

► LITERATURE REVIEW

From Implementation to Impact: Building the Evidence Base for the Retail Program Standards

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Abstract Numerous studies have evaluated individual components of retail food safety systems, including the Food and Drug Administration (FDA) *Food Code*, certified food protection managers, Active Managerial Control, and routine inspection. Far less attention has been paid to whether the FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) function as an integrated systems intervention that improves public health outcomes. This article traces how outbreak science was translated into measurable risk factors, describes the retail regulatory program as the delivery system through which those risks are managed, and assesses what the published literature establishes for each link between Retail Program Standards conformance and population health. Evidence for individual components is substantial and, in several cases, outcome-linked, but no identified study evaluates the framework as a whole or asks whether incremental gains in conformance yield incremental improvements in outcomes. We set out the mechanisms the framework presumes and the evaluation question that follows from them.

Keywords: retail food safety, Retail Program Standards, foodborne illness prevention, foodborne illness risk factors, regulatory program capacity, program evaluation

Introduction

Although numerous studies have evaluated individual components of retail food safety systems, including the Food and Drug Administration (FDA) *Food Code*, certified food protection managers, Active Managerial Control, and routine inspection, surprisingly little research has examined whether the FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) function as an integrated systems intervention that improves public health outcomes. The Retail Program Standards rest on the premise that food safety depends on the coordinated performance of an entire regulatory program rather than on

any single regulatory activity. That premise has not been tested.

This article makes the case for testing it. We first trace how outbreak science was translated into a set of measurable, controllable risk factors, then describe the retail regulatory program as the delivery system through which those risks are managed, and set out the Standards as the framework intended to strengthen that system. We then assess what the published literature does and does not establish for each link in that framework and identify the remaining gap. The aim is not to present new data but to specify, clearly enough to be acted on, the evaluation question the field has yet to answer.

Background: Foodborne Illness as a Preventable Public Health Challenge

Foodborne illness remains a significant public health burden despite decades of advances in food safety regulation, surveillance, and industry practices. National surveillance systems have documented thousands of foodborne disease outbreaks and have produced an increasingly detailed understanding of the pathogens, foods, and environmental conditions associated with illness. Their fundamental purpose has remained consistent: To identify outbreaks, characterize their causes, and generate information that can guide prevention (Centers for Disease Control and Prevention [CDC], n.d., 2026a).

As national outbreak surveillance matured, investigators increasingly recognized that outbreaks were rarely isolated or unpredictable events. Investigations repeatedly identified environmental and operational conditions that enabled contamination, pathogen survival, or pathogen proliferation in retail food establishments. These recurring conditions demonstrated that foodborne illness often resulted from preventable failures in food handling, preparation, and management rather than from random or unavoidable events (CDC, 2026b).

Environmental assessments became an essential part of these investigations, supplying the operational context needed to under-

stand how and why outbreaks occurred. The Centers for Disease Control and Prevention (CDC) describe them as complementary to epidemiologic and laboratory investigation, with the purpose of identifying the environmental conditions and contributing factors behind an outbreak and informing interventions to prevent similar events (CDC, 2026b).

Outbreak investigation is nevertheless inherently retrospective, explaining events only after illness has already occurred. It does not, by itself, give regulatory agencies a practical framework for identifying and controlling these conditions before outbreaks develop (CDC, 2026b). The challenge was therefore no longer limited to understanding why outbreaks occurred, but to translating that understanding into preventive approaches embedded in routine regulatory practice.

Translating Outbreak Science Into Prevention

The growing understanding of the conditions associated with foodborne illness created an opportunity for regulatory agencies to move from retrospective response toward prospective prevention (FDA, 2000, 2006a). Drawing on CDC outbreak surveillance data from 1988 through 1992, FDA identified recurring patterns organized into five broad categories of retail foodborne illness risk factors: 1) food from unsafe sources, 2) inadequate cooking, 3) improper holding temperatures, 4) contaminated equipment, and 5) poor personal hygiene. These categories described controllable operational conditions rather than disease outcomes, giving regulators measurable targets for intervention before illness occurred (Bean et al., 1996; FDA, 2000).

FDA further recognized that foodborne illness itself was not an appropriate performance measure for routine regulatory oversight, because illnesses are substantially underreported and numerous external factors influence detection. The occurrence of known risk factors offered a more practical and meaningful indicator of retail food safety performance than outbreak counts alone (FDA, 2000). This framework became the foundation for the Retail Food Risk Factor Study, which established a standardized methodology for measuring the occurrence of the five risk factors nationwide, repeated through an initial 10-year study and a second long-term study initiated in 2013

(FDA, 2000; FDA National Retail Food Team, 2009).

FDA has continued to strengthen preventive practice through successive editions of the *Food Code*, which translate current scientific knowledge into model regulatory provisions and provide the science-based foundation for evaluating food safety practices across jurisdictions (FDA, 2023). Requirements alone, however, are not prevention. FDA has increasingly emphasized Active Managerial Control, the process by which establishments identify hazards, implement preventive procedures, monitor their effectiveness, and take corrective action before unsafe conditions develop, thereby shifting the locus of food safety from periodic inspection to daily operations (FDA, 2006b, 2014).

Retail Food Regulatory Programs as the Public Health Delivery System

Preventing foodborne illness ultimately depends on the practices and conditions present within individual retail establishments. The *Food Code* sets out science-based recommendations and Active Managerial Control assigns responsibility for applying them, but these principles must be implemented consistently across hundreds of thousands of diverse operations. Retail food regulatory programs are the mechanism through which that implementation is evaluated, reinforced, and promoted (FDA, 2006b, 2014, 2023).

These programs do considerably more than conduct routine inspections. Their functions include plan review, permitting, complaint investigation, outbreak response, compliance and enforcement, education, and technical assistance. Together, these activities allow an agency to evaluate practices, identify risk-factor conditions, communicate corrective actions, and verify that deficiencies have been addressed (FDA, 2006b, 2014, 2023).

Despite a common public health mission, retail food regulatory programs vary considerably in organization, staffing, inspection methods, data systems, quality assurance, and approaches to compliance and enforcement. Earlier evaluations produced mixed evidence on the effectiveness of inspection frequency and food handler education considered in isolation, but more recent work indicates that program characteristics may influence both establishment behavior and public health

outcomes (Kim et al., 2021). That evidence is examined in detail in the following sections.

Recognizing the need for greater consistency in how retail food regulatory programs are delivered and evaluated, FDA developed the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) as a framework for continuous program improvement. The standards do not impose requirements on retail establishments; they define the essential elements of an effective regulatory program, including program management, workforce competency, inspection quality, risk-based approaches, quality assurance, and continuous improvement (FDA, 2026).

The Voluntary National Retail Food Regulatory Program Standards

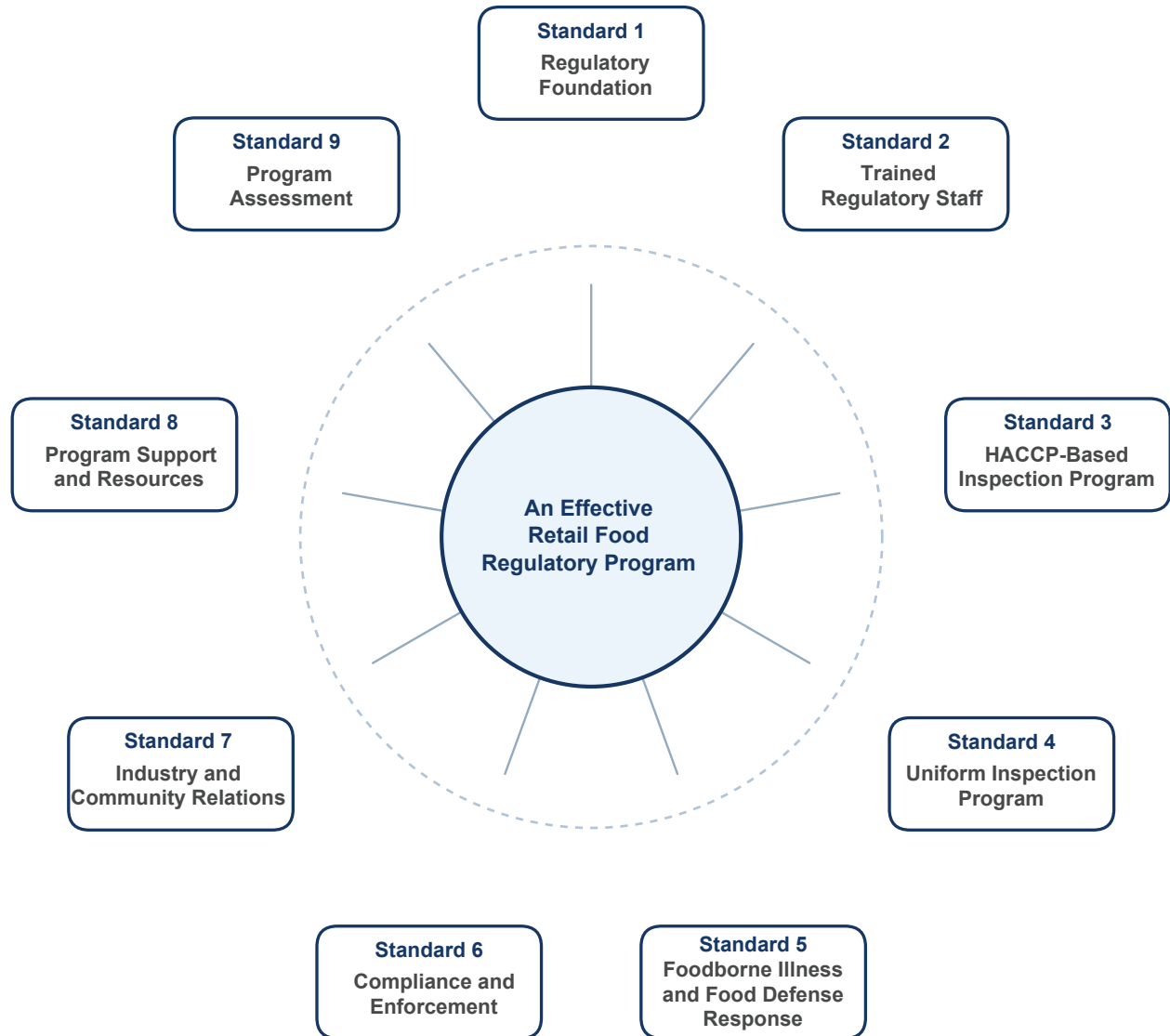
Although retail food establishments are ultimately responsible for producing safe food, the effectiveness of those efforts is shaped by the regulatory environment in which they operate. The Retail Program Standards were developed to strengthen the public health infrastructure supporting retail food safety, improving the programs responsible for implementing and verifying science-based practices rather than regulating establishments directly (FDA, 2026).

The Retail Program Standards were introduced in 2000 and have been revised periodically to reflect advances in food safety science and regulatory practice. They establish nationally recognized performance standards for state, local, tribal, and territorial retail food regulatory programs and serve as the primary model for continuous program improvement in the U.S. Participation is voluntary, but the Retail Program Standards have become the recognized benchmark for evaluating the capacity and performance of these programs (FDA, 2026). The nine standards address the organizational, operational, and technical components required to support consistent implementation of science-based food safety practices (Figure 1).

The Retail Program Standards are interdependent rather than independent, and the dependencies run in several directions at once. A uniform inspection program (Standard 4) is difficult to sustain without trained regulatory staff (Standard 2), and neither achieves much without the resources to support them (Standard 8). Risk-based

FIGURE 1

The Nine Voluntary National Retail Food Regulatory Program Standards From the Food and Drug Administration



Note. HACCP = hazard analysis critical control point.

inspection (Standard 3) generates the data on which program assessment (Standard 9) depends, and assessment in turn identifies where inspection practice needs to change. Outbreak response (Standard 5) both draws on and informs routine oversight. The effectiveness of any one standard, therefore, depends on the performance of others, and it is this interdependence that distinguishes the Retail Program Standards from the indi-

vidual interventions that the literature has traditionally evaluated.

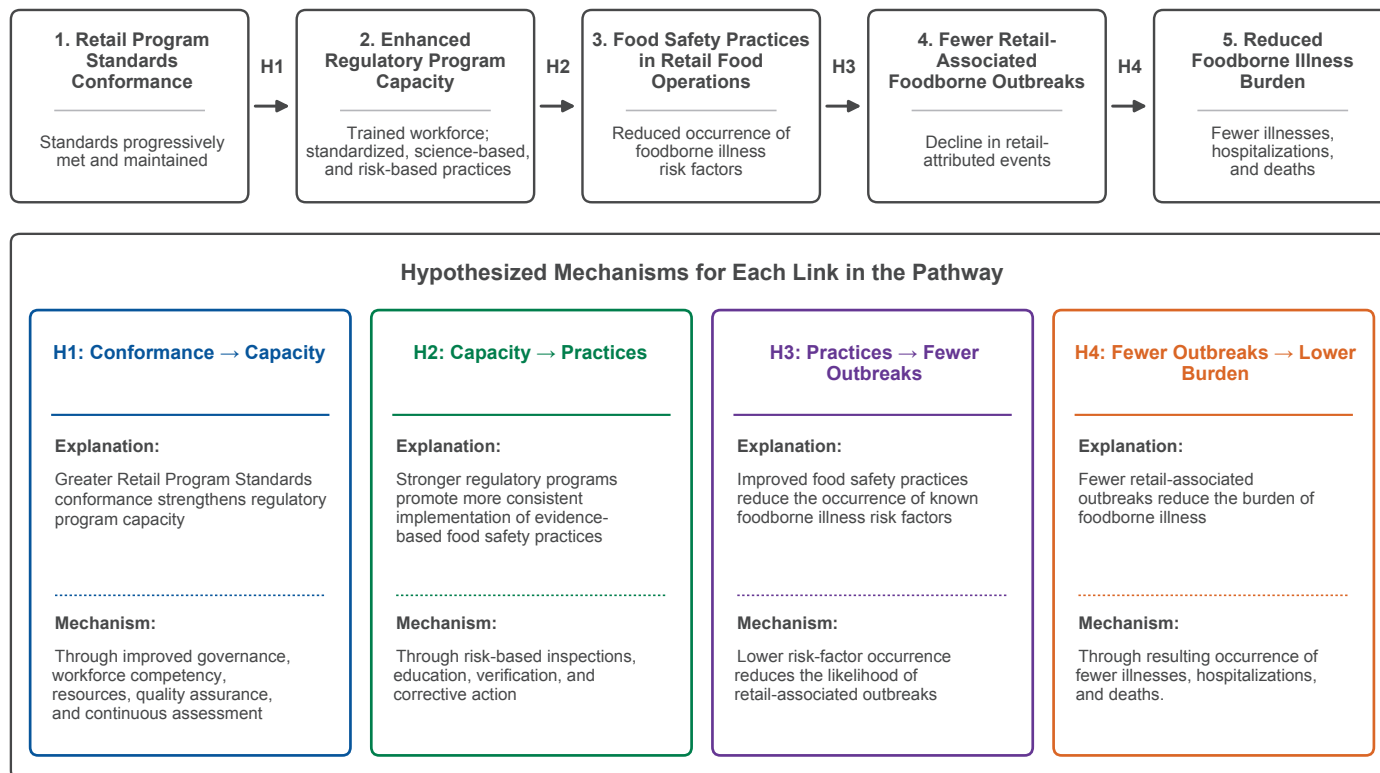
The standards articulate a theory of how stronger regulatory systems improve public health: Programs with sufficient capacity, competent personnel, consistent science-based practice, and effective partnerships are better positioned to influence food safety behavior in retail establishments, thereby reducing risk factors and, ultimately, improving public

health outcomes. Figure 2 sets out that pathway, numbering each link and stating the presumed mechanism operating at each.

A diagram of this kind asserts relationships; it does not establish them. The mechanisms set out in Figure 2 are propositions rather than findings, and they are not equally well supported: H4 (hypothesized pathway 4) is close to definitional, while H1 (the link that most distinguishes the Retail Program Standards

FIGURE 2

Conceptual Framework: Hypothesized Pathway From Retail Program Standards Conformance to Public Health Impact



Note. This framework, conceptualized by the authors, illustrates a hypothesized pathway (i.e., H1, H2, H3, H4) by which the implementation of the Food and Drug Administration's Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) might reduce the burden of foodborne illness. Further, H1–H4 denote the proposed relationships between stages, together with the mechanism presumed to operate at each. These are propositions for empirical evaluation, not established findings. This model applies to all retail food regulatory programs that voluntarily conform to the Retail Program Standards, regardless of funding source.

from their individual components) has the least direct evidence behind it. The section that follows examines what the published literature establishes for each pathway, and the empirical work that follows this article will test them individually rather than as a single claim.

Evidence Base and Integrated-Framework Gap

The preceding sections traced a single line of reasoning—that recurring, controllable conditions give rise to most foodborne illness, that retail regulatory programs are the system through which control of those conditions is promoted and verified, and that the Retail Program Standards organize the components of an effective program into a coherent framework. That framework describes a theory of change. It does not, by itself, establish that the

published evidence supports each step in it. Table 1 summarizes what the literature does and does not establish for each component. This evidence was drawn from peer-reviewed databases, supplemented by reports from relevant federal agencies and public health organizations, covering work published between 1994 and 2023. Searches paired the names of individual program components with terms for foodborne illness, outbreaks, and inspection outcomes, and a source was retained when it linked a component to a public health or intermediate outcome and could be verified against the primary publication.

The final link in this chain is close to definitional. The five foodborne illness risk factors were derived from recurring contributing factors identified through outbreak investigations. Because they represent con-

trollable conditions repeatedly implicated in outbreaks, reducing their occurrence is expected to reduce the likelihood of foodborne illness (Bean et al., 1996; FDA, 2000). Evidence concerning establishment-level practices supports several links in this pathway. Adoption of selected *Food Code* provisions has been associated with lower rates of reported foodborne norovirus outbreaks (Kambhampati et al., 2016). Certified food protection managers have been associated with improved inspection outcomes and were less common in outbreak restaurants than in comparison restaurants (Cates et al., 2009; Hedberg et al., 2006). FDA risk-factor studies have also associated the presence of certified managers and well-developed food safety management systems with improved control of foodborne illness risk factors, consistent

TABLE 1

Evidence Base for Components of the Retail Food Safety System

Component	Strength of Evidence	Representative Evidence
FDA Food Code	Strong	Adoption of specific provisions associated with lower norovirus outbreak rates (Kambhampati et al., 2016)
Active Managerial Control	Strong	Well-developed food safety management systems associated with improved control of risk factors (FDA, 2014; FDA National Retail Food Team, 2009)
Certified food protection managers	Strong	Associated with fewer outbreaks and fewer critical inspection violations (Cates et al., 2009; Hedberg et al., 2006)
Routine inspections	Mixed	Scores and frequency alone inconsistently predict illness (Jones et al., 2004; Riben et al., 1994); point-of-service disclosure and grading show clearer associations (Firestone & Hedberg, 2018; Kim et al., 2021, 2022)
Program capacity (e.g., workforce, budget, experience)	Moderate	County-level capacity associated with lower foodborne illness morbidity (Zablotsky Kufel et al., 2011)
Retail Program Standards as an integrated system	Limited	Adoption and implementation described (Gill et al., 2023; National Association of County and City Health Officials, 2017); no identified study evaluates the framework as a whole

Note. FDA = Food and Drug Administration; Retail Program Standards = Voluntary National Retail Food Regulatory Program Standards.

with the mechanism underlying Active Managerial Control (FDA, 2014; FDA National Retail Food Team, 2009).

Evidence also exists for the regulatory activities the Retail Program Standards are designed to strengthen. Routine inspection data can distinguish outbreak-associated establishments from others, and specific violations correspond to outbreak-associated risk (Buchholz et al., 2002; FDA, 2006b; Hedberg et al., 2006; Petran et al., 2012a, 2012b). Point-of-service disclosure and grading have been associated with improved inspection-program outcomes and fewer reported foodborne outbreaks. In New York City, letter grading was also associated with declining *Salmonella* infection rates, and the outbreak association was subsequently examined using national surveillance data (Firestone & Hedberg, 2018; Kim et al., 2021, 2022). Measures of local program capacity, including workforce size, budget, experience, and inspection rate, have been associated with lower county-level foodborne illness (Zablotsky Kufel et al., 2011).

The evidence is not uniformly positive. Studies of inspection frequency and scores, considered in isolation, have produced mixed results (Jones et al., 2004; Riben et al., 1994; Zablotsky Kufel et al., 2011), suggesting that inspection activity alone, absent the broader program characteristics that the Retail Program Standards address, does not

reliably predict food safety performance. Outbreak response and environmental assessment functions identify contributing factors that inform future prevention efforts, even when their independent effect on illness is harder to quantify (CDC, 2026b; Lipcsei et al., 2019; Moritz et al., 2023). In one jurisdiction participating in the Retail Program Standards, certain risk-factor violations were more common in restaurants associated with sporadic *Salmonella* cases than in restaurants included in an FDA risk-factor survey (Appling et al., 2018).

The literature therefore supports many of the individual components incorporated into the Retail Program Standards, several of them linked directly to public health outcomes. What it does not support is the proposition that most distinguishes the standards from their constituent parts. The standards are presented as an integrated framework whose components are intended to operate together, yet the links that framework depends on, namely that greater conformance produces stronger program performance and that stronger performance changes establishment behavior across a jurisdiction, are the least directly evaluated. Nearly every study cited previously examines a single component in a single setting. We identified no study testing whether strengthening a regulatory program as a system yields corresponding improvements in food safety practices or public health outcomes.

The published work that concerns the Retail Program Standards directly has focused on implementation rather than effect. Evaluations of mentorship programs, peer networks, enrollment, and funding mechanisms describe how jurisdictions adopt the Retail Program Standards and progress toward conformance, but not whether that progress is accompanied by measurable changes in outcomes (Gill et al., 2023; National Association of County and City Health Officials, 2017). Many jurisdictions have conducted risk factor studies under Standard 9, but these have not been synthesized across jurisdictions. Because relatively few jurisdictions have achieved conformance with all nine standards and most strengthen their programs incrementally, regulatory capacity is better understood as a continuum than as a pass-or-fail designation. Any assessment of the public health value of the Retail Program Standards should therefore ask not only whether fully conforming programs differ from nonparticipating ones but also whether incremental gains in conformance yield incremental improvements in outcomes.

From Prevention Science to Program Evaluation

The Retail Program Standards bring together decades of research, regulatory experience, and public health practice aimed at preventing foodborne illness. Their contribution lies

less in any new prevention strategy than in organizing established evidence-based principles into a single framework for developing and sustaining effective regulatory programs.

Addressing the integrated framework gap requires examining regulatory programs as complex public health systems and treating regulatory capacity as a continuum rather than a binary designation. Future work should test whether progressively greater conformance with the Retail Program Standards is associated with corresponding improvements in food safety practices, reductions in foodborne illness risk factors, and, ultimately, improved public health outcomes.

The evolution of retail food safety over the past several decades has shown that scientific discovery alone does not improve public

health. Meaningful reductions in foodborne illness depend on translating evidence into consistent regulatory practice and building organizational capacity to sustain prevention over time. The Retail Program Standards are among the most comprehensive efforts to operationalize that translation. Testing whether they work is the logical next step. ✿

Conflict of Interest and Funding Disclosure:

The empirical impact study that motivates the hypotheses and future evaluation described in this article was reviewed and approved by the California Baptist University Institutional Review Board (IRB No. 027-2526-EXM).

Several authors are employed by the National Environmental Health Association (NEHA), which administers programs

supporting implementation of the Retail Program Standards, including the NEHA–FDA Retail Flexible Funding Model Grant Program evaluated in Gill et al. (2023). The authors therefore have an interest in the continued use of the Retail Program Standards. That interest is precisely why we argue for independent evaluation rather than for expanded implementation on the basis of the existing evidence. This work was supported through FDA Cooperative Agreement No. 3U19FD008288.

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