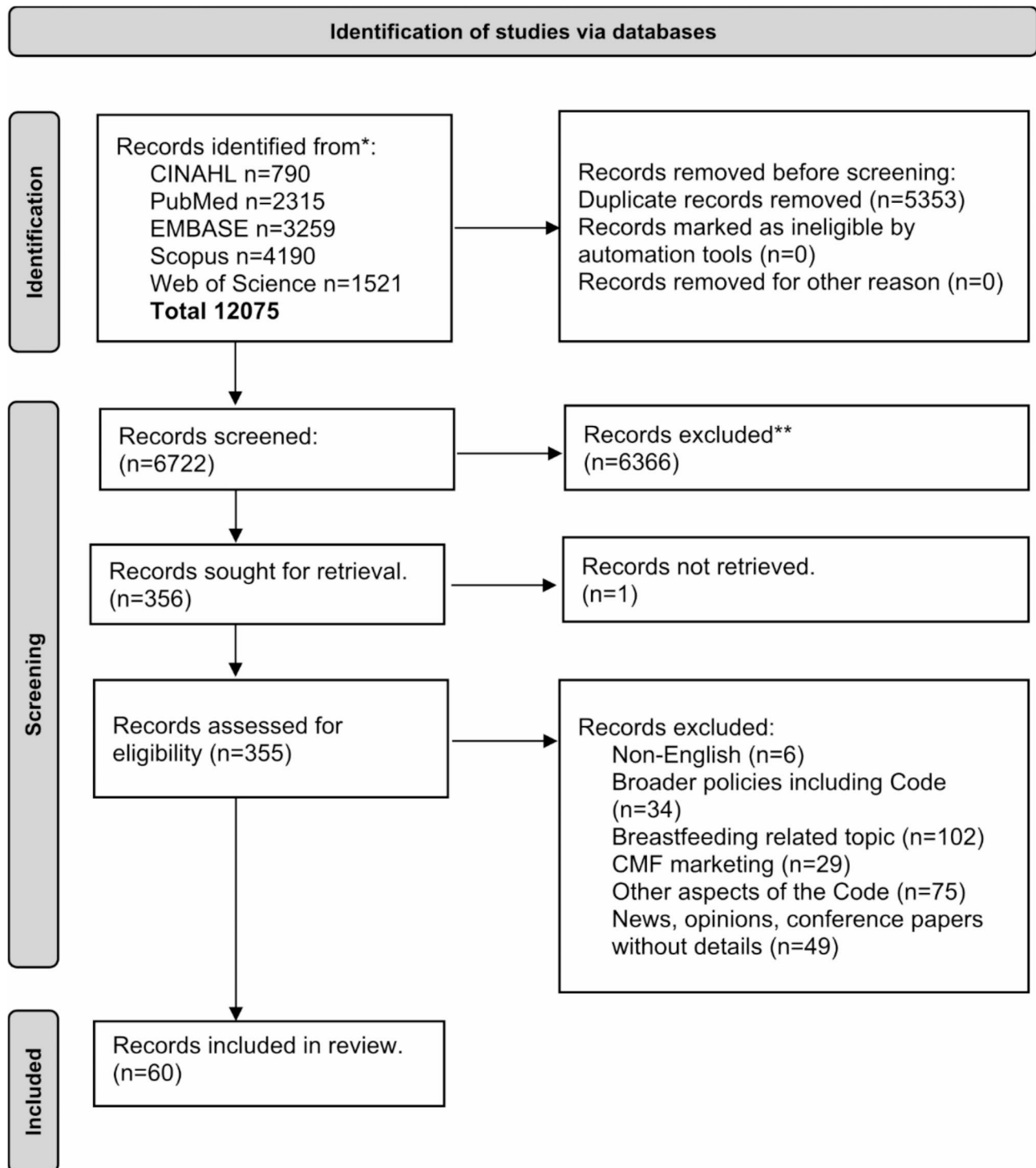


Fig. 1 PRISMA flow diagram

varied significantly across countries, regardless of the robustness of legal provisions included in the Law (see Supplementary Table 6, Additional File 1). Qualitative findings from South Africa [58, 59] revealed that mothers reported no observation of infant formula promotion, but noted various promotions for other unregulated CMFs

that were appealing, and the packaging influenced their perceptions of the product quality. Similar patterns were observed in Australia, where mothers perceived growing-up milk advertisements as promoting infant formula and tended to believe health claims on the label [56].

Table 3 Characteristics of included articles and countries covered

A. Characteristics of all included articles	N=60	%
Specific implementation outcomes ^(a)		
- Feasibility	1	1.7
- Acceptability	5	8.3
- Compliance	57	95.0
Year of publication		
• 1990–2000	4	6.7
• 2001–2010	3	5.0
• 2011–2020	30	50.0
• 2021–2022 (last 2 years)	23	38.3
Study design		
• Quantitative study	33	55.0
• Qualitative study	19	31.7
• Mixed method	8	13.3
Study sites		
• Multiple countries	7	11.7
• Single country	53	88.3
B. Characteristics of study countries covered in the included articles	N=28	(%)
WHO regions		
• African	8	28.6
• Americas	5	17.9
• Eastern Mediterranean	1	3.6
• European	3	10.7
• South-East Asia	6	21.4
• Western Pacific	5	17.9
Income		
• Low-income country	2	7.1
• Middle-income country	20	71.4
• High-income country	6	21.4
Status of legal provisions in national law as rated by WHO [18]		
• Weak (included some provisions of the Code)	9	32.1
• Moderate (included many provisions of the Code)	10	35.7
• Strong (included most provisions of the Code)	9	32.1

Note: (°) one article can have more than one implementation outcome

Compliance assessed through health workers and in healthcare settings

A total of 22 studies reported health workers' awareness of the national law existence, their compliance with national law and exposure to CMF promotion, and health facilities' compliance [29, 30, 33, 43–47, 49–57, 68–72]. Of 7 studies examining awareness (see Supplementary Table 7, Additional File 1), health workers in 4 studies had high awareness of national law (more than 50% of participants) [29, 33, 44, 47]. However, the percentage of health workers who received training on national law was relatively low [29, 44, 53].

On legal compliance, health workers across countries appeared to not fully comply with national law. In Pakistan, although prohibited by the law, health workers reported receiving gifts, samples, and sponsorship for conferences from CMF companies [45]. While health

workers in Indonesia [54] and the UK [69] reported good compliance with national law by not contacting CMF companies, a few in Mexico reported contact despite it being prohibited [47]. However, the highest percentage of health workers reporting contact with CMF companies was in Côte d'Ivoire where such interaction was not prohibited [53]. Physicians were reported to receive incentives when prescribing CMF in Mexico [55], and health workers in the UK [69] and South Africa [68] perceived information from CMF companies as necessary, suggesting these were possible reasons for non-compliance. Additionally, CMF companies still offered incentives to health workers and violated national law, as observed in Brazil [44]. Other tactics employed by CMF companies included hiring former hospital staff as CMF representatives to gain access to hospitals and contact mothers in Vietnam [52].

Findings showed various levels of non-compliance with national law in health facilities, such as accepting gifts and distributing free samples to mothers in China [43], and having CMF materials with logos in the UK [69] and Vietnam [70], and receiving donations of infant formula in Burkina Faso [50]. The data also revealed significant disparities in compliance between public and private health facilities, by which public hospitals had better compliance than private hospitals in many countries including South Africa [68], Vietnam [52], Mexico [55], and Côte d'Ivoire [53].

Compliance of CMF promotion in media

Of 22 articles describing CMF promotion in media, referring to any platforms or channels that could be used to share CMF promotions to target groups and the general public, it was reported from television ($n=1$) [32], publications ($n=3$) [35, 38, 73], websites ($n=4$) [31, 74–76], social media and mobile applications ($n=4$) [77–80], and a combination of media channels ($n=10$) [29, 30, 33, 34, 36, 39, 46, 49, 50, 81]. We found the first reported CMF media promotion in 2003, with mentions growing significantly over time with the transition from traditional media (television, radio, publication) to digital media (websites, social media, parental applications) from 2016 onwards. Findings indicated that compliance with national law for regulated products was generally strong, particularly the promotion of CMF for children 0–12 months, or infant formula, observed across countries was limited [29–37], except in China [79] and Ecuador [46] where legal provisions were weaker. Cross-country analysis also demonstrated that national law can effectively curb media promotion of regulated products, but was less successful in preventing the promotion of unregulated CMFs [38]. Widespread advertisements of unregulated CMF products, especially toddler milk, were reported worldwide [29, 31, 32, 34, 35, 38, 39], along with

cross-promotion strategies using similar branding and product design to indirectly promote the regulated products and undermine restrictions [34, 75, 76]. Other popular marketing patterns observed across media channels included the use of health and nutrition claims [34, 75, 81], greater emphasis on brand recognition to increase consumer recall of brands [36], and the appeal of premiumization [74]. Among online platforms, including social media, websites, and mobile applications, most observed non-compliant advertisements included the use of text and images to idealize CMF use [74, 81] and invitations aimed at encouraging mothers to make contact with companies [30], occasionally accompanied by rewards [77]. Among social media platforms, Facebook was the most common platform being observed for CMF media promotion during 2021–2022 [29, 77, 78] followed by Instagram [29, 77].

Compliance of point-of-sale (POS) promotion

In total, 15 studies described POS promotion [29, 30, 33, 39–43, 46, 47, 49–51, 82, 83]. Many retail shops (over 40%) in most countries had non-compliant POS promotions [39–43]. Among the types of promotions observed, the price-related strategy was most reported with the highest prevalence in most countries [29, 30, 40, 41, 46], except Indonesia [33] and China [43] where the distribution of free gifts at POS was more common (Supplementary Table 8, Additional File 1). Compliance of POS appeared not to correlate with the strength of legal provisions in national Law as countries without restrictions on CMF marketing at POS, such as Ecuador [46], Indonesia [33], and China [43], reported lower percentages of price-related POS promotions, compared to countries with restrictions, including Thailand [29] and Brazil [41]. Additional findings from Brazil indicated that retail stores that were part of chains and had managers receiving visits from CMF representatives were significantly less likely to comply with POS promotion restrictions [82].

Compliance of product labels

Of 13 articles reporting labeling compliance [29, 30, 33, 43, 46–51, 80, 84–86], 7 reported CMF product labeling compliance, 6 on CPCF, and 1 on teats and bottles. Most reported compliance but only with parts of the Code, notably, Article 9 which requires the labels to be designed in a way that does not discourage breastfeeding, and to provide necessary information about the appropriate preparation and use of the products and important messages i.e. superiority of breastfeeding, the use on the advice of health workers, and warning against the health hazards, while one article from Thailand reported compliance with the Code and the national law [29]. Regarding CMF product labels, the percentages of labels with

at least one non-compliance with the Code were high across countries. The most common non-compliance included the presence of text or images idealizing product use [29, 30, 33, 43, 46–48], and the absence of a statement of the superiority of breastfeeding [29, 30, 47, 48]. The absence of warning of health hazards of inappropriate use was less observed [33, 48]. The common patterns found in product labels and packages of CPCF included the absence of age-specific recommendations [43, 47, 85] and the use of images to idealize product use [43, 85, 86]. Moreover, a high percentage of sampled labels in Cambodia, Senegal [85], and Mexico [47] had invitations to contact the CMF companies. Focusing on bottles and teats, a study reported that most labels included usage information, but many packages also included text and images idealizing bottle feeding with only 40% addressing potential problems related to bottle feeding and around 60% of teats and bottles containing promotions [84].

Acceptability

Five articles covering Australia, South Africa (2 articles), the UK, and Vietnam explored the perceived acceptability of national law using qualitative or mixed methods among health workers [56, 70, 87, 88] and mothers [59]. Health workers' perceptions were mixed among those aware of the national law, with some expressing reluctance to fully support its implementation. In Vietnam, some health workers were afraid to lose benefits provided by CMF companies (e.g., gifts, free samples, sales bonuses, sponsorship for scientific meetings), while others questioned the national law's necessity as they felt that exposure to CMF companies' perks would not affect their professional practices [70]. In Australia and the UK, health workers reported challenges in providing accurate CMF information to mothers due to prohibitions on distributing CMF materials to health workers [56] or having contact with CMF representatives [87]. In South Africa, most dietitians recognized the necessity of national law and their roles in monitoring violations, but considered the law enforcement unsatisfactory as no actions were taken after reporting and they received insufficient information about regulated products [88]. Pregnant women and mothers in South Africa, when informed about national law, expressed anger about strict CMF marketing regulations because it made accessing CMF information more difficult and thus affected their perceived autonomy over infant feeding choices [59].

Feasibility

Only 1 article reported on feasibility [89], in reviewing a pilot program for monitoring and enforcing national law in Cambodia. Authors found that monitoring activities for violation of national law could be carried out successfully when national and subnational inspectors were

sufficiently trained, informed of clear roles and responsibilities, given simplified tools (e.g., checklists and reporting forms), and assigned reporting protocols. However, challenges hampering the feasibility of national law implementation included staff's limitations, insufficient financial resources, and a reporting system inadequately integrated with the existing chain of command.

Discussion

This systematic review is, to our knowledge, the first to describe the outcomes of regulating CMF promotions with national law adopted from the Code. Most articles examined compliance with national law as the main implementation outcome, with only 6 studies focusing on other outcomes such as acceptability or feasibility. Our study revealed a generally high level of compliance for the media promotion of CMF for infants aged 0–12 months, but lower compliance for promotions at the point of sale, within health facilities, and among health workers across different countries. Moreover, we observed similar CMF industry tactics across the different countries, with a heavy emphasis on digital marketing, cross-promotion of CMF products not covered by the laws, and premiumization. Our findings suggest that disparities in compliance may be attributed to the relative difficulties in monitoring promotions at the point of sales or personal interactions between CMF industry representatives and health workers. As these activities tend to be conducted more discreetly and may require more resources for effective oversight along with more efforts to raise awareness of the detrimental impacts of such activities in the retail and healthcare sectors.

Our findings also indicate that government agencies should sustain effective control over CMF promotions that already demonstrate good compliance, especially those in mass media. Surveillance and monitoring activities are essential, yet require sufficient resources [90, 91], utilizing technology-driven monitoring solutions can help alleviate the human resource constraints faced by resource-limited countries. Additionally, the proliferation of direct engagement between CMF industries and mothers through digital marketing and counseling presents new challenges for regulators [52, 92–94]. Therefore, governments should leverage technology-assisted solutions to enhance monitoring capabilities for detecting online violations, such as using artificial intelligence to censor content that may involve CMF advertisements and may violate the law.

To address the non-compliance with POS promotions, communication strategies targeting shop managers should be prioritized to ensure they understand the related provisions in national laws and readdress potential influence from CMF representatives [82]. Similarly, the poor compliance of health workers with national

laws, despite their significant influence on maternal feeding choices [95], underscores the importance of effective interventions. This non-compliance of health workers could be attributed to a lack of knowledge and understanding of related provisions in the national law as indicated in our result that very few of them received training on national law, although a high percentage were aware of its existence. Given that health workers typically lack training in marketing, business, and legal matters, they may struggle to comprehend the significance and relevance of national laws in regulating CMF marketing, including their legal intricacies. Thus, raising awareness and providing adequate training on the rationale, benefits, and key provisions of these laws could increase their understanding, and may lead to more acceptance and better compliance [91].

However, training might not be effective in raising awareness and ensuring compliance of health workers who disagree or do not comply with the law due to other reasons, for example, the perceived challenges in accessing CMF information or foregone benefits offered by CMF industries. Addressing concerns about limited information among health workers and a common practice of advising CMF use to mothers requires further investigation and intervention to determine the CMF knowledge that health professionals require for objectively advising mothers and free from conflict of interest. This may also help address the concerns of some mothers about perceived difficulty accessing CMF information. Moreover, providing incentives to health workers, as shown in other contexts [96], such as social recognition, prizes, or awards, possibly facilitates improved compliance and acceptability. Additionally, scaling up existing policies in health facilities, like the Baby-Friendly Hospital Initiative (BFHI), can bolster breastfeeding promotion efforts within healthcare settings [97], and integrating legal implementation into the BFHI can enhance health workers' adherence to national laws, as exemplified by successful experiences in Vietnam [52].

Our findings reveal significant variability in the compliance of CMF promotions across different countries. This variance can be attributed to a range of context-specific factors influencing the implementation of laws in each country, including the specific legislative provisions incorporated into national laws [49, 91], the roles of national authorities, collaboration of multi-sectoral stakeholders [49, 89, 98–105], implementation activities [13], and enforcement mechanisms [13, 89, 98, 99, 103, 106]. According to the WHO assessment [18], only a few countries have national laws with robust legal provisions, while the majority fail to regulate CMF products for young children up to the age of 3 years or address emerging marketing strategies as recommended by WHO [107]. This regulatory gap provides an opportunity for

CMF industries to promote unregulated products using innovative tactics, such as cross-promotion and brand recognition, as revealed in our study, which could potentially undermine existing laws.

Therefore, we recommend that countries review and update their legal provisions to be comprehensive, aligning with the Code and other subsequent relevant WHA resolutions [9, 107]. It is crucial to extend the scope of regulated products to include CMF for 0–36 months and implement provisions to prohibit cross-promotion, CMF promotion in healthcare facilities, sponsorship of health professionals [8, 18, 92, 108, 109], and digital marketing [110]. Additionally, extending restrictions to limit the promotion of CMF for pregnant and lactating women, a common practice by CMF industries to establish brand familiarity and loyalty [111], could be beneficial, especially in countries with a high prevalence of mothers exposed to CMF marketing.

Furthermore, we observed a significant increase in publications related to the implementation of the Code in countries where it has been legislated as national laws after 2010, indicating a growing global trend of restricting CMF marketing through legal measures. However, the global attention was uneven across WHO regions, with the majority of included articles originating from Africa, Southeast Asia, and the Western Pacific. This trend underscores the heightened focus on national law implementation in middle-income countries where CMF use is high and marketing is aggressive [112]. Given the significance of effective monitoring [90], every country should establish and implement a routine monitoring plan, particularly in countries with weak provisions in the national law and a high prevalence of non-compliance. WHO headquarters and regional offices should offer technical support to facilitate uniform monitoring across regions and systematically report agreed-upon outcomes of Code implementation.

In considering our application of the Proctor et al. framework in assessing implementation outcomes of the Code as a legal measure, we found it aligned well with our study objectives, particularly in evaluating dimensions such as acceptability, feasibility, and compliance, but did not address other dimensions for several reasons. First, our study focused on implementation rather than pre-adoption outcomes such as appropriateness, which are typically evaluated before policy enactment. Second, outcomes such as ‘penetration’ or ‘cost’ were not directly applicable to assessing the Code’s regulatory focus on marketing practices within CMF industries. Third, the Code as a legal measure prioritizes outcomes related to enforcement effectiveness rather than longer-term impacts such as sustainability.

The adaptation of terminology to emphasize ‘compliance’ over ‘fidelity’ or ‘adherence’ was critical due to the Code’s

regulatory context, which mandates nationwide enforcement of specific provisions, and ensured our study accurately reflected how stakeholders comply with these legal requirements. We further refined this adjustment by categorizing compliance into five types, enabling a detailed examination of compliance behaviors among manufacturers, health workers, mothers, and other stakeholders. This adaptation aligns with recent studies using the internationally recognized NetCode protocol [28, 113], and facilitates standardized and comparable assessments of compliance across countries.

This systematic review has several limitations. Our study may not have included all relevant articles as we did not include unpublished technical literature. Heterogeneity in the scope of regulated products and legal restrictions across countries made synthesis challenging, leading us to report findings broadly and focus primarily on restrictions imposed on CMF for infants aged 0–12 months, the most discussed product. Future research studies might focus on summarizing compliance with specific legal provisions, for each CMF product, or comparing compliance between countries with and without national law. Qualitative methods can offer context-specific insights into other implementation outcomes, including the acceptability of the law among relevant stakeholders. Understanding the perceptions of stakeholders and the association between acceptability and compliance may enhance overall acceptance among stakeholders and contribute to improved law implementation outcomes.

Conclusion

While implementing the Code as national law has improved the regulation of CMF promotions, significant challenges persist in addressing promotions for unregulated products, as well as promotions at points of sale and in healthcare facilities. To bolster the effectiveness of law implementation, countries should adopt robust legislative provisions that restrict the promotion of CMF for children aged 0–36 months, address digital marketing and cross-promotion, and establish infrastructures to regularly monitor compliance, particularly at the point of sales and in healthcare settings.

Abbreviations

CMF	Commercial Milk Formula
Code	The International Code of Marketing of Breast-milk Substitutes and relevant subsequent World Health Assembly Resolutions
CPCF	Commercially Produced Complementary Foods
POS	Point-of-sale

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13006-024-00676-3>.

Supplementary Material 1

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Author contributions

CT, MC, and YE conceptualized the study. CT and YE developed the search strategy. CT and NC conducted screening, data extraction, and quality assessment. CT analysed the data with supervision from MC and YE and advice from VT and NH. CT drafted the initial manuscript. All authors reviewed drafts and NH, VT, MC, and YE provided critical revisions. All authors approved the final version before submission.

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Data availability

No datasets were generated or analysed during the current study.

Declarations**Ethical approval**

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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