



A blueprint for the design and implementation of large-scale food fortification programs

Evidence-based guidance to support large-scale food fortification program managers and planners

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Nourish Life



THE IMPACT OF VITAMIN AND MINERAL DEFICIENCIES

As per recently released global estimates, over half (56% or 372 million) of preschool-aged children and about two-thirds (69% or 1.2 billion) of women of reproductive age suffer from vitamin and mineral deficiencies, or deficiencies in essential nutrients such as folic acid, vitamin A, iron, iodine and zinc.

The impacts of such deficiencies are devasting for individuals, families and entire countries. Poor diet and limited access to nutritious foods are among the key reasons for lack of such essential nutrients.

Large-scale food fortification (LSFF) is one means by which to address these nutritional inadequacies. With the addition of essential vitamins and minerals to commonly consumed and industrially processed foods — such as wheat and maize flour, cooking oil, salt and rice — during their processing, fortification is a proven and effective intervention to increase the nutritional quality of food by providing populations with critical nutrients that may be inadequate in or absent from the diet. Consequently, fortification can decrease the health and economic burden associated with nutritionally inadequate diets.

ABOUT NUTRITION INTERNATIONAL AND LSFF

Together with government, industry stakeholders and other key partners, Nutrition International works through mandatory fortification programs and social safety net programs to:

- Support the development and operationalization of food fortification legislation, policies, plans and standards in harmony with regional and international guidelines
- Facilitate the establishment and strengthening of multistakeholder coordination platforms for fortification and nutrition
- Provide technical assistance to establish effective regulatory frameworks, strengthen the capacity of regulators to monitor and enforce and strengthen systematic quality assurance and quality control systems
- Build industry readiness and capacity for food fortification by providing production and customized business advisory assistance to industry partners
- Support global networks and organizations to strengthen the worldwide fortification agenda and add to evidencebased programming guidance



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A blueprint for the design and implementation of large-scale food fortification programs

OVERVIEW

This Fortification Blueprint is the result of a collaboration between Nutrition International and the Food Fortification Initiative that occurred between January and June 2021. At the time of writing, various partners and organizations working in fortification have created and are using different food fortification frameworks to guide program managers throughout the design, implementation, scale up and monitoring of fortification programs. With these multiple frameworks, it can be challenging for nations to determine optimal methods for sustaining and/or implementing food fortification programs, particularly following the cessation of external technical support. To this end, Nutritional International and the Food Fortification Initiative (FFI) conducted a comprehensive literature review accompanied by stakeholder interviews to assess existing food fortification frameworks and craft a novel approach with ideals derived from current frameworks. Based on the findings, including strengths, weaknesses, innovate concepts and gaps found in existing frameworks and obtained from stakeholder discussions, the proposed Fortification Blueprint was drafted.

The goal of the Blueprint is to provide a broad-spectrum guide for program managers (within governments and/or partner organizations) of large-scale, mandatory food fortification programs to follow. The Blueprint considers learnings from a multitude of organizations and individuals, in addition to components known about current fortification programming shortcomings (e.g., limited attention given to reassessing fortification program design, to effective private sector business models, or to capacitating national academic institutions).

The Blueprint is organized into seven major programming actions, with each action further separated into specific detailed components. Where relevant, the Blueprint provides existing tools and/or resources, which have been chosen based on evidence of applicability, technical accuracy and practical application, to ensure each step is actionable by the user.

Although the Blueprint provides the seven major programming actions as a sequence of steps, one following the other, it should be noted that several of the activities could occur simultaneously. The sequencing of the seven actions should be taken as a general guide and should not be interpreted as requiring countries to explicitly follow actions as numbered. For example, although countries will need to establish standards before the private sector begins fortification, a fortification strategy or policy does not necessarily have to be formally prepared before standards or legislation are finalized. Similarly, engaging and/or strengthening civil society or national laboratories can commence in the early stages of fortification implementation and does not have to wait until the formulation of policies or strategies.

As new tools and resources become available and/or the knowledge of the fortification landscape changes, the Blueprint will be updated by the designers accordingly.

A Technical Working Group, comprised of representatives from Nutrition International, FFI, UNICEF, USAID and the Bill and Melinda Gates Foundation, came together between 2021 and 2022 to review the content of the Fortification Blueprint and agree upon the set of tools and resources that are provided herein. We thank these organizations and individuals for their contributions and inputs into the current Blueprint. The Technical Working Group will continue to meet to ensure the contents and structure of the Blueprint are kept up to date and relevant as new learnings and resources are established. A permanent online "home" for the Blueprint is currently being sought that would ensure wide and relevant use by key stakeholders and organizations.







HOW THE BLUEPRINT SHOULD BE USED

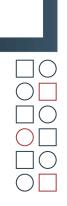
Large-scale food fortification programs are only effective and sustainable when they are led by relevant in-country leaders and owned and operated by national governments and private sector stakeholders. The Blueprint has been designed as a general guiding structure for any entity or stakeholder. For example, it could be used as they embark on leading a new or revising an existing national program or if they are a key stakeholder integral to the success of a fortification program attempting to better understand what their role is and how they can effectively carry out that role. Another example would be for an external partner providing short-term advice or support to a country attempting to begin or improve their national program. As currently designed, the Blueprint is agnostic to the user, however, the central theme that needs to be understood when using the Blueprint is the fact that national fortification programs are just that — national programs — to be owned and operated long-term by the country. The guidance presented within this resource needs to be applied with that understanding and appreciation for it to be effective.





2. High level overview of the Fortification Blueprint

	<u> </u>
	JUSTIFY: Identify need and feasibility with national stakeholders
Assess	a) Identify need and relevance of fortification; assess fortification as part of a mix of interventions
	b) Demonstrate feasibility of fortification
	c) Provide justification for fortification
	2. GALVANIZE: Map and motivate key stakeholders
	a) Map fortification stakeholders
	b) Build partnerships/alliances
Analyze	c) Garner political will
, ,	d) Support national budgetary inclusions
	e) Support political, private and civic sector advocacy
	f) Align national programs with global/regional efforts and guidance bodies
	g) Identify and mobilize fortification champions
	ENABLE: Establish guiding structures related to policy, legislation, standards and monitoring guidelines
	a) Draft fortification policy
	b) Draft fortification legislation
	c) Establish fortification requirements included in food standards or food regulations
	d) Identify/establish inspection, audit and enforcement opportunities within existing food control system
	4. OPERATIONALIZE: Establish an enabling environment for industry
	a) Identify industry scale-up support; ensure strong QA/QC protocols (including quality premix and equipment)
Act	b) Explore effective business models for food producers
	c) Ensure creation of a level playing field
	5. MONITOR: Enable inspection, audit and enforcement
	Establish and strengthen regulatory monitoring and enforcement systems (including training inspectors on regulatory monitoring practices or an alternative means of assessing compliance)
	b) Capacitate civil society to hold industry accountable
	c) Strengthen laboratories
	6. EVALUATE: Establish coverage and nutritional impact assessment and evaluation
	a) Support integration of key indicators into ongoing national surveys
	b) Capacitate academic institutions
	7. REVIEW & REASSESS: Ensure continued program harmonization and optimization
Reassess	Review relevance and appropriateness of fortification standards and program design; make adjustments as necessary
	INSTITUTIONALIZE: Ensure national program ownership
Cross-	a) Integrate fortification into existing nutrition plans and national systems
cutting theme	b) Support the creation of academic curriculum on fortification
	c) Establish mechanisms that favor financial self-sustainability



3. Fortification Blueprint: Detailed program guidance

1. JUSTIFY: IDENTIFY NEED AND FEASIBILITY WITH NATIONAL STAKEHOLDERS

a) Identify need and relevance of fortification; Assess fortification as part of an optimal mix of interventions

Identify professionals and institutions within the country with knowledge, credibility and experience in public health nutrition who can champion or influence fortification programming in-country.

Obtain up-to-date micronutrient deficiency data and/or dietary inadequacy data and establish the need to improve population nutrient intake for specific vitamins and minerals, disaggregated by geography and demographics as possible. Map the pattern of micronutrient deficiencies and/or dietary inadequacy to ascertain the target population in need (this step includes determining the demographic and geographic groups affected by micronutrient deficiencies). Identify other current micronutrient interventions in place and model the contribution of fortification/fortified foods vis-à-vis other micronutrient interventions to diets and to reducing micronutrient inadequacies. Determine sufficiency of existing micronutrient strategies to address the identified nutritional need, demonstrate that fortification can fill the nutritional gap while complementing other nutrition-specific interventions and assess regional fortification efforts and implications nationally.

Tools/resources: Coverage and impact data for other micronutrient interventions: Fortification assessment coverage toolkit (FACT), if a fortification program is already in place | Micronutrient survey manual and toolkit includes resources to help assess and monitor vitamin and mineral deficiencies | National level surveys, i.e., Demographic Health Survey (DHS), Household Income and Expenditure Surveys (HIES), Multiple Indicator Cluster Survey (MICS), national nutrition surveys | WHO Vitamin and Mineral Nutrition Information System (VMNIS) | OPTIMA Nutrition | The Lives Saved Tool LiST | WFP's Fill the Nutrient Gap | FANTA Optifood. Optimization assessments: University of California at Davis MINIMOD tool | Micronutrient Action Policy Support (MAPS)

b) Demonstrate feasibility of fortification

Based on knowledge of the target population obtained in step "1a" above, identify appropriate vehicle(s) via the "5 Cs": coverage, cost, consumption, central processing, compatibility, as well as physiological availability, presence of inhibitors in the diet and flour extraction rates. Assess milling/production infrastructures, reach and readiness of production facilities; conduct market analysis (including a review of storage conditions); conduct a supply chain diagnostic; consider economic implications and/or conduct an economic analysis.

Tools/resources: Consumption and/or coverage data: Catalogues for completed surveys, some of which provide datasets for download in certain instances: World Bank's Living Standards

Measurement Survey (LSMS) microdata library | International Household Survey Network (IHSN).

(In order to analyze nutrient gaps, however, the apparent intake data require food composition tables to convert intake into micronutrient content). FAO country profiles for food availability data in grams per capita per day | FAO INFOODS for national and regional food composition tables FAO/GIFT for country-specific food consumption data | Fortification Rapid Assessment Tool (FRAT) | GENUS Dataverse | Global Health Data Exchange (GFDx) | International Household Survey Network |

National-level HIES/HCES survey data | Tufts Global Dietary Databases | WHO/CDC e-Catalogue (quality, coverage, biological indicators, process indicators)

Supply chain assessment: Example supply chain diagnostic template for rice.

c) Provide justification for fortification

Based on evidence collected above on need, relevance and feasibility, build a case to present to government that justifies the inclusion of fortification into the national nutrition strategy and/or implementation plans.

Tools/resources: Cost Benefit Analysis (CBA) tool for wheat flour and cooking oil.

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2. GALVANIZE: MAP AND MOTIVATE KEY STAKEHOLDERS

a) Map fortification stakeholders

Identify all government stakeholders that will be involved in a fortification program to gauge existing capacity and the gaps that need to be filled. Determine all partner organizations providing nutrition-specific and nutrition-sensitive support to the government. Assess the added value of additional external partners support for fortification based on technical abilities, budgets, timelines and mandates. Build partnerships/alliances with other development partners working in the country on nutrition interventions and messaging in order to provide a harmonized message to government.

Tools/resources: Example of partner mapping assessment

b) Build partnerships/alliances

Identify and convene all stakeholders including, but not limited to, producers, civil society (e.g., consumer groups, parent and physician groups), necessary government agencies including regulatory bodies, academia and external partners. Establish an alliance platform (often referred to as a National Fortification Alliance or NFA), agree on roles and responsibilities of stakeholders, identify the lead or home agency/ministry responsible for guiding the national fortification program and identify means of long-term functionality for this alliance. Industry engagement in this context should include consultation with food producers regarding the scope of legislation, standards, implications on regional trade and implementation timelines. NFAs are useful mechanisms to allow different stakeholders to establish roles and responsibilities, coordinate efforts, drive collective decision-making and take shared action. The establishment of a coordination or oversight structure is critical since inadequate or ineffective coordintion is, in many cases, one of the weakest points of mandatory fortification programs.

Tools/resources: "What is a national fortification alliance?"

c) Garner political will

Conduct a political readiness assessment and obtain permission and willingness of government to move forward. Make a formal presentation to the relevant government body that recommends effective staples and market channels based on diagnostic results. Support the relevant government agency to establish a plan and move to the next phase. The primary actions government will need to include (i) drafting a policy; (ii) passing legislation; (iii) inspecting, auditing and enforcing; (iv) coordinating/overseeing and maintaining long-term; and (v) assessing and evaluating. Each action is vital to the success of the program; different sectors of government will be responsible for each action.

d) Support national budgetary inclusions

Outline all expected one-time and recurring government costs required for the program. Initiate high-level discussions that include a line item for fortification in fiscal year budgets. Discussions should outline one-time and recurring costs and establish the paying entity for each activity. The budget should include requirements for routine monitoring and alliance meetings and may also include surveillance/impact work.

The University of California at Davis <u>MINIMOD</u> tool, used to help inform optimal interventions, contains a costing module with line items to calculate the cost of implementing fortification from the regulatory perspective. Since this component is not publicly available, users will need to work directly with <u>MINIMOD researchers</u> to access this budget template

e) Support political, private and civic sector advocacy

Assess the type of targeted advocacy that may be needed including civic sector, ministerial level and/or private sector.

Civic sector: Engage neurosurgeons, consumers associations, parents groups, political groups, local leaders.





Ministerial level: Advocate across ministries including health, finance, education, trade and commerce. Include cost-effectiveness analyses (outlined in 1b), if appropriate.

Private sector: Engage food producers, industry associations, other private sector entities. Demonstrate to the private sector their potential contribution to national-level nutritional and economic impacts and assess perceived barriers to implementation by the private sector. Assess consumer perceptions of fortification, address any misconceptions and outline cost implications for consumers.

Tools/resources: Advocacy toolkit for individuals advocating for fortification as a means of preventing brain and spine birth defects in Africa. The toolkit can be adapted for use in other regions. | FFI fortification advocacy toolkit and workbook

f) Align national programs with global/regional efforts and guidance bodies Engage regional bodies, such as CARICOM, ECSA, SADC, ECOWAS; ensure harmonization with global guidelines, regional standards, or neighboring countries; obtain support as needed for

global guidelines, regional standards, or neighboring countries; obtain support as needed for implementation. Advocate for the inclusion of fortification into Scaling Up Nutrition (SUN) activities or other national/regional/global nutrition efforts.

Tools/resources: CARICOM (the Caribbean Community) regional fortification standards | Economic Community of West African States (ECOWAS) harmonized regional fortification standards | ECSA (East, Central and Southern Africa) Health Community wheat flour, maize flour and edible fats fortification standards | ECSA inspection guidelines at POE and Markets and ECSA Internal and External Inspection Guidelines | Southern Africa Development Community (SADC) minimum standards for fortification

g) Identify Fortification Champions

Ideally, this group will include individuals who can advocate for fortification in the country. Champions could be, but are not limited to, a political appointee, celebrity, or members of civil society, such a neurosurgeon or an academician.

Tools/resources: Example advocacy declaration: <u>The North American Teratology Society - Resolution</u> on Folic Acid Fortification



3. ENABLE:

ESTABLISH GUIDING STRUCTURES RELATED TO POLICY, LEGISLATION, STANDARDS AND MONITORING GUIDELINES

a) Draft fortification policy

The government should draft and adopt a national fortification policy as a stand-alone policy or strategy or integrate the fortification policy within an existing national nutrition or micronutrient policy or strategy. Such a policy or strategy does not necessarily need to be formalized prior to the adoption of relevant legislation, but the process of formalization should be initiated at this early stage of programming.

Tools/resources: Example fortification and micronutrient policies or strategies: Malawi fortification strategy | Malawi national micronutrient strategy | Tanzania fortification action plan

b) Draft fortification legislation

Map the legislative process for a mandatory fortification program and support efficient enactment of the legislation. Address potential communication gaps between industry leaders and public sector leaders often resulting in legislation and standards that restrict, rather than enable, private sector investment in fortification. Legislation (and standards) for fortification should be within the national food control system, rather than a "stand-alone" intervention. The food control system sets basic requirements for food quality and safety; fortification should be legislated as a component of this system to facilitate implementation, enforcement and sustainability.

Tools/resources: <u>FFI document checklist</u>: Fortification legislation, standards and monitoring often miss key items. Use this checklist to review necessary components in English, French, Russian and Spanish.

c) Establish fortification requirements included in food standards or food regulations

Ensure alignment of the formulation of premix and specific nutrients levels and ranges intended to fill the identified nutritional gaps with up-to-date consumption data. Ensure harmonization of fortification standards with existing interventions/policies and regional fortification standards. Standards should include up-to-date guidance on most appropriate fortificant forms and methods to establish realistic target levels and ranges. Include all relevant stakeholders in the standards setting process and ensure the regulations are enforceable in the context. Standards (and legislation) for fortification should be requirements within the national food control system rather than a "stand-alone" intervention. The food control system sets basic requirements for food quality and safety; fortification standards should be a component of this system to facilitate implementation, enforcement and sustainability.

Tools/resources: FFI document checklist: Fortification legislation, standards and monitoring often miss key items. Use this checklist to review materials in English, French, Russian and Spanish | WHO guidelines on fortification | WHO Intake, Monitoring, Assessment, and Planning Program (IMPAPP) and related software to estimate intake distributions | Tools for establishing country-specific fortification standards: Food Fortification Formulator | Proposing nutrients and nutrient levels for rice fortification | WHO recommended fortification levels (salt, wheat and maize flour)

d) Identify/establish inspection, audit and enforcement opportunities within existing food control system

Agree upon and draft realistic guidelines for government inspection, auditing and enforcement to ensure compliance with national standards, including effective incentives and penalties for production of fortified foods and for the production of compliant fortified foods; establish linkages to food safety.

Tools/resources: FFI document checklist: Fortification legislation, standards and monitoring often miss key items. Use this checklist to review materials in English, French, Russian and Spanish. | 2018 Regulatory Monitoring Policy Guidance document; template for the adaptation of the Regulatory Monitoring Policy Guidance Document to a country specific context.



4. OPERATIONALIZE:

ESTABLISH AN ENABLING ENVIRONMENT FOR INDUSTRY (FORTIFICATION BEGINS)

a) Identify industry scale-up support and ensure strong quality assurance and quality control (e.g., internal monitoring) protocols (including quality premix and equipment)

Secure technical support to industry in the scale-up for fortification including sourcing, installation and maintenance of proper equipment; sourcing and importation of quality premix; and creation of strong quality assurance and quality control systems. Continue to engage industry associations and continue to involve industry in discussions concerning legislation, standards, monitoring and implementation timelines.

Tools/resources: <u>Basic checklist for fortification practice</u> | <u>FFI flour miller's toolkit</u> | <u>Flour Miller's quick guide checklist</u> | <u>Global Alliance for Improved Nutrition (GAIN) Global Premix Facility</u> | <u>Rice Miller's toolkit</u>

b) Exploration of effective business models for food producers

Producer perspective model: determine models to incentivize producers/businesses to fortify food, assess potential approaches that could be used to create consumer demand and examine the feasibility and structure of potential tax breaks. Ensure that premix and fortification equipment are included as duty-free products nationally. Make attempts to address foreign exchange issues, if relevant, and explore operational efficiencies to offset fortification costs. These efforts should be explored even in light of mandatory legislation for fortification, to ensure an enabling environment for food producers.

c) Ensure creation of level playing field

Assess the types of consumer advocacy government is willing to undertake once industries commence fortifying food. Determine how government can ensure that communities are accepting of fortified food. The private sector can communicate consumer benefits of specific products, but the public sector can more credibly communicate the health and national development benefits.

Tools/resources: Example communication plan from the Solomon Islands for government, industry and consumers with separate activity plans by audience.

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5. MONITOR:

ENABLE INSPECTION, AUDITING AND ENFORCEMENT

a) Establish and strengthen monitoring systems

Train inspectors on assessing process monitoring, conducting audits, leading end-product inspections and carrying out enforcement measures within food production facilities as outlined in national monitoring guidance documents. If food safety inspectors/inspections do not have capacity or if food safety inspectors/inspections do not exist within a country, determine alternative means of retrieving compliance information, including the potential roles of consumer groups and existing national databases in providing said information.

Tools/resources: Case studies on flour fortification monitoring | 2018 regulatory monitoring policy guidance document

Example self-regulation model used in Nigeria: <u>Technoserve Micronutrient Fortification Index</u>

b) Capacitate civil society to hold industry accountable

Capacitate consumer groups, parent groups (i.e., spina bifida associations) and/or academia to assess fortified products sold in the market for compliance to national standards, as necessary and appropriate.

Tools/resources: "Pull Strategy" report and toolkit

c) Strengthen laboratories

Ensure designated national or regional labs have the necessary infrastructure and capacity to quantitatively or qualitatively test for nutrients in food.

Tools/resources: ECSA laboratory manuals | Qualitative spot test for iron in fortified rice



6. EVALUATE:

ESTABLISH COVERAGE AND NUTRITIONAL IMPACT ASSESSMENT AND EVALUATION

a) Support integration of key indicators into ongoing national surveys

Incorporate relevant fortification, micronutrient and food coverage and consumption indicators into national Demographic and Health Surveys (DHS) and/or other relevant national studies as a means to gauge changes in nutritional status or consumption patterns throughout the life of the program.

Tools/resources: Examples from countries include: 1) a micronutrient module included in the-Papua New Guinea DHS. Existing government surveillance systems for neural tube defects could be used to assess changes in nutritional status: this Birth Defect Surveillance tool includes a manual for program managers and an online, self-paced course for health professional or other interested individuals in English, Spanish and French. Existing health management information systems could also be used to share trends before and after fortification.

b) Capacitate academic institutions

Strengthen and commission academic institutions to conduct and support surveys, surveillance, analysis and impact studies.

Tools/resources: CDC micronutrient survey toolkit | Fortification assessment coverage toolkit (FACT) | FORTIMAS (FORTIMAS uses sentinel surveillance sites to assess trends in fortification production and access to fortified foods) | This Birth Defect Surveillance tool includes a manual for program managers and an online, self-paced course for health professional or other interested individuals in English, Spanish and French.



7. REVIEW AND REASSESS:

ENSURE CONTINUED PROGRAM HARMONIZATION AND OPTIMIZATION

a) Review relevance and appropriateness of fortification standards and program design (in light of national changes and regional or global recommendations) and make adjustments as necessary

Program managers should review the overall design of the fortification program, including fortification requirements in food standards, every five years to coincide with the formulation of national nutrition and health plans and/or with national changes in dietary patterns, nutritional deficiencies, environmental health, production capacity and profiles, or implemented nutrition programs. The review should include efforts to generate evidence and sustain political will as necessary. Program managers should view fortification programs as dynamic and under constant evolution with the ability to respond to contextual changes. The review of fortification program design, including fortification standards, should be led by the in-country "home" ministry or agency of the program.

CROSS-CUTTING THEMES

Institutionalize: If the fortification program receives external support, focus should be placed on design, advocacy and establishment of programming guidelines. Structures should be established in the country that allow for ownership of the program including appropriate budget allocations, knowledge of programming aspects and champions to advocate for fortification during political turnover/transitions.

a) Integration of fortification into existing national systems

Although this component is embedded throughout specific blueprint activities outlined above, including references to tools and resources to further enable institutionalization of fortification, it is worth emphasizing this component again as a cross-cutting theme that program managers should considered throughout program planning and implementation. Mandatory fortification of staple foods should be integrated into existing systems and structures to ensure sustainability. This integration includes fortification as part of national nutrition strategies or policies; fortification legislation under the national food act or equivalent; fortification requirements imbedded into national food standards; premix included on duty-free importation lists; inspections, audits and enforcement conducted through routine food control or safety protocols; on-going fortification maintenance costs accounted for in national budgets and fortification program indicators integrated into routine national surveys.

b) Support the creation of academic curriculum on fortification

Ensure that nutrition programs within academic institutions cover the purpose, components, methods and impact of fortification programming.

Tools/resources: Kansas State University (KSU) and Food Fortification Initiative (FFI) training module | KSU/FFI/GAIN online courses for wheat flour and rice fortification monitoring | Kenya's Africa School of Milling Training

c) Establish mechanisms that favor financial self-sustainability

These mechanisms may include components ensuring purchases of duty-free premix and fortification equipment and/or, if not declared as duty-free, committing funds generated from these taxed items to budgets to monitoring the food industry and enforcing compliance to national fortification standards.



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