



Food & Beverage ISSUE ALLIANCE

September 3, 2020

National Advisory Committee on Standardization for the Regulation and Promotion of Health
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Directorate-General of Standards, Ministry of the Economy
Sent via email: normasomc@economia.gob.mx and jose.ramosr@economia.gob.mx and
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Re: FBIA Comments on Mexico's Decree amending, supplementing and repealing various provisions of the Regulations on Sanitary Control of Products and Services and the Implementing Regulations to the General Law on Health with Respect to Advertising (G/TBT/N/MEX/468)

Dear Sir or Madam,

The Food Beverage Issue Alliance (FBIA) represents fifty-seven allied US-based food and beverage trade associations. As stakeholders and representatives of the US food and beverage industry, the undersigned associations appreciate the opportunity to provide comments on these important food labeling and advertising regulations.

In December 2019, FBIA provided detailed comments on concerns around Mexican Nutrition Labeling Standard for Prepackaged Food and Non-Alcoholic Beverages (NOM-051) regulations and submitted comments on the corresponding implementing regulations in July 2020. FBIA members appreciate the grace period, until November 30, 2020, provided by Mexico to permit additional time to comply new regulations such as NOM-051 in light of the COVID-19 pandemic. We are, however, disappointed that the government of Mexico did not address our earlier stated concerns, and further dismayed with the additional implementing regulations which significantly restrict the ability to ensure the Mexican consumer has access to important nutrients critical to good health. These additional regulations only increase the troubling aspects of the regulations which are not based on scientific rationale.

FBIA members are therefore submitting the following comments, made to Mexico during the comment period related to *Implementing Regulations to the General Law on Health with Respect to Advertising*, as they relate to NOM-51.

The members of the FBIA appreciate Mexico's consideration of these comments that outline our concerns and recommendations.

Sincerely,

American Bakers Association

American Beverage Association

American Frozen Food Institute

American Herbal Products Association

Calorie Control Council

Corn Refiners Association

FMI-The Food Industry Association

Independent Bakers Association

Institute of Shortening and Edible Oils

International Dairy Foods Association

International Food Additives Council

Juice Products Association

National Confectioners Association

National Pasta Association

North American Millers Association

SNAC International

The Association for Dressings & Sauces

Vinegar Institute



Food & Beverage ISSUE ALLIANCE

July 1, 2020

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Re: Amendments to Mexico's Front-of-Pack Labeling and Advertising Regulations

Dear Sir or Madam,

The Food Beverage Issue Alliance (FBIA) represents fifty-seven allied US-based food and beverage trade associations. As stakeholders and representatives of the US food and beverage industry, the undersigned associations appreciate the opportunity to provide comments to La Comisión Nacional de Mejora Regulatoria (CONAMER) on proposed regulations related to the labeling of prepacked foods and beverages. FBIA, through collaboration with regulatory authorities, strives to ensure that all health-related regulation or guidance is justified by verifiable, peer-reviewed, and published science that is accessible through an open and transparent process which also enhances consumer understanding. In addition, FBIA believes it is essential that regulation implementation timelines are reasonable, achievable, and economically feasible for both small and large food and beverage manufacturers.

FBIA, along with others in the food and beverage industry provided comments on the Mexican Nutrition Labeling Standard for Prepackaged Food and Non-Alcoholic Beverages (NOM-051)¹

explaining our concerns regarding the lack of scientific basis as well as the likelihood the label will lead to consumer confusion. With the onset of COVID-19, the United States, along with numerous other countries, raised concerns that the compliance date of October 1, 2020 was unreasonable. Under normal conditions manufacturers need at least 18-24 months to analyze the nutrient content in accordance with the regulation and update the labeling. A six-month implementation time is unreasonable under normal circumstances but given the unprecedented demands on the food industry during the pandemic it is even more unrealistic and unattainable. We are disappointed that the government of Mexico did not address our earlier stated concerns, and further dismayed with the additional regulations which significantly restrict the ability to ensure the Mexican consumer has access to important nutrients critical to good health. These additional regulations only increase the troubling aspects of the regulations which are not based on scientific rationale.

Additional Restriction of Product Formulations is not Science Based and Threatens Product Innovation

Restriction on Added Nutrients

FBIA supports labeling that empowers consumers to make informed dietary choices that are grounded in strong sound science. The NOM-051 regulatory approach is not scientifically based and violates the principle that food and beverages should be considered in relation to their holistic role to overall health and a balanced daily diet. The additional provisions published June 2, 2020, specifically modifications to Article 161, further restrict beneficial product formulation; and thus, add to our strong apprehension. A major concern is that as a result, many foods will no longer be allowed to be fortified with important public health nutrients including dietary fiber, vitamins, and protein.

The scope of the prohibition against fortification is unclear. In particular, the proposal lacks clarity as to whether the prohibition applies only to products that must bear one of the icons for excess critical nutrients or would also apply to products that must bear one of the other precautionary legends such as “Contains sweeteners, not recommended for children.” There are no scientific or nutrition policy grounds on which to ban such fortified products.

The Case for Fortification

Diets in Mexico are failing to meet nutritional targets for micronutrients, and certain population groups, such as teenagers and adults. According to the National Health and Nutrition Survey

¹ The final rule mandates a front of package labeling (FOPL) system on all packaged foods, to warn consumers against products that exceed strict thresholds of caloric content, added sugars, saturated fats, sodium, and also establishes advertising and claims limitations for products that exceed the defined thresholds. The final rule outlines a multi “phase” implementation process for the various provisions in the rule. Based on the phases described, the implementation date for the FOPL warnings is October 2020, with more stringent nutrient thresholds starting in October 2023.

2018 more than 50% of the urban population and 70% of the rural population have some degree of food insecurity, that is, they do not have access to sufficient or adequate food.² Results from a 2018 survey in Mexican localities under 100,000 inhabitants (the ENSANUT 100K Survey), showed that 23% of children from 1-4 years have anemia, 18.6% are zinc deficient, and iron deficiency was present in 7.2% of the cases³. Results of the National Health and Nutrition Survey 2012 showed that the proportion of inadequate intake of micronutrients such as folic acid, calcium, vitamin A, iron, zinc and vitamin C continue to be prevalent in preschool, schoolchildren and adolescents, despite the mandatory flour fortification of wheat and corn.^{4,5} Micronutrient deficiencies can negatively affect the physical and mental development of people and increase susceptibility to infections. Moreover, deficiencies amplify the effect of every disease. This is especially relevant in today's environment with the COVID-19 pandemic. These micronutrient deficiencies can be addressed by inclusion and encouragement for voluntary fortification in food products.

The World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) recognize voluntary fortification as the most cost-effective strategy to address micronutrient inadequacy intakes in most cases driven by the low consumption of nutritionally rich foods⁶. In its guidelines for food fortification with micronutrients, the WHO and FAO highlight that processed food plays an important role as a source of important nutrients, as food fortification can deliver micronutrients to those who may not be able to afford a highly diverse diet. Specifically, WHO and FAO point out that

- Food fortification is the preferred approach in terms of sustainability, intakes and cost-effectiveness to control malnutrition due to micronutrient deficiency;
- Voluntary fortification can play a positive role in public health by helping to meet nutrient needs and therefore to reduce the risk of deficiencies;
- Voluntary fortification can also improve the supply of micronutrients, since it would be difficult to add them in sufficient quantity through mandatory fortification, due to safety aspects, technical feasibility or costs; and
- The incentive for voluntary fortification usually comes from industry and consumers seeking to obtain potential health benefits through increased micronutrient intakes.

Fortification has been used for decades in industrialized countries for a number of critical purposes. These include: correcting dietary insufficiencies that can result in nutritional deficiency diseases; restoring micronutrients such as B vitamins lost during food processing;

² Instituto Nacional de Estadística, Geografía e informática. Instituto Nacional de Salud Pública. Encuesta Nacional de Salud y Nutrición 2018. Presentación de resultados. Disponible en

https://ensanut.insp.mx/encuestas/ensanut2018/doctos/informes/ensanut_2018_presentacion_resultados.pdf

³ De la Cruz-Góngora, et al. Anemia, deficiencias de zinc y hierro, consumo de suplementos y morbilidad en niños mexicanos de 1 a 4 años: resultados de la ENSANUT 100K. *Salud Publica Mex.* 2019;61:821-832.

<https://doi.org/10.21149/10557>

⁴<https://www.slaninternacional.org/congreso2018/avisos/presentacion-resultados-ensanut-2018.php>

⁵ Rivera J, et al. Overview of the Dietary intakes of the Mexican population: results from the National Health and Nutrition Survey 2012. *J Nutr* 2016;146(Suppl):1851S–5S.

⁶ Allen L. Guías para la fortificación de alimentos con micronutrientes. © Organización Mundial de la Salud y Organización de las Naciones Unidas para la Alimentación y la Agricultura, 2017.

<https://apps.who.int/iris/bitstream/handle/10665/255541/9789243594019-spa.pdf?ua=1>

balancing the vitamin, mineral, and protein content of foods; and ensuring that foods such as low fat milk are not nutritionally inferior to their traditional counterparts like full fat milk. Poor diets drive malnutrition in early childhood and fortification of staple foods with micronutrients can be a cost-effective intervention to combat hidden hunger across the population. Additionally, food fortification of widely distributed and widely consumed foods has the potential to improve the nutritional status of a large proportion of the population, both poor and wealthy; and the nutrients they provide become relevant particularly in the population with social vulnerability in which poverty and social determinants are the main factor in the type of food consumed. While in the new provisions, there is an exception for the addition of mandatory nutrients as specified for specific products in the regulation, such as iodine in salt, the new requirements pose a unique challenge for products that are voluntarily fortified to help meet consumer needs. Public health concerns such as iron deficiency impact many countries including Mexico.

The Mexican government should be defending these WHO and FAO recommendations. These new provisions go against core recommendations that Mexico has committed to defend, including that labeling regulations align to WHO recommendations, and orienting policies to protect the poorest in Mexico.

Examples of Successful Voluntary Fortification Efforts

Many products are fortified with beneficial nutrients, including iron, to aid consumers in reaching critical nutritional needs and prevent deficiencies of nutrients required for adequate health. For example, dietary fiber plays an essential role in health, including aiding in laxation, helping to reduce blood cholesterol, and helping control blood glucose. For many consumers, including those in Mexico, dietary fiber is a nutrient of public health concern as much of the public is not meeting the recommended intake. This creates a “fiber gap,” and FBIA is concerned that the new provision would further exacerbate this gap by no longer allowing its addition to many products the public may consume to reach their recommended daily intake.

Additionally, many cereal and grains products are fortified with folate or folic acid in order to address concerns surrounding birth defects. These products are fortified so that pregnant women or those of child-bearing age receive enough folate or folic acid to help prevent possible birth defects, such as spina bifida, during early stages of gestation. In Mexico, comparisons between pre- and post-fortification prevalence of neural tube defects showed that fortification efforts were effective in reducing neural tube defects prevalence by 59% (1999-2006).⁷ The inability to fortify cereal and grain products with folate or folic acid could have a significant detrimental impact on adequate folate stores for expectant women and their infants, thus increasing their risk.

Many products are also fortified with additional protein, which is essential for building and repairing muscle. Many segments of the population are often lacking sufficient protein intake and may look to fortified products to achieve daily intakes. We are concerned that restricting the fortification of some products with protein could have a negative impact among a substantial segment of consumers.

⁷ Rosenthal J, et al. Neural tube defects in Latin America and the impact of fortification: a literature review. *Public Health Nutr* 2014; 17(3):537-550. doi:10.1017/S1368980013000256

We encourage the Health Ministry to consider the unintended consequences of this additional provision. Consumers depend on these fortified nutrients to meet their needs, regardless of whether they are added mandatorily or voluntarily. Shelf stable foods have provided key nutrients and dietary components (whole grains, vitamins, minerals) and convenience to many families in Mexico and around the globe. Limiting fortification means going back on a public policy that has demonstrated its benefit throughout the world, putting the most vulnerable population at risk. Instead of vilifying these nutritious foods that help Mexican consumers meet critical nutrient needs, manufacturers should be encouraged to continue to innovate to provide nutrient dense foods that Mexican consumers enjoy. Additionally, these companies, along with the government can work together to provide scientifically supported information on how to select and consume a variety of different foods, in moderation, to ensure good health.

In addition, experience with front of pack labeling requirements supports that such warnings do not change consumer behavior in a way that translates to public health outcomes. In the five years following the creation of a new front of pack labeling system, Chile's obesity rate has continued to climb and there is no clear evidence that consumer behavior in fact changed in a manner that reduced the obesity growth rate.⁸ Accordingly, proposed Article 161, if enacted, could lead to widespread nutrient deficiency without producing the change in behaviors that the Mexican government seeks to encourage.

Product Formulation Restrictions Do Not Align with International Standards and Trade Commitments

These additional restrictions proposed by Mexico do not align with Codex and other international standards. In the US, for example, the Food and Drug Administration (FDA) has a Fortification Policy that encourages the appropriate addition of nutrients to foods as an effective way of maintaining and improving the overall nutritional quality of the nation's food supply.⁹ That Policy discourages, but does not prohibit, the fortification of certain candies and snack products.¹⁰ Importantly, the FDA Fortification Policy is only a guideline and is not legally binding in most cases because it was not promulgated through notice and comment rulemaking. The policy has been given binding legal effect through incorporation into the nutrient content claim regulations for certain labeling claims, such as "more," "fortified," "enriched," "added," "extra," plus," "high potency," and for certain foods that bear "healthy" claims. For foods not bearing these labeling claims, compliance with the Fortification Policy is not mandatory. In contrast, Mexico's proposal, if enacted, would be mandatory, and would prohibit an extraordinary portion of the Mexican food supply from including beneficial nutrients. Moreover, the Health Ministry seems to broadly define "nutrients" to include all vitamins, dietary fiber, and protein. This stands at odds with FDA's Fortification Policy and other international approaches to nutrient enhancement of the food supply. Fortifying foods continues to ensure that consumers have access to nutrients that are often hard to obtain and should be permitted.

⁸ FAO, Chile Country Report (2018), <http://www.fao.org/faostat/en/#country/40>.

⁹ 21 CFR 104.20; US FDA, Questions and Answers on FDA's Fortification Policy (2015), <https://www.fda.gov/media/94563/download>.

¹⁰ *Id.*

The proposed amendment to Article 161 is also inconsistent with Mexico's international obligations under Article 2.2 of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) — as well as Article 11.3.1(a) of the US-Mexico-Canada Agreement (USMCA), which incorporates Article 2.2 of TBT — which requires that a measure to not be more trade-restrictive than necessary. By apparently prohibiting added nutrients from broad categories of foods and beverages marketed in Mexico, the proposed amendment effectively prohibits a large number of exporters from marketing in Mexico products that they may lawfully sell in other countries. The fact that Mexico's proposed measure is an outlier approach not based on international standards would likely compound the anticipated burden on trade. In fact, as explained above, the proposed amendment is likely to lead to unintended and widespread negative health outcomes, without advancing the intended goal of reducing obesity and encouraging informed and balanced dietary choices. Mexico's health concerns should be addressed by less trade-restrictive measures that are better tailored to Mexico's specific concerns. For example, Mexico could propose a voluntary fortification policy, similar to the U.S. FDA's approach.

Determination of Health Risk

The June 2, 2020 provisions propose that at any time, “the Secretariat will determine those additives, ingredients or substances that, present in the products or at certain levels, can create a health risk in which case the products that contain them they must include a precautionary legend about their consumption.” This clarification in the regulation is particularly concerning given that the criteria for determining that an additive can cause a “health risk” is unclear. In the absence of clearly defined timelines, processes, or parameters to ensure scientific justification for these determinations, the result could be the addition of arbitrary warning labels that are not based on scientific consensus. For example, warning statements could be required for certain ingredients in the absence of scientific consensus of health concerns, but in which there may be social pressure for labeling. A determination lacking scientific rigor, could create concerns of non-tariff trade barriers opening Mexico up to trade disputes.

NOM051 is already estimated to result in more than 80 percent of all packaged foods found on Mexican grocery shelves to contain warning labels, many of which, like those for sweeteners and caffeine, are not backed by robust scientific evidence or rationale. The potential oversaturation of warning labels will only be worsened by the addition of warnings for other additives or ingredients in the future.

Process for Establishing Portion Sizes

The Health Ministry proposes in its June 2, 2020 provisions that the Ministry establish portion sizes in coordination with research and higher education institutions by publishing a notice in the official portal. If the Ministry implements these provisions, FBIA strongly encourages a process that would allow adequate notice and an opportunity for food companies and other relevant stakeholders to participate in this process. Further, any changes to currently-established portion sizes and corresponding label requirements should be science-based and grounded in evidence.

Further Advertising Restrictions May Impact Health and International Trade

As noted above, FBIA supports labeling that empowers consumers to make informed dietary choices that are grounded in strong sound science. Domestically, FBIA members are partnering with the FDA and US Department of Agriculture (USDA) to promote clear, factual, and effective labeling along with consumer nutrition labeling education. We appreciate that the Codex Alimentarius Commission, the World Health Organization (WHO), and the Food and Agriculture Organization (FAO) of the United Nations support the need to assist consumers in making healthier choices through the use of simplified, science-based nutrition information on the front of food packages. But NOM-051 and the corresponding June 2, 2020 provisions could inhibit Mexican consumers from making informed decisions when comparing products since most packaged products would be branded with warning labels while failing to easily inform consumers of the important positive nutrients included. It is important to note that foods without the warning labels, though low in negative nutrients may also be low in positive nutrients, thus leaving consumers in the difficult position of figuring out how to make up a diet that improves their health.

Prohibition on other forms of front of pack nutrition labeling

Current NOM-051 regulations already limit the use of claims denoting important positive nutrients found in shelf stable foods. This limit to positive claims takes away important tools for both consumers and manufacturers.¹¹ For example, consumers will no longer be able to use claims to easily distinguish between an original product and one reformulated to contain lower sugar. The June 2, 2020 provision further restricted the use of any other front of package nutrition seal on products that exceed thresholds defined in NOM-051 and require front of package warning labels via a statement noting that these products “...must not include stamps or legends of recommendation or recognition by organizations or associations professionals.” It is therefore unclear if these provisions apply to claims that are useful to consumers such as whole grain¹² or heart healthy¹³ seals. If so, this proposal would unjustifiably restrict food manufacturers from communicating positive aspects of their food, depriving consumers of information needed to make informed consumption decisions and failing to recognize that foods with front of pack labeling statements can be part of a balanced diet and confer health benefits.

Restrictions on promotional materials

Mexico’s NOM-051 regulations already ban trademarked characters on packaging. The June 2, 2020 proposed provisions further infringe on intellectual property rights and the value of trademarks by extending the prohibition on the use of images targeted to children to all advertising, not only for packaging. The regulations specify that advertising for these products that include warning labels based on NOM051 nutrient profiles “...must not include [children] characters, animations, cartoons, celebrities, athletes or pets, interactive elements, such as visual-special games or digital downloads, aimed at children who incite, promote or encourage

¹¹ Christoforou A, Dachner N, Mendelson R, Tarasuk V. Front-of-package nutrition references are positively associated with food processing. <https://www.ncbi.nlm.nih.gov/pubmed/29227216>. January 2018.

¹² <https://wholegrainscouncil.org/whole-grain-stamp>

¹³ <https://www.heart.org/en/healthy-living/company-collaboration/heart-check-certification>

consumption, purchase or choice of such products.” The regulation is unclear as to whether the proposed restriction on including celebrities, athletes, pets, and interactive elements in advertising would impact all products, or just products intended to be sold to children, creating further uncertainty for food companies.

The food and beverage industry is already working together with the public health community to commit to responsible advertising to children.¹⁴ Combined, NOM-051 and the additional June 2, 2020 advertising provisions will impose severe restrictions on creative promotional and educational opportunities (e.g., sponsorships to encourage activities through sporting events and associations, as well as professional or medical endorsements). It also bans the use of existing and iconic brand characters that can encourage better diets and healthier lifestyles, including drawings, celebrities, gifts, and promotions. Restrictions on speech such as those proposed are inherently pernicious because they substitute the opinion of government for the manufacturer’s intended message and deprive consumers of information that they may find useful. Restricting the use of characters is irrelevant to the nutritional profiles of food products, and there is no clear evidence that such a restriction will have a positive effect on fighting obesity.

Advertising Restrictions Do Not Align with International Standards and Trade Commitments

These requirements also run counter to Mexico’s obligations in trade agreements, including WTO/TBT Article 2.22, and Article 11.3.1(a) of USMCA, which seek to ensure that technical regulations do not create unnecessary trade barriers and require that they be no more restrictive than necessary to achieve the objective. Under Article 11.5.8 of USMCA, Mexico has further committed to “ensure that its technical regulations concerning labels . . . do not create unnecessary obstacles to trade between the Parties,” so as to “avoid disrupting North American trade.” By restricting and proposing to further restrict the ability of exporters to use their labels and advertising to communicate important promotional and educational information to consumers the requirements would create unnecessary obstacles to trade. The creeping and unjustified restrictions on the legitimate use of trademarked characters also raise grave concerns in light of Mexico’s obligations under Article 20 of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which prohibits an unjustifiable encumbrance to the use of trademark in the course of trade.

The June 2, 2020 provisions also baselessly restrict advertising from “indicat[ing] or suggest[ing] that the use or consumption of a product . . . is a determining factor in modifying people’s behavior.” This is an unjustified restriction on speech, which restricts manufacturers’ ability to make truthful and substantiated claims about their products and prevents consumers from learning about a product’s benefits. Moreover, the scope of this prohibition is unclear, making it difficult for marketers to know what types of communications are intended to be prohibited, and therefore potentially restricting more claims than necessary. For example, it is unclear whether a beverage specially formulated to replenish fluids lost during exercise (but requiring, for example, a front of pack sodium statement) would be restricted from making truthful and substantiated claims about its ability to improve consumers’ exercise performance.

¹⁴ <https://bbbprograms.org/programs/all-programs/cfbai/cfbai-core-principles>

There is no scientific basis for prohibiting manufacturers from making truthful and substantiated statements about their products.

Finally, the June 2, 2020 provisions inappropriately increase the authority of the Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) by requiring companies to submit all their advertising to the Agency for prior authorization before use. This will likely cause additional delays and regulatory burden for companies wishing to communicate the benefits of their products in Mexico.

It is Critical the Food Industry is Granted Additional Time to Comply

Nutrient analysis and subsequent label changes take time, a minimum of 18-24 months. The unprecedented demands of COVID-19 have significantly disrupted the supply chain at all levels, locally and globally, including packaging suppliers, many of which have not been operating or doing so at significantly reduced capacity due to the pandemic. Manufacturers will now have to redirect critical resources to meet Mexico's 6-month implementation period. If concerns noted above are not addressed, FBIA is highlighting the need for additional time for compliance as well as detailed guidance to clarify how to comply with the regulation. As such, FBIA requests the compliance date for these proposed regulations be extended at least one additional year. At the same time, FBIA members request that the Mexican government permit extended use of stickers during this label change process.

Closing

FBIA and its member associations support efforts to promote healthy eating, however, NOM-051 and the June 2, 2020 additional provisions are overly prescriptive and will result in consumer confusion, economic burden, and barriers to trade. We believe the regulation will not meet the intended effect of improving the public health of consumers. The additional provisions, if enacted, would also unreasonably restrict manufacturers' ability to fortify a wide range of foods that make up a significant percentage of the Mexican food supply. Experience with front of pack labeling requirements suggests that Mexico may see no corresponding behavior changes, meaning that the Ministry's proposal may lead to widespread nutrient deficiencies, undermining the Ministry's goal of improving public health. The additional provisions would also violate Mexico's international obligations under the WTO and USMCA, by introducing measures that are more trade-restrictive than necessary to accomplish the intended goal of reducing obesity and encouraging informed and balanced diet on exporters, creating unjustifiable encumbrance to the use of important intellectual property right, and creating an outlier approach divorced from the standards of trading partners, each of which would contribute to significant disruption to trade. Additionally, while the industry continues to deal with the complexities of the pandemic and with little more than four months before the implementation date of October 1, 2020, a minimum of a one-year implementation delay is vital.

The members of the FBIA appreciate Mexico's consideration of these comments that outline our concerns and recommendations.

Sincerely,

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