Legislation on marketing of breast-milk substitutes in digital and social media: a scoping review

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ABSTRACT
Innovative and continuously changing methods of digital marketing are routinely used to reach young women and their families with advertisements that normalise infant artificial feeding and undermine breastfeeding. Legislation and provisions regulating digital and social media marketing are limited across countries. The aim of this scoping review was to systematically identify and summarise worldwide legislation implemented to regulate breast-milk substitutes (BMS) marketing on digital and social media, as well as identifying areas of opportunity to strengthen and improve it. Documents published from January 2012 to April 2022 were examined using search strategies including multiple databases and citation tracking. A total of 127 sources were evaluated, and only 28 documents from 24 countries meeting the inclusion criteria were retained. Most of the reviewed documents explicitly stated that digital marketing was prohibited (n=23), as opposed to being regulated only, with prior approval from the relevant authorities in each country. Regarding monitoring, from the countries included in this scoping review, only 14 of 24 (58.3%) stipulate a monitoring process for compliance with legal measures and have designated an actor responsible for monitoring. In addition, 22 of 24 (91.6%) countries included have designated a different actor responsible for the monitoring and tracking of BMS marketing. The results highlight the urgent call for the explicit regulation of BMS marketing in digital and social media worldwide, as well as the public documentation of such legal measures. Likewise, it is important that there are effective, transparent and free of commercial influence national monitoring systems used to ensure compliance with legal measures.

INTRODUCTION
Breastfeeding (BF) has been documented as one of the most effective ways to improve short-term and long-term health outcomes for both mothers and infants. Concurrently, there has been documented health consequences and economic loss when BF practices are inadequate.1,1

The WHO recommends the initiation of BF within the first hour of the infant’s life, exclusive BF for the first 6 months and, thereafter, the provision of adequate and safe complementary foods while BF continues until 2 years or beyond.2,3 Exclusive BF rates increased from 35% in 2005 to 44% in 2020 in low-income and middle-income countries.4 Despite this improvement, unethical and aggressive breast-milk substitutes (BMS) marketing remains one of the main obstacles for infant feeding practices as recommended.

A recent multi-country study reported that 51% of women interviewed had seen or heard commercial milk formula (CMF) marketing. The highest proportion were found in urban China (97%), Viet Nam (92%), UK (84%) and Mexico (39%).5 These countries have a different legal status of the International...
Code of Marketing of BMS (the Code), according to the Code’s 2022 status report.\textsuperscript{6} China and the UK have included some provisions of the Code, Viet Nam is substantially aligned with the Code, and Mexico is moderately aligned.\textsuperscript{6,6a}

Since in some countries more than 80\% of BMS marketing is conducted through digital media, it is considered one of the major threats undermining child and maternal well-being.\textsuperscript{7,8} The modern methods of digital marketing and social media (eg, industry-sponsored online social groups, Facebook posts, blogs, online magazines, discounted internet sales, among others) are routinely used to reach women and their families with advertisements that normalise artificial feeding and undermine BF.\textsuperscript{3,7} Following the adoption in 1981 of the Code,\textsuperscript{10} 18 subsequent World Health Assembly (WHA) resolutions and decisions have addressed the health risks introduced by the promotion of BMS. The WHA Resolution 54.2 was issued as an update to the Code, encouraging governments to strengthen mechanisms to ensure that no BMS marketing takes place in any form of media, thereby including digital marketing.\textsuperscript{11} More recently, the Seventy-third WHA (2020), in resolution WHA 73.26 requested the Director-General to prepare a comprehensive report to understand the scope and impact of digital marketing strategies for the promotion of BMS.\textsuperscript{12} Having considered the report,\textsuperscript{8} the Seventy-fifth WHA (2022) decided to request WHO to develop guidance for Member States on regulatory measures to restrict the digital marketing of BMS. Such guidance could contribute to ensuring that existing and new regulations designed to implement the Code and subsequent WHA resolutions adequately address digital marketing practices.\textsuperscript{13} Regardless of international efforts to regulate the marketing of BMS, the CMF industry employs evolving tactics to defy and circumvent them.\textsuperscript{9} According to WHO’s 2022 document on the scope and impact of BMS digital marketing, the global formula market has been valued at more than US$52\ billion.\textsuperscript{8,9}

Given the limited and inexplicit legislation surrounding the regulation of digital marketing and social media in all countries, the development of stronger legal instruments to better regulate countries’ digital marketing practices is paramount.\textsuperscript{14} Therefore, the aim of this scoping review was to systematically identify and summarise worldwide legislation implemented to regulate BMS marketing on the digital and social media, as well as identifying areas of opportunity to strengthen and improve it.

METHODS

The review was carried out following the framework outlined by the Joanna Briggs Institute\textsuperscript{15} and it was reported according to the guidance provided in the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews.\textsuperscript{16} This scoping review is part of a broader research project aiming at developing and testing a monitoring system of BMS marketing in digital media in Mexico. The methodology included a workshop with international experts on the Code, digital marketing, and legislation. Based on the consultations and the experiences of our research group,\textsuperscript{17,18} the protocol for this scoping review study was developed. The complete process of the broader research project will be described in another publication.

Research question

“What legal measures are in place to regulate BMS marketing in digital and social media, in which countries and what do they include?”

Information sources and search strategy

A MeSH (Medical Subject Headings) search strategy was developed to retrieve the sources of interest, such as primary research studies, technical reports, websites, official government documents and non-governmental organisations documents, from the selected databases (table 1). Based on a previous study\textsuperscript{17} that identified interest in digital marketing over the last 10 years, searches were limited from January 2012 to April 2022. An initial limited search was conducted in two online databases (PubMed-Central and EBSCO) to identify keywords of articles and documents that would help answer the research question. The words contained in the titles and abstracts of the retrieved papers were analysed, as well as the index terms used to describe the articles. The keywords that were identified most frequently in the retrieved documents, and the tested terms that yielded the highest number of results were selected. Then, a second search, using all identified keywords and index terms, was undertaken across all included academic databases and Google Scholar. Online supplemental table 1 contains information sources and search strategies. Although only English and Spanish were considered for the keywords, documents in other languages were translated using an online translator (DeepL Traductor).

Finally, a third search was conducted to obtain additional sources in the reference list of documents included in the review. As result of the search strategy used, sources listed in the reference section of key documents (eg, Code Status Report 2022\textsuperscript{6} and several documents published before 2012\textsuperscript{8,19–30}) were included even though they did not meet the established time frame.

Eligibility criteria

All sources mentioning BMS digital marketing legislation or regulations were included regardless of study design. The definitions of ‘digital marketing’ and ‘breast-milk substitutes’ from the WHO and the Code were used.\textsuperscript{8,31,32} The concept of interest was decrees, regulations, sanctions, agreements, laws and/or administrative orders (hereafter referred to as ‘legal measures documents (LMDs)’) regulating BMS marketing in digital and social media implemented across the countries (table 1). Legal measures mentioning ‘promotion in any advertising medium is prohibited’, ‘any advertising is prohibited’ or
no person shall advertise’ were excluded due to the fact that it is uncertain whether digital and social media are included.

**Selection process**
First, titles were screened, and duplicates were removed. Then, abstracts found in the searches were independently screened by three researchers (BF-L, VL-M and CVV) against the agreed inclusion criteria. Disagreements between researchers were resolved by consensus, and if not, then resolved by the decision of a fourth reviewer (SH-C). Prior to the extraction of the information, an exercise was carried out in order to standardise the information collected within the research team. Subsequently, the full-text screening was carried out. A data extraction tool, using Microsoft Excel spreadsheets, was developed to collect the information about legal measures considering the promotion of BMS in digital and social media specifically. The following information was extracted: geographical location, covered products, scope, digital platforms covered, monitoring and sanctions in place. Finally, after the extraction of information from the LMDs, a descriptive qualitative content analysis was performed. This analysis included basic coding to provide a summary of the data coded into particular categories. It should be noted that only documents with the most up-to-date amendments have been included in this review (eg, in the case of Nigeria we found two documents on the same regulation, one dated 2005 and the other 2019, the latter with amendments, so we made sure to include the most up-to-date version).

**Patient and public involvement**
This study is a scoping review including only published literature/documents. Therefore, it did not involve patients.

**RESULTS**

**Literature search**
Based on database search and grey literature review, an initial sample of 302 documents was obtained. After removing duplicates, 209 unique documents were obtained for title and abstract screening. Subsequently, 163 documents were excluded mainly for not mentioning regulations for BMS marketing. Therefore, 46 documents were retained for full-text assessment. During the full-text screening, 81 additional sources were identified through backward citation chaining and included in the assessment. A total of 99 sources were eliminated for not specifying the inclusion of digital media, for the unavailability of the full text and due to the format and quality of the document (eg, scanned documents that made translation impractical). Of the 99 LMDs excluded, 57 were due to the lack of explicit regulation on digital and social media (eg, LMDs mentioning ‘promotion in any advertising medium is prohibited’) (online supplemental table 2). With respect to these 57 LMDs, the majority covered BMS targeting infants aged 0–24 months (n=17), followed by 0–12 months (n=13) and 0–36 months (n=12). Fifteen of the LMDs do not specify the age range. In relation to the type of products covered, most LMDs included CMF (n=53) and 27 covered related products, such as teas and feeding bottles. In addition, 16 have stipulated monitoring systems while 35 have defined sanctions, but only 20 sources have designated an actor responsible for the application of sanctions. Finally, 28 sources were included in this scoping review by having explicit regulations on digital and social media marketing (figure 1).

**Study characteristics**
The LMDs included in the scoping review belong to 24 countries around the world. Most of them are from

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**Table 1** Scoping review databases, strategies and inclusion criteria

<table>
<thead>
<tr>
<th>Databases</th>
<th>EBSCO, PubMed-Central and Web of Science. In addition, Google scholar was used to identify grey literature and Government and International Organisation reports.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keywords combinations</td>
<td>((breastmilk substitutes OR breastmilk substitutes marketing OR breastfeeding) AND (legislation OR violation OR public health) AND (Code of marketing OR WHO Code OR policies))</td>
</tr>
</tbody>
</table>
| Concept             | ► Legal measures documents regulating the marketing of BMS through digital (eg, websites, online retailers, online groups, mobile applications, among others) and social media (eg, Facebook, Instagram, TikTok, Twitter, YouTube, among others).  
  ► Digital marketing: any promotional activity, delivered through a digital medium, that seeks to maximise the impact through creative and/or analytical methods including industry-sponsored online social groups, individually targeted ads, paid blogging, paid blogs and discounted internet sales.  
  ► Breast-milk substitutes: any food or milk that is marketed as partially or fully replacing breast-milk and specifically for feeding children up to 3 years of age, such as infant formula (0–6 months), follow-up formula (7–12 months), growing-up milk (13–36 months), any other food or liquid, bottles and teats. |
| Population studied  | Legal measures documents from countries around the world. |
| Context             | Worldwide settings. |
| Time frame          | 1 January 2012 to 30 April 2022 (additional sources identified via backward citation chaining did not have a time frame). |
| Language            | All languages. |
| Access              | Full-text article accessible. |
the South-East Asian Region (SEAR) (n=7),\textsuperscript{25–27, 33–36} and African Region (AFR) (n=7),\textsuperscript{19, 20, 37–41} followed by Western Pacific Region (WPR) (n=5),\textsuperscript{21, 22, 42–44} Region of the Americas (AMR) (n=5),\textsuperscript{23, 24, 45–47} Eastern Mediterranean Region (EMR) (n=3),\textsuperscript{29, 30, 48} and European Region (EUR) (n=1).\textsuperscript{28} In three countries more than one document was identified (Indonesia (n=2),\textsuperscript{35, 36} Lao People’s Democratic Republic (n=2),\textsuperscript{21, 44} and Brazil (n=3)).\textsuperscript{24, 46, 47} Most LMDs that mention BMS marketing in digital and social media explicitly prohibit the promotion of the regulated products (n=23). These documents correspond to the AFR (n=7),\textsuperscript{19, 20, 37–41} SEAR (n=6),\textsuperscript{26, 27, 33–36} AMR (n=4),\textsuperscript{23, 24, 46, 47} WPR (n=3),\textsuperscript{21, 22, 43} EMR (n=2),\textsuperscript{30, 48} and EUR (n=1).\textsuperscript{28} The remaining documents (n=5) only state the ‘regulation’ of designated product marketing (eg, the advertisements in Lao People’s Democratic Republic, through all types of media and all forms of marketing activities, must receive approval from the Health department and other concerned sectors). Regarding the language of the documents included (n=28), 22 were in English, 4 in Spanish, 1 in French and 1 in Russian, the latter 2 being the ones translated.

**Publication date of the legal measures documents (LMDs)**

According to the LMDs included in this scoping review, since 2002 (Brazil), countries have begun to include legal measures about digital and social media. The most recent sources found are from 2019 (table 2).

**Scope and products covered by LMDs**

A range of scopes was found in the LMDs included. The majority of sources covered BMS targeting infants aged 0–36 months (n=14), followed by 0–24 months (n=9),\textsuperscript{21, 23, 25, 26, 34, 38, 39, 43} and 0–12 months (n=2).\textsuperscript{50, 36} The remaining three documents did not specify the scope (Indonesia,\textsuperscript{35} Afghanistan,\textsuperscript{38} and Cook Islands\textsuperscript{42}). Regarding the
covered products, all LMDs covered CMF, most of them considering infant (n=27) and follow-on formula (n=24). Only LMDs from Kyrgyzstan, Bolivia, Kenya, Brazil, Lao People’s Democratic Republic and Saudi Arabia specified the inclusion of growing-up milk, or sometimes referred to as ‘toddler formula’. In addition, eight countries from SEAR (Maldives and Myanmar), AMR (Brazil), WPR (Lao People’s Democratic Republic) and AFR (South Africa,
Kenya, Malawi, and Botswana) covered CMF for specific medical conditions. Most LMDs covered complementary foods (n=23). Related products, such as feeding bottles, teats and pacifiers, are covered by most of the LMDs (n=22). In addition, some LMDs from AMR (Brazil), AFR (Botswana), EUR (Kyrgyzstan) and EMR (Saudi Arabia) regulate the promotion of less frequent products, such as breast pumps and nipple shields (table 2).

Digital and social media covered by LMDs
The internet, electronic media and email were the most frequently mentioned digital media in the LMDs. By contrast, the least mentioned media were mobile applications, baby clubs, smart devices, social media and electronic newspapers. The AFR includes more and different types of digital media (figure 2). According to the findings of this review, Botswana is the only country explicitly covering baby clubs, while Nigeria covers social media. Nevertheless, in the LMDs from the Philippines, Lebanon, Cambodia, Maldives and Myanmar, a legend was identified mentioning that the regulation is not limited only to the media cited. In addition, most of the LMDs described the types of media covered in the definitions article (eg, in the definition of the word ‘advertisement’, ‘promote’ or ‘promotion’) and were not detailed again in later sections (n=13).

Monitoring and enforcement
Regarding the implementation of regular monitoring of compliance to the legislation, only 14 countries explicitly included this clarification in their LMDs. However, these provisions are not defined in the LMDs as specific to digital marketing, but are assumed to apply by virtue of being included in the scope of the legislation. The majority of these correspond to the AFR (n=3), SEAR (n=3) and EMR (n=3). Out of the five AMR documents, only Brazil recently included such clarification. In contrast, all the countries in EUR and EMR included a monitoring process in their LMDs. All 14 countries considering monitoring have designated an actor responsible for these functions (table 3). The main monitoring authorities in the different countries are the inspectors of the Ministry of Health, the Food and Drug Supervisory/Administration and the Committees appointed for this purpose. As for sanctions, they were considered by a great number of countries (n=22). Of the 22 countries, 6 included the three types of sanctions: administrative, economic and penal (table 3). The LMDs for South Africa, Cambodia, Brazil, Kyrgyzstan and Lebanon refer to another source for further details on the type of sanctions. As opposed to monitoring, only 17 countries specify the entity responsible for carrying out sanctions.

DISCUSSION
This scoping review summarised the available current state of the legislation worldwide to regulate BMS marketing on the digital and social media. We identified 127 LMDs regulating BMS marketing in any media, of which, only 28 included explicit digital marketing regulation. Most of the reviewed LMDs explicitly state the digital marketing prohibition (n=23), as opposed to regulation only with prior approval from relevant authorities in each country. Although prior approval is not the ideal solution, it may become a way for countries to continue regulating without enacting an outright ban that can be
The limited number of countries regulating BMS promotions on digital and social media is alarming, given the

digitally challenged. The countries with digital and social media BMS marketing regulation were mostly from the SEAR and AFR (six and seven countries on each, respectively), and only one from the EUR (Kyrgyzstan).

**Table 3** Countries that monitor and have sanctions stipulated for compliance with regulations (n=28)

<table>
<thead>
<tr>
<th>Country</th>
<th>Monitoring defined</th>
<th>Monitoring responsible entity</th>
<th>Sanctions defined</th>
<th>Sanctions responsible entity</th>
<th>Sanctions type</th>
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<td>Western Pacific Region</td>
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</tbody>
</table>

*Economic sanction: fines.
†Administrative sanction: warning letters, suspensions or revocations of operating licenses and confiscations or recalls of products.
‡Penal sanction: periods of imprisonment.
NA, no information available on the issue in the document; NS, the information is not specified in the document consulted but refers to another document.
recent trend of companies shifting in favour of digital media to promote their products, from which BMS producers and distributors are not excluded.

According to a report published by the WHO, women across regions are highly exposed to BMS digital marketing. Mothers’ decisions on infant feeding practices are influenced by socioeconomic, cultural and individual factors, including BMS marketing through any means (traditional and emerging). Companies have invested efforts and resources into diverse marketing techniques, including digital marketing, which, together with other complex factors (eg, product diversification, cross-promotion, medicalisation, among others), has resulted in an increase in CMF sales by 115% between 2005 and 2019. Regulating BMS digital and social media marketing represents an enormous challenge. The current digital technologies offer the manufacturers and distributors cost-effective marketing tools that enable greater reach and impact of product promotions. BMS advertisements and promotions monitoring is very complex, given that they can be sent directly to personal accounts, or through other means, such as social media influencers, who are not direct employees from BMS producers companies.

Even though the Code broadly states that there should be no advertising or any other form of BMS promotion (article 5), it does not specifically address the digital marketing strategies currently available. Since 2001, the WHA has expressed concern about the use of modern methods to promote products and has called for ensuring compliance with the Code in all media. From the LMDs identified in this scoping review, the earliest, explicitly prohibiting the promotion of BMS on electronic means, was adopted in Brazil in 2002. Since then, there has been a rapid increase, mainly in the last 10 years, of LMDs prohibiting and regulating promotions in social and digital media. The most recent legal documents identified were those in Saudi Arabia, Ethiopia, Nigeria and Lao People’s Democratic Republic from 2019. The former is corresponding with the rise in the use of social media, with around 4 billion active users of social media worldwide. The increase in users and the challenges posed by digital marketing for the monitoring and enforcement of national legislation calls for global guidance on regulatory measures to restrict the digital marketing of BMS. This was already recognised in the Seventy-fifth WHA (2022), where WHO was requested to develop further guidance for Member States on regulatory measures to close gaps in the digital marketing of BMS.

Recent evidence from a multi-country study on the scope and impact of digital marketing strategies for the promotion of BMS shows how these products are promoted through ‘a wide range of online channels and social media platforms’. Some examples of the diversity of ways to promote BMS in the digital media are: use of parenting applications, virtual support groups (known as baby clubs), real-time contact with women (chat platforms), highly-targeted marketing through the application of algorithms driven by internet user data, among others. Our scoping review revealed that the most common digital media regulated were internet, electronic media and email. There is currently no national regulation of BMS promotion on other important digital media such as: mobile applications, baby clubs, smart devices and social media (Twitter, Facebook). Therefore, women using these types of media are unprotected from inappropriate and unethical BMS promotion. Existing and new regulations designed to implement the Code should adequately address digital marketing practices. Some suggestions to be considered include prohibiting the use of data-brokering or analytics that allow advertisers to target pregnant women and mothers. Another strategy to address BMS digital marketing could be restricting the use of influencers sponsored by BMS sales, and company participation in baby clubs and virtual support groups. In addition, emphasis should be placed on including a transnational legal framework to address the BMS promotion that is exported from other countries.

To protect women, their children and their families from inappropriate and unethical BMS marketing, it is not enough to regulate it through legislation. It is equally important to have continuous monitoring of compliance with the stipulations of the standards, laws and legal documents. Periodic monitoring is necessary to determine compliance with the regulations, which requires the assignment of financial resources and an entity, free of conflict of interest, in charge of this activity to ensure its implementation. In this regard, it is important to mention examples of attempts that certain countries have documented on digital media monitoring, as is the case of the Philippines or China. The Department of Health of the Philippines developed a reporting platform for citizens to report violations of the law related to BF. The platform allows reporting, processing and resolution of Code violation issues through different channels: websites, mobile applications and SMS (short messaging service). The example related to China, although not specific to the Code, is an initiative to consider broader digital safeguards, as they proposed that in order to speak on certain subjects, online influencers must have the appropriate qualifications.

Likewise, in the event of non-compliance with legal measures, it is necessary to specifically stipulate the type of sanctions and the actor responsible for carrying them out. From our results, only 14 of 24 (58.3%) countries included, stipulate a monitoring process for compliance with legal measures and have assigned an entity responsible for monitoring. The majority are from countries located in the AFR, SEAR and EMR. Regarding sanctions, 22 of 24 (91.6%) countries included have defined them, but only 17 (70%) countries specify the entity responsible for enforcement. For instance, in some countries the monitoring process depends on the establishment of a specific committee to carry out this function (Afghanistan, Bangladesh, Madagascar and Myanmar).
The creation of a strategic group that would include key stakeholders and also ensure continuous vigilance against BMS marketing and BMS producers’ tactics, in order to successfully translate the Code into the country’s legislation and enforce its legal measures, has also been described by others. While it is important to acknowledge the existence of LMDs regulating or prohibiting specifically BMS marketing in digital and social media, these results highlight that further efforts are needed to improve and strengthen legislation in this area, globally. In this regard, it has been reported that existing sanctions imposed on the offender, especially the BMS industry, are not sufficient to encourage compliance with the legislation.

Another factor influencing compliance is the facility that digital marketing platforms allow advertisers to reach across national borders. It can be more cost-effective to disseminate marketing content in more than one country than to create fresh content in each country. This helps circumvent national restrictions on BMS promotion. For this reason, transnational legal frameworks are urgently required to protect BF and safeguard the health of mothers and babies.

To our knowledge, there are few studies exploring the existing legislation and regulation of BMS digital marketing. In the last Code Status Report, of the 144 countries with legal measures on the Code, only 37 explicitly mention promotion of BMS on the internet, digital channels or other electronic means. In most cases, this explicit mention of digital media is limited to the definition of advertising (28 countries) or mentioning digital media in the text prohibiting general promotion to the public (6 countries). However, none of the legislation that prohibits BMS promotions explicitly exempts digital. These results differ from ours mainly in the methodology used to identify LMD, which in our case was through a systematic search to identify all open access documents, unlike the information that WHO mainly obtains, from countries relevant authorities (through ministries of health with the assistance of WHO regional and country offices). Our approach is useful, because it shows the results that stakeholders would get on the subject of BMS legislation, without having direct access to governments’ information or as anyone could have access.

Our study has some limitations, some of them related to the methodology used in the scoping review. A limit of keywords in English and Spanish was used, which might exclude some documents that did not contain the words used. It is also important to mention the limitation of public documentation of LMDs. As a consequence, there could be an underestimation or under-reporting of what is presented here. However, compared with the Code Status Report, the other study that explores this topic, our scoping review reveals results in the same direction in terms of the proportion of LMDs including aspects of BMS marketing on digital and social media. The absence of an explicit ‘mention’ of digital marketing does not necessarily indicate the absence of safeguards, as there may be legislation that is not specific to BMS that falls outside the scope but covers BMS.

In conclusion, progress has been made, including in some countries legislation the prohibition or regulation of BMS marketing in digital and social media; however, gaps remain that must be addressed. There is an urgent need to prohibit and make explicit in the laws of worldwide countries BMS marketing in digital and social media, as well as compliance monitoring. Also, it is of paramount importance to specify an effective, transparent and free of commercial influence national monitoring system, including the entity in charge of such monitoring, and a component to follow-up on sanctions for contraventions to local legislations.

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