

**San Francisco Department of the Environment Regulation SFE-18-01-AUIFA
Regulations Implementing the Antibiotic Use in Food Animals Ordinance
(Ordinance No. 204-17)**

Regulation Effective Date: Upon Director's Signature

A. Authorization.

The Antibiotic Use in Food Animals Ordinance (Ordinance) was signed by the Mayor on October 24, 2017 and became effective on November 23, 2017. The Ordinance requires certain retailers of raw meat and poultry to report on antibiotics used to produce such products to the Department of the Environment (Department), and requires City departments to report on antibiotics used to produce raw meat and poultry purchased by the City to the Department, as codified in Municipal Code: Environment Code, Chapter 27 (Chapter 27).

The Director of the Department (Director) promulgates these regulations pursuant to her authority to adopt rules necessary to implement this Ordinance pursuant to Chapter 27, Section 2707.

B. Scope.

The Antibiotic Use in Food Animals Ordinance requires that Grocers report to the Department, on a form prescribed by the Director, the Antibiotic Use Policy for each Product Group sold in the City of San Francisco (City) during the previous year. A Grocer, as defined in Chapter 27, Section 2702, means an entity that owns and/or operates a grocery store in the City and also owns or operates 25 or more grocery stores anywhere. Antibiotic Use Policy, as defined in Chapter 27, Section 2702, means a description of the antibiotic use practices of a Producer of each Product Group sold in a Grocer's stores. Violation of the Ordinance may result in administrative penalties, including fines, and/or suspension or revocation of any permits held.

These regulations specify the contents of the form required by Chapter 27, Section 2703(a), and provide guidance on petitioning for a waiver of any reporting requirement under Chapter 27, Section 2703(b). The final format for the reporting form will be available on the Department's website, www.sfenvironment.org/antibiotics-ordinance, and will incorporate the contents described in Appendix A below. To receive notification of important meetings and updates, email ABXordinance@sfgov.org to be added to the mailing list.

These regulations do not duplicate the Ordinance and must be read together with the Ordinance. They provide additional explanation of the terms.

C. Definitions:

"Antibiotic Use Reporting Form" or "Form" – the form for Grocers to report antibiotic use for each Product Group to the Department. The format of the form may change over time. The most current version of the Form is available on the Department's website, www.sfenvironment.org/antibiotics-ordinance.

"Retail Banner" – means the grocery store name, which may be different than the name of the Grocer.

"Substantial Evidence" – means evidence that a reasonable person would deem adequate to support a conclusion. Substantial evidence shall include facts, reasonable assumptions predicated upon facts, and expert opinion supported by facts.

"Third-Party Certification" – means certification by an organization that is not affiliated with the Grocer and that addresses antibiotic use by producers of a Product Group sold by the Grocer. The Director may, from time to time via regulations, add to this list of acceptable certifications. The following Third-Party Certifications are accepted by the Department: U.S. Department of Agriculture ("USDA") Organic, USDA No Antibiotics Administered Process Verified (or equivalent USDA "process verified" claim), Global Animal Partnership, Certified Responsible Antibiotic Use, Certified Humane, Animal Welfare Approved and American Grassfed (AGA-Certified Grassfed).

D. Interpretive Regulations and Guidelines

1.0 **Contents of the Form.** Each Grocer shall provide information to the Department on an annual basis regarding the use of antibiotics for each of its raw meat and poultry Product Groups, as required in Section 2703(a) of the Ordinance. Such information shall be provided on the Department's Form, the content of which is specified in Appendix A and is available on the Department's website. Refer to the website for the latest version of and instructions on submitting the Form. Note that the Form's format may change over time (e.g., from database to online survey software).

1.1 **Compliance.** Compliance with the Ordinance requires that a Grocer report antibiotic use policies and practices for all of its raw meat and poultry Product Groups on a Form prescribed by the Department. As required in Section 2703(a) of the Ordinance, a Grocer shall fill out a separate Form for each distinct Retail Banner operated and/or owned by the Grocer. Each Form shall be submitted to the Department according to the instructions for submission provided on the Department's website. A Grocer may seek a waiver for any element of the Form, pursuant to section 2.0, below.

1.1.1 **Reduced Reporting.** Where a Grocer had a storewide policy prohibiting medically important antibiotic use across some or all raw meat or poultry animal species during the reporting period, the Grocer's reporting requirements are reduced, as described in the instructions to the Form. The Grocer must provide documentation that evidences the policy and the process used to enforce the policy. The Department will review the Grocer's documentation within 60 days. If the Department determines that the Grocer's storewide policy or the documentation is insufficient, the Grocer will have 30 days from the date of the Department's determination or from the filing deadline, whichever is later, to provide additional evidence of the policy or to submit an updated Form covering all Product Groups of any animals not covered by a storewide policy prohibiting medically important antibiotic use.

1.2 **Reporting Period.** The reporting period for this Ordinance is the calendar year, from January through December, prior to the year in which the Form is due. For example, the reporting period for Forms due by May 3, 2019 is January 1, 2018 through December 31, 2018.

1.3 **Maintaining Documentation.** Where a Grocer had a storewide policy prohibiting medically important antibiotic use across some or all raw meat or poultry animal species, the Grocer must maintain, for five

(5) years from filing the Form, physical or digital documentation of their storewide antibiotic use policies and the process for enforcing this policy. This documentation shall be made available to the Department upon request.

- 1.4 **More Than One Producer for a Product Group.** Where a Product Group includes meat from more than one Producer, the Grocer shall report information for each of these Producers. For example, if three Producers supply pork chops for a Grocer's "Naturally Natural" Product Group, data from each of the three Producers shall be reported on the Form for "Naturally Natural". That is, if Producer A supplies 20%, Producer B supplies 45% and Producer C supplies 35% of the pork chops used for the "Naturally Natural" Product Group, these percentages shall be reported.
- 2.0 **Waiver.** A Grocer may request a waiver of specific elements of the Form by submitting a petition to the Department, in compliance with the instructions for submission provided on the Department's website. If the factors supporting the petition are sufficiently similar, a Grocer may file a single waiver petition that covers multiple Product Groups and product types. Without an approved waiver, failure to provide information constitutes a delay in submitting the required report. Guidance for waiver petitions is provided in sections 2.1 and 2.2 below.
- 2.1 **Waiver Petition Contents.** To be eligible for a waiver from reporting any of the information required on the Antibiotic Use Reporting Form, an applicant must demonstrate, based on substantial evidence, that it is not feasible to provide the required information without significant hardship. To be considered, a waiver petition must, at minimum, include the following:
- 2.1.1 Name of Grocer or Grocers Association filing the petition;
 - 2.1.2 Name(s) of additional Grocer(s) on whose behalf the petition is being filed, if any;
 - 2.1.3 Name(s) of Retail Banner store(s) covered by waiver petition, and, if filing for some but not all of Grocer's Retail Banner stores, provide addresses of the Retail Banner stores covered by the waiver petition;
 - 2.1.4 Name, email and telephone number of person preparing the waiver petition;
 - 2.1.5 Name, email and telephone number of contact(s) who can address questions about the waiver petition, if different from person preparing the waiver petition;
 - 2.1.6 Product Group(s) for which a waiver is being sought (including species of animal(s), brand and sub-brand);
 - 2.1.7 Specific element(s) of the Form for which waiver is sought;
 - 2.1.8 Demonstration as to why it is not feasible to provide the required information without significant hardship;
 - 2.1.9 Steps required to obtain the information and Grocer's plan for obtaining the information in the future;
 - 2.1.10 Estimate of time required by Grocer(s) to obtain and report the required information, and the basis for this estimate; and
 - 2.1.11 Any supporting documentation that Grocer relies upon.
- 2.2 **Considerations For Waiver Petition.** The Department will consider waiver petitions on a case-by-case basis. When granting or denying a petition, the Department will take into consideration information including, but not limited to, the following:

- What hardship is the petitioner claiming?
- What steps, if any, has the petitioner taken to gather and report the information for which the petitioner is seeking a waiver? What additional steps will be needed to report the information, and how much time and effort will these steps require?
- What documentation has the petitioner provided to show its efforts to report the information for which the petitioner is seeking a waiver?
- Did terms of a contract prevent or prohibit Grocer from obtaining or reporting information from a Producer? Could these terms be modified to allow Grocer to obtain the required information from Producer, and if so, when?
- The quality and comprehensiveness of the information that pertains to the factors specified in section 2.1, above.

2.3 **Supplemental Information Requests.** The Department may request that the petitioner provide, within a specified timeframe, additional information to assist the review of the waiver petition.

2.4 **Petitioner Filing On Behalf of Multiple Grocers.** One Grocer or organization of Grocers may file a petition on behalf of multiple Grocers seeking a waiver for the same elements of the Form for a Product Group or other grouping of products. If the factors supporting the petition are sufficiently similar, the same waiver could be granted for all Grocers covered by the petition. The petition must list every Grocer, as well as the name for each distinct Retail Banner, to be included in the petition. The petition must also provide the information listed in section 2.1, above.

2.5 **Duration of Waiver.** The Department has discretion to approve a waiver for a reasonable duration based on the evidence provided by the petitioner and other relevant information.

3.0 **Deadline for Filing Reporting Form.** The deadline for submitting the Form is 11:59PM on May 3 of each year (or the next business day if May 3 falls on a weekend). Grocers are encouraged to file early.

3.1 **Deadline for Filing Waiver Petition.** The deadline for filing a petition to waive reporting requirements is 11:59PM on March 1 of the same year as the reporting deadline. For example, for reporting due May 3, 2019, the deadline for filing a waiver petition shall be March 1, 2019. The Department may, at its discretion, accept petitions filed for good cause after this filing deadline. Grocers are encouraged to file early.

The Director of the Department of the Environment hereby adopts these regulations as of the date specified below.

Deborah O. Raphael
 Director Department of the Environment

Approved:



Date:
 10/23/18

Appendix A: Content of the Antibiotic Use Reporting Form

Instructions: Grocers must submit an Antibiotic Use Reporting Form for each distinct Retail Banner operating in San Francisco during the prior calendar year. Grocers are required to report on all Product Groups sold in San Francisco of the following five raw meat and poultry species: chicken, turkey, beef (including veal products), pork, and sheep (including lamb/mutton/other sheep products).

The format of the Antibiotic Use Reporting Form ("Form") may change over time, but the contents of the Form, as shown in Parts 1-2 below, will remain consistent. The Form is comprised of two parts: Part 1: Grocer Registration ("Part 1"), and Part 2: Product Group Details ("Part 2"). All Grocers will have to fill out Part 1, which collects basic information about the Grocer and its storewide policies regarding medically important antibiotics. Some Grocers will also have to fill out Part 2, which gathers information about Product Groups sold by Grocers that do not have a storewide policy prohibiting medically important antibiotics. The Form and waiver petition are available on the Department's website at www.sfenvironment.org/antibiotics-ordinance.

- If you are a Grocer that had a storewide policy prohibiting medically important antibiotic use across all five raw meat and poultry animal species sold during the reporting period, follow these steps:
 1. Review questions in Part 1. Before completing Part 1, submit a waiver petition for any reporting requirement(s) that the Grocer is seeking to waive.
 2. Complete Part 1. Follow the instructions in Part 1 to upload PDF copies of relevant purchasing and/or enforcement policies and Internet links to statements about your storewide policy prohibiting medically important antibiotic use. Submit the Form.
 - Note: The Department will review the Grocer's antibiotic use and enforcement policies within 60 days of receipt. If the Department determines that the Grocer's storewide policy or the documentation is sufficient, the Grocer will not be required to submit Part 2. Otherwise, the Grocer will have 30 days from the date of the Department's determination or from the filing deadline, whichever is later, to provide additional evidence of the policy or to submit Part 2, covering all Product Groups of any animals not covered by a storewide policy prohibiting medically important antibiotic use.

- If you are a Grocer that did not have a storewide policy prohibiting medically important antibiotic use across all five raw meat and poultry animal species sold during the reporting period, follow these steps:
 1. Review Parts 1 and 2. Before completing them, submit a waiver petition for any reporting requirement(s) that the Grocer is seeking to waive.
 2. Report on all Product Groups of any animal species not covered by a storewide policy prohibiting medically important antibiotics by completing Part 2. Reference where necessary the approval number for any waiver granted for the reporting period.
 - For example, a Grocer with a storewide policy prohibiting medically important antibiotics across its raw turkey Product Groups, but not across any other meat or poultry species, does not need to fill out Part 2 for any of its raw turkey Product Groups, but will for the rest of its Product Groups.
 3. Complete Part 1. Follow the instructions in Part 1 to upload the completed Part 2. Then submit the Form.

Part 1 – Grocer Registration

Information About Grocer and Retail Banner

1. Grocer name (e.g., Four Seasons Grocers, LLC):
2. Retail Banner name (if different from Grocer name) (e.g., Summertime, Inc.):
3. Addresses of the Retail Banner stores covered by this Reporting Form, *if filing for some but not all of Grocer's Retail Banner stores* (e.g., list addresses of those Summertime, Inc. stores in San Francisco covered by this Form):
4. Contact name (i.e., person who can answer questions about Retail Banner's reporting):
5. Contact title:
6. Contact email:
7. Contact phone number:
8. Which raw meat and poultry animal species did Grocer sell during the reporting period?
9. For which of the animal species sold did the Retail Banner have a storewide policy prohibiting medically important antibiotic use?
 - a. For any animal species covered by a storewide policy prohibiting medically important antibiotic use, provide documentation of the policy (e.g., public statement, website, etc.) and process by which the Grocer enforced the policy (e.g., purchasing specifications, third-party certifications, etc.).
 - b. For any animal species not covered by a storewide policy prohibiting medically important antibiotic use, complete Part 2 for all Product Groups of that animal species.

Signature of Person Preparing This Form

10. Preparer's Name
11. Title
12. Grocer, Grocers Association, Business or Organization Name
13. Email
14. Phone Number
15. Mailing Address
16. Preparer's Declaration to be completed by the Form's preparer when submitting the Form:

I declare that I prepared this Form on behalf of the Grocer(s), that it is based on all the information of which the Grocer(s) has (have) knowledge, and that the information is true to the best of my knowledge and that of the Grocer(s).

Signature of Preparer:

Date of Signature:

Part 2 – Product Group Details

Information About Product Group

1. Raw meat or poultry species (chicken, turkey, beef, pork, sheep):
2. Product Group's brand name (e.g., Happiest Happy Farms):
3. Product Group's sub-brand name (e.g., Happiest Happy Farms' Naturally Natural):
4. Was this Product Group organic or raised without antibiotics? Yes/No
 - a. If yes, provide the name of the Third-Party Certification. If the Third-Party Certification is USDA Organic, USDA No Antibiotics Administered Process Verified (or equivalent USDA "process verified" claim), Global Animal Partnership, or AGA-Certified Grassfed, STOP here; otherwise, continue to the next question. Grocers shall provide documentation verifying the Third-Party Certification upon request from the Department.
 - b. If no, continue to the next question.
Note: If multiple Producers provided meat or poultry to the Product Group, but at least one of the Producers is not organic or uses antibiotics, the answer to this question should be no.
5. Was this Product Group raised without medically important antibiotics? Yes/No
 - a. If yes, provide the name of the Third-Party Certification. Then continue to the next question.
 - b. If no, continue to the next question.
Note: If multiple Producers provided meat or poultry to the Product Group, but at least one of the Producers administered medically important antibiotics, answer "no".

Antibiotic Use Policy for the Product Group

6. Did the policies for this Product Group:
 - a. require veterinarian oversight (e.g., a veterinary feed directive or other prescription) for all medically important antibiotics administered (including for injections and topical applications)?
 - b. prohibit the use of medically important antibiotics for "growth promotion"?
Note: If the meat or poultry animals for this Product Group were raised in the United States for their entire lives, answer "yes".
 - c. prohibit the use of medically important antibiotics for disease prevention?
Note: If unsure, answer "no".
 - d. allow the use of medically important antibiotics for "disease control," i.e., to stop the spread of a bacterial disease present in the flock or herd?
 - i. If yes, was a diagnosis of disease in the flock or herd required before antibiotics were administered?
 - ii. If yes, was medically important antibiotic use limited to animals within the housing unit in which sick animals were present?
 - e. allow the use of medically important antibiotics for "disease treatment"?

Note: The following applies to Questions 7-10. For each Producer that supplies the Product Group, provide the specific number of animals raised (see Table 1, below, for meaning of "raised") and volume of medically important antibiotics used for the Product Group during the reporting period. Alternatively, if this information is not available, provide the total number of animals raised and the total volume of medically important antibiotics used by each Producer's entire operation during the reporting period, excluding those animals raised

for products labelled No Antibiotics Ever and Organic. This information will be used to generate a metric for average annual antibiotic use.

Information About the Producer(s) of and Number of Animals Raised for the Product Group

Note: If there was more than one Producer for the Product Group, provide the requested information for each Producer.

7. Indicate the total number of Producers that provided meat or poultry for this Product Group in the reporting period.
8. Producer name(s):
9. If more than one Producer, percentage of the Product Group that each Producer represented (must total 100%):
10. Number of animals raised by each Producer for the Product Group. Provide this information according to the schedule below, which recognizes weight differences between animal sub-types within the same species.

Table 1 – Meaning of “raised” for Question 10

For pork:

of slaughtered pigs; and
of living sows.

For chicken:

of slaughtered chickens

For turkey:

of slaughtered turkeys

For beef, veal:

of slaughtered cows/bullocks/steers/bulls (older than 12 months); and
of slaughtered heifers; and
of slaughtered calves/young cattle (12 months old or younger).

For lamb, mutton, other sheep products:

of slaughtered sheep; and
of living sheep.

Information About Medically Important Antibiotics Used in Product Group during Reporting Period

11. Using the information below, how many kilograms of active ingredient of each medically important antibiotic class were used by each Producer for this Product Group?

For example, if a Producer used 10kg of Hygromycin B, 12kg of Neomycin, and 4kg of Sulfamethazine in 2018, a Grocer would report that Producer used 22kg of Aminoglycosides (since Hygromycin and Neomycin are Aminoglycosides) and 4kg of Sulfonamides.

In 2018, the following twelve antibiotic classes (underlined) were considered medically important. For your convenience, the list also identifies the specific antibiotics from each class that have been approved for use by FDA, as of 2018. (For other years, consult Appendix A of FDA’s Guidance for Industry #152 and subsequent revisions for a current list of the classes of medically important antibiotics covered by the regulations.)

1. Aminoglycosides
 - 1.1. Dihydrostreptomycin
 - 1.2. Gentamicin
 - 1.3. Hygromycin B
 - 1.4. Neomycin
 - 1.5. Spectinomycin
2. Amphenicols
 - 2.1. Florfenicol
3. Cephalosporins
 - 3.1. Ceftiofur
 - 3.2. Cephapirin
4. Diaminopyrimidines
 - 4.1. Ormetoprim
5. Fluoroquinolones
 - 5.1. Danofloxacin
- 5.2. Enrofloxacin
6. Lincosamides
 - 6.1. Lincomycin
 - 6.2. Pirlimycin
7. Macrolides
 - 7.1. Erythromycin
 - 7.2. Gamithromycin
 - 7.3. Tildipirosin
 - 7.4. Tilmicosin
 - 7.5. Tulathromycin
 - 7.6. Tylosin
 - 7.7. Tylvalosin
8. Penicillins
 - 8.1. Amoxicillin
 - 8.2. Ampicillin
- 8.3. Cloxacillin
- 8.4. Penicillin
9. Polymyxins
 - 9.1. Polymyxin
10. Streptogramins
 - 10.1. Virginiamycin
11. Sulfonamides
 - 11.1. Sulfadimethoxine
 - 11.2. Sulfamethazine
12. Tetracyclines
 - 12.1. Chlortetracycline
 - 12.2. Oxytetracycline
 - 12.3. Tetracycline