



FOOD ANIMAL CONCERNS TRUST

3525 W. Peterson Ave.

STE. #213

Chicago, Illinois 60659

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Poisonous Pork: Carbadox Residue Violations in USDA Testing

By Madeleine Kleven and Steve Roach

Food Animal Concerns Trust

Since at least 2016, the most common residue violation detected during random sampling by the United States Department of Agriculture (USDA) in pigsⁱ is the known carcinogen, carbadox. The International Standard setting body for food safety, Codex Alimentariusⁱⁱ, has determined “there is no safe level of residues of carbadox or its metabolites in food that represents an acceptable risk to consumers.”ⁱⁱⁱ Most countries, agreeing with this, have banned the use of carbadox altogether. However, the U.S. has instead chosen to define “no residue” as no residue above a certain level and they have allowed the continued use of the drug. The result is, year after year, USDA finds carbadox in violative levels in about 1% of the roaster pigs it tests. One percent sounds small, but with about 650,000 roaster pigs slaughtered each year that’s over 6,500 pigs or 390,000^{iv} generous servings of carcinogenic pork each year. **Remember, there is no safe level for this drug.** Since USDA only tests a few hundred roaster pigs a year, most of this carcinogenic pork slips through the safety net and is eaten by children and adults across the country. And it only gets worse - The United States Food and Drug Administration (FDA) is seeking to withdraw the method to test for safety because it is not sensitive enough to detect all of the carcinogenic residues present in the pork tissue^v and thus not able to show there is “no residue” under the FDA’s own criteria. So, those 390,000 toxic servings are an underestimate, based on a flawed method. Nobody knows how many people are actually exposed to carcinogenic residues from this deadly animal feed additive. However, based on the limited data we do have from USDA, we know the FDA, USDA, the pork industry, and the drug maker knowingly allow pork with unacceptable carcinogenic residue levels to be sold year after year. It’s time for the FDA to place the public’s health over the interests of the animal drug industry and get this dangerous drug off the market.

What is carbadox?

Carbadox is a known mutagenic and genotoxic carcinogenic pig drug primarily used^{vi} to control diarrhea in pigs raised in crowded confinement operations where space is limited.^{vii} Pig producers also use carbadox to make pigs grow faster. The drug perpetuates poor living standards for pigs, fosters the development of antibiotic resistance^{viii}, is a hazard to food workers^{ix} and its use results in carcinogenic residues in pork products. These concerning residues increase the risk of cancer in children and adults

who consume pork that was given carbadox. The dangers and risks associated with its use cannot be understated. Its continued use on factory farms presents an unacceptable public health risk.

Why hasn't the drug been banned?

The FDA knows how dangerous this drug is and has been working, albeit slowly, since 2016 to get it removed from the market.^x However, the FDA has been met with strong resistance from the drug maker and from the pork industry.^{xi} After the FDA's action in 2016, Phibro Animal Health, the company that makes carbadox (brand name: Mecadox) launched a legal challenge to the FDA's proposed withdrawal. The withdrawal did not move forward, and instead the FDA tried a new approach for removing the drug in 2020 - a proposed revocation of the method for detecting residues of carbadox. As the FDA explained in 2016, and reiterated in its 2020 order, the current approved method for detecting residues of carcinogenic concern from the use of carbadox is inadequate.^{xii} Effectively this means that the method for determining whether or not consumers are being exposed to carcinogenic residues does not work. It is not sensitive enough to tell whether or not consumers are ingesting amounts of cancer-causing chemicals that will cause long-term health effects.

Carbadox is the one remaining animal feed additive still approved under a government provision which allows carcinogenic drugs to be given to animals under the strict condition that they do not result in carcinogenic residues in edible tissues of the animal.^{xiii} Despite this, as these data show, carbadox use in pigs routinely results in carcinogenic residues in the edible tissues of pigs.

What is the current method for detecting carcinogenic residues?

The USDA and the FDA work together to monitor for residues of veterinary drugs in animal products. The Food and Drug Administration sets a maximum residue level, approves a detection method for approved animal drugs, and determines a length of time between administration of the drug and slaughter when the FDA no longer expects the residues to be at an unsafe level in any edible tissues. The USDA then uses that approved method to test tissues of slaughtered animals for the residues to monitor whether the food animal producers are waiting long enough between use and slaughter.

Each year, the USDA tests a specific number of animals for a set of veterinary drugs and carbadox is one of the drugs USDA routinely tests for in roaster pigs. The FDA-approved method for carbadox used by the USDA to determine if there are residues of carcinogenic concern in pork, measures a metabolite called QCA. As carbadox breaks down in the pig's liver it is converted to QCA along with other residues.^{xiv} QCA was chosen because it is not a carcinogen and FDA believed that when QCA reached a low enough level (30 parts per billion or 30 ppb) there would no longer be enough of the other carcinogenic residues left in the tissues to create a human health risk. Conversely, if QCA is above 30 ppb, then that means there are additional residues present in the pork tissue which *are* carcinogenic and

thus it is not safe to consume - this represents a “violation”. (The FDA has defined “no residue” for carbadox as occurring when QCA is below 30 ppb.)

After the FDA had approved the method, and set a required length of time between use of the drug and slaughter, new studies in 2003^{xv} found that carcinogenic residues actually persisted in the pork tissue and were detectable in the meat longer than previously believed. More recent research ^{xvi} has shown that QCA does not persist as long in pigs as another residue of carbadox DCBX. DCBX, unlike QCA, *is* a known carcinogen. This suggests that the presence of QCA in pork tissue likely indicates the presence of the carcinogenic metabolite DCBX as well. In 2009, Canadian researchers found they could detect DCBX in pig tissues where *no* QCA was detectable, thus concluding QCA is not a suitable marker residue for carbadox and its presence in pork tissue almost certainly means carcinogenic residues are still present.^{xvii} Remember, the current approved method says QCA levels need to be below 30 ppb. However, we now know levels below 30 ppb may still have unsafe residues present in pork. It also means that **when QCA is above 30 ppb there almost certainly will be dangerous residues.**

Despite its flaws, the approved QCA method still finds unacceptable levels of carcinogens

Year	Tolerance Level Value	Concentration (Violative Level Detected)	# of Violations	# of Samples Collected	Percentage of Samples in Violation	Pig Population*	Estimated number of pigs in violation
2016	30 PPB	78.035, 131.001, 31.406, 68.511 PPB	4	215	1.86%	695,524	12,939.98
2017	30 PPB	NA	3	213	1.41%	602,539	8,486.46
2018	30 PPB	97.66, 68.16, 275.16, 65.26 PPB	4	310	1.29%	708,131	9,137.17
2019	0.03 PPM	207.22, 375.8, 40.8 PPM ^{xviii}	3	396	0.76%	668,402	5,063.65
2020	0.03 PPM	130 PPM	1	312	0.32%	668,649	2,143.11
2021	30 PPB	60 PPB	1	311	0.32%	668,649	2,150.00
2022	30 PPB	199, 52.5, 43.6, 71.8 PPB	4	268	1.49%	668,649	9,979.84
2023	30 PPB	64.7 PPB	1	280	0.36%	668,649	2,388.03
Average Per Year:					0.98%		6536.03

* Roaster swine slaughter data is only publicly available from FY 2016-2019.^{xix} For the years in which that data is unavailable the average of those 4 years was used to estimate the pig population (668,649).

Even with a residue detection method that lacks the sensitivity necessary to ensure human safety, there are consistent residue violations in the United States year after year, some quite a bit higher than the established safety limit.^{xx} Take the results from 2018 for instance, the lowest value detected was almost 10 times the tolerance value. (275.16 actual vs 30 threshold).

Pork samples have been taken primarily from roaster swine liver tissue in the past.^{xxi} Over the course of 7 years, from 2016 to 2023 between 200-400 samples have been collected per year. When considering the average violations per year and the number of pigs slaughtered, each year an average of 0.98% of samples are violative resulting in approximately 6,536 pigs each year that have residue levels which are unsafe to consume. Cancer-causing residues present in any form in pork tissue available to purchase is absolutely unacceptable and presents a significant human health risk and is in violation of the Food, Drug and Cosmetic Act.

As of June 1, 2023, there were 72.4 million hogs and pigs on U.S. farms.^{xxii} USDA only samples roaster pigs, rather than market hogs, thus it is impossible to say how many of those millions of pigs have unsafe residue levels. However, given the huge limitations on the current method for detecting residues of this carcinogen in our food supply - USDA's very limited sample size (only a couple hundred samples per year), limited sample type (only roaster swine) and limited sampling method (flawed, not sensitive enough method) - we are likely missing a **significant** portion of pork which is contaminated with carcinogenic residues.

Even with better testing and a more sensitive method, there would still be violations each year. And, there is no safe level of carbadox in food. The only way to ensure consumer safety is to get this drug off the market. It is high time the FDA ensures consumers and workers are not at an increased risk of cancer from this genotoxic carcinogen used in swine production. The FDA needs to expedite its process to ban the drug and take more swift and aggressive action to hold the drug maker responsible and protect public health. In the meantime, pork producers, fast food chains, food distributors and all parties involved with producing and selling pork don't need to wait for a ban. They can protect consumers now by implementing strict policies prohibiting the use of carbadox in their pork supply.

ⁱ On average it is the most commonly detected residue in pigs for USDA's planned domestic scheduled sampling. Inspector-generated sampling does not sample for carbadox.

ⁱⁱ Codex standards are provided by independent international risk assessment bodies or ad-hoc consultations organized by the Food and Agriculture Organization of the United Nations and the World Health Organization. <https://www.fao.org/fao-who-codexalimentarius/about-codex/en/#c453333>

ⁱⁱⁱ Food and Agriculture Organization of the United Nations, and World Health Organization. "Veterinary Drug Detail | CODEX ALIMENTARIUS International Food Standards." Veterinary Drug Details - Carbadox. Accessed August 18, 2023. https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/vetdrugs/veterinary-drug-detail/en/?d_id=9.

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- ^{iv} The average roaster pig is 60 pounds dressed (see FY2016-FY2020 sampling plans below) and it is recommended to prepare a pound per person. See footnote. Booren, Alden. “Planning a Roast Pig Barbecue.” MSU Extension, February 16, 2016. https://www.canr.msu.edu/resources/planning_a_roast_pig_barbecue_e1604.
- ^v Food and Drug Administration. “Notice: Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method.” Regulations.gov, July 19, 2020. <https://www.regulations.gov/document/FDA-2016-N-0832-0069>.
- ^{vi} United States Department of, Animal and Plant Health Inspection Service, and National Animal Health Monitoring System. “Antimicrobial Use and Stewardship on U.S. Swine Operations, 2017,” May 2019. https://www.aphis.usda.gov/animal_health/naahms/downloads/amu-swine-operations.pdf
- ^{vii} Phibro Animal Health Corporation. “Mecadox ®(Carbadox) Brochure,” n.d. https://www.phibropro.com/wp-content/uploads/2018/05/MX17006USA1217_Mecadox_8pg_Brochure_5.8.18.pdf.
- ^{viii} Stanton, Thaddeus B., Samuel B. Humphrey, Vijay K. Sharma, and Richard L. Zuerner. “Collateral Effects of Antibiotics: Carbadox and Metronidazole Induce VSH-1 and Facilitate Gene Transfer among *Brachyspira Hyodysenteriae* Strains.” *Applied and Environmental Microbiology* 74, no. 10 (May 2008): 2950–56. <https://doi.org/10.1128/AEM.00189-08>. ;
- Bearson, Bradley L., Heather K. Allen, Brian W. Brunelle, In Soo Lee, Sherwood R. Casjens, and Thaddeus B. Stanton. “The Agricultural Antibiotic Carbadox Induces Phage-Mediated Gene Transfer in *Salmonella*.” *Frontiers in Microbiology* 5 (2014): 52. <https://doi.org/10.3389/fmicb.2014.00052>. ;
- Price, Lance B. “Bacterial Whack-a-Mole: Reconsidering the Public Health Relevance of Using Carbadox in Food Animals.” *MBio* 8, no. 5 (September 26, 2017): e01490-17. <https://doi.org/10.1128/mBio.01490-17>. ;
- Johnson, Timothy A., Torey Looft, Andrew J. Severin, Darrell O. Bayles, Daniel J. Nasko, K. Eric Wommack, Adina Howe, and Heather K. Allen. “The In-Feed Antibiotic Carbadox Induces Phage Gene Transcription in the Swine Gut Microbiome.” *MBio* 8, no. 4 (August 8, 2017): e00709-17. <https://doi.org/10.1128/mBio.00709-17>.
- ^{ix} Santa Cruz Biotechnology, Inc. “Material Safety Data Sheet: Carbadox,” July 21, 2008. ;
- Commission Regulation (EC) No 2788/98 of 22 December 1998 amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards the withdrawal of authorisation for certain growth promoters, 347 OJ L § (1998). <http://data.europa.eu/eli/reg/1998/2788/oj/eng>. ;
- Baars, A.J. “Carbadox - An Evaluation.” Ministry of Agriculture, Nature Management & Fisheries. Department of Agriculture., April 1997.
- ^x U.S. Food & Drug Administration |Center for Veterinary Medicine. “FDA Takes Steps to Withdraw Approval of the Swine Drug Carbadox Due to Safety Concerns.” FDA News Release. FDA, April 8, 2016. <https://www.fda.gov/news-events/press-announcements/fda-takes-steps-withdraw-approval-swine-drug-carbadox-due-safety-concerns>.
- ^{xi} Federal Register. “Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing: A Notice by the Food and Drug Administration.” Federal Register, April 12, 2016. <https://www.federalregister.gov/documents/2016/04/12/2016-08327/phibro-animal-health-corp-carbadox-in-medicated-swine-feed-opportunity-for-hearing>.
- ^{xii} Federal Register Online via the Government Publishing Office. “Federal Register, Volume 85 Issue 139 Pages 43853-43858.” www.gpo.gov, July 20, 2020. <https://www.govinfo.gov/content/pkg/FR-2020-07-20/html/2020-15246.htm>.
- ^{xiii} Delaney Clause (section 512(d)(1)(I) (21 U.S.C. 360b(d)(1)(I)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), FDA generally cannot approve a new animal drug application (NADA) if the drug that is the subject of that application induces cancer in humans or animals. An exception to this general rule is the Diethylstilbestrol “DES” Proviso, which allows for the approval of a carcinogenic new animal drug where FDA finds that under the approved conditions of use: (1) The drug will not adversely affect the animals treated with the drug and (2) no residues of the drug will be found by an approved regulatory method in any edible tissues of, or in any foods yielded by, the animal (section 512(d)(1)(I) of the FD&C Act).
- ^{xiv} United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “Screen of Carbadox Metabolite QCA by HPLC-MS-MS,” March 31, 2016. https://www.fsis.usda.gov/sites/default/files/media_file/2020-09/CLG-CBX4.pdf.

^{xv} 60th JECFA Report, FAO Food and Nutrition Paper 41/15, 2003. p. 1.

<https://www.fao.org/3/y4858E/y4858E00.pdf>

^{xvi} Zhang, Jie, Wei Qu, Zongchao Wang, and Yuanhu Pan. “Metabolism and Tissue Depletion of Carbadox in Swine, Broilers, and Rats.” *ACS Agricultural Science & Technology* 2, no. 3 (June 20, 2022): 477–85.

<https://doi.org/10.1021/acsagscitech.1c00260>.

^{xvii} Boison, Joe O., Stephen C. Lee, and Ron G. Gedir. “A Determinative and Confirmatory Method for Residues of the Metabolites of Carbadox and Olaquinox in Porcine Tissues.” *Analytica Chimica Acta* 637, no. 1–2 (April 1, 2009): 128–34. <https://doi.org/10.1016/j.aca.2008.09.016>.

^{xviii} While the sampling data for 2019 and 2020 uses PPM as the unit of measurement, this would make the sampled values significantly higher than the surrounding years. We suspect there may have been an error in reporting and values should be in PPB rather than PPM. We have not confirmed this with USDA.

^{xix} We are unable to access the data for the other years because it is located within USDA’s Public Health Information System (PHIS). PHIS is a web-based application that can only be accessed by USDA or industry employees. It cannot be accessed by the public. Below are the available slaughter data sources:

United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “2017 Residue Sampling Plans October 1, 2016 to September 30, 2017.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products, n.d.

https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/2017-Blue-Book.pdf ;

United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “2018 Residue Sampling Plans October 1, 2017 to September 30, 2018.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products, n.d.

https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/2018-Blue-book.pdf ;

United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “2019 Residue Sampling Plans October 1, 2018 to September 30, 2019.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products, September 17, 2018.

https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/2019-blue-book.pdf ;

United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “FY 2020 NRP: Estimated Amount of Domestically Produced Meat, Poultry, and Egg Products.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products.

https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/2020-nrp_appendix_III.pdf

^{xx} **FY 2016:** United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “FY 2016 Residue Sample Results.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products, May, 2017. https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/Residue-Sampling-Results-Fiscal_Year_2016_Red_Book.pdf ;

FY 2017: United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “FY 2017 Residue Sample Results.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products, December 31, 2017. https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/2017-Red-Book.pdf ;

FY 2018: United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “FY 2018 Residue Sample Results.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products, December 31, 2018. https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/2018-red-book.pdf ;

FY 2019: United States Department of Agriculture, Food Safety and Inspection Service, and Office of Public Health Science. “FY 2019 Residue Sample Results.” UNITED STATES National Residue Program for Meat, Poultry, and Egg Products. https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/fy2019-red-book.pdf

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FY 2020: United States Department of Agriculture, Food Safety and Inspection Service. “USDA Food Safety and Inspection Service Annual Sampling Summary Report Fiscal Year 2020.”

https://www.fsis.usda.gov/sites/default/files/media_file/2021-05/FY_2020_Sampling_Summary_Report.pdf ;

FY 2021: United States Department of Agriculture, Food Safety and Inspection Service. “USDA Food Safety and Inspection Service Annual Sampling Summary Report Fiscal Year 2021.”

https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/FY2021-Sampling-Summary-Report.pdf;

FY 2022: United States Department of Agriculture, Food Safety and Inspection Service. “USDA Food Safety and Inspection Service Annual Sampling Summary Report Fiscal Year 2022.”

https://www.fsis.usda.gov/sites/default/files/media_file/documents/FY2022-Sampling-Summary-Report.pdf ;

FY 2023: United States Department of Agriculture, Food Safety and Inspection Service. “National Residue Program Quarterly Report (October-December 2022).”

https://www.fsis.usda.gov/sites/default/files/media_file/documents/Dataset_QSR_Residue_Tolerances_Summary_Report_FY23Q1.pdf ;

United States Department of Agriculture, Food Safety and Inspection Service. “National Residue Program Quarterly Report (January-March 2023).”

https://www.fsis.usda.gov/sites/default/files/media_file/documents/Dataset_QSR_Residue_Tolerances_Summary_Report_FY23Q2.pdf ;

United States Department of Agriculture, Food Safety and Inspection Service. “National Residue Program Quarterly Report (April-June 2023).” https://www.fsis.usda.gov/sites/default/files/media_file/documents/FY23-Quarterly-Sampling-Summary-Report_Residue_Q3.pdf

^{xxi} Roaster swine are animals of both sexes and any age that are marketed with the carcass unsplit and with the head on.

^{xxiii} USDA National Agricultural Statistics Service. “United States Hog Inventory up Slightly.” [Nass.usda.gov](https://www.nass.usda.gov), June 29, 2023. <https://www.nass.usda.gov/Newsroom/2023/06-29-2023.php>.