Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
9 CFR Part 381
[Docket No. FSIS–2021–0004]

Federal Register
Vol. 87, No. 49
Monday, March 14, 2022

Condemnation of Poultry Carcasses Affected With Any Form of Avian Leukosis Complex; Rescission

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the poultry products inspection regulations to rescind several regulations related to the inspection and condemnation of poultry carcasses affected with any of the forms of avian leukosis complex.

DATES: Submit comments on or before May 13, 2022.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

• Federal eRulemaking Portal: This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to https://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.


Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2021–0004. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to https://www.regulations.gov.

Docket: For access to background documents or comments received, call (202) 205–0495 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT:
Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

The poultry products inspection regulations require that carcasses of poultry affected with any one or more of the several forms of the avian visceral leukosis complex be condemned (9 CFR 381.82). On March 1, 2019, FSIS received a petition from the National Chicken Council (NCC) https://www.fsis.usda.gov/wps/wcm/connect/85a6a9f6-0f63-43f7-9b56-153f2618c419/19-01-Petition-National-Chicken-Council-03012019.pdf?MOD=AJPERES requesting that the Agency amend the regulations to designate avian leukosis as a trimmable condition rather than a condition that requires condemnation of the entire carcass. The petition also requests that FSIS rescind the regulations at 9 CFR 381.36(f)(3) that require young chicken establishments operating under the NPIS to provide a location at a point along the production line to permit an FSIS inspector to inspect for leukosis the first 300 carcasses of each flock, together with their corresponding viscera. In addition, the petition requests that FSIS rescind the regulations at 9 CFR 381.76(b)(6)(iv) that prescribe the 300-bird leukosis inspection procedure under the NPIS. The petition asserts that the current regulations related to leukosis are based on an outdated understanding of this poultry disease, impose unnecessary costs on industry, and present a potential barrier to young chicken establishments that may want to convert to NPIS.

To determine its response to the petition, the Agency evaluated the available scientific information on avian leukosis and reviewed the original basis for the regulations requiring condemnation of young chicken carcasses affected with avian leukosis. Based on this evaluation, FSIS concluded that there is scientific support for treating avian leukosis as a trimmable condition under 9 CFR 381.87 in all poultry establishments operating under FSIS’ mandatory and voluntary inspection. Therefore, on July 16, 2020, FSIS issued a response granting the NCC petition, stating that FSIS has “determined that current scientific evidence supports treating avian leukosis as a trimmable condition and that the actions requested in your petition would reduce regulatory burdens on the industry.”

Avian Leukosis Complex (also referred to as avian leukosis) is a rare condition in chickens that includes three virally-induced, tumor-causing diseases, none of which are transmissible to humans. Avian Leukosis Complex may also be referred to as avian oncogenic viruses. The three characterized diseases are Marek’s Disease, Lymphoid Leukosis, and Reticuloendotheliosis. The most common of the avian oncogenic viruses is Marek’s Disease caused by Marek’s Disease Virus (MDV), a DNA herpesvirus that is ubiquitous in the environment. Lymphoid Leukosis, caused by the Avian Leukosis Virus (ALV), an RNA retrovirus, is the second most common disease of the avian oncogenic viruses. Reticuloendotheliosis also a RNA retrovirus is the third of the avian oncogenic viruses. Additionally, avian visceral leukosis is a rare manifestation of the viral disease leukosis in young chickens, and also not transmissible to humans. Also, if visceral leukosis does

1 Currently, three fowl establishments have waivers to operate under NPIS. If this proposed rule becomes final, FSIS will update their waivers to make them consistent with the final rule.


3 Avian Leukosis Complex also includes Lymphoproliferative Disease of Turkeys, a disease that does not occur in the United States.


occur in young chickens it usually occurs on a flock basis.

Although avian leukosis does not present a human health concern, the poultry post-mortem inspection regulations cited above currently require the condemnation of carcasses affected with leukosis because the condition had historically rendered carcasses unwholesome or otherwise unfit for human food, and thus adulterated under the Poultry Products Inspection Act (PPIA; 21 U.S.C. 453(g)(3)). The current regulations at 9 CFR 381.82 require condemnation of the entire carcass and corresponding viscera if one or more lesions consistent with avian leukosis are observed on the viscera or carcass. Significantly, avian leukosis is the only condemnable disease in which lesions may develop on the viscera without necessarily manifesting itself on other parts of the carcass.

When the post-mortem avian leukosis inspection regulations were enacted, avian oncogenic (tumor-causing) viruses were of low mortality to the poultry industry and birds affected with these viruses were covered in tumors and often paralyzed. Thus, the carcasses of these birds were considered unwholesome due to the extent of disease progression. However, because it is now common commercial practice to vaccinate each chicken flock for Marek’s Disease and to breed leukosis-resistant birds, the occurrence of the condition described above is rare. As FSIS explained in the proposed rule “Modernization of Poultry Slaughter Inspection,” national data from 1984 revealed that all forms of leukosis (skin, visceral, other viral leukoses) resulted in the condemnation of 0.017 percent of the approximately 7.4 billion young chickens slaughtered (77 FR 4408, 4422). While it is possible for a vaccinated bird to develop Marek’s Disease, especially if the virus is highly virulent, the presentation of the disease is usually restricted to a few enlarged feather follicles, possibly a few lymphoid tumors on an organ, or an enlarged spleen. These are localized lesions that do not affect other parts of the carcass. In addition, these types of lesions are not specific to Marek’s Disease, and the diagnosis cannot be confirmed by further testing because all birds that have been vaccinated will test positive for the disease. Since all birds are vaccinated for MDV with a modified-live vaccine, the virus is present in the tissues regardless of the presence of lesions. Thus, a positive test result for Marek’s Disease is not necessarily an indicator of a diseased state that would render the carcass unwholesome.

**History**

The first evidence of Avian Leukosis and its viral etiology in poultry was documented in 1908. At the time, viral oncology was a foreign concept and not much research progressed until the 1920s through the 1940s. During this time, the avian oncogenic viruses (still an unknown etiology, other than an unidentified virus) became a major cause of mortality to the expanding poultry industry, especially with the poultry industry shifting from low-density, low-producing backyard flocks to high-density, high-producing farms. The birds infected with any of the avian oncogenic viruses were unhealthy, covered in tumors, and often paralyzed. The United States, as well as other countries across the world, started devoting more resources into researching the cause of the avian oncogenic viruses.

The research on the avian oncogenic viruses proliferated during the 1950s and 1960s; however, the exact etiology was still unknown at the time the PPIA was passed. Thus, when the regulations implementing the PPIA were promulgated, the presence of Avian Leukosis deemed a whole carcass condemnable, based on the typical extent of disease progression at the time. However, as discussed above, because of current commercial practices, Avian Leukosis is now rare and, if present, is usually restricted to a few localized lesions such as enlarged feather follicles, possibly a few lymphoid tumors on an organ, or an enlarged spleen, which do not render other parts of the carcass unwholesome or unfit for human food.

**Continued Support for Lack of Public Health Significance**

In August 2014, FSIS published the final rule that established the NPIS and required FSIS to inspect the final 300 birds from each flock of young chickens to determine whether leukosis is present in the flock (79 FR 49566, 49586). The preamble to the final rule noted that leukosis does not present a human health concern; however, under the final rule FSIS continued to require condemnation of the entire carcass of birds affected by visceral leukosis under the NPIS and other inspection systems, based on the past determination that the disease rendered poultry unsound or otherwise unfit for human food.

In response to a waiver request, FSIS conducted an evaluation on issues associated with avian leukosis in young chickens. The results of the evaluation show that avian leukosis does not present a human health concern. The literature review found that while several studies confirmed the presence of antibodies to MDV, Avian Lymphoid Leukosis, and Reticuloendotheliosis viruses in people working in poultry slaughter and processing establishments, there have been no indications that these poultry diseases are involved in human disease, including cancer or Multiple Sclerosis. Furthermore, experimental laboratory studies have been unable to establish that any of the avian oncogenic viruses have the ability to infect and replicate.

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in mammalian cells, including humans.\textsuperscript{11}

This recent research is consistent with findings extending back into the 1950’s that assessed the public health risk of the three oncogenic viruses that occur in United States poultry.\textsuperscript{12} The majority of research examined the public health risk of MDV because this virus is ubiquitous in the poultry farm environment and the vaccine for MDV is a modified live vaccine. A modified live vaccine of the MDV herpesvirus means that the virus infects the cells and is persistently present in all cells of the bird. Everyone who raises, slaughters, processes, or eats chicken is exposed to the virus in the vaccine, regardless of the presence of any lesions. This level of profound exposure enabled researchers to conduct numerous epidemiological studies to assess the association between human disease and MDV. An extensive literature review on the public health impact related to MDV exposure performed in 1986 concluded that “[t]he large body of experimental evidence in both avian and human virology, serology, pathology, and epidemiology strongly supports the conclusion that no etiologic relationship exists between avian herpesviruses and human cancer.”\textsuperscript{13} Additional studies after 1986 demonstrated the presence of antibodies against MDV in human populations, especially populations that are heavily exposed to MDV in poultry.\textsuperscript{14} However, seroconversion, which is “the development of detectable antibodies in the blood that are directed against an infectious agent”,\textsuperscript{15} is not a remarkable finding alone and is not unexpected considering the high prevalence of MDV in the environment. The presence of antibodies does not prove a causal relationship between the virus and human disease.\textsuperscript{16}

Current Practices

Under the NPIS, carcasses are presented to the online inspector without the corresponding viscera because all poultry diseases and conditions, except for avian visceral leukosis, are readily identified by observing the carcass alone. To address avian visceral leukosis under the NPIS, an offline inspector observes the viscera of the first 300 birds slaughtered from each young chicken flock to determine whether the disease is present in the flock. As noted above, it is common commercial practice to vaccinate each chicken flock for Marek’s Disease. On rare occasions, the vaccine is not effective. If the vaccine is not effective, visceral leukosis will be present on a flock basis. In the rare event that the disease is present, FSIS will adjust the NPIS inspection procedures and slow the line to inspect each carcass with its corresponding viscera and, if one or more lesions consistent with leukosis are observed in the viscera, the entire carcass must be condemned. However, if FSIS rescinds the regulations that require condemnation of carcasses affected by the avian leukosis complex, the 300-bird leukosis check for NPIS young chicken establishments would no longer be necessary because the carcasses of birds with leukosis lesions on their viscera would not be considered adulterated and any tumors present on the carcass, regardless of the cause, would be trimmed and removed by establishment employees before the carcass is presented to the FSIS online inspector.

Currently, under traditional inspection, FSIS inspection personnel perform inspection on each carcass and condemn carcasses affected by the avian leukosis complex. Under the proposed regulations in establishments under traditional inspection, after identifying lesions on young chicken viscera or carcasses, FSIS inspection personnel would direct establishment employees to trim and remove any tumors present on carcasses. If the disease has metastasized or if the entire carcass is otherwise affected, FSIS inspection personnel would condemn the entire carcass.

Proposed Changes

FSIS is proposing to rescind 9 CFR 381.82, the regulation that requires condemnation of poultry carcasses affected with one or more of the forms of the avian leukosis complex. Under the proposed rule, carcasses affected with avian leukosis would be addressed by 9 CFR 381.87, which provides that any organ or other carcass part affected with tumors may be trimmed and that the unaffected parts of the carcass may be inspected and passed. FSIS is also proposing to rescind 9 CFR 381.36(f)(3), the regulation that requires NPIS young chicken establishments to provide a leukosis inspection area along the slaughter line, as well as 9 CFR 381.76(b)(6)(iv), the regulation that prescribes inspection procedures for avian visceral leukosis in NPIS young chicken establishments. These regulations do not apply to turkey establishments operating under the NPIS because avian visceral leukosis is extremely rare in turkeys.

Executive Order 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as a “non-significant” regulatory action under section 3(f) of E.O. 12866. Accordingly, the proposed rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Impact Analysis

This proposed rule would benefit young chicken slaughter establishments by decreasing the number of carcasses condemned for leukosis. An average of 62,445 young chicken carcasses, which represents less than 0.01 percent of total young chickens slaughtered,\textsuperscript{17} are condemned every year for leukosis, based on Agency data from 2015 to 2019.\textsuperscript{18} Based on data from the NCC and the USDA Economic Research Service, the average market weight of a young chicken is 6.21 pounds\textsuperscript{19} and the wholesale price is 0.91 cents per pound.\textsuperscript{20} As such, these chickens would have a wholesale value of roughly $352,883 per year. Allowing establishments to address leukosis by

\textsuperscript{12} Ibid.
\textsuperscript{13} Purchase HG, Witter RL. Public health concerns from humans exposed to oncogenic avian herpesviruses. JAVMA 1986; 189(11):1430–1436.
\textsuperscript{15} www.medicinenet.com.
\textsuperscript{17} From 2015 to 2019, approximately 9 billion young chickens were slaughtered annually.
\textsuperscript{18} FSIS used data from the Public Health Information System (PHIS). PHIS is FSIS’ electronic data analytic system, used to collect, consolidate, and analyze data in order to improve public health.
trimming affected areas, rather than condemning the entire carcass, would result in industry cost savings of approximately $352,883 per year.

This proposed rule would also remove a potential barrier for young chicken establishments that want to convert to the NPIS by eliminating the need to reconfigure lines and make other changes to provide an inspection area for FSIS to conduct the 300-bird leukosis check. Converting to NPIS would benefit these establishments because they would have more flexibility to design and implement production measures tailored to their operations. The proposed rule would also reduce production costs for NPIS young chicken establishments by removing the inefficiencies associated with the current 300-bird leukosis checks, such as crowing the line if a leukosis positive flock is identified. Eliminating the 300-bird leukosis checks would also allow FSIS to shift inspection resources currently required for performing leukosis checks to other offline activities ensuring food safety.

This proposed rule is deregulatory and is not expected to result in additional costs to industry, consumers, or FSIS.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). FSIS does not expect this proposed rule to result in costs to small entities because only large and high-volume establishments are expected to operate under NPIS and need to hire and train additional employees to sort and trim carcasses. In non-NPIS establishments, FSIS inspectors would continue to direct establishment employees to trim localized defects. If finalized, FSIS expects that this proposed rule would lead to minimal cost savings across the industry. In 2018, total poultry industry revenue was estimated at $65.2 billion,21 as such, the estimated cost savings of $352,883 would be less than .01 percent of industry revenue and would be considered an insignificant economic impact.

From 2015 to 2019, about 28 percent of the establishments that had poultry carcasses condemned for leukosis were classified as Hazard Analysis and Critical Control Point (HACCP) size small and about 15 percent were HACCP size very small.22 Small and very small poultry establishments would benefit from the expected cost savings associated with trimming, if this proposed rule is finalized.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident. Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA’s TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint and at any USDA office or write a letter addressed to USDAs and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: program.intake@usda.gov. USDA is an equal opportunity provider, employer, and lender.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will

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22 FSIS used data from the Public Health Information System (PHIS) to identify these establishments by HACCP category.
announce this Federal Register publication on-line through the FSIS web page located at: https://www.fsis.usda.gov/federal-register.

FSIS will also announce and provide a link to it 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: https://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 381

Poultry inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTIONS REGULATIONS

§ 381.36 [Amended]

§ 381.76 [Amended]

§ 381.82 [Removed and Reserved]

§ 381.87 [Tumors]

(a) Tumors, including those possibly caused by avian leukosis complex, may be trimmed from any affected organ or other part of a carcass where there is no evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor. Trimmed carcasses otherwise found to be not adulterated shall be passed as human food.

(b) Any organ or other part of a carcass which is affected by a tumor where there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor, shall be condemned.

Paul Kiecker,
Administrator.

[FR Doc. 2022-05294 Filed 3–11–22; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF ENERGY

10 CFR Part 431


RIN 1904–AE42

Energy Conservation Program: Energy Conservation Standards for Variable Refrigerant Flow Multi-Split Air Conditioners and Heat Pumps; Clarification


ACTION: Notice of proposed rulemaking and request for comment; clarification.

SUMMARY: On February 10, 2022, the U.S. Department of Energy (“DOE” or “the Department”) submitted a notice of proposed rulemaking (“NORP”) to the Federal Register proposing amended energy conservation standards for variable refrigerant flow (“VRF”) multi-split air conditioners and VRF multi-split heat pumps, collectively referred to as “VRF multi-split systems” (“2022 VRF NOPR”). After submission of the NOPR to the Office of the Federal Register for publication, the U.S. District Court for the Western District of Louisiana issued a preliminary injunction on February 11, 2022, in the case of State of Louisiana v. Biden, which prohibits certain actions relating to the monetization of benefits associated with greenhouse gas emissions reductions. Through this clarification document, DOE is clarifying its response to a public comment in the 2022 VRF NOPR so as to avoid any confusion or ambiguity of DOE’s response in light of the court’s preliminary injunction and to reiterate that no emissions analysis (or related monetization) was conducted for this proposed rulemaking.

DATES: This clarification goes into effect on March 14, 2022.


SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to the Energy Policy and Conservation Act (42 U.S.C. 6291 et seq.), DOE must periodically review its energy conservation standards for covered consumer products and certain industrial equipment, including VRF multi-split systems (see specifically 42 U.S.C. 6313(a)(6)(A)–(C)). DOE initiated a review of its existing standards for VRF multi-split systems through a notice of data availability and request for information (“NODA/RFT”) published in the Federal Register on July 8, 2019 (“2019 VRF NODA/RFT”). 84 FR 32328. The 2022 VRF NOPR was issued (signed) on February 9, 2022, see 87 FR 11335, 11354 (noting the document’s signature date), after which DOE forwarded it to the Office of the Federal Register on February 10, 2022, for publication, and then the Office of the Federal Register placed it for public inspection on February 28, 2022, before ultimately publishing it in the Federal Register on March 1, 2022. 87 FR 11335.

In the 2022 VRF NOPR, DOE explained that because it lacks clear and convincing evidence to support adoption of standard levels more stringent than those contained in the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (“ASHRAE”) Standard 90.1, the Department is proposing to adopt the ASHRAE levels, as required by statute. DOE concluded that it did not need to prepare an emissions analysis or monetization of emissions for this rulemaking in order to support the adoption of the ASHRAE levels.

In this NOPR, DOE also responded to a number of public comments submitted on the 2019 VRF NODA/RFT. One such comment was submitted by the Institute for Policy Integrity at New York University (“NYU”)’ School of Law (hereafter “Policy Integrity”), in which it commented that DOE should monetize the full benefits of emissions reductions and use the global estimate

1 ASHRAE Standard 90.1 is titled “Energy Standards for Buildings Except Low-Rise Residential Buildings.”