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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service [Docket No. FSIS-2014-0034] Availability of Revised Compliance Guidelines for Controlling Salmonella and Campylobacter in Raw Poultry AGENCY: Food Safety and Inspection Service, USDA. ACTION: Notice of availability and response to comments. The Food Safety and Inspection Service (FSIS) is SUMMARY: announcing the availability of revised guidelines to assist poultry establishments in controlling Salmonella and Campylobacter in raw poultry. The Agency has revised the content of the guidelines in light of new scientific and technical information, public comments received on the 2015 guideline, and the Agency's decision to issue two separate guidelines - one on controlling Salmonella and the other on controlling Campylobacter. The guidelines provide "best practice" recommendations that poultry establishments may follow to reduce Salmonella and Campylobacter contamination of raw products.

ADDRESSES: Downloadable versions of the revised guidelines are available at

https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatorycompliance/guidelines. The Agency has not published hard copies of these documents. FOR FURTHER INFORMATION CONTACT: Rachel A. Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS; Telephone: (202)-205-0495.

SUPPLEMENTARY INFORMATION:

Background

On December 16, 2015, FSIS published a **Federal Register** notice (80 FR 78166) announcing the availability of and opportunity to comment on a revised Agency compliance guideline for controlling *Salmonella* and *Campylobacter* in raw poultry. This revision was the fourth edition of the guideline the Agency had developed to assist establishments that slaughter or process raw poultry products to minimize or prevent the risk of *Salmonella* and *Campylobacter* in their operations.

Updated Guidelines

FSIS has updated the guideline contents to reflect the most recent best practices, supported by current peer-reviewed literature and analyses of FSIS data. Updates include information on using neutralizing agents in sampling to prevent carryover of antimicrobial substances and a current list of antimicrobials for establishment use. Also included are improvements in the information on pre-harvest practices, with a comprehensive revision of the litter/bedding section. With the updated information, establishments of various sizes and configurations have practical options for reducing and inhibiting the growth of pathogens commonly found in raw poultry. In response to the comments, FSIS also reviewed the recommendations in the previous version of the guideline and assessed each section for utility and effectiveness. The resulting changes include a complete revision of the sections on litter and bedding and updates to FSIS data on the rate at which *Salmonella* or *Campylobacter* contamination can be attributed to source materials of different composition. Also, the Agency is now issuing the revised document as two separate guidelines, one focused on control of *Salmonella*, and the other on *Campylobacter*. The guidelines are posted at https://www.fsis.usda.gov/policy/fsis-guidelines. Although comments will no longer be accepted through regulations.gov on these guidelines, FSIS will update these documents as necessary if new information becomes available.

Comments and Responses

FSIS received fifteen comments in response to the December 16, 2015, **Federal Register** notice and guideline. The commenters included consumer and industry associations, individuals, and firms that specialize in providing technology and services to the regulated industry. The comments and the Agency's responses, discussed below, have been grouped by topic area. *Pre-Harvest*

Comment: A poultry industry association remarked that considerations and sampling for Salmonella and Campylobacter should not affect the Hazard Analysis and Critical Control Point (HACCP) system of the receiving establishment. The same association stated that, while good husbandry practices are important, the goal of obtaining pathogen-free flocks and many of the recommendations for doing so are unrealistic and unnecessary. According to the association, the Agency should revise the discussion of pre-harvest practices in the guideline to reflect currently available, commercially proven methods that can be practically implemented.

Response: Information about pre-harvest conditions and particularly, pathogen levels on incoming flocks, can inform the establishment's hazard analysis and decisions on controls to include in its HACCP plan. In the guideline, FSIS acknowledges that there may be no single pre-harvest intervention that eliminates Salmonella and Campylobacter as pre-harvest hazards. The Agency recommends instead a multi-hurdle approach involving successive interventions that can have a cumulative effect in reducing the pathogen contamination of birds. The Agency has modified some language in the pre-harvest section of the guideline to reflect current scientific literature.

Comment: The poultry industry association said that another area of concern is the recommendation to change bedding between each flock. According to the poultry industry association, that is not always the best way to control *Salmonella* growth because new litter can be a bigger risk factor for *Salmonella* than old litter, depending on the pH profile involved. The poultry industry association argued that the section on transportation crate maintenance is similarly impractical.

Response: Litter, or bedding, can be considered a potential reservoir for contamination with Salmonella and other pathogens. The presence or absence of contamination in litter is among the pre-harvest conditions of which a prudent establishment should be aware, along with clean transport crates. FSIS has updated the pre-harvest and transportation sections of the guideline with practical suggestions, based on informative studies, and also updated the section on scheduled slaughter (taking account of pathogen loads on incoming flocks). Sanitation

Comment: An animal health and food-safety technology and services provider recommended changes in the guideline discussion of cleaning procedures by adding, after the removal of debris, dry-pickup of gross soils and pre-rinsing to remove remaining soil before using a cleaning agent, such as a detergent. This commenter also recommended that the guideline include a table (provided by the commenter) showing the factors to consider when choosing a sanitizer for a particular application.

Response: FSIS has accepted the recommended edits to the discussion of cleaning procedures in the sanitation section. The Agency has also removed some outdated references that the commenter noted and added the table of sanitizer characteristics. *Comment:* The poultry industry association said that the guideline includes prescriptive practices that are neither reasonable nor necessary and that are not conducive to chicken processing. For example, the association stated that sanitizing hand-held knives between each carcass is not reasonable, nor would it result in significant pathogen reduction on final products. According to the association, sanitization between each carcass would increase handling time and create more opportunity for pathogen outgrowth, thereby increasing food-safety risks.

Response: The guideline recommends sanitizing knives in 180-degree water or an antimicrobial solution after cutting or trimming each carcass, which should result in the reduced transfer of pathogens from one carcass to the next.

FSIS guidance is intended to offer practical solutions to food safety problems, with some recommendations likely more useful in small and very small establishments and others more suitable for large establishments. Most of the information in this guidance should be useful to all establishments, including small and very small establishments. Although bacterial outgrowth is not a result of time alone, it would certainly be one consideration for an establishment contemplating this factor in its process.

Comment: The poultry industry association added that other recommendations in the guidelines, such as that to limit

solution reuse during injection marinating to prevent contamination, is not supported by scientific evidence.

Response: FSIS updated the guidelines to include citations to scientific studies indicating that marination of non-heattreated poultry parts can result in larger bacterial populations on the poultry, ¹ depending on the type of marinade used.² Injection or other contact across carcasses can introduce a potential point for cross-contamination. A prime example in the quidance showing this mechanism of internalizing pathogens is an outbreak of Escherichia coli 0157:H7 in beef steaks that occurred in 2007.³ Establishments should consider the effects of injected solutions in their hazard analyses (9 CFR 417.2(a)) and support all decisions made in the hazard analysis, 9 CFR 417.5(a)(1). At this step in a process, an establishment could address the risk in several ways, depending on its process. One approach described in the guidelines is the use of an ultraviolet light intervention applied to the marinade solution between uses.⁴ Additionally, the formulation of a marinade may include antimicrobial components, to achieve a specific pH or

³ See FSIS. 2007. "Pennsylvania Firm Recalls Beef Products for Possible E. coli O157:H7" Recall Release. Available at: https://www.fsis.usda.gov/wps/wcm/connect/5a217ede-de72-474a-b384-6643a8ac12f8/Recall_019_2007_Release.pdf?MOD=AJPERES. ⁴ Beers KL, Cook PE, Coleman CW, and Waldroup AL. 2010. Efficacy of ultraviolet light systems for control of microorganisms in poultry and beef brine and marinade solutions. Poult Sci. 89 (E-Supplement 1): 615.

¹ See Hinton, et al., (ARS) abstract for International Association for Food Protection (2004), "Comparison of psychrotrophic bacterial flora of fresh and marinated chicken breast fillets during refrigerated storage."
² See R. Thanissery and D.P. Smith, "Effect of Marinade Containing Thyme and Orange Oils on Broiler Breast Fillet and Whole Wing Aerobic Bacteria During Refrigerated Storage," in The Journal of Applied Poultry Research 23 (2): 228-232; May 2014

antimicrobial activity; examples of acceptable ingredients for this use are listed in the lookup table of FSIS Directive 7120.1, "Safe and Suitable Ingredients."

Lotting practices

Comment: A poultry industry association asked the Agency to revise its recommendations on lotting practices to remove the emphasis on "microbiological independence" relating to pathogens that do not legally adulterate raw product by their presence alone, or per se.

Response: FSIS did not make changes to its recommendations on lotting practices. Concepts related to microbiological independence, or the unlikelihood of cross-contamination, apply to all pathogens. Considering lotting practices in such cases can help to maximize the value of testing and process control throughout production. Under HACCP, establishments may test for pathogens to verify that they are adequately addressing microbial hazards.

Also, as discussed in the December 6, 2012, Federal Register Notice on HACCP-plan reassessment for not-ready-to-eat (NRTE) comminuted poultry products (77 FR 72686, at 72689), when a NRTE product is credibly linked to an outbreak of illness caused by a pathogen, FSIS may consider the product to be adulterated, even if the pathogen does not adulterate the implicated NRTE product per se.

Comment: The poultry industry association said that, in addition to the above concerns regarding microbiologically-based

lotting practices, the Agency should be aware that: lottraceback information may be commercially sensitive; separation in time and space is difficult in establishments running multiple lines and mixing flocks; and microbiological testing takes days to complete - too late for processed poultry already in commerce. For these reasons, according to the poultry industry association, the Agency should remove these recommendations from the guideline.

Response: As mentioned in the previous response, in situations where pathogenic organisms in NRTE products have been linked to foodborne illness outbreaks, FSIS has deemed the products to be adulterated. FSIS and members of the regulated industry have been interested in preventing situations like those. Accordingly, the guideline contains recommendations for lot separation, traceback, and microbiological testing. These approaches to monitoring, tracking, and controlling potentially contaminated products can help in preventing pathogen spread and illness outbreaks.

Comment: The poultry industry association said that recordkeeping recommendations must be relevant to establishment operations and must allow for flexibility according to establishment size and resources.

Response: The recordkeeping recommendations in the guideline are premised on the assumption that the establishment already has records that meets the HACCP, Sanitation Standard Operating Procedures, and other regulatory requirements. Establishments have significant flexibility in meeting these recordkeeping requirements and recordkeeping will vary in technical and other aspects from establishment to establishment. Additionally, the guideline sets out recordkeeping elements that are associated with sampling and testing and that are fairly basic and general. As such, FSIS has not revised the recordkeeping guidance.

Process Control

Comment: A poultry industry association requested that the Agency clarify key concepts and terms used in the guidance. For example, the association said that, while FSIS states throughout the guidance that establishments should reduce pathogens to "acceptable levels," the guideline is not clear enough about what those acceptable levels are. The poultry industry association suggested that FSIS use its pathogen reduction performance standards as examples of acceptable levels and state that other metrics than prevalence might be used in evaluating acceptable levels.

Response: In the context used in the guidelines, "acceptable levels" of pathogens are defined by an establishment for use as control parameters in its HACCP system. These upper and lower control limits may use prevalence to measure control of a hazard over time. As defined in the 2009 review of FSIS public health risk-based systems by the Institute of Medicine, "[a] process is in control when, within the limits of a stable and predictable process variation, all hazards are controlled to an acceptable level."⁵

Data collected initially by the establishment can be used in process mapping for HACCP validation. The establishment can compare pathogen levels on incoming and final product to determine whether the process is achieving the desired reduction in microbial loads. Then, if the pathogen testing results demonstrate that the process is functioning correctly, the establishment can use the testing results for indicator bacteria to set a maximum limit for each indicator at each collection point. FSIS agrees with the commenter, however, that where the Agency's pathogen-reduction performance standards apply, an acceptable level would be one that is at or below the pathogen limit of a standard. Just as in the 2015 guidance, the updated guidance continues to advise an establishment seeking to reduce microbial hazards to consider FSIS's applicable Salmonella and Campylobacter performance standards for carcasses, parts, and comminuted poultry.

Comment: The poultry industry association said that, additionally, the guideline frequently instructs establishments to reevaluate their processes if they are resulting in "high numbers" of *Campylobacter* or *Salmonella* subtypes more commonly associated with human illness, without defining what the Agency views as a "high level" of these serotypes. Further, the

⁵ IOM (Institute of Medicine). 2009. Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System: A Letter Report. Washington, DC: The National Academies Press. P.12.

poultry industry association argued that serotypes have little or no practical impact on HACCP systems. According to the commenter, a good HACCP system should work to control all *Salmonella* serotypes or *Campylobacter* species regardless of their serotype.

Response: Under HACCP, criteria for additional testing or actions are defined by the establishment. These criteria could be derived from the establishment's own baseline data, as well as the frequency at which serotypes of human-health concern are identified in that baseline. While FSIS agrees that HACCP systems should address all pathogens, FSIS uses characterization data, including serotypes of increased human health concern, to prioritize further evaluation and assessment of an establishment's HACCP system. Specifically, if an establishment does not meet FSIS performance standards, as part of the public health review evaluation (PHRE), FSIS will assess whether the Agency has found frequent serotypes of public health concern in the establishment's product. If so, FSIS will also likely conduct a food safety assessment (FSA) at the establishment.

Comment: A poultry industry association noted that the 2015 guidance appears to conflate the terms "prevalence" and "load" when referring to recommendations for decreasing Salmonella and Campylobacter. According to the poultry industry association, the "prevalence" of a pathogen on raw poultry product is a distinctly different microbial sampling metric than the "load," or quantity, of pathogen on a raw poultry product. The prevalence of a pathogen refers to the presence or absence of a pathogen, regardless of quantity and is usually expressed as a percentage or rate of occurrence over time. By contrast, the microbial load of a pathogen refers to the concentration of bacteria (for example, in colony-forming units) in or on a unit of product. Yet, according to the poultry industry association, the guideline uses the terms "prevalence" and "load" interchangeably when recommending practices to decrease the "prevalence" or "load" of Salmonella and Campylobacter on raw poultry products. The poultry industry association argued that these two metrics are not, in fact, interchangeable. Since FSIS had reiterated that the Agency will focus on the presence of Salmonella or Campylobacter rather than on load, the poultry industry association recommended that the Agency revise the guidance for consistency in referring to "prevalence" rather than "load." According to the poultry industry association, the guidance should refer to "prevalence" rather than "load."

Response: FSIS disagrees that it conflated the terms "prevalence" and "load" and did not make the poultry association's recommended changes to the guidelines. Establishments are not limited to considering only prevalence, which may be derived from qualitative test results over time, when designing and implementing a HACCP system. Available tools for enumeration can help inform a prudent establishment so that it can consider the impact of pathogen load, or the actual levels of contamination in positive samples, along with the prevalence information in order to improve process-control systems.

Comment: The poultry industry association offered several recommendations intended to improve discussion in the guidance of data analysis techniques. Thus, in the area of process mapping, the poultry industry association recommended that FSIS give establishments the flexibility to use process indicators that reliably reflect their operations and environments. The poultry industry association also suggested edits to make the text more consistent with tables that show median values for indicator organisms on poultry carcasses and parts. The poultry industry association remarked that linking a product with human illness is not necessarily evidence of a loss of control by the establishment that prepared the product. The poultry industry association also stated that the use of (microbiological) performance standards is not the only way to evaluate process controls. The commenter also stated that the "moving window" approach to monitoring and assessing whether establishments meet performance standards and use of the category-ranking system has not been evaluated for assessing process control.

Response: Establishments are free to choose appropriate microbiological indicators for determining process-control effectiveness. FSIS has removed some of the material about sampling for specific indicator organisms, including the sections regarding median indicator values, as more detail is provided in the FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection-Microbiological Sampling of Raw Poultry⁶ to assist small and very small establishments that may not have their own baseline information.

While microbiological performance standards may not be the only measures of process control, they do help focus industry attention on the public health aspects of poultry processing and the need to improve processes as necessary to prevent foodborne illnesses. During the past two years, FSIS has been employing the "moving window" data-frame for microbiological test results on poultry products as a way of determining whether establishments meet performance standards over time. FSIS has evaluated the technique as a more consistent replacement for sampling sets that can better identify trends, such as seasonality, over time.

Comment: The poultry industry association recommended that FSIS adjust its picture caption concerning optimal application of antimicrobial spray to a conveyor belt and products on the belt. The poultry industry association also noted that application of the spray does reduce pathogens even if the coverage of the spray is less than complete.

Response: FSIS has modified the language of the caption in question in the guidance to clarify the point that not all the belt is being treated. The Agency acknowledges that there will be some pathogen-reduction effects like those in the

⁶ Available at: https://www.fsis.usda.gov/guidelines/2015-0013

illustration but recommends that the spray adequately cover the belt and products.

Comment: The poultry industry association stated that the 2015 guidance instructed establishments to evaluate their process if they encountered "high numbers" of serotypes of public health concern. According to the poultry industry association, the Agency should instead advise establishments to work at controlling all species of *Salmonella* or *Campylobacter*, regardless of serotype.

Response: The guidance encourages establishments to control all Salmonella and Campylobacter throughout their process. Establishments should consider all available information about hazards identified from their operations. This may include information about the point in the process where hazards are most often recovered, the lot or flock information, and characterization of the hazard recovered, including serotype. FSIS provides Salmonella serotype results to establishments to facilitate their efforts in identifying the appropriate response, which could include both serotype-specific interventions at pre-harvest (e.g., vaccines) as well as Salmonella controls in the establishment.

Comment: The poultry industry association said in the section of the guidance on sampling and testing, it appeared that the Agency expected sampling and testing results for pathogens to be available in real time to assess bacterial load

just before processing. The poultry industry association noted that this is not possible.

Response: FSIS has clarified the language in this section of the guidance to note that these testing options would need to be performed with adequate time allowed for the results to be used as effective tools. A number of rapid-testing methodologies may be fit-for-purpose for this use.

Comment: The poultry industry association stated that the Agency should provide additional information relating to its exploratory sampling results for raw, comminuted chicken in the guidance. The associated noted that Table 6 presents the prevalence rates of *Salmonella* and *Campylobacter* in mechanically separated chicken and ground and comminuted chicken products, organized by whether the source material had bone or skin in it. According to the poultry industry association, it would be useful to know how many samples were available for each of the statistics generated for the percent prevalence for these products, given the limited number of samples in the 2015 guideline dataset.

Response: FSIS has updated the statistics reported in Table 6 of the guidance with additional data points to strengthen the analysis. These updated tables represent 934 comminuted turkey samples and 2,688 comminuted chicken samples, more than 10 times the data points for chicken and 40 times the data points for turkey versus the data points used for the 2015 guidance. Analyses of FSIS comminuted poultry exploratory sampling results shows that it is more likely that comminuted chicken will be positive for *Salmonella* when its source materials contain both bone and skin (56.0%). However, for *Campylobacter*, comminuted chicken products made from bone-in and skinless source materials were highest. Comminuted chicken made from deboned and skinless source materials had the lowest prevalence for both pathogens (34.8% for *Salmonella*, and 1.7% for *Campylobacter*). Statistical analyses, including that for independence and for significance, were used to evaluate the data before compiling the relative risk tables that have been updated in this edition of the guidance.

Antimicrobial interventions

Comment: An environmental advocacy group questioned the Agency's continued support for food irradiation.

Response: The guidance includes irradiation among the safe and effective physical interventions available. While FSIS does not recommend the use of specific interventions or lethality treatments, food irradiation has been demonstrated to be both safe and effective in controlling pathogens. FSIS and the Food and Drug Administration (FDA) regulations authorize its use in the treatment of ready-to-cook poultry (9 CFR 424.22(c), citing 21 CFR 179.26)).

Comment: The same advocacy group noted that the Agency continues to recommend the use of various chemical agents to reduce the levels of *Salmonella* and *Campylobacter* in poultry processing. It asked about the role played by the Occupational Safety and Health Administration (OSHA) in determining permissible exposure levels (PELs) for these substances and their impact on FSIS inspectors and on plant employees.

Response: While FSIS does not recommend the use of specific interventions, many chemical products have been demonstrated to be both safe and effective. Chemical substances used in the processing of meat, poultry, and egg products are approved by both FDA and FSIS before they can be used in official establishments. They are listed in the on-line table referred to in FSIS Directive 7120.1, "Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products,"⁷ which is updated regularly.

FSIS does not allow the use of chemicals in a manner that may be a health risk to inspection personnel. Inspectors in every establishment verify that establishments use only approved chemicals as ingredients and only within approved limits, as outlined in FSIS Directive 7120.1. In addition, the Agency has a network of occupational safety and health experts in its inspection districts and distributes information on health hazards to its workforce. The information includes the OSHA PELs and other exposure limits applying to chemicals that may be used in meat, poultry, and egg products plants. (See https://www.fsis.usda.gov/wps/portal/informational/aboutfsis/aud ience-employees/employee-safety/environmental-safety-health.)

⁷ Available at: https://www.fsis.usda.gov/wps/wcm/connect/bab10e09-aefa-483b-8be8-809a1f051d4c/7120.1.pdf?MOD=AJPERES.

Comment: A poultry industry association advised FSIS to replace the "requirement" to wait "at least 60 seconds" for drip time before collecting a product sample with "a drip time appropriate to prevent excessive antimicrobial carryover." According to the poultry industry association, establishments are familiar with the antimicrobial treatments applied to products in their operations and the appropriate neutralization periods for each treatment.

Response: FSIS has edited the language in the guidance to be more inclusive of the many antimicrobial interventions available and the manufacturers' instructions specific to each.

Comment: A poultry industry association recommended that the guidance reflect differences between *Salmonella* and *Campylobacter*. According to the association, the guideline's assertion (in the section on actions to take in response to test results) that an intervention to prevent, eliminate, or reduce *Salmonella* will also reduce or prevent *Campylobacter* is not scientifically accurate.

Response: The Agency has modified the language in question to account for the different effects of different interventions. Also, the Agency has divided the guidance into two separate documents -- one addressing Salmonella, the other Campylobacter -- with the aim of accounting for differences between the pathogens and ensuring that recommended controls will be effective. FSIS also revised the guidance to include additional literature supporting controls for the pathogens. The updated references may assist establishments in identifying the best process controls for *Salmonella* and *Campylobacter* in their operations.

FSIS agrees that an intervention for controlling one microorganism will not necessarily have a similar effect on the other. For example, hard freezing is likely to be more effective against *Campylobacter* than *Salmonella*. On the other hand, vaccine development for controlling *Salmonella* in flocks is clearly in advance of that for controlling *Campylobacter*. *New Technology Review*

Comment: The poultry industry association said that FSIS has recommended several interventions that the industry has sought but that are still awaiting review or approval by FSIS. According to the poultry industry association, the Agency should consider an expedited review and approval process.

Response: The Agency does not have a backlog of new technology submissions. The Agency reviews a new technology to determine whether it may express its "non-disapproval" for use of the technology. The technology should be safe to use, compliant with pertinent regulations, not interfere with inspection procedures, and help the establishment achieve the objectives of its HACCP system. FSIS has made available a guideline to assist the industry in preparing and submitting new-technology notifications and protocols to the Agency (See https://www.fsis.usda.gov/guidelines/2015-0012). By following the advice in the guideline, the submitter can assist the Agency in completing its review within a reasonable timeframe. FSIS Directive 7,120.1, on "Safe and Suitable Ingredients," is updated every month to incorporate newly approved entries, including new interventions (See https://www.fsis.usda.gov/wps/wcm/connect/bab10e09-aefa-483b-8be8-809a1f051d4c/7120.1.pdf?MOD=AJPERES).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this notice on-line through the FSIS webpage located at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/fede ral-register.

FSIS also will make copies of this **Federal Register** publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

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Administrator.

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