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New agreement on additives and processing aids in food, beverages and dietary supplements: first comprehensive update in over a decade

On August 21, 2026, the Ministry of Health published in the Federal Official Gazette (*Diario Oficial de la Federación*) the new Agreement establishing the additives and processing aids permitted in food, beverages and dietary supplements, their uses and applicable health regulations (the “New Agreement”).

This is the first substantive overhaul of the additive regulatory framework since 2012. The only subsequent amendments (in 2013 and 2016) were limited to targeted adjustments of specific substances in Annex I, without altering the structure or procedures of the Agreement.

The New Agreement expressly repeals the 2012 Agreement and its 2013 and 2016 amendments. It will enter into force 60 business days after publication, i.e., on November 17, 2026. The most significant changes from the previous regime are set out below.

I. A new procedure is created to authorize new, unlisted uses

Under the 2012 regime, when a product or category was not expressly covered by Annexes I, III or VII, manufacturers could use the additive by referencing the Codex Alimentarius or the regulations of the United States, Canada or the European Union, without needing to submit the matter to the authority. The New Agreement eliminates this direct self-application. Manufacturers must now file an application with the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), accompanied by: (i) the applicable provisions of the Codex Alimentarius and the regulations of the United States, Canada and the European Union; (ii) an exposure calculation against the already permitted categories; and (iii) evidence of consumption data for the Mexican population. Based on this information, the authority will assess and confirm the safety of the proposed use before granting authorization.

II. More transparent annex update mechanism with defined timelines

The 2012 text provided for periodic updates to the additive lists, but without a defined schedule. The New Agreement establishes clearer rules: notifications regarding authorized, restricted or prohibited additives will be communicated by official letter to the applicant and published on the COFEPRIS website. Additionally, the annexes reflecting modified additives will be updated on that website every three months, and the full Agreement will be republished in the Federal Official Gazette every six months.

III. Adjustments to functional classes and to the catalogue of flavorings

The list of functional classes and technological functions retains its general structure, but the New Agreement refines and updates definitions. For example, it now expressly distinguishes between natural colorants and synthetic or artificial colorants—a distinction that was not previously defined.

Regarding flavorings, the IOFI (International Organization of the Flavor Industry) is added as a recognized approval source, joining those already recognized since 2012: JECFA (Joint FAO/WHO Expert Committee on Food Additives), the European Union and FDA (Food and Drug Administration) - FEMA (Flavor and Extract Manufacturers Association). This broadens the admissible international references for flavoring use.

IV. New contaminant limits for additives and colorants

For the first time, the New Agreement expressly establishes maximum contaminant limits applicable to additives in general—arsenic, heavy metals and lead—as well as additional limits specific to the colorants listed in Annexes III and IV—mercury and residual solvents. For other contaminants, the Agreement refers to JECFA monographs. This level of detail was not included as a standalone provision in the 2012 text.

V. Transitional rules to bring existing formulations into compliance

The transitional regime of the New Agreement provides staggered timelines depending on the type of adjustment required: (i) 24 months to reformulate products affected by the new numerical limits established for Annex III colorants that were previously permitted under Good Manufacturing Practices; (ii) 12 months to notify uses of additives in categories not included in Annexes I, III and VII under the former mechanism, with an additional 24 months to reformulate if the application is denied; and (iii) a specific 6- and 18-month scheme for gold, silver and aluminum colorants not included in the New Agreement. This is a more granular transitional regime than the one provided for in 2012, which set out more general and uniform timelines.

VI. Updated legal basis and strengthened role of COFEPRIS

The New Agreement updates its express legal basis by explicitly incorporating the right to health protection enshrined in Article 4 of the Constitution, and by referring more precisely to the powers of COFEPRIS under the General Health Law and its Regulations. This strengthens the role of COFEPRIS as an evaluating authority, rather than merely a dissemination channel, as was the case under the previous framework.

Overall, the New Agreement not only updates the catalog of permitted substances after more than a decade without structural review, but also introduces a more rigorous procedure for authorizing new uses, greater predictability in annex updates, and a detailed transitional regime for the industry to adjust its formulations before the effective date.

We remain at your disposal to analyze the specific impact of this new regulation on your operations and to assist you in the timely compliance with the obligations arising from the New Agreement.

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