The FDA Must Take Stronger Action on Antibiotics in Chinese Tilapia Imports

The Food and Drug Administration (FDA) prohibits the use of unapproved antibiotics – including nitrofurans and sulfadiazine, among others – in aquaculture over safety and health concerns.[1] The use of unapproved veterinary drugs in tilapia aquaculture, and the consumption of fish contaminated with these drug residues, contributes to the development of antimicrobial resistant pathogens, which the World Health Organization has designated one of the "top global public health and development threats" as it "makes infections harder to treat and makes other medical procedures and treatments – such as surgery, caesarean sections and cancer chemotherapy – much riskier."[2] In addition, nitrofurans are carcinogenic and genotoxic, and accordingly, consumption of food products containing this antibiotic present severe health risks.[3] Unfortunately, the FDA's actions to prevent contaminated Chinese tilapia from reaching American consumers has been insufficient and must be enhanced.

Tilapia is one of the most popular whitefish in the United States; Americans consume over 200 million pounds each year.[4] 83 percent of this is supplied by Chinese tilapia farmers.[5] However, as recognized by academics, non-profits,[6] and the FDA itself, antibiotic use is widespread in Chinese tilapia aquaculture. For example, according to a 2016 study of 25 tilapia farms in the Guangdong province, "the diseases streptococcosis, exophthalmia, enteritis, and liver enlargement were 'frequently' treated using sulfadiazine, trimethoprim, oxytetracycline, florfenicol, and amoxicillin."[7] Of these, only florfenicol is on the FDA's list of approved aquaculture drugs for tilapia, and only for treatment of streptococcal septicemia.[8] Similarly, a 2021 study of feed and sediments in twenty tilapia ponds in southern China found that all of the eighteen sealed-bag feed samples tested contained quinolones and two contained sulfonamides, while seven open-bag feed samples contained tetracyclines, four of which also contained florfenicol. These antibiotics were also present in pond surface sediments at high rates, demonstrating the widespread usage of these drugs in tilapia aquaculture.[9]

Under section 801 of the Food Drug & Cosmetic Act, the FDA has the duty to ensure the safety of imported seafood through foreign facility inspections and import controls. However, despite acknowledging the widespread use of unapproved antibiotics in Chinese aquaculture and the risk associated with Chinese farmed tilapia specifically, neither mechanism is being properly utilized to curb the import of antibiotic-laden tilapia.[10] According to the Government Accountability Office (GAO), the FDA fails to conduct safety inspections of foreign facilities at the level deemed necessary to ensure the safety of imported food. The FDA conducts only 917 foreign food safety inspections per year – just 19.5 percent of its target of 4,695.[11] Surprisingly, the FDA reported that "they do not use the target number in any way as part of FDA's planning process for conducting foreign inspections."[12] Indeed, it is clear that the FDA is not sufficiently inspecting Chinese tilapia farms, as none of the top ten Chinese exporters of frozen tilapia fillets to the U.S. – which account for over 50 percent of all 2023 tilapia imports – have undergone inspection in the past five years, while half of them have never been inspected.[13]

The FDA is also doing very little to ensure the safety of imported tilapia at the border, despite having significant authority to prevent the entry of contaminated seafood. The agency has determined that Chinese aquaculture of other seafood products such as shrimp, dace, and eel consistently contain antibiotic residues such that the agency placed a country-wide Import Alert on shipments of these products (with certain limited exceptions) since 2007.[14] All available public evidence indicates that tilapia aquaculture in China presents the same risks as those of shrimp, dace, and eel. However, the FDA does not maintain a country-wide Import Alert for Chinese tilapia, despite listing farmed tilapia as having high potential for "aquaculture drug hazards" in a 2022 report.[15]

Furthermore, the FDA's rate of sampling tilapia imports appears to have significantly declined in recent years. Between 2015 and 2019, the FDA refused 142 shipments of Chinese tilapia for containing unapproved veterinary drug residues.[16] However, from 2020 to 2024, that number dropped dramatically to just 30 refusals. In fiscal year 2015 – the year for which data is most recently available – the FDA inspected just 0.1 percent of seafood imports for drug residues, yet a remarkable 12 percent of the tilapia tested was positive for these residues.[17] There is no evidence that Chinese tilapia farmers have stopped using unapproved antibiotics.[18] Rather, it appears that the amount of the FDA's sampling of tilapia – the rates of which are not publicly reported – is severely deficient.

As a result of the lack of enforcement actions, Americans are consuming antibiotic-laden tilapia. Congress should provide more oversight and request the FDA to do more. Particularly, Congress can do the following:

- Engage with the FDA to determine the level of import testing on shipments of Chinese tilapia.
- Request that the FDA conduct a thorough sampling study to determine whether Chinese tilapia should be placed on Import Alert 16-131, limiting imports only to those producers that prove their shipments are antibiotic-free in accordance with U.S. food safety laws and regulations.
- Engage with the FDA to determine how the agency plans to implement recommendations by the GAO with respect to increasing foreign facility inspections to ensure the safety of America's food supply, particularly regarding seafood.

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[1] Department of Health and Human Services, "Fish and Fishery Products Hazards and Controls Guidance," (June 2022 Edition) at Chapter 11, p.5, available for download at https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls.

[2] World Health Organization, "Antimicrobial Resistance," (Nov. 21, 2023), https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance.

[3] U.S. Food & Drug Administration, Import Alert 16-129 (Apr. 24, 2024), https://www.accessdata.fda.gov/cms_ia/importalert_31.html#:~:text=Absolutely%2C%20no%20extra%2Dlabel%20use,any%20food%20animals%2C%20including%20seafood.

[4] To calculate the total amount of tilapia consumed in the U.S., we combined the total amount of imported tilapia for each year with domestic production. *See* Appendix at Table 1; *see also* Aquatic Network, "U.S. Tilapia Imports," https://www.aquanet.com/us-tilapia-imports#:~:text=The%20U.S.%20tilapia%20market%20is,75%25%20of%20the%20total%20production

[5] Since 2020, Chinese imports have accounted for 87 percent of total tilapia imports. *See* Appendix at Table 1. About 5 percent of tilapia is produced domestically. *See* Aquatic Network, "U.S. Tilapia Imports," https://www.aquanet.com/us-tilapia-imports#:~:text=The%20U.S.%20tilapia%20market%20is,75%25%20of%20the%20total%20production Tilapia production in China primarily relies on various aquaculture methods rather than wild-capture, including intensive monoculture, semi-intensive polyculture, intensive culture in brackish ponds, integrated fish/duck culture, cage culture, and integrated tilapia/rice culture. *See* Monterey Bay Aquarium Seafood Watch, "Tilapia" (Nov. 14, 2018) https://www.seafoodwatch.org/globalassets/sfw-data-blocks/reports/T/MBA_SeafoodWatch_TilapiaChinaReport.pdf.

[6] *See* Monterey Bay Aquarium Seafood Watch, "Tilapia – China," (Nov. 14, 2018), available for download at https://www.seafoodwatch.org/recommendation/tilapia/nile-tilapia-1988?species=228. Seafood Watch rated tilapia from China "Critical" for chemicals including antibiotics.

[7] Monterey Bay Aquarium Seafood Watch, "Tilapia – China," (Nov. 14, 2018) at 40, available for download at https://www.seafoodwatch.org/recommendation/tilapia/nile-tilapia-1988?species=228.

[8] FDA, "Approved Aquaculture Drugs," https://www.fda.gov/animal-veterinary/aquaculture/approved-aquaculture-drugs (last accessed Jan. 10, 2025).

[9] *Id*. *See* Appendix at Figure 1.

[10] *See* FDA Import Alert 16-131 (Detention Without Physical Examination of Aquacultured, Shrimp, Dace, and Eel from China and Hong Kong SAR - Presence of New Animal Drugs and/or Unsafe Food Additives), https://www.accessdata.fda.gov/cms_ia/importalert_33.html; Department of Health and Human Services, "Fish and Fishery Products Hazards and Controls Guidance," (June 2022 Edition) at Chapter 3, p.34, available for download at https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls.

[11] Notably, Congress had previously instructed the FDA to reach a target of 19,200 foreign facility inspections by 2016 through the Food Safety Modernization Act. *See* U.S. Government Accountability Office, "Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply," GAO-25-107571 (Jan. 8, 2025) at 13, https://www.gao.gov/assets/gao-25-107571.pdf.

[12] U.S. Government Accountability Office, "Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply," GAO-25-107571 (Jan. 8, 2025) at 13, https://www.gao.gov/assets/gao-25-107571.pdf.

[13] *See* Appendix at Table 1 and Table 2.

[14] *See* FDA Import Alert 16-131 (Detention Without Physical Examination of Aquacultured, Shrimp, Dace, and Eel from China and Hong Kong SAR - Presence of New Animal Drugs and/or Unsafe Food Additives), https://www.accessdata.fda.gov/cms_ia/importalert_33.html. This import alert has also previously included farmed catfish and basa from China.

[15] Department of Health and Human Services, "Fish and Fishery Products Hazards and Controls Guidance," (June 2022 Edition), available for download at https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls. The FDA does maintain import alerts on a product-producer basis for antibiotic residues. Certain Chinese tilapia producers are on these lists due to the presence of residues such as malachite green, sulfadiazine, enrofloxacin, ciprofloxacin, and nitrofurans. *See* FDA Import Alert 16-129 (Detention Without Physical Examination of Seafood Products Due To Nitrofurans), https://www.accessdata.fda.gov/cms_ia/importalert_31.html; FDA Import Alert 16-124 (Detention Without Physical Examination of Aquaculture Seafood Products Due To Unapproved Drugs), https://www.accessdata.fda.gov/cms_ia/importalert_27.html.

[16] *See* U.S. Food & Drug Administration, "Import Refusals," https://datadashboard.fda.gov/ora/cd/imprefusals.htm Antibiotic refusal reference codes include: 72, 2860, 2900, 3220, and 3885. *See also* Appendix at Figure 2.

[17] United States Government Accountability Office, Report to the Chairman, Committee on Appropriations, U.S. Senate, "FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues," GAO-17-443 at 19 (Sept. 2017), https://www.gao.gov/assets/gao-17-443.pdf.

[18] *See* Monterey Bay Aquarium Seafood Watch, "Tilapia – China," (Nov. 14, 2018) at 35, available for download at https://www.seafoodwatch.org/recommendation/tilapia/nile-tilapia-1988?species=228.

APPENDIX

Table 1: U.S. tilapia fillet imports for consumption by quantity (kg) (2022 – Nov. 2024)

Country	2020	2021	2022	2023	2024 (Jan – Nov)
China	103,778,103	95,296,563	92,471,510	82,115,737	72,030,627
Indonesia	6,270,381	6,258,386	7,208,037	6,375,129	7,328,882
Honduras	2,146,735	2,108,219	1,611,517	564,339	697,961
Taiwan	946,373	1,240,791	1,501,874	1,179,437	917,884
Mexico	1,880,899	983,064	269,682	308,925	61,832
Brazil	197,974	886,721	1,199,597	315,733	442,258
Malaysia	331,883	422,783	758,345	497,215	602,254
Peru	252,038	379,097	261,184	277,604	244,699
Colombia	98,504	243,097	484,518	325,470	172,948
Costa Rica	94,182	241,819	16,334	81,573	17,636
Vietnam	53,760	109,302	105,696	19,803	604,155
Thailand	78,516	219,848	116,977	-	-
Panama	30,998	33,059	42,399	29,316	21,442
Netherlands	-	10,231	60,434	-	-
Canada	-	16,599	18,114	11,617	-
Hong Kong	41,567	-	-	-	11,340
Ecuador	19,595	-	3,175	-	23,850
India	-	-	-	-	22,677
Burma	10,214	3,640	1,000	-	1,020
Mozambique	-	-	14,140	-	-
Ghana	2,934	5,504	2,645	-	-
France	8,585	-	-	-	-
Egypt	-	-	-	-	25,786
Nicaragua	4,759	-	-	-	-
Total	**116,248,000**	**108,458,723**	**106,147,178**	**92,101,898**	**83,227,251**

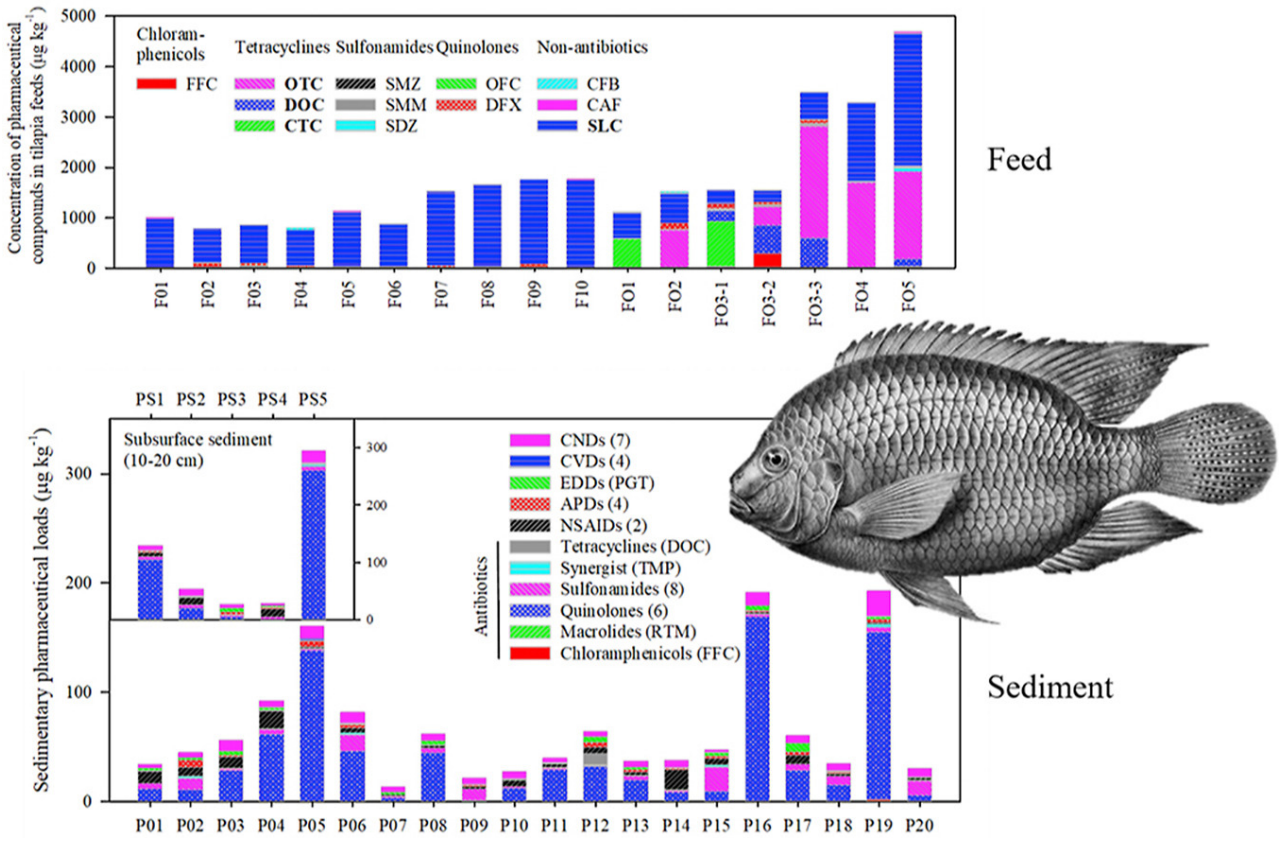
Source: USITC Dataweb, https://dataweb.usitc.gov/, HTS code 0304.61.

Table 2: Largest shippers of Chinese tilapia fillets to the U.S. (2023)

Company	Shipments	Weight (kg)	Inspected?
Hainan Xintaisheng Industry Co., Ltd	354	8,287,638	Y – 2019
Tongwei Hainan Aquatic Products., Ltd	325	8,040,233	Y - 2019
Hainan Sky Blue Ocean Foods Co. Ltd	359	8,025,068	N
Maoming Hongye Aquatic Products Co., Ltd.	306	6,966,073	N
Guangdong Universal Aquatic Food Co., Ltd.	234	5,737,990	Y - 2019
Guangxi Baijia Food Co., Ltd.	180	3,910,277	Y - 2019
Zhanjiang Shuanghu Food Co., Ltd.	171	4,179,680	Y - 2019
Hainan Jiadexin Foodstuff	169	3,823,239	N
Hainan Qinfu Foods Co., Ltd.	160	3,498,295	N
Hainan Troplake Foods Co., Ltd.	125	3,181,564	N

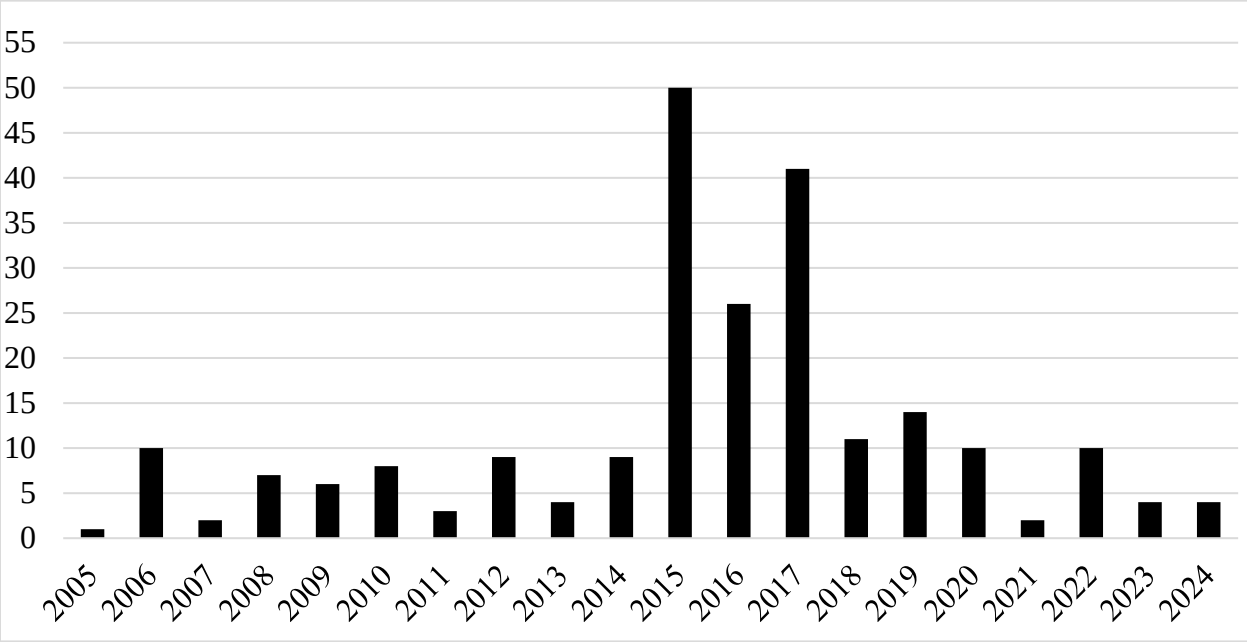
Source: Panjiva, https://panjiva.com, search term “Tilapia fillet,” from China;
https://datadashboard.fda.gov/ora/fd/fser.htm.

Figure 1: Contaminants in Chinese Tilapia Feed and Pond Sediment



Source: Min Zhou, Shen Yu, Bing Hong, Juan Li, Han Han, Guang Qie, Antibiotics control in aquaculture requires more than antibiotic-free feeds: A tilapia farming case, *Environmental Pollution*, Volume 268, Part B, 2021, 115854, https://doi.org/10.1016/j.envpol.2020.115854.

Figure 2: FDA refusals of Chinese tilapia shipments for antibiotic residues (2005 –2024)



Source: *See* U.S. Food & Drug Administration, "Import Refusals," https://datadashboard.fda.gov/ora/cd/imprefusals.htm Antibiotic refusal reference codes include: 72, 2860, 2900, 3220, and 3885.