

PETITION TO OFFER CERTIFIED RESPONSIBLE ANTIBIOTIC USE CHICKEN TO SCHOOLS IN THE NATIONAL SCHOOL LUNCH PROGRAM THROUGH THE USDA FOODS PROGRAM

Filed October 20, 2016

I. Introduction

The Natural Resources Defense Council (NRDC), Urban School Food Alliance, and School Food Focus submit this petition under 7 C.F.R. § 1.28 to request that the Secretary of Agriculture offer chicken produced without the routine use of antibiotics important to human medicine (“certified responsible antibiotic use chicken”) to schools in the National School Lunch Program through the USDA Foods program.¹ Specifically, this petition asks the Secretary to create commodity specifications for certified responsible antibiotic use chicken products, and add those products to the USDA Foods List, so that schools and State Distributing Agencies may order them.

Antibiotic use in animal agriculture contributes to the serious and growing public health threat of antibiotic resistance. Parents and consumers across the country are concerned about this issue and are seeking meat and poultry raised without the inappropriate use of antibiotics. Many schools are also working to serve these products to their students. Offering certified responsible antibiotic use chicken through the USDA Foods program would help address a pressing public health threat, respond to school and parent demand, and further the purpose of the National School Lunch Program.

II. The overuse of antibiotics in livestock production threatens public health

Antibiotic-resistant bacteria are a major public health threat, leading to increasing numbers of infections that can be difficult to treat, longer and more expensive hospital stays, and infections that are more likely to be fatal.² In fact, there are already some infections for which there are now few or zero effective antibiotics.³ In 2013, the Centers for Disease Control and Prevention (CDC) estimated that more than 2 million people are sickened every year from antibiotic-resistant infections, and at least 23,000 die.⁴ Compounding the problem, the development of new antibiotics has slowed to a trickle.⁵

While improper use of antibiotics in the health-care sector is a contributing factor, the CDC and the World Health Organization recognize that the “overuse and misuse of antibiotics in food animals” is a major contributor to the spread of the antibiotic-resistant bacteria that can affect

¹ In this petition, “certified responsible use chicken” is defined as meeting the requirements of School Food Focus’ CERTIFIED RESPONSIBLE ANTIBIOTIC USE STANDARD (Sept. 29, 2016), attached.

² CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013 11 (2013), <http://www.cdc.gov/drugresistance/threat-report-2013/index.html>.

³ *Id.* at 22.

⁴ *Id.* at 6.

⁵ Anthony Coates & Gerry Halls, *Antibiotics in Phase II and III Clinical Trials*, 211 HANDBOOK OF EXPERIMENTAL PHARMACOLOGY 167-83 (2012).

humans.⁶ Approximately 70 percent of all sales of medically important antibiotics in the United States are for livestock use.⁷ Often these drugs are not used to treat sick animals but instead to compensate for crowded and unsanitary conditions.⁸ This inappropriate use of antibiotics to raise livestock promotes the growth of drug-resistant bacteria on the farm, which can then spread to our communities through soil, air, water, food, and farmworkers.⁹

Eliminating the use of human antibiotics except to treat sick birds will help slow the emergence of antibiotic-resistant bacteria, as USDA acknowledges. For instance, in 2010, Dr. John Clifford, USDA's Chief Veterinary Officer, told Congress, "USDA believes that it is likely that the use of antimicrobials in animal agriculture does lead to some cases of antimicrobial resistance among humans and in animals themselves, and we believe that we must use medically important antimicrobials judiciously."¹⁰

III. Consumers are responding to the threat of antibiotic resistance

A. Strong demand is driving improvement in industry practices

Increasingly, there are meaningful alternatives to the overuse of antibiotics in livestock production, particularly in the chicken industry. Over the last several years, consumers have exerted considerable pressure on the chicken industry to provide chicken raised without antibiotics. In 2014, the *Wall Street Journal* reported that sales of "antibiotic-free" chicken in the U.S. rose 34 percent by value over the previous year, and that consumers had spent upwards of \$1 billion purchasing fresh, "antibiotic-free" chicken in 2013, not including restaurant and other commercial purchasing.¹¹

The chicken industry is responding to this demand—bringing no antibiotics administered chicken and chicken raised without routine use of antibiotics into the mainstream. Perdue Farms, the fourth-largest chicken producer in the U.S., announced that it is now raising 95 percent of its birds without antibiotics that are important to human medicine, with the remaining use limited to

⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2, at 31; WORLD HEALTH ORG., TACKLING ANTIBIOTIC RESISTANCE FROM A FOOD SAFETY PERSPECTIVE IN EUROPE 6 (2011), http://www.euro.who.int/__data/assets/pdf_file/0005/136454/e94889.pdf.

⁷ FOOD & DRUG ADMIN., CTR. FOR VETERINARY MED., 2013 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 49 (2015), <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf>.

⁸ See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-801 ANTIBIOTIC RESISTANCE: AGENCIES HAVE MADE LIMITED PROGRESS ADDRESSING ANTIBIOTIC USE IN ANIMALS 6-7 (2011), <http://www.gao.gov/new.items/d11801.pdf>.

⁹ *Id.* at 5-6.

¹⁰ *Hearing on Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. (2010) (statement of Dr. John Clifford, Deputy Administrator for Veterinary Services, Animal & Plant Health Inspection Service), <https://www.gpo.gov/fdsys/pkg/CHRG-111hrg77921/pdf/CHRG-111hrg77921.pdf>. Additionally, one of the "Guiding Principles" of the National Strategy for Combatting Antibiotic Resistant Bacteria is that "misuse and overuse of antibiotics in healthcare and food production continue to hasten the development of bacterial drug resistance, leading to loss of efficacy of existing antibiotics." NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 4 (2014), https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf.

¹¹ David Kesmodel, *Meat Companies Go Antibiotics-Free as More Consumers Demand It*, WALL STREET J. (Nov. 3, 2014), <http://www.wsj.com/articles/meat-companies-go-antibiotics-free-as-more-consumers-demand-it-1415071802>.

treating chickens that are sick.¹² And Tyson Foods, the country's largest chicken producer, announced in April of 2015 that it will phase out the use of all human antibiotics, except to treat sick flocks, by 2017.¹³ In addition to these large producers switching their entire operations, many other producers are making organic and no antibiotics administered chicken available as well.

Food-service companies are also taking note of the shift in consumer preferences and are helping drive change. In August, McDonalds completed its transition of its chicken supply, reporting that an impressive 100 percent of the chicken served at its roughly 14,000 U.S. restaurants is now raised without antibiotics important in human medicine.¹⁴ Subway has committed to serving chicken raised entirely without antibiotics (as well as other meats) and reports that roughly 67 percent of its chicken is now raised without antibiotics.¹⁵ Wendy's reports that 50 percent of its chicken is raised without antibiotics important in human medicine, and that its entire chicken supply will comply with its policy by the end of 2017.¹⁶ Chick-fil-A, which reports that it is the largest U.S. chicken chain by domestic sales volume, provided an update on progress toward its commitment to serve 100% no antibiotics administered chicken in all of its U.S. restaurants by 2019.¹⁷ As of earlier this year, Chick-fil-A had converted 23% of its chicken supply.¹⁸ These companies are among the largest in food service,¹⁹ but many others, including Panera and Chipotle,²⁰ are exercising leadership as well.

B. School districts are leading the charge for certified responsible antibiotic use chicken

Importantly, numerous school districts are purchasing or seeking to purchase “no antibiotics ever” chicken or certified responsible antibiotic use chicken. In fact, six of the largest districts in the country, which together make up the Urban School Food Alliance (“the Alliance”),

¹² Gary Thornton, *Top US Broiler Companies: 2013 profiles*, WATT POULTRY USA (Mar. 2013), <http://www.wattpoultryusa-digital.com/201303#&pageSet=0&contentItem=0>; Press Release, Perdue Farms, Perdue Foods Reaches Milestone in Reducing Antibiotic Use, Sets Standard for Responsible Use (Sep. 3, 2014), http://www.perdufarm.com/News_Room/Press_Releases/details.asp?id=1104&title=Perdue%20Foods%20reaches%20milestone%20in%20reducing%20antibiotic%20use,%20sets%20standard%20for%20responsible%20use.

¹³ Press Release, Tyson Foods, Tyson Foods Strives to Eliminate Human Antibiotics from Broiler Chicken Flocks by 2017 (Apr. 28, 2015), <http://ir.tyson.com/investor-relations/news-releases/news-releases-details/2015/Tyson-Foods-Strives-to-Eliminate-Human-Antibiotics-From-Broiler-Chicken-Flocks-by-2017/default.aspx>; see also Tyson Foods, *Antibiotic Use*, <http://www.tysonfoods.com/Media/Position-Statements/Antibiotic-Use.aspx>.

¹⁴ McDonald's, *McDonald's USA Announces Big Changes to its Food* (August 1 2016), <http://news.mcdonalds.com/US/news-stories/2016/McDonald-s-USA-Announces-BigChanges-to-its-Food>.

¹⁵ Subway, *SUBWAY Restaurant Elevates Current Antibiotic-Free Policy* (Oct. 20, 2015), <http://www.subway.com/PressReleases/AntibioticFreeRelease10.20.15.pdf>

¹⁶ Lisa Baertlein, *Exclusive: Wendy's to ban chickens with human antibiotics by 2017*, Reuters (August 4, 2016), <http://www.reuters.com/article/us-wendy-antibiotics-idUSKCN10F2MT>.

¹⁷ Maria Godoy, *Americans Want Antibiotic-Free Chicken, And The Industry Is Listening*, Nat'l Pub. Radio (Feb. 19, 2014), <http://www.npr.org/blogs/thesalt/2014/02/14/276976353/americans-wantantibiotic-free-chicken-and-the-industry-is-listening>.

¹⁸ Chick-fil-A, *Chickens Raised With No Antibiotics Ever*, <http://www.chick-fil-a.com/Antibiotic-Free>.

¹⁹ QSR, *The QSR 50*, (Aug. 2014), <http://www.qsrmagazine.com/reports/qs50-2014-top-50-chart>.

²⁰ Panera Bread, *Positive Impact: Animal Welfare Infographic*, (Nov. 2015), <https://www.panerabread.com/en-us/company/animal-welfare-infographic.html>; Chipotle, *Food with Integrity*, <http://chipotle.com/food-with-integrity#saying-no-to-drugs> (last visited Oct. 13, 2016).

committed in late 2014 to purchasing only chicken produced with certified responsible antibiotic use—seeking ultimately to buy no antibiotics administered chicken.²¹ The districts in the Alliance—New York, Los Angeles, Chicago, Dallas, Miami, and Orlando—serve nearly 3 million children each day. In making its chicken-standard announcement, the Alliance stated that “providing the best possible, highest-quality food for students shouldn’t be a privilege, it should be a standard.”²² And it emphasized the importance of chicken in school meals, saying, “The Alliance’s landmark action today focuses on chicken because it is one of the most popular items served at cafeterias across the country.”²³ Eric Goldstein, Alliance Chairman and Chief Executive Officer of School Support Services for the New York City Department of Education, also said, “This move by the Alliance shows that school food directors across the country truly care about the health and wellness of students.”²⁴ As the Alliance stated, this interest is not limited to these large districts, as many other districts without the market power to make such demands are likely interested as well.

Additionally, in November 2014, School Food Focus created and circulated its Certified Responsible Antibiotic Use (CRAU) standard and announced in May 2015 completion of the first CRAU audit. The standard was developed with the input of more than “15 school districts that serve 2.3 million children nationwide.”²⁵ School Food Focus explained that “the new standard was created in response to a demand for more sustainably produced school food.”²⁶ The standard was updated in September 2016, and this petition references this latest version of the standard.

C. With USDA’s help, more school districts could meet demand for certified responsible antibiotic use chicken

Given the broad consumer and parental interest in certified responsible antibiotic use chicken, many more districts would likely purchase this type of chicken if it were available through the USDA Foods program. While the large districts discussed above have made progress on this issue, there are more than 14,000 school districts across the country that have much more limited purchasing power.²⁷ Notably, many school districts purchase much of their protein from USDA Foods. Poultry products are the most popular protein choice; in 2013, schools and State Distributing Agencies spent 22% of their USDA Foods funds on poultry.²⁸ Many schools find that using their USDA Foods entitlement for their chicken and other protein needs makes

²¹ Press Release, Natural Res. Def. Council, Nation’s Largest School Districts to Procure Antibiotic-Free Chicken (Dec. 9, 2014), <http://www.nrdc.org/media/2014/141209b.asp>.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Press Release, Pew Charitable Trusts, Pew, School Food FOCUS Announce Antibiotic Standard for Poultry (May 7, 2015), <http://www.pewtrusts.org/en/about/news-room/press-releases/2015/05/07/pew-school-food-focus-announce-antibiotic-standard-for-poultry>.

²⁶ *Id.*

²⁷ U.S. Census Bureau, *School Districts*, <https://www.census.gov/did/www/schooldistricts/> (last visited Oct. 13, 2016).

²⁸ LAURA CASTRO, USDA, FOOD & NUTRITION SERV., USDA FOODS: STATE OF AFFAIRS 3 (2014), <http://www.commodityfoods.org/assets/2014ACDAPowerPointPresentations/usda%20foods-state%20of%20affairs.pdf>.

financial sense for them—and allows them to stretch their limited funding further and improve the quality of meals they serve.²⁹ As USDA itself says, one important aspect of the program is “the federal government’s large volume purchasing power, allowing the procurement of food at a lower unit cost than if a school were purchasing it on its own.”³⁰ USDA should continue to respond to parent and school interest in new products and offer certified responsible antibiotic use chicken.

IV. The National School Lunch Program can and should offer certified responsible antibiotic use chicken

A. The National School Lunch Program helps schools nationwide to nourish kids with a variety of healthy foods

The National School Lunch Program is a federally assisted meal program serving more than 31 million children each day in over 100,000 schools and child-care institutions nationwide.³¹ As part of the School Lunch Program, schools receive cash reimbursements for all meals served, and are entitled to receive USDA Foods, which is an allotment of agricultural commodities purchased by USDA. For FY 2015-2016, the USDA Foods allocation had a value of 23.75 cents for each meal served.³² In other words, for each meal served, schools may choose 23.75 cents worth of food from a list of 180 foods offered by the USDA—from potatoes to peaches to poultry.³³

Importantly, USDA Foods is a major source of food for kids nationwide. USDA Foods dispenses about \$1 billion worth of agricultural commodities each year that make up 15 to 20% of the food on school lunch plates.³⁴ According to the Let’s Move program, many children consume most of their daily calories at school, and food served at school may be the only food many children eat regularly.³⁵

USDA’s procurement process for the National School Lunch Program allows the agency to respond to school demand by adding new products. The agency maintains the USDA Foods List, which informs schools and State Distributing Agencies of the commodities that they may obtain through the USDA.³⁶ For each product on the list, a detailed description or specification sets out

²⁹ FOOD & NUTRITION SERV., WHITE PAPER: USDA FOODS IN THE NATIONAL SCHOOL LUNCH PROGRAM 3 (2010), <http://www.fns.usda.gov/sites/default/files/WhitePaper.pdf>.

³⁰ *Id.*

³¹ USDA, Food & Nutrition Serv., NATIONAL SCHOOL LUNCH PROGRAM FACT SHEET 1 (2013), <http://www.fns.usda.gov/sites/default/files/NSLPFactSheet.pdf>.

³² USDA, Food & Nutrition Serv., *Food Distribution: Value of Donated Foods*, (Aug. 16, 2016), <http://www.fns.usda.gov/fdd/value-donated-foods-notices>. 79 Fed. Reg. 41532, 41532 (July 16, 2014).

³³ USDA Food & Nutrition Serv., *USDA Foods Available List for School Year 2016 for Schools and Institutions*, (July 5, 2016), http://www.fns.usda.gov/sites/default/files/fdd/USDA_Foods_Available_List.pdf.

³⁴ USDA FOODS: HEALTHY CHOICES FOR OUR SCHOOLS (2011), http://www.fns.usda.gov/sites/default/files/8_USDAFHCFUS.pdf; USDA Foods, *USDA Foods Processing: Frequently Asked Questions*, <http://www.fns.usda.gov/fdd/usda-foods-processing-frequently-asked-questions> (last visited June 13, 2016).

³⁵ Let’s Move, *Child Nutrition Programs*, (Aug. 29, 2016), <http://www.letsmove.gov/child-nutrition-programs>.

³⁶ See USDA FOODS, *supra* note 34.

requirements for the product’s weight, packaging, labeling, and other criteria.³⁷ Specifications play the dual role of allowing schools and State Distributing Agencies to choose the best products for their needs and providing contractors with precise guidelines for filling orders. To add new products to the USDA Foods List, as Petitioners request, USDA engages in the routine process of creating new specifications.³⁸

Over the years, USDA has created many new specifications and has regularly expanded the USDA Foods List to improve the variety of foods offered under the USDA Foods program. In 1981, USDA offered only 47 different products to schools; today it offers over 180 products.³⁹ The agency has also worked to improve the quality of the food offered by including lower-fat meat products, lower-sodium products, and more whole-grain items. As the agency puts it, “USDA is continually responding to the dynamic needs of the National School Lunch Program by making more fresh fruits and vegetables available to schools, substantially improving the quality and nutritional profile of products provided, and better accommodating schools’ needs through such innovations as promoting the processing of USDA Foods into more usable end products for the school lunch line.”⁴⁰

As USDA continues to work to diversify and improve the offerings of USDA Foods, the agency should begin to offer certified responsible antibiotic use chicken. Doing so is feasible given the current procurement process for USDA Foods, is in keeping with USDA’s efforts to improve the program in recent years, would help address a serious public health threat, and would respond to parent and school interest.

B. USDA has legal authority to purchase certified responsible antibiotic use chicken for the National School Lunch Program

Granting this petition would involve a routine exercise of USDA’s authority. The Russell Act, which created the National School Lunch Program, and federal contracting law, which regulates USDA Foods procurement procedures, enable USDA to issue specifications that respond both to the threat of antibiotic resistance and to schools’ demand for new varieties of chicken.

1. The Russell Act allows USDA to purchase certified responsible antibiotic use chicken

The Russell Act created the National School Lunch Program “to safeguard the health and well-being of the Nation’s children and to encourage the domestic consumption of nutritious agricultural commodities and other food.”⁴¹ The Act grants USDA discretion to make purchasing decisions that fulfill the Program’s purpose: “The Secretary [of Agriculture] shall . . . to the maximum extent practicable, in purchasing and processing commodities for use in school nutrition programs . . . purchase the widest variety of healthful foods that reflect the most recent

³⁷ FOOD & NUTRITION SERV., *supra* note 29, at 10; *see* Food & Nutrition Serv., *Food Distribution: Specifications & US Grade Standards*, (May 20, 2016), <http://www.fns.usda.gov/fdd/specifications-us-grading-standards>.

³⁸ FOOD & NUTRITION SERV., *supra* note 29, at 10.

³⁹ *Id.* at 13.

⁴⁰ *Id.* at 15.

⁴¹ 42 U.S.C. § 1751.

Dietary Guidelines for Americans.”⁴² This provision identifies three factors that USDA should consider when purchasing food for the Program: (1) variety, (2) healthfulness, and (3) the Dietary Guidelines for Americans. USDA’s purchases should conform to these factors to the “maximum extent practicable.”

The flexible purchasing authority afforded by the Russell Act allows USDA to adapt to shifts in consumer preferences and advances in nutritional science. Over the past thirty years, USDA has nearly quadrupled the number of products it offers to schools through USDA Foods.⁴³ It has established the National School Lunch Program as a “customer driven, value-added commodity system designed to provide recipients more of what they want, when they want it.”⁴⁴ USDA puts schools at the center of its procurement decision making, purchasing commodities “based on the demand from schools to help meet the[ir] menu planning needs, student taste preferences, school nutrition goals, and local wellness initiatives.”⁴⁵

Because the Russell Act encourages USDA to purchase healthful, in-demand products, it authorizes USDA to issue specifications for certified responsible antibiotic use chicken. Schools want to offer this type of chicken to their students, attested to by the fact that six school districts serving 3 million students each day have committed to purchasing this chicken—and the numerous schools supporting this petition by letter. Moreover, certified responsible antibiotic use chicken is a healthful source of protein consistent with the Dietary Guidelines for Americans.⁴⁶ It is also practicable for USDA to issue the requested specifications because, as discussed above, many large vendors and others are already producing and serving such chicken. USDA has the authority to answer schools’ calls for increased variety by granting this petition and issuing specifications for certified responsible antibiotic use chicken.

2. Federal procurement law allows USDA to purchase certified responsible antibiotic use chicken

Although USDA selects commodities for the School Lunch Program according to the factors set out in the Russell Act, USDA purchases those commodities according to the process established by the Competition in Contracting Act of 1984.⁴⁷ The Competition in Contracting Act demands “full and open competition” in federal contracting, which means that, whenever possible,

⁴² *Id.* § 1758(a)(4)(C)(iii).

⁴³ See FOOD & NUTRITION SERV., *supra* note 29, at 13.

⁴⁴ *Id.* at 12.

⁴⁵ Press Release, USDA, USDA Announces Additional Choices for Beef Products in the Upcoming School Year (Mar. 15, 2012), <http://www.usda.gov/wps/portal/usda/usdahome?contentid=2012/03/0094.xml>.

⁴⁶ See USDA & U.S. DEP’T OF HEALTH & HUMAN SERVS., DIETARY GUIDELINES FOR AMERICANS, 2015-2020 Appendix 3 (2015) (identifying poultry as a source of protein in the USDA Food Pattern). To begin offering chicken raised with the judicious use of antibiotics, USDA only needs to find that these products are healthy options, not that they are healthier than the chicken products currently available to schools. For instance, USDA offers beef products made without lean, finely textured beef, even though USDA does not believe those products to be any healthier than beef products containing lean, finely textured beef. USDA Press Release, *supra* note 45. Instead, it offers both products and allows schools to choose according to their preferences. *Id.*

⁴⁷ See 41 U.S.C. § 3101(a). Procurement procedures must also follow the Federal Acquisition Regulation (FAR), 48 C.F.R. § 1.000 *et seq.*; 41 U.S.C. § 3101(a). The FAR contains a section with special requirements for USDA procurement called the Agriculture Acquisition Regulation System (AGAR). 48 C.F.R. Pt. 401.

agencies must allow all qualified contractors to bid for agency contracts.⁴⁸ Competitive contracting procedures promote fairness and efficiency, creating a level playing field for suppliers and avoiding waste of government resources.⁴⁹

The Competition in Contracting Act's "full and open competition" requirement does not bar agencies from purchasing the products best suited to meet their needs, nor does it prevent USDA from purchasing certified responsible antibiotic use chicken. The Act prohibits agencies from imposing *unnecessary* restrictions on their product solicitations.⁵⁰ An agency cannot, for instance, solicit bids for a particular brand of product, when other brands with the same features could meet its needs.⁵¹ The Act, however, leaves agencies free to set any restrictions that are necessary to fulfill their contracting needs.⁵²

The Competition in Contracting Act allows agencies to look beyond price when deciding which products to purchase.⁵³ Agencies have wide latitude to identify their contracting needs and to decide which restrictions are necessary in order to meet them.⁵⁴ Courts will not second-guess those determinations.⁵⁵ An agency may, for example, structure its specifications to minimize risks to public health and safety from the performance of its contracts.⁵⁶

Agencies must also consider the environmental impacts of their purchases. Although agencies ultimately decide which products will best meet their needs, federal procurement regulations and Executive Order 13693 instruct agencies to purchase "environmentally preferable" products whenever possible.⁵⁷ On June 2, 2015, the President removed any doubt that agencies' procurement authority extends to limiting the use of antibiotics in livestock production, when he instructed all agencies to develop a procurement preference for vendors that offer meat and poultry raised with the "responsible use" of antibiotics and directed the General Services Administration (GSA) to begin offering "responsible-use" meat and poultry in the cafeterias it manages.⁵⁸

USDA specifications for chicken raised with the certified responsible antibiotic use would satisfy the Competition in Contracting Act's "full and open competition" requirement. When exercising its purchasing authority under the Russell Act, USDA's contracting needs include providing

⁴⁸ 41 U.S.C. §§ 107, 113, 3301.

⁴⁹ See *Corel Corp. v. United States*, 165 F. Supp. 2d 12, 18-19 (D.D.C. 2001).

⁵⁰ 41 U.S.C. § 3306(a)(2)(B).

⁵¹ See *Software Testing Sols., Inc. v. United States*, 58 Fed. Cl. 533, 539-40 (2003).

⁵² *Great Lakes Dredge & Dock Co. v. United States*, 60 Fed. Cl. 350, 362 (2004) ("[The] solicitation . . . may have been restrictive, but necessarily so. It was not an inadequacy in the solicitation, but rather the nature of the work to be performed, that resulted in the restrictive [solicitation].").

⁵³ 41 U.S.C. § 3306(c)(1).

⁵⁴ *Wit Assocs., Inc. v. United States*, 62 Fed. Cl. 657, 662 (2004).

⁵⁵ *Id.*

⁵⁶ See *XTRA Lease, Inc. v. United States*, 50 Fed. Cl. 612, 624-25 (2001) (upholding the Postal Service's determination that its minimum needs in a solicitation for mail-delivery trucks included promoting road safety by requiring trucks to have anti-lock braking systems).

⁵⁷ 48 C.F.R. § 23.703(a); *id.* § 423.703; Executive Order 13693, 80 Fed. Reg. 15871, 15875 (Mar. 25, 2015).

⁵⁸ PRESIDENT BARACK OBAMA, MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES: CREATING A PREFERENCE FOR MEAT AND POULTRY PRODUCED ACCORDING TO RESPONSIBLE ANTIBIOTIC-USE POLICIES 1 (JUNE 2, 2015) [hereinafter President's Procurement Memo].

schools with a variety of healthy foods. Consequently, the specification requested by Petitioners would not contain any unnecessary restrictions – the only way to meet schools’ demand for certified responsible antibiotic use chicken is to start offering such chicken. As detailed above, multiple vendors can now provide such chicken. Federal procurement law also calls upon USDA to incorporate pressing public health and environmental challenges into its procurement decision making.⁵⁹ Just as the GSA can offer “responsible-use” chicken in its cafeterias,⁶⁰ so, too, can USDA consider antibiotic resistance when buying chicken for the National School Lunch Program. In sum, USDA can issue new specifications for certified responsible antibiotic use chicken to better serve schools and to help protect public health.

C. Offering certified responsible antibiotic use chicken will address a public-health threat and continue USDA’s long tradition of increasing variety in response to demand from schools

The President and federal agencies have repeatedly recognized the threats posed by antibiotic-resistant bacteria and have made some efforts to address those threats. The National Strategy for Combating Antibiotic-Resistant Bacteria commits the United States Government to “[i]dentify[ing] and implement[ing] measures to foster stewardship of antibiotics in animals.”⁶¹ Adjusting federal procurement practices is one way to make progress towards that goal. As discussed above, the President recently directed the GSA to start offering meat and poultry produced with the “responsible use” of antibiotics in its cafeterias.⁶² By 2020, all cafeterias operated by the federal agencies serving civilian employees and visitors must implement a preference for “responsible-use” meat and poultry.⁶³ In issuing this directive, the President declared, “It is the policy of the Federal Government to encourage responsible uses of medically important antibiotics in the meat and poultry supply chain by supporting the emerging market for meat that has been produced according to responsible antibiotic-use policies.”⁶⁴

In Fiscal Year 2015, USDA spent over \$312 million to purchase over 354 million pounds of chicken.⁶⁵ Consequently, the National School Lunch Program presents an opportunity for USDA “to encourage responsible uses of medically important antibiotics in the meat and poultry supply chain by supporting the emerging market for meat that has been produced according to responsible antibiotic-use policies.”⁶⁶ Creating specifications for certified responsible antibiotic use chicken will update USDA’s procurement practices to reflect the agency’s commitment to safeguarding the agricultural economy and the public health of our nation.

The action requested by this petition also advances the goals of the National School Lunch Program and the USDA Foods program. It will build on USDA’s record of improving the variety and quality of foods that it offers—improvements motivated by schools’ preferences and nutritional science. School districts across the country have made their voices heard: they want

⁵⁹ See 48 C.F.R. § 23.703(a); *id.* § 423.703; 80 Fed. Reg. at 15871, 15875.

⁶⁰ President’s Procurement Memo, *supra* note 58, at 1.

⁶¹ NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC RESISTANT BACTERIA, *supra* note 10, at 9.

⁶² President’s Procurement Memo, *supra* note 58, at 1-2.

⁶³ *Id.* at 3-4.

⁶⁴ *Id.* at 1.

⁶⁵ USDA, AGRIC. MKTG. SERV., ANNUAL PURCHASE SUMMARY (2015).

⁶⁶ President’s Procurement Memo, *supra* note 58, at 1.

access to certified responsible use chicken. USDA can and should facilitate that access. Doing so will not impose any burdens on industry or the agency. It will simply connect willing buyers with willing sellers in transactions that benefit not only schools and producers, but also the general public.

V. Conclusion

For the foregoing reasons, Petitioners request that USDA adopt specifications for certified responsible antibiotic use chicken, add these chicken products to the USDA Foods List, and thereby make certified responsible antibiotic use chicken more available to schools through the National School Lunch Program.

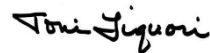
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SEPTEMBER 29, 2016

School Food Focus Certified Responsible Antibiotic Use Standard

No administration of antibiotics pre-hatch.

Antibiotics with analogues in human medicine are not allowed for:

- Disease prevention;
- Growth promotion;
- Feed efficiency; or
- Weight gain.



Antibiotics with analogues in human medicine can only be used therapeutically to:

- Treat disease in poultry diagnosed with bacterial disease; and
- Control disease in poultry exposed to infectious bacteria.



Background and Purpose

School Food Focus (Focus) developed the Certified Responsible Antibiotic Use Standard (CRAU) with support from The Pew Charitable Trusts to minimize the use of antibiotics in poultry production and offer school districts and other institutional purchasers a viable way to put poultry raised with responsible antibiotic use on the menu. Poultry producers in conformance with CRAU are prohibited from using antibiotics with analogues in human medicine in any regular pattern of use for any reason, including growth promotion, weight gain, feed efficiency and disease prevention. Use of antibiotics with analogues in human medicine must be rare, well documented with medical justification, and prescribed by a licensed veterinarian. Antibiotics that do not have analogues in human medicine have no further restrictions, as their use at this time is believed to present minimal risk to public health. Focus will change its CRAU standard if scientific evidence reveals a link.

CRAU builds on the following ‘judicious use’ principles of practice that were developed by FDA in cooperation with the American Veterinary Medical Association:

- Emphasis on sound preventive programs, including vaccination and testing;
- Documented need for antibiotics and demonstration that no viable alternative exists;
- Veterinarians consulted prior to use of antibiotics;
- Records kept of treatment and outcome;
- Treatment for grouped animals is done at barn/house level. Animals in adjacent housing should not be treated if not exposed;

- Environmental contamination is minimized
- See *“Judicious Use of Antimicrobials for Poultry Veterinarians”* by Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine

The Focus CRAU standard improves upon the above ‘judicious use’ principles with amendments to FDA guidelines that explicitly restrict and document antibiotic use on the farm:

1. Medically important antibiotics are used only if prescribed by a licensed veterinarian.
2. A written veterinary report to Focus is required whenever medically important antibiotics are used more than two consecutive growing cycles. This report must describe the underlying problem(s) and outline a plan of action to correct it if not already resolved. If the problem is not resolved, the site is no longer CRAU approved and will be removed from the Focus and USDA official listing of approved programs.
3. Growers maintain records of all feed and water additives for each growing cycle for the most current two years.
4. Regular 3rd party verification of antibiotic use documentation and on-site practices by the U.S. Department of Agriculture (USDA) is required.
5. No antibiotics allowed pre-hatch.
6. The classes of antibiotics with analogues in human medicine are specifically listed in the CRAU audit guidance documents.
7. Focus specifically defines its use of the terms “therapeutic and “non-therapeutic” in the CRAU standard.



Responsible Antibiotic Use

1. CRAU drug classes restricted to therapeutic use only include:
 - Aminoglycosides (Spectinomycin, Neomycin)
 - Lincosamides (Lincomycin)
 - Macrolides (Tylosin, Erythromycin, Tilmicosin, Oleandomycin)
 - Penicillin (Penicillin G procaine)
 - Streptogramins (Virginiamycin)
 - Sulfonamides (Sulfantran, Sulfadimethoxine, Sulfamethazine, Sulfaquinoxaline, Sulfathiazole)
 - Tetracyclines (Chlortetracycline, Oxytetracycline)
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2. In CRAU, “therapeutic use” refers to antibiotics with analogues to human drugs, i.e. veterinary antibiotics that are identical or very closely related to drugs used in human medicine. CRAU defines “therapeutic use” as follows:
 - The use of antibiotics with analogues to human drugs in poultry diagnosed with bacterial disease (treatment); or
 - The use of antibiotics with analogues to human drugs after poultry is exposed to infectious bacteria but before onset of clinical signs (control/metaphylaxis).
 - There must be a valid veterinarian-client-patient relationship (VCPR) as defined in 21 CFR 530.3(i). A valid VCPR is defined as one in which:
 - (a) A veterinarian is responsible for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the

owner of the animal or animals or other caretaker) is responsible for following the instructions of the veterinarian;

(b) The veterinarian is responsible for having sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(c) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

- If antibiotics are used therapeutically as defined above, records of diagnosis, treatment [antibiotic(s) prescribed, dosage, duration, estimated # of animals treated], and outcome must be retained for auditor review.

THERAPEUTIC VS. NON-THERAPEUTIC USE

These terms are widely used and can have different meanings in different contexts. The U.S. Food and Drug Administration (FDA) describes “therapeutic use” broadly, as the treatment, prevention, and control of disease. CRAU defines both terms more specifically and prohibits prevention uses of medically important antibiotics.



Responsible Antibiotic Use

3. If any antibiotics with analogues to human drugs are used for more than two consecutive growing cycles within the same poultry barn/house, a written veterinary statement must be submitted to Focus stating the underlying problem(s) that required the use of medically important antibiotics and a plan of corrective action to rectify the problem(s). If the underlying problem has been resolved, the veterinary statement may indicate that a successful solution has been found that does not include the use of antibiotics, and that no further plan of action is needed. In all cases, a written veterinary report of antibiotic use, including documentation of treatment and outcomes that includes culture and sensitivity reports, must be retained for auditor.
 - o Prevention is the use of antibiotics in the absence of bacterial disease or exposure to disease as documented by a veterinarian through testing or other means that a pathogenic organism is present in the flock or barn.
4. Non-therapeutic use of antibiotics with analogues in human medicine is disallowed. CRAU defines “non-therapeutic use” as the administration of medically important antibiotics for growth promotion, feed efficiency, weight gain, and disease prevention.
5. Use of drugs with no analogues in human medicine—aminocoumarins, glycolipids, ionophores, and oligosaccharides—is allowed. These permitted veterinary drugs have no relationship to human drugs and are not used in treating human disease. At this time they are the only drugs with no analogues in human medicine that are approved for use by the FDA and currently used by poultry producers.
6. A feed containing a Veterinary Feed Directive drug (a VFD feed) shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian’s professional practice and within the confines of a valid veterinarian-client-patient relationship.



Required Management Principles

- Emphasis on sound preventive programs, including vaccination and serologic monitoring for disease exposure;
- Treatment for grouped animals is done at barn/house level. Animals in adjacent housing will not be treated if not exposed; and
- Growers will maintain records of all feed and water additives for each growing cycle for the most current two years for auditor review.

Assurance of Conformance

CRAU requires USDA as the third-party certifier [e.g. USDA Process Verified Program (PVP) or Quality System Assessment (QSA)] to audit the producer/complex* to ensure compliance with the above restrictions and requirements and to submit audit reports to Focus.

* The relevant processes/facilities subject to audit include hatcheries, feed mills, grow out farms/barns, and slaughter/processing/packaging sites. The audit must document systems for proper identification and segregation of CRAU product through live delivery, slaughter, further processing and packaging.