An Updated Framework for Industry Funding of Food and Nutrition Research: Managing Financial Conflicts and Scientific Integrity

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ABSTRACT

Although the food and beverage industry plays a critical role in advancing food and nutrition science, industry-funded research is subject to intense scrutiny as a result of various perceived and real biases related to funding sources. To address this, the Institute for the Advancement of Food and Nutrition Sciences (IAFNS) Assembly on Scientific Integrity has updated its Guiding Principles for Funding Food Science and Nutrition Research to provide a modernized framework for minimizing bias and promoting integrity in industry-funded research. Existing best practices for managing conflicts and maintaining trust in science, as well as coverage related to conflicts in industry-funded research, were reviewed to inform the development of the updated Guiding Principles. The updated Guiding Principles continue to provide conflict-of-interest guidelines to protect the integrity and credibility of the scientific record. These updates provide clarification, strengthen the guardrails that separate the funding from the science, and reflect the shift within the scientific community toward increased transparency and open science. If the principles are followed as intended, there should be little reason to dispute the results of industry-funded studies, other than to debate the science itself. This article issues a challenge to the research community to strive for just that. J Nutr 2022;152:1812–1818.

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Conflicts of Interest and Bias in Nutrition Research

Despite its prevalence in the food and nutrition sciences—including in highly regarded peer-reviewed journals—there is widespread skepticism about the credibility and transparency of industry-funded nutrition research (1–3). In recent years this conversation has had heightened visibility stemming from a variety of factors, including adoption within the scientific community of more robust standards for transparency and disclosure, discussions about trust in science reaching broader and more general audiences in the mass and social media, and exposés of partnerships with industry gone wrong (4). Moreover, this skepticism is not limited to the research itself; by extension, the credibility of investigators having research and advisory relationships with the food industry has been called into question, along with their suitability for serving on public panels (5). The underlying concern is one of trust: Does industry funding make research less valid and credible than that funded by other sources? For food and nutrition science in particular, can the results of studies funded by industry be trusted?

In evaluating whether a conflict of interest undermines a study’s credibility or not, it is important to remember that interests, in and of themselves, are not necessarily determinants of bias. The definition of “interest” offered by the US Department of Health & Human Services Office of Research Integrity (ORI) is “a commitment, goal, or value held by an individual or an institution” (6). Interests can be financial, such as a food manufacturer’s interest in turning a profit, or nonfinancial, such as an academic investigator’s interest in building a compelling resume for tenure. When ≥2 interests that relate to an activity are contradictory, the conflict lies in the situation rather than in any behavior (or lack thereof) by the individual or entity. A conflict of interest, therefore, is not intrinsically a bad thing. As a hypothetical example, consider an investigator who has built a research career investigating the health benefits of a specific dietary pattern, and who also profits financially by authoring books about the healthfulness of that dietary pattern. When that investigator applies for funding to advance that line of research, the potential for financial gain from book sales—particularly if the research is supportive of the dietary pattern—represents a financial conflict of interest. It is inherent to the situation, but it neither represents wrongdoing nor guarantees impartiality or bias on the investigator’s part.

Bias, on the other hand, is what introduces error into the scientific process and requires active management by all
participants to preserve the integrity of research, by identifying potential sources and taking measures to prevent its occurrence. In its simplest form, bias is a systematic and measurable deviation from the truth. There are many forms of bias, and the University of Oxford’s Catalogue of Bias Collaboration has identified ≥49 types that can occur throughout various stages of the research life cycle and influence the magnitude and direction of research results (7). During study conceptualization, confirmation bias, for example, may lead an investigator to search for and use information that supports their own ideas or beliefs. In the selection of study participants, ascertainment bias may lead to systematic differences between the study sample and the target population. Recall bias (when accuracy and volume of memories are influenced by subsequent events and experiences) and the Hawthorne effect (when individuals modify their behavior in response to their awareness of being observed) are examples of biases that can occur during the conduct of research. In the reporting of research, positive results bias (the tendency to submit and publish positive results rather than nonsignificant or negative results) and spin bias (distortions in the interpretation of research results) are just 2 examples that can surface. These biases and others can be introduced by poor study design and reporting practices, improper use of statistical and scientific methods, or from intentional misconduct—indeed independently of funding source.

Although some researchers have pointed out what actually is or appears to be bias in industry-related research (8), bias can also exist in publications in opposition to industry interests. “White hat” bias, leading to distortion of information by the researcher in the service of what may be perceived to be righteous ends, has also been documented with both quantitative and anecdotal evidence (9, 10). For example, in a meta-analysis of 88 studies, investigators examined the association between soft drink consumption and nutrition and health outcomes. A positive association was found between soft drink intake and increased energy intake and body weight, with studies funded by the food industry reporting significantly smaller effect sizes than non-industry-funded studies (11). Although action by the food industry to bias study results in an attempt to minimize any association between soft drink intake and body weight is one conceivable explanation for this, independent investigators found a different underlying factor. An examination of the meta-analysis data file revealed that a standard test of publication bias, which determines whether the probability of a study being published is dependent on its outcome, was significant (9). This indicates that investigators were more likely to publish positive statistically significant findings than null findings. Interestingly, this bias was present only for non-industry-funded research, suggesting non-industry-funded scientists tended to not publish their studies if they did not show a significant positive association between soft drink intake and increased energy intake or body weight. These findings reinforce that all investigators—regardless of funding source—must be active and vigilant in minimizing bias.

As a final example, confirmation bias, or the tendency to interpret new evidence in support of existing theories or beliefs, can skew findings in favor of any interest. Revisiting the previous example of the dietary pattern investigator/book author, this person’s research would be considered biased if the study was designed to favor a particular hypothesis, if it excluded relevant data that were in opposition to the investigator’s hypothesis, or if the investigator published only the subset of results that supported the healthfulness of the diet while not mentioning negative or null findings. Ultimately, bias can present itself in a multitude of ways, with no person, entity, or sector free from its grasp.

Existing Checks on Bias

The scientific community has a system of checks and balances in place to detect and flag improper research practices, bias, scientific misconduct, and fraud—instances of which happen within all sectors. Pressure from peers and others serves as a check on such behaviors, with scrutiny coming from meetings, conferences, and other professional engagements; from tenure and promotion decisions within universities and research institutions; in commentaries and letters to the editor in peer-reviewed journals; and, importantly, from the process of peer review during research proposal evaluation and manuscript publication. Imperfect as it may be (12), the peer review process in particular serves as an important gatekeeper of scientific integrity, helping to ensure that research entering the public domain is designed to appropriately answer the question at hand, and that conclusions of the authors are substantiated by the evidence presented. Innovative publication formats such as the Center for Open Science’s Registered Reports take the review process one step further, allowing peers to review and provide feedback on the research design itself before study initiation (13), rather than initiating peer review on the report/publication of what has already happened as in the traditional peer review system. This innovative workflow can help eliminate questionable research practices, including publication bias. Finally, for work that has not yet undergone peer review, preprint servers offer the opportunity for the wider scientific community to review and comment on work in advance of publication.

The government also implements checks against bias and improper research practices in grants and contracts. The US National Library of Medicine’s database clinicaltrials.gov serves as an important check against publication bias, as well as in differentiating confirmatory from exploratory research (14). Moreover, there is government oversight within the granting
agencies and federal research establishment itself, such as the US Department of Health and Human Services ORI (15) and similar bodies in other federal agencies. These offices develop policies, procedures, and regulations related to the prevention of research misconduct, executing misconduct investigations, and implementing programs and activities to promote responsible conduct of research. In addition, the National Academies of Sciences, Engineering, and Medicine has announced the creation of a new body called the Strategic Council for Research Excellence, Integrity, and Trust (16). The new Strategic Council is charged with “advancing the overall health, quality, and effectiveness of the research enterprise across all domains that fund, execute, disseminate, and apply scientific work in the public interest.” Conflicts of interest, assessment of researchers, and retractions represent just a few of the potential topics for the Strategic Council to address.

Finally, the mass media and consumers of science may also exert pressures that serve to mitigate bias and research impropriety. Through mass and social media, broad audiences are able to participate in dialogue on research methods and findings. These channels can, however, present a double-edged sword; although they facilitate communication among peers, participants in the public discourse often have diverse levels of understanding of the nuances of specific areas of research, with bots and clone accounts playing a significant role in the science communications landscape on social media (17). Further, there is no agreed-upon process for setting the record straight, as is the case with retractions and corrections in the peer-reviewed literature, should actors in these discussions be biased themselves.

Although these systems serve to bolster confidence in published works, they do not guarantee research quality or the absence of bias. So then, how does one evaluate a study in the face of real, potential, or perceived biases? Most scientists would agree that what matters most when considering the credibility of research is the rigor, quality, and transparency of the underlying science. The following set of questions can be used to assess these qualities (18):

- Is the research question important?
- Does the study design address the question?
- Were steps taken to ensure objectivity?
- Was the study well performed?
- Were the proper statistical analyses used?
- Are the conclusions drawn supported by the evidence presented?
- Is enough information reported for the reader to answer these questions?

If the answers to the foregoing questions are “yes,” disputes that arise over the results of such a study are likely to be motivated by factors other than the science itself. When pursuing research relationships and partnerships within and across sectors, having an established set of guidelines in place and enforced for protecting the integrity of these qualities and minimizing bias allows for greater scientific advancement than does avoiding any relationship in which a potential conflict of interest exists.

Need for an Updated Framework

In 2009, a set of 8 Guiding Principles were developed by the International Life Sciences Institute (ILSI) North America [now an independent organization, the Institute for the Advancement of Food and Nutrition Sciences (IAFNS) evolved from ILSI North America] to serve as a checklist for minimizing funding-related bias in research results from industry-funded activities. They were the first of their kind, appearing simultaneously in full or in excerpt form in 6 peer-reviewed journals (19-24).

In the years since the Guiding Principles were first published, there have been shifts in how research is conducted and communicated, and where people turn to get information. The last decade has seen the introduction and rise in popularity of mechanisms that provide immediate access to reviewed and unreviewed research. Some journals post full-text copies of accepted manuscripts before copyediting, typesetting, and review of the final proof by the authors. Online preprint servers such as bioRxiv (25) offer early public access to unpublished research before it undergoes peer review. Platforms such as the Center for Open Science’s Open Science Framework enable investigators to share their research throughout the entire project cycle, from experimental design preregistration to data collection to report publication, even offering viewers suggested citation formats to reference active, ongoing work (26). As a result, research enters the public domain early and often, having undergone varying levels of review by peers.

A second reason for updating the Guiding Principles is greater attention to issues of conflicts of interest and bias in scientific publications. Although conflicts of interest do not necessarily introduce bias into the research process, it is nonetheless essential that mechanisms are in place to safeguard the science against potential bias, and that these mechanisms reflect the current research environment. The Global Research Report on Research Integrity developed by the Institute for Scientific Information highlights key points along the research and publication cycle that are susceptible to violations of research integrity (27):

- Research problem, literature review, hypothesis and plan
- Research, experiment, and data collection
- Data analysis, hypothesis testing, data preservation
- Manuscript preparation
- Choice of publication venue and submission
- Editorial and peer review process, including revisions
- Publication
- Use of the publication record

Actions that have undue influence on the design, conduct, and reporting of research include egregious forms of misconduct such as falsification, fabrication, and plagiarism. More subtle actions include questionable research practices, misrepresentation, and other actions that may be intentional or the result of unintentional or unrecognized biases. It is imperative that investigators—and all others involved in the research process, regardless of sector—have measures in place to safeguard against these violations of integrity.

In the years since the original Guiding Principles were developed (19), other sets of guidelines and principles for ensuring integrity in research and trust in science have also been published (12, 28–31), but these offer investigator-specific guidance for the conduct of research itself and do not offer specific guidance for funders and investigators to address potential sources of bias in industry-funded food and nutrition research. Recognizing that the food industry does and will continue to play a significant role in supporting nutrition research, the IAFNS Assembly on Scientific Integrity has updated its Guiding Principles for Funding Food Science and Nutrition Research to provide a modernized framework for avoiding bias in industry-supported research. These updates
To inform the development of the updated Guiding Principles, existing best practices for managing conflicts and maintaining trust in research (12, 19, 28–35) and coverage related to conflicts in industry-funded research (1, 2, 4) were reviewed. The revised Guiding Principles were then reviewed by an external set of stakeholders, including those from nutrition and food safety professional societies. Although these guidelines are written for providing information relevant to the context of public–private research relationships, they are applicable to research relationships between and within any sector.

Guiding Principles: An Updated Framework for Industry Funding of Food and Nutrition Research

In the conduct of public–private research relationships, all relevant parties shall:

1) Conduct or sponsor research that is factual, transparent, and designed objectively; according to accepted principles of scientific inquiry, the research design will investigate an appropriately phrased hypothesis and/or question, rather than favor a particular outcome;

2) Require control of the study design, the research itself, and the interpretation of findings to remain with scientific investigators;

3) Neither offer nor accept remuneration geared to the outcome of a research project;

4) Before the commencement of studies, ensure that there is a written agreement that the investigative team has an obligation to attempt to publish the findings within a specified timeframe and the freedom to choose the journal to which the work will be submitted;

5) Require, in publications and conference presentations, full written or oral disclosure, as appropriate, of all relevant relationships (financial and nonfinancial);

6) Not participate in undisclosed authorship arrangements in publications or presentations;

7) Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/peer reviewers; when possible, encourage the practice of open science, including depositing data and methodology on a public repository;

8) Require that academic researchers, when they work in contract research organizations or act as contract researchers, make clear statements of all their affiliations; require that such researchers publish under the auspices of the contract research organization;

9) Require, in publications and conference presentations, disclosure of whether the funder advised on the study design, conduct of research, and/or the development of the manuscript.

Notes: Guideline 3 does not prohibit the sponsoring agency from awarding funds using a phased approach, in which decisions to proceed to subsequent phases of a project are dependent upon the results of the preceding phase. However, in this case the decision criteria for each phase must be identified in advance in the written Agreement, before the first phase begins. It also does not preclude deciding which, if any, new work is to be undertaken based on results of a prior study. Guideline 4: The investigator’s obligation to attempt to publish the research findings should persist independently of whether the results are expected or unexpected. Guideline 7 is intended to apply to peer reviewers not associated with the funding entity and appropriate scientific auditors. For those practicing open science, the Center for Open Science’s Open Science Framework is an example of a suitable option for making data, analyses, methodology, and code available to the public, and is available to researchers at no cost. Guideline 8: Such academic researchers who are working in a contract research organization are encouraged to disclose their academic affiliation as well when publishing under the auspices of the contract research organization.

Like its predecessor, this set of revised Guiding Principles is intended to be dynamic, and to prompt ongoing discussion and refinement in an effort to foster a culture of integrity in industry-supported research. Supplemental Table 1 provides a side-by-side comparison of the original and the updated Guiding Principles. Many of the updates to the Guiding Principles (and to their notes) are meant to simplify language and provide improved clarity. However, several substantive updates were also made to make explicit certain items related to scope that were previously only implied. For example, Guiding Principle 2 has been updated to specify that in addition to maintaining control of the study design and the research itself, investigators also maintain control of the interpretation of data generated as part of the study. Whereas discussion of research findings—ideally with a diverse group of peers—remains an important part of scientific advancement, compulsory adherence to “interpretive guidance” from the funder has no place in public–private research relationships.

Updates have been made to the guidelines to address actions and processes that occur pre- and post-publication. The Guiding Principles now specify that not only does the investigative team have the freedom and obligation to publish, but they also retain the freedom to choose the most appropriate journal to which to submit their work. The Guiding Principles continue to highlight the importance of attempting to publish all research, even if the results are unanticipated or null, and even if it takes multiple submissions to find an appropriate peer-reviewed journal. Guiding Principle 6, which prohibits undisclosed authorship in scientific publications and presentations, has been expanded to include all types of arrangements—paid or otherwise—and made independent of which sector or entity is the sponsor. The purpose of the seventh Guiding Principle is to enable independent investigations of submitted work during and after the peer review process. This update to the Guiding Principles clarifies that this is meant to apply to peer reviewers and independent investigators; it is not meant to guarantee accessibility of the data to the entire public. However, it is recognized that the practice of open science has many benefits, including promoting actions that can increase the quality and reliability of scientific work (36). Open science therefore is now encouraged where possible, and the Center for Open Science’s Open Science Framework (26) is referenced as an example of one suitable platform for exercising open science. Finally, the modification to the eighth Guiding Principle was made to recognize that many academic scientists hold joint appointments at private consulting firms or other establishments, and in these cases all relevant affiliations should be disclosed.

On the topic of disclosures, updates have been made to the requirements outlined in Guiding Principle 5. The language was
updated from requiring “full signed disclosure” of interests to “full written or oral disclosure, as appropriate,” because signed disclosure is not an applicable or effective means of disclosure in the context of conferences or other presentations. In addition, the phrase “financial interests” has been replaced with “relevant relationships,” in recognition that not all interests pertaining to the conduct of research are financial.

Finally, in this update a new Guiding Principle 9 was established with the aim of providing greater transparency of relevant interactions between the funder and the investigator in public–private research relationships. This new Guiding Principle requires disclosure of whether the funder advised on the study design, conduct of research, and/or the development of the manuscript. It is recognized that whether and how the funder is involved in the development, conduct, and interpretation of research may significantly affect what and how results are presented in the peer-reviewed literature. Although requests for improved clarity and refined scope are a routine part of the proposal review and grants administration process—including for federally funded research—disclosure of engagement above and beyond this will help investigators avoid the perception of concealing information relevant to the study at hand and provide readers with context about how the study’s findings were derived. This Guiding Principle is intended to achieve more robust disclosures of funder-investigator interactions; however, it should not be interpreted as granting funders of the work the authority to direct or approve the research results, discussion, or conclusions. These types of interactions are what the updated Guiding Principles are intended to prevent.

Discussion
With the limited availability of funds from US federal agencies, nongovernmental sources of funding, including industry, play a critical role in offering new opportunities for advancement and innovation and relieving pressure on government agendas and budgets to respond to all research needs. In the United States, diet-related diseases such as obesity, diabetes, cardiovascular disease, and cancers cause half a million deaths each year. Further, it is estimated that 85% of national health care spending is due to management of diet-related chronic diseases; US government expenditures on direct medical care for diabetes alone are estimated at $160 billion/year (37). Compared with the magnitude of these burdens, resources available for research on the health effects of foods and nutrients are limited. In 2020, the NIH—the nation’s largest funder of nutrition research—spent an estimated 4.5% ($1.9 billion) of its budget on nutrition research (38). The second-largest funder of nutrition research in the United States, the USDA, spent a fraction of that, with 5% spent by the USDA’s National Institute of Food and Agriculture (NIFA) on its Agriculture and Food Research Initiative (AFRI); this program largely supports agriculture-related research but does include some related to food safety, nutrition, and health (39).

With the relevant scientific expertise and the resources to support scientific research, the food industry is well-equipped to engage in the pursuit of advancing food and nutrition science. The industry’s interest in maintaining profitability does not negate its inherent interest in not harming its consumer base, nor that it is legally responsible for demonstrating the safety of its products and ensuring that any nutrient content and/or health claims it makes about them are substantiated (40–43).

The food industry has specialized scientists with backgrounds in chemistry, biology, toxicology, nutrition, food science, and epidemiology—with skills that are honed in applied nutrition and food safety—and an intimate knowledge of the wants and needs of consumers. Moreover, it has unique expertise that does not typically exist in other food and nutrition research settings, including knowledge of food and dietary supplement supply chains, commercial-scale ingredient substitutions, and testing methods for various food matrices, all of which are needed to realize shifts in product nutrient composition for the betterment of public health.

Industry scientists are not a niche group; in a trend of increasing private sector employment of scientists—particularly in the life and health sciences—educational institutions now employ fewer than half of PhD scientists in the United States (44). For nutrition specifically, the 2019 Survey of Doctorate Recipients found that the private sector—including private for-profit, private not-for-profit, and self-employed business owners—employed 39% of PhD nutrition scientists in the United States, with 54% and 7% employed by educational institutions and government, respectively (45). As might be expected, food scientists are employed by the private sector at a higher rate, with ~57% of PhD food scientists in the United States employed by the private sector, and 33% and 9% employed by educational institutions and government, respectively (45).

In addition to offering investigators and their institutions opportunities for scientific advancement and innovation, multisector collaborations may also have the added benefit of improving research quality. A retrospective cross-sectional study evaluated the quality of studies used in systematic reviews extracted from 3 databases: the Academy of Nutrition and Dietetics’ Evidence Analysis Library, the Agency for Healthcare Research and Quality (AHRQ) Evidence Analysis Library, and the USDA Nutrition Evidence Library (46) (this study was supported by ILSI North America). In this study, 5 risk-of-bias domains—selection bias, performance bias, detection bias, attrition bias, and reporting bias—were evaluated in conjunction with other variables to quantify the research quality of >5600 nutrition-related studies. The investigators found that studies with “combined” funding sources—typically the work of public–private research partnerships—were higher in quality, by and large, than studies with single-source funding. Moreover, the review found that industry-funded studies were generally not lower in quality than those funded solely by government; publication year and study design were more consistent predictors of research quality than study funding source. As evidenced by emphasis on team science, cross-disciplinary and interdisciplinary collaborations in research institutions, and federal calls for proposals, it is widely recognized that there is a benefit for research collaboration as experts bring different perspectives to the table.

The Guiding Principles provide conflict-of-interest guidelines to protect the integrity and credibility of the scientific record, and the updates presented herein strengthen the guardrails that separate the funding from the science and reflect the shift within the scientific community toward increased transparency and open science. Although the updated Guiding Principles more accurately represent the spirit of “full disclosure” in today’s research environment, they by no means solve the dilemma that exists with disclosures of interests and relevant relationships. There is no consensus on what constitutes disclosure-worthy
information, particularly as it relates to nutrition research (47, 48). Further, scientific journals—including those related to food and nutrition science—have inconsistent guidelines and requirements for author disclosures, making a process that already requires a great deal of subjectivity even more cumbersome. What the investigator considers to be “relevant” to the work at hand may differ from what peers or readers consider to be relevant. Should past relationships be declared in addition to current ones? What about future commitments? Are relationships of the investigator’s immediate family members “relevant”? In research on dietary patterns, at what point do the investigator’s own food preferences or religious/philosophical beliefs become “relevant”? Inevitably, investigators are occasionally called out for failing to disclose certain relationships, and they commonly respond, “I didn’t think I needed to declare that.”

Some organizations have already made efforts to standardize disclosure guidelines. For example, the International Committee of Medical Journal Editors (ICMJE) has created a uniform form (49, 50) for disclosure of potential conflicts of interest which is utilized by all ICMJE journals (51). As recommended in the Blue Ribbon Panel’s report “Best Practices in Nutrition Science to Earn and Keep the Public’s Trust” (28), the ASN has created a Model Disclosure Form that covers financial and other conflict of interest sources to serve as a model for its members, stakeholders, and staff. A possible strategy cited by the National Academies of Sciences, Engineering, and Medicine Strategic Council for this issue is the extension of publication lists on Open Researcher and Contributor ID (ORCID) to include lists of current and prior employment, activities, commitments, and financial holdings (16). This information would be publicly available for readers to view and decide which relationships might be relevant. Although there is much discussion and debate around disclosures in nutrition research, there is general agreement that transparency in this area is necessary to encourage public trust in science.

Regarding the implementation of the Guiding Principles presented herein, organizations wishing to adopt these guidelines must develop a plan that outlines how they will be implemented, monitored, and enforced. An essential component of such a plan is ensuring transparency and understanding of the Guiding Principles by all relevant parties, including individuals within the funding organization as well as those at the research-performing organization. This could be accomplished, as IAFNS itself does, by including the Guiding Principles—and the expectation that they will be adhered to by all parties in resulting research partnerships—on public-facing websites, in calls for research proposals, and in formal research agreements. Communications between the funder and investigator should foster a culture of integrity and transparency. Funding organizations may find internal audits and/or other tracking systems to be helpful in monitoring whether the Guiding Principles are being implemented as intended.

Conclusion

In conclusion, the updated Guiding Principles presented here provide a modernized framework for minimizing funding-related bias in research results from industry-funded activities. This updated framework takes into account shifts within the scientific community toward open science and more robust disclosures of relevant relationships, and it strengthens the guardrails that separate the funding sources from the science. We hope these Guiding Principles will serve as a guide for those engaging in public–private research relationships, and that all involved parties will advocate for their vigorous implementation and enforcement. If the Guiding Principles are followed as intended, there should be little reason to dispute a resulting study, other than to debate the science itself. Let this be a challenge to the research community to strive for just that.

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