

UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE

In re:)
)
Sandhills Beef Company; and) FMIA Docket No. 20-J-0043
Jacob Wingebach,) FMIA Docket No. 20-J-0044
)
Respondents.)

REC'D - USDA/OALJ/OHC
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DECISION AND ORDER ON THE WRITTEN RECORD

Appearances:

Ciarra A. Toomey, Esq.; Tracy McGowan, Esq.; and Matthew Scott Weiner, Esq., with the Office of the General Counsel, United States Department of Agriculture, Washington, DC, for the Complainant, the Administrator of the Food and Safety Inspection Service (“FSIS”)

Jacob Wingebach, pro se Respondent representing Sandhills Beef Company

Before Tierney Carlos, Administrative Law Judge

Preliminary Statement

This is an administrative proceeding to deny Federal inspection services to Sandhills Beef Company and Jacob Wingebach. This proceeding was instituted by a complaint filed by the Administrator of the Food Safety and Inspection Service, United States Department of Agriculture, alleging that Sandhills Beef Company and Jacob Wingebach (“Respondents”) are unfit to receive Federal inspection services under Title I of the Federal Meat Inspection Act.

For the reasons discussed herein, I affirm the Administrator’s refusal to grant Respondents’ application for Federal inspection services.

Procedural History

This proceeding initiated with a complaint filed on February 21, 2020 by the Administrator of the Food Safety and Inspection Service, United States Department of Agriculture (“Complainant” or “FSIS”). The Complaint alleges Respondents are unfit to receive

Federal inspection services under Title I of the Federal Meat Inspection Act, as amended, (“FMIA”), 21 U.S.C. §§ 601 *et seq.*

Respondents filed an answer to the Complaint on March 2, 2020, which admitted the jurisdictional allegations in paragraph 1 of the Complaint and that the Secretary has jurisdiction in this matter. Respondents denied the remaining allegations. During subsequent telephone conferences with the parties, Respondents waived the right to be represented by counsel, waived the right to an oral hearing, and agreed the matter could be decided upon written submissions of both parties.

On May 8, 2020, I issued an order setting a briefing schedule for the parties.¹ In accordance therewith, Complainant filed its Opening Brief, List of Exhibits, Exhibits, List of Declarants, and Declarations on July 8, 2020. Respondents filed their Opening Brief, List of Exhibits, and Exhibits on August 7, 2020. On August 17, 2020, Complainant filed a Reply Brief thereto. Respondents also filed a Reply Brief on August 24, 2020.²

Written submission for both parties were reviewed, and the case is ready for decision.

Jurisdiction and Burden of Proof

¹ See Summary of May 7, 2020 Telephone Conference and Order Setting Briefing Schedule at 1-2.

² On August 25, 2020, Complainant filed a Motion to Strike Respondents’ Reply Brief. See Motion to Strike at 2 (“Complainant requests that the ‘Respondant’s Reply Brief’ filed on 8/24/2020 be stricken from the record to be considered in this proceeding. . . . In the event that this motion is denied, Complainant requests 10 days from the ALJ’s decision to file a sur-reply.”). On August 26, 2020, Respondent filed a response “request[ing] that the Court *not* strike ‘Respondents’ Reply Brief’ filed on August 24.” Response at 1 (emphasis added). Although the Rules of Practice do not grant Respondents the “*right to reply to the response,*” the Judge may, in his or her discretion, order that a reply be filed. 7 C.F.R. § 1.143(d) (emphasis added). Further, Complainant has not shown how it would be prejudiced by my admitting the Reply Brief to the record. See *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (“A document filed *pro se* is to be liberally construed[.]”). Therefore, Complainant’s Motion to Strike Respondents’ Reply Brief, including Complainant’s request to submit a sur-reply, is DENIED.

This is a proceeding under the Federal Meat Inspection Act (21 U.S.C. §§ 601.1 *et seq.*) and the regulations promulgated thereunder (9 C.F.R. Subchapter E) (“Regulations”). FSIS filed its Complaint pursuant to the Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes (7 C.F.R. §§ 1.130 through 1.151) (“Rules of Practice”) and the Rules of Practice that govern proceedings under the FMIA (9 C.F.R. §§ 500.1 through 500.8). The case was assigned to my docket on March 12, 2020 and is properly before me for resolution.

As the proponent of an order in this proceeding, Complainant FSIS has the burden of proof.³ The standard of proof applicable to adjudicatory proceedings under the Administrative Procedure Act,⁴ such as this one, is the preponderance of the evidence.⁵ I find that a preponderance of the evidence supports the findings that Respondents have failed to comply with the FMIA and Regulations as alleged in the Complaint, and Respondents should therefore be denied Federal inspection services.

Discussion

The Federal Meat Inspection Act (“FMIA”) governs the slaughtering of livestock and the processing and distribution of meat products in the United States.⁶ In accordance with sections 603 and 621 of the FMIA, among other provisions, the Secretary is authorized to make rules and

³ 5 U.S.C. § 556(d).

⁴ 5 U.S.C. §§ 551 *et seq.*

⁵ See *Herman & Maclean v. Huddleston*, 459 U.S. 375, 387-91 (1983); *Steadman v. SEC*, 450 U.S. 91, 92-104 (1981); *Pearson*, 68 Agric. Dec. 685, 727-28 (U.S.D.A. 2009), *aff'd*, 411 F. App'x 866 (6th Cir. 2011); *Havana Potatoes of N.Y. Corp.*, 56 Agric. Dec. 1017, 1021 (U.S.D.A. 1997) (Order Den. Pet. for Recons.).

⁶ See *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 455-56 (2012); *Levine v. Vilsack*, 587 F.3d 986, 988-89 (9th Cir. 2009); *Norwich Beef Co.*, 38 Agric. Dec. 380, 394-96 (U.S.D.A. 1979), *aff'd*, No. H79-210 (D. Conn. Feb. 6, 1981).

regulations setting national standards for meat inspection. To that end, the Secretary has promulgated 9 C.F.R. Subchapter A, Part 301 *et seq.*, which regulates meat inspection.

For federally inspected plants, the FMIA and Poultry Products Inspection Act (21 U.S.C. §§ 451 *et seq.*) charge the Secretary with a number of responsibilities, including ante- and post-mortem inspection of the livestock and carcasses, sanitation inspection in the establishments, enforcement of record-keeping requirements, and the training and supplying of inspectors to carry out these responsibilities. *See* 21 U.S.C. §§ 602-06; 21 U.S.C. §§ 455-57, 463. The Secretary in turn has established standards, including facilities requirements, inspection requirements, sanitation requirements, and record-keeping requirements. 9 C.F.R. §§ 301-35, 381; *see Dailey v. Veneman*, No. 01-3146, 2002 WL 31780191, at *2 (6th Cir. Dec. 3, 2002).

An establishment seeking Federal inspection services under FMIA must apply to the FSIS Administrator for a grant of inspection. 9 C.F.R. § 304.1(a). The granting of inspection services requires the submission of a Sanitation Standard Operating Procedures (“SSOP”) Plan in compliance with 9 C.F.R. part 416 and a Hazard Analysis and Critical Control Point (“HACCP”) Plan in compliance with 9 C.F.R. part 417.

FSIS Regulations authorize the Administrator to refuse to grant Federal inspection services if the applicant fails to submit a SSOP in compliance with 9 C.F.R. part 416 or a HACCP in compliance with C.F.R. part 417. *See* 9 C.F.R. § 500.7. In addition, 9 C.F.R. § 304.2(b) provides that “any application for inspection may be refused in accordance with the Rules of Practice in part 500 of this chapter.” Under FSIS Rules of Practice, the FSIS Administrator may refuse to grant Federal inspection if an applicant: “(1) Does not have a

HACCP plan as required by part 417 of this chapter; [or] (2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter[.]” 9 C.F.R. § 500.7(a)(1) and (2).

After review of the application submitted by Respondents and the written submissions of the parties, I find Respondents failed to submit a SSOP that meets the requirement of 9 C.F.R. part 416 and a HACCP that meets the requirements of 9 C.F.R. part 417 and that the Administrator of FSIS was correct in denying Respondents Federal inspection services.

Respondents’ application fails to provide a SSOP that meets the requirements of 9 C.F.R. part 416.

Before being granted Federal inspection services, an establishment must develop written SSOPs, as required by 9 C.F.R. part 416 (9 C.F.R. § 304.3(a)). Pursuant to 9 C.F.R. § 416.12, an establishment’s SSOPs “shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).” Procedures in the SSOPs that are to be conducted prior to operations shall be identified as such and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. 9 C.F.R. § 416.12(c).

To begin with, Respondents acknowledge that 9 C.F.R. part 304 requires the submission of written procedures, SSOPs, recall procedures, and a HACCP; however, they argue that 9 C.F.R. part 304 does not require them to demonstrate the ability to implement any of the procedures contained in the documents, nor are they required to “assuage” FSIS concerns over the implementation of those procedures. Respondents are mistaken. As previously noted, FSIS Regulations authorize the Administrator to refuse to grant Federal inspection services if the applicant fails to submit a SSOP in compliance with 9 C.F.R. part 416 or a HACCP in compliance with C.F.R. part 417. *See* 9 C.F.R. § 500.7. Inherent in the authority to refuse to grant Federal inspection services is the authority to review an establishment’s ability to

implement the procedures it has submitted in its application. Respondents' argument that they can submit any written documents and be entitled to a conditional grant of inspection without any review or critique by FSIS ignores the statutory authority of FSIS, the purpose behind 9 C.F.R., and common sense. According to Respondents' logic, they could submit a piece of paper entitled "SSOP" or "HACCP" with procedures they have no ability or intention of following, yet FSIS would be required to issue a conditional grant of inspection. FSIS has the statutory obligation and authority to review the written documents to insure they meet the requirements of 9 C.F.R. parts 416 and 417. Inherent in that authority is the authority to require establishments to prove the ability to implement the submitted procedures and the requirements of 9 C.F.R. parts 416 and 417 are met. To hold otherwise would render the Regulations meaningless and unenforceable.

The SSOPs submitted by Respondents in their application define a "food contact surface" as "the surface of a facility, equipment, or utensils intentionally, routinely and purposefully placed in direct contact with edible tissue" (CX-13 at 57). The SSOPs then "differentiate between edible and inedible tissue based on the status of the tissue as US Inspected and Passed, or not US Inspected and Passed, respectfully[sic]" (CX-13 at 57). Respondents' SSOPs also specify that "[s]urfaces intentionally, routinely and purposefully placed in direct contact[sic] edible tissues prior to FSIS postmortem inspection are non-food contact surfaces," and "[s]urfaces intentionally, routinely and purposefully placed in direct contact[sic] edible tissues after FSIS postmortem inspection are food contact surfaces" (*Id.* at 57-58). The food contact surfaces listed in the SSOPs include slaughter knives, slaughter hand saws, slaughter tables, and slaughter lugs/totes that "directly contact US Inspected & Passed carcasses and parts" (*Id.* at 59).

During the application process, FSIS repeatedly informed Respondents that their definition of “food contact surface” was not acceptable. Respondents refuse to accept FSIS’s determination and insist that they are allowed to define “food contact surface” how they choose (CX-12; CX-15; CX-17). Respondents, a meat process plant and owner/operator, argue that since “food contact surfaces” is not defined in the statute, they, Respondents, can use their own definition of “food contact surfaces.”⁷ Respondents argue that food does not become food until it is edible and that food does not become edible until it is inspected and passed by FSIS.⁸ Respondents’ definition of “food” and thereby “food contact surface” is contrary to the common meaning of “food,” contrary to common sense, contrary to industrywide standards, and contrary to the regulatory purpose of the FMIA.

Respondents’ arguments in both their brief and reply brief consist largely of their interpretation of the relevant C.F.R. parts. However, Respondents’ interpretation of the regulations is just that—Respondents’ interpretation—and as such is entitled to little to no deference. It is well settled that an agency’s interpretation of the statute which it is charged with administering, and especially an agency’s interpretation of its own regulation, is entitled to great deference unless it is clearly erroneous or inconsistent with the language it interprets. *See Chem. Mfrs. Ass’n v. Nat. Resources Defense Council*, 470 U.S. 116, 125-126 (1985); *Immigration & Naturalization Serv. v. Stanisic*, 395 U.S. 62, 72 (1969); *see also Chevron, U.S.A., Inc. v. Nat.*

⁷ Respondents switch their arguments regarding definitions to suit their needs. Regarding the definition of “food,” they argue that since the term is not defined in the regulations, they, Respondents, get to define “food,” completely ignoring the dictionary definition and common sense and logic and instead defines it by differentiating between edible and inedible to somehow determine that something is not “food” until it is inspected and passed by FSIS inspectors. When defining “occur,” they argue that when a word is not defined in the regulation it is appropriate to use the standard definition in the dictionary; however, even when using the dictionary use of occur they ignore the first definition in the dictionary and use only the second definition.

⁸ *See* Respondents’ Opening Brief at 18-19.

Resources Defense Council, 467 U.S. 837, 844 (1984); *Bailey v. Fed. Intermediate Credit Bank*, 788 F.2d 498, 499-500 (8th Cir. 1986), *cert. denied*, 479 U.S. 915 (1986). FSIS's interpretation of the meaning of "food" and thus, "food contact surface," and its interpretation of 9 C.F.R part 416 are not clearly erroneous or inconsistent with the language of C.F.R part 416 and are entitled to controlling weight. *See Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *see also Stanistic*, 395 U.S. at 72; *Udall v. Tallman*, 380 U.S. 1, 16, 17 (1965).

Moreover, Respondents' argument that it is reasonable to define "food" and thus "food contact surface" by differentiating between edible and inedible and the status of whether or not it has been inspected fails for several reasons. First, there is no need to define "food" and "food contact surface." As discussed below, there is no confusion as to the meaning of "food" or "food contact surface" and certainly no need to define it by such a convoluted method. Second, Respondents' differentiating between edible and inedible largely ignores the definition of edible, *i.e.*, "intended for use as human food." The whole point of the slaughter/inspection process is to process carcasses for use as human food. While the carcasses may be inedible for the purposes of sale, transport, or being placed in commerce because they have not been inspected, they are still edible because they are "intended for use as human food"; as such, anything they contact during the slaughter process is a food contact surface. By insisting on defining "food" and "food contact surface" by differentiating between edible and inedible and when it is inspected, Respondents have purposely created confusion where there is none.

Unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning. *See Bilski v. Kappos*, 561 U.S. 593, 603 (2010) (citing *Diamond v. Diehr*, 450 U.S. 175, 182 (1981)).

The plain and ordinary meaning of “food” is something that is capable of being eaten. Its status as food does not depend on whether or not it has been inspected by a Federal inspector. According to Respondents’ definition of “food,” an apple on a tree, a tomato grown in a backyard garden, and a fish caught by a recreational fisherman would not be edible and thus, not food, because they were never inspected by a FSIS inspector.

Respondents allege that in the absence of a definition, they are unable to differentiate between “food contact surface” and “non-food contact surface.” A simple internet search would determine that the USDA defines “food contact surface” as any surface that may come in direct contact with exposed meat or poultry products; examples include conveyor belts, table tops, saw blades, augers, and suffers (CX-24). This definition is in accordance with common sense and logic, especially when used in the context of meat processing procedures. It is also in accordance with industry standards; for example, *Emerging Methods and Principles in Food Contact Surfaces Decontamination/Prevention* states that “food contact surfaces” comprise all surfaces that may come into contact with food products during production, processing and packing. Torstein Skara & Jan T. Rosnes, *Emerging Methods and Principles in Food Contact Surfaces Decontamination/Prevention*, INNOVATION & TRENDS IN FOOD MANUFACTURING & SUPPLY CHAIN TECHNOLOGIES 151 (C.E. Leadley ed., 2016) .

The ordinary, common definition of “food” is also consistent with the definitions used by PDS, Office of Policy and Program Development when it reviewed Respondents’ application. PDS used the term “meat food product” as defined in 21 U.S.C. § 610(k) (“any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep swine or goat”) and the term “capable of use as human food” as defined in 9 C.F.R. § 301.2 (“applies to any carcass, or part, or product of a carcass, of any

animal, unless it is denatured or otherwise identified as required by the regulations prescribed by the Secretary to deter its use as human food or is naturally inedible to humans (such as hoof, horns, and hides in their natural state”). *See* Linville Decl. ¶ 11.

Respondents’ definition of “food contact surface” is also inconsistent with the definition of “food” in *Merriam-Webster Dictionary*, American Standard Version, which defines “food” as “material consisting essentially of protein, carbohydrate, and fat used in the body of an organism to sustain growth, repair, and vital processes and to furnish energy” or more simply “nutriment in solid form” (CX-26). Meat product satisfies this definition of “food” regardless of its location on the slaughter line. The same meat that qualifies as food once it receives the mark of Federal inspection is food prior to receiving the mark. Indeed, under Respondents’ definition of “food,” the meat products they prepare in their custom exempt slaughter operation would not be considered food at all because those products are not subject to Federal inspection.

Respondents’ definition of “food contact surface” is also inconsistent with 9 C.F.R. § 416.12, which states that the SSOPs that are to be conducted prior to operations shall address at a minimum the cleaning of food contact surfaces of facilities, equipment, and utensils. Thus, 9 C.F.R. § 416.12 recognizes that the cleaning of food contact surfaces shall be conducted prior to the start of operations. Under Respondents’ definition of “food contact surface,” it would be impossible to have food contact surfaces prior to beginning operations since food would not become food until after it had processed, inspected, and passed by FSIS inspectors.

Respondents’ claim that the phrase “food contact surface” is so vague “that men of common intelligence must necessarily guess at its meaning and differ as to their application” and thus violates “due process” deserves little discussion. 9 C.F.R. part 416 and the phrase “food contact surface” have been in use for over twenty years. I have been unable to find any litigation

over the definition or meaning of “food” or “food contact surface.” Apparently, men of common intelligence have had no problem understanding the terms for over twenty years. The food processing industry has used and adopted the term in its publications and training without any confusion. There is no need to define “food” or “food contact surface” because any person of common intelligence knows what food means and understands that food contact surface means a surface that food comes into contact with. Respondents’ claim of confusion and lack of understating of this basic and universal acceptable phrase is simply not credible; rather, it is an attempt to avoid the regulatory requirements of 9 C.F.R. part 416.⁹

By ignoring the ordinary and plain meaning of “food” and instead restricting the definition of “food contact surface” to only those surfaces that come into contact with carcasses and parts that have been “U.S. Inspected and Passed,” Respondents have purposely excluded sanitation procedures for equipment and utensils that come into contact with carcasses and parts prior to the point of final post-mortem inspection by FSIS. As a result, the SSOPs do not address sanitation procedures for equipment and hand tools used in the slaughter steps prior to post-mortem inspection, where contamination is likely to occur (CX-25; Sidrak Decl. ¶¶ 2, 3, 7; Linville Decl. ¶ 14).

Respondents argue that their definition of “food contact surface” does not exclude sanitation procedures for equipment and utensils throughout the slaughter process but rather cause such procedures to be addressed in their sanitation performance standards, which are not required to be provided prior to granting of a conditional grant of inspection. This argument fails for the simple reason that their definition of “food contact surface” is wrong. Respondents do not

⁹ Respondents’ “due process” claim is also dismissed because they are receiving “due process” by the hearing process specified in 9 C.F.R. § 500.7(b)).

get to choose where to address sanitation procedures for food contact surfaces by using their own self-serving, illogical, and convoluted definition of “food contact surface.” The cleaning of food contact surfaces of facilities, equipment, and utensils must be addressed in written SSOPs. 9 C.F.R. § 416(12).

FSIS’s refusal to grant inspection services to an establishment that does not consider the meat it is processing to be food until it is inspected and passed by the FSIS is entirely reasonable. The self-serving, illogical definition of “food contact surface” and the refusal to provide an SSOP for equipment and utensils that contact edible carcasses and parts prior to post-mortem inspection by FSIS are sufficient grounds to deny Respondents’ application for Federal inspection services.

The application fails to provide a HACCP that meets the requirements of 9 C.F.R. part 417.

Part 417 of 9 C.F.R. provides:

Every official establishment shall conduct or have conducted for it, a hazard analysis to determine food safety hazards reasonably likely to occur in the production process and identify the preventive measures the food establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred or because that is a reasonably likely to occur in the particular type of product being processed, in the absence of those controls.

9 C.F.R. § 417.2. Thus, 9 C.F.R. part 417 requires a HACCP plan that identifies food safety hazards (“FSHs”) reasonably likely to occur (“RLTO”) in the production process and preventive measures to control those hazards. In their application, Respondents determined that FSHs were RLTO at the Restrain/Stun/Bleed step in the processing procedure. However, their HACCP plan then determined that FSHs are NRLTO at any subsequent steps, including dehidating and evisceration.

Respondents argue that because they identified the restrain/stun/bleed step as an area where FSHs are RLTC, they do not need to identify any other subsequent steps because those are not new FSHs but merely continuing FSHs from the restrain/stun/bleed step. Respondents argue that while 9 C.F.R. requires they determine FSHs RLTO in the production process, this language does not require them to identify every process or step in the production process where FSHs occur.

Respondents again argue that because the word “occur” is not defined in the Regulation, they can choose the definition. However, this time instead of making up a definition that suits their needs, Respondents argue they can choose the definition from the dictionary they deem appropriate.

Respondents rely on the American Standard Dictionary’s definition of the term “occur,” which is (1) to be found or met with or (2) to come into existence. Respondents claim they can choose which definition to apply when developing their HACCP, and they choose the second definition: “to come into existence.” They use this definition to support their claim that they are not required to identify FSHs at any step subsequent to restrain/stun/bleed because the FSHs came into existence at the restrain/stun/bleed step, and any FSHs after that step is a continuing hazard and not one that “comes into existence” at a subsequent step in the process.

This argument fails for several reasons. First, Respondents do not get to pick and choose the definition that suits their purposes; second, it ignores the first definition of “occur” in the American Standard Dictionary; and third, it ignores the language of 9 C.F.R. and standard industry practices.

As previously pointed out, when words are not defined in a regulation they are assigned their ordinary, contemporary common meaning. *See Bilski v. Kappos*, 561 U.S. 593, 130 S. Ct.

3218, 3211 (2010). The definition of “occur” in the American Standard Dictionary is (1) to be found or met with or (2) to come into existence. Respondents cannot simply ignore the first meaning in the dictionary, especially when used in the context of FSHs and given that the purpose behind the Regulation is food safety for the American public. The common, plain meaning of the word “occur” is to be found or to come into existence. The common, everyday plain meaning of the word “occur” requires establishments to deal with FSH that are found or that come into existence during any stage in the production process. Using Respondents’ definition of “come into existence” while ignoring “to be found” defeats the entire purpose of the Regulation. Under Respondents’ definition, a meat processing plant would not need to identify any FSHs found after the restrain/stun/bleed step in the process.

Food safety hazards are found at various stages or steps throughout the meat processing production (Sidrak Decl. ¶ 7). 9 C.F.R. part 417 states the requirement to identify food safety hazards **in the production process**. See 7 C.F.R. § 417.2(a)(1). The requirement to identify FSH and preventive measure at each stage of the process is clear from the language. Raw meat products may become contaminated with pathogenic or disease-causing microorganisms such as salmonella, campylobacter, and shiga toxin producing Escherichia coli (“STES”) throughout slaughter, sanitary dressing, and additional processing and handling steps. Once introduced, microorganisms may multiply and some cases produce toxins if the environmental conditions such as warm temperatures, allow. For this reason, establishments often have strict procedures to ensure that carcasses are dressed and processed in a cold environment and that the product is moved in a timely manner for storage in a cooler or freezer, as colder temperatures will inhibit growth of many microorganisms. (Sidrak Decl. ¶ 7). By failing to identify and address those additional hazards, FSIS determined that Respondents’ HACCP failed to meet 9 C.F.R. part 417.

FSIS's interpretation of 9 C.F.R part 417 is not clearly erroneous or inconsistent with the language of 9 C.F.R part 417 and is entitled to controlling weight. *See Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *see also Immigration & Naturalization Serv. v. Stanisic*, 395 U.S. 62, 72 (1969); *Udall v. Tallman*, 380 U.S. 1, 16, 17 (1965).

Respondents' HACCP Plan fails to provide any supporting rationale for determining that FSHs are NRLTC at any steps subsequent to Restrain/Stun/Bleed.

Respondents' HACCP plan determines that FSHs are RLTC at the Restrain/Stun/Bleed step of the production process. At all subsequent steps, including remove hair/hide, remove Head/Viscera, Harvest Variety Meats, Split carcass, Trim, Wash, Antimicrobial Treatment, Refrigerated Storage, and Ship steps in the application, Respondents determined that FSHs are NRLTO. In support of their determination Respondents repeat the following seemingly contradictory statement:

Establishment grounds, facilities, equipment, utensils, sanitary operations and employee hygiene are potential sources of biological, chemical, or physical properties that may cause a food to be unsafe for human consumption. Since 2015, Sandhills Beef Company has slaughtered livestock under provisions of 9 CFR 303.1(a)(2). **Historically, biological, chemical, or physical properties that cause a food to be unsafe for human consumption have not been identified with establishment grounds, facilities, equipment, utensils, sanitary operations and employees. As a prudent establishment, Sandhills Beef Company would not establish preventive measures for establishment grounds, facilities, equipment, utensils, sanitary operations and employee hygiene.**¹⁰

(CX-13 at 44, 45, 46, 47) (emphasis added).

¹⁰ This not only contradictory statement in the application. In the "Trim" section of his application, Respondents acknowledge that "[t]rimming is the only means of removing feces, ingest, and milk contamination from beef carcasses based upon the judgement that trimming is more effective for removing fecal contamination than alternative approaches. . . . As a prudent establishment Sandhills Beef Company would not establish preventive measures for visible fecal material" (CX-13 at 46).

The above statement acknowledges that the establishment grounds, facilities, equipment, utensils, sanitary operations, and employee hygiene are potential sources of biological, chemical, and physical properties that may cause a food to be unsafe for human consumption, yet Respondents refuse to establish preventive measures because Sandhills Beef Company has not “historically” had problems. According to Respondents’ logic, because they have operated a custom exempt facility since 2015 and no food safety hazards have been identified, that means they are exempt from the 9 C.F.R. part 417 provisions requiring written procedures for all operations in the future.

Apparently, Respondents believe that because something hasn’t occurred in past, it will not occur in the future. This rational ignores the language “or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.”

FSIS has acknowledged that Respondents’ determination that FSHs are NRLTO at subsequent steps in the production process may be a reasonable determination if Respondents can reference a prerequisite program in place to prevent or address the potential hazard (Linville Decl. ¶ 6). However, Respondents’ application does not contain or reference any supporting prerequisite programs for the determinations that FSH are NRLTO at any steps subsequent to Restrain/Stun/Bleed and Respondents have repeatedly refused requests by FSIS for changes or additional documents in support of their application.

In addition, the statement in Respondents’ application that they will “not establish preventive measures for establishment grounds, facilities, equipment, utensils, sanitary operations, and employee hygiene” (CX-13 at 44) because they have not had problems in the past is alone sufficient grounds to deny Federal inspection services, as it ignores the language “or

because that is a reasonably likely to occur in the particular type of product being processed, in the absence of those controls” and does not identify food safety hazards (“FSHs”) reasonably likely to occur in the production process and preventive measures to control those hazards.

FSIS’s determination that Respondents’ HACCP was not in compliance with 9 C.F.R. part 417 was proper.

Respondents have not incorporated written Specified Risk Materials (SRMs) procedures into their HACCPs, SSOPs, or other prerequisite programs.

“Specified Risk Materials” (“SRM”) are defined as material or tissue that can harbor bovine spongiform encephalopathy (“BSE”), including brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column from cattle thirty months or older. *See* 9 C.F.R. § 310.22(a). 9 C.F.R § 310.22(e) requires establishments to implement written SRM procedures and incorporate those procedures into their HACCP, SSOPs or other prerequisite programs. Respondents have acknowledged the requirement to submit written SRM procedures but stated they will not do so until FSIS inspection services are granted. The Regulations require establishments to implement written SRM procedures into their HACCP, SSOP, or other prerequisite program. 9 C.F.R. § 310.22(e)(1). Respondents did not provide any prerequisite programs. Again, Respondents acknowledge the requirement but refuse to comply until they deem it appropriate. That is not how the process works. Accordingly, the FSIS Administrator’s denial of inspection services due to the refusal to provide written SRM procedures was proper.

In sum, FSIS’s interpretation of 9 C.F.R parts 416 and 417 is not clearly erroneous or inconsistent with the language it interprets. FSIS’s determination that Respondents’ HACCP and SSOP were not in compliance with 9 C.F.R. parts 416 and 417 was proper and justifies denial of Federal inspection services. Respondents’ refusal to provide written SRMs in their HACCP, SSOP, or prerequisite programs also justifies denial of inspection services.

Findings of Fact

1. Sandhills Beef Company, Respondents' business, is and at all times material herein is a small meat slaughter and processing facility located in Mullen, Nebraska, and whose mailing address is Sandhills Beef Company, P.O. Box 513, Mullen, Nebraska 69152.
2. Respondent Jacob Wingeback is the applicant and a responsibly connected individual to Sandhills Beef Company.
3. Respondents currently operate a custom exempt slaughter facility under the name of "Hooker County Meat and Packing Company" (CX-01; Sprouls Decl. ¶ 4). A custom exempt facility slaughters livestock owned by someone else and prepares the meat for the exclusive use of the livestock owner. It does not sell the meat. Custom exempt facilities are exempt from FMIA provisions requiring carcass-by-carcass inspection and daily presence of inspectors during slaughter and processing operations, but they must comply with the FMIA's adulteration, misbranding, and humane handling provisions, as well as certain sanitation and recordkeeping requirements (Sprouls Decl. ¶ 4). FSIS periodically reviews custom exempt operations to verify the facilities are being operated and maintained in accordance with FMIA requirements (Sprouls Decl. ¶ 4; CX-22).
4. On March 20, 2019, FSIS Consumer Safety Inspector [REDACTED] visited the facility to conduct an inspection of Hooker County Meat's custom exempt operations. During that visit Respondents expressed interest in applying for Federal inspection services at the facility. Inspector [REDACTED] provided Respondents with the contact information for [REDACTED], a frontline supervisor working out of FSIS's Office of Field Operations, Denver District Office ("DDO") (Sprouls Decl. ¶ 4; CX-01).

5. On April 10, 2019, Dr. [REDACTED] visited Respondents' facility to discuss the Federal inspection application process with Respondents. Dr. [REDACTED] directed Respondents to the FSIS website and other resources available to Respondents and sent a follow-up email attaching an on-site survey checklist (Sprouls Decl. ¶ 5; CX-02)
6. On or about September 3, 2019, Respondents submitted an application for Federal inspection services, dated August 30, 2019, to FSIS (CX-04).
7. Dr. [REDACTED], a FSIS supervisory Public Health Veterinarian, reviewed the application with input from other staff. On October 18, 2019, Dr. [REDACTED] sent an email to Respondents providing details on the deficiencies with the application, including multiple instances where Respondents' HACCP plan failed to identify and control food safety hazards ("FSH") and noting that while the plan acknowledged that FSHs were reasonable likely to occur ("RLTO") at the receiving step, it did not identify any FSHs at subsequent steps in the process (CX-07). Dr. [REDACTED] offered to meet with Respondents to explain the deficiencies further and answer any questions (Sprouls Decl. ¶ 8; CX-07).
8. On October 23, 2019, Dr. [REDACTED] and Dr. [REDACTED] spoke with Respondents and reviewed the issues raised by Dr. [REDACTED]. Following that conversation, Dr. [REDACTED] sent Respondents reference material for their review (CX-08).
9. On October 29, 2019, Respondents sent an email to Dr. [REDACTED] responding to the issues raised by Dr. [REDACTED]'s review of their application (CX-09).
10. On October 31, 2019, Respondents provide an updated version of their operational plan to Dr. [REDACTED] (CX-11).
11. On November 7, 2019, a conference call was held with Dr. [REDACTED], Dr. [REDACTED], Respondents, and Respondents' consultant, Dr. [REDACTED], to discuss Respondents'

application (Sprouls Decl. ¶ 12). Dr. [REDACTED] Dr. [REDACTED] restated their concerns with the application, while Respondents argued the application met all regulatory requirements. Another call was scheduled for November 26, 2019 (Sprouls Decl. ¶ 12).

12. On November 26, 2019, a telephone conference was held with Dr. [REDACTED] Dr. [REDACTED] DDO supervisor Dr. [REDACTED], DDO supervisor Dr. [REDACTED], Respondents, and Dr. [REDACTED]. The parties discussed Respondents' application and Respondents' determination that safety hazards were not reasonably likely to occur ("NRLTO") at all steps subsequent to receive of livestock step. At the end of call, Dr. [REDACTED] agreed that he would further review Respondents' application. (Sprouls Decl. ¶ 13; Reeder Decl. ¶ 3).
13. Dr. [REDACTED] reviewed the application and identified multiple deficiencies, including Respondents' conclusion that a food surface contact does not exist until after FSIS inspection. In addition, Dr. [REDACTED] noted the HACCP failed to consider that FSHs may occur at additional stages of slaughter, sanitary dressing, and additional processing steps (Reeder Decl. ¶¶ 3-5).
14. To ensure his review was consistent with FSIS regulatory policy, Dr. [REDACTED] consulted with Policy Development Staff ("PDS") in FSIS's Office of Policy and Development. Consistent with Dr. [REDACTED] review, PDS disagreed with Respondents' definition of "food contact surface" (Reeder Decl. ¶¶ 6-7). Applying the definition of "meat food product" found in 21 U.S.C. § 601(j) and "capable of use as human food" found in 9 C.F.R § 301.2, PDS concluded that equipment and surfaces that contact the carcass or parts of carcass throughout the slaughter process are food contact surfaces (Linville Decl. ¶¶ 9-11).
15. On December 10, 2019, Dr. [REDACTED], Acting District Manager for DDO, sent a letter via email to Respondents detailing the deficiencies in the application, including the HACCP

plan's failure to identify food safety hazards throughout the slaughter and processing process and Respondents' definition of "food contact surface" (CX-12).

16. On or about December 23, 2019, Respondents emailed a response to Dr. [REDACTED]'s email of December 19, 2019 and attached a new application, which included a new HACCP plan and new SSOPs (CX-13). In the email, Respondents stated that any documentation submitted prior to December 21, 2019 was withdrawn and did not constitute their official application for Federal inspection. The HACCP and SSOPs submitted in the December 21, 2019 application differed from the application submitted on August 30, 2019. While the previous operation plan included prerequisite programs for Specified Risk Materials ("SRM"s), Procedures, Residue Control Good Manufacturing Practices ("GMP"), Trim, Prerequisite Procedure, and Cold Chain GMPs and controls for the relevant hazards, the December 21, 2019 HACCPs and SSOPs did not (Clay Decl. ¶ 6).

17. On January 1, 2020, Ms. [REDACTED] assumed the position of District Manager for DDO, and Dr. [REDACTED] returned to serving full time as District Manager for the Des Moines District Office (Clay Decl. ¶ 3). During the turnover process, Dr. [REDACTED] briefed Ms. [REDACTED] on Respondents' application. Ms. [REDACTED] spoke to Respondents several times between January 13 and January 15, 2020 (Clay Decl. ¶ 4). On January 13, 2020, Ms. [REDACTED] sent an email to Respondents listing the deficiencies with Respondents' application (CX-15). Respondents responded to the email on January 14, 2020 (CX-15).

18. During this timeframe, Ms. [REDACTED] consulted with FSIS's PDS office and Risk Management Innovations Staff ("RMIS") to determine whether Respondents' December 21, 2019 applications met regulatory requirements (Clay Decl. ¶ 6). During a January 22, 2020 telephone call between PDS and RMIS it was noted that the new application did not contain

any prerequisite programs that were contained in the withdrawn October 13, 2019 application. Both PDS and RMIS opined that Respondents' HACCP and SSOPs did not comply with the requirements of 9 C.F.R. parts 416 and 417.

19. On January 24, 2020, Respondents visited DDO and spoke to Ms. [REDACTED] regarding their application. Respondents told Ms. [REDACTED] that they believed their application met the regulatory requirements to receive a conditional grant of inspection and that they would not make any changes to the HACCP or SSOP (Clay Decl. ¶ 7).
20. On January 28, 2020, FSIS Office of Investigation, Enforcement and Audit ("OIEA") requested PDS to review Respondents' December 21, 2019 response to Dr. [REDACTED] December 10, 2019 letter regarding the deficiencies in Respondents' application (Linville Decl. ¶ 13). Upon review, PDS determined that Respondents' HACCP: (1) failed to identify any biological hazards at the hide dressing and evisceration steps; (2) failed to identify outgrowth of pathogens after the hot carcasses leave the slaughter floor and enter refrigerated storage; and (3) failed to adequately address specified risk material ("SRM"s). PDS also determined that Respondents' definition of "food contact surfaces" in the SSOP excluded procedures for equipment and utensils that contact edible carcasses and parts prior to post-mortem inspection by FSIS inspection in violation of 9 C.F.R. part 416 (Linville Decl. ¶ 14).
21. On January 29, 2020, Ms. [REDACTED] sent an email to Respondents again stating FSIS's position regarding the deficiencies in Respondents' application, including Respondents' incorrect definition of "food contact surfaces" and the failure of the HACCP to address the biological hazards during the dehidng and slaughter process (CX-17) (Linville Decl. ¶ 14).

22. On January 29, 2020 Respondents responded to Ms. [REDACTED]'s email, affirming their belief that their definition of "food contact surface" was appropriate and repeating their positions on the other issues raised by FSIS (CX-18).
23. On February 5, 2020, FSIS personnel conducted a conference call with Respondents and Dr. [REDACTED]. FSIS reviewed the areas of noncompliance with Respondents and Dr. [REDACTED]. Respondents were informed: (1) the SSOPs did not identify "food contact surfaces" vs. "non-food contact surfaces" and thus did not contain all procedures necessary to prevent the direct contamination or adulteration of product, as required by 9 C.F.R. § 416.12(a); and (2) the HACCP did not identify all hazards RLTO in slaughter operations, as required by 9 C.F.R. § 417.2(a)(1) (Clay Decl. ¶ 9; Safian Decl. ¶ 6). Both Respondents and Dr. [REDACTED] were given the opportunity to respond and to make changes or submit additional material to the application. Respondents stated they would not be making any changes to their application.
24. On February 14, 2020, Respondents sent an email requesting a written decision from FSIS on their application for inspection services (CX-20).
25. On or about February 18, 2020, FSIS notified Respondents that FSIS was refusing to grant Federal inspection services at Sandhills Beef Company (CX-21) and listed four reasons: (1) the SSOPs did not meet the requirements of 9 C.F.R. part 416, because the definition of "food contact surfaces" excluded procedures for equipment contacting edible carcasses and parts prior to post-mortem inspection contrary to 9 C.F.R. § 416.12(a), which requires that SSOPs describe all procedures the establishment will conduct before and during operations sufficient to prevent direct contamination or adulteration of meat product; (2) the Hazard Analysis did not identify all hazards RLTO in slaughter operations, as required by 9 C.F.R. § 417.2(a)(1), because it recognized biological hazards from fecal, ingesta, and milk

contamination but failed to recognize such hazards at the hide dressing and evisceration production steps; (3) the Hazard Analysis did not identify all hazards RLTO in slaughter operations, as required by 9 C.F.R. § 417.2(a)(1), because its determination that biological hazards are NRLTO at the refrigerated storage and subsequent steps is unfounded and fails to recognize hazards from the outgrowth of pathogens after hot carcasses leave the slaughter floor and enter refrigeration or as a result of temperature abuse; and (4) the Hazard Analysis did not adequately address SRMs, a known hazard in beef slaughter operations, as required by 9 C.F.R. § 417.2(a)(1), and the firm did not incorporate SRM procedures in its HACCP plan, SSOPs or any prerequisite programs as required by 9 C.F.R. § 310.22(e)(1) (CX-21).

Conclusions of Law

1. The Secretary has jurisdiction in this matter.
2. Respondents' application for inspection services was properly denied due to failure to submit an application in compliance with 9 C.F.R parts 416 and 417.

ORDER

Federal inspection services to Respondents Sandhills Beef Company and Jacob Wingeback are hereby DENIED.

This Decision and Order shall be final and effective without further proceedings thirty-five (35) days after service upon Respondents, unless an appeal to the Judicial Officer is filed with the Hearing Clerk within thirty (30) days after service as provided in section 1.145 of the Rules of Practice (7 C.F.R. § 1.145).

Copies of the Decision and Order shall be served by the Hearing Clerk upon the parties and counsel.

Done at Washington, DC,
this 1st day of September 2020



Tierney Carlos
Administrative Law Judge

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