

Public Comments and Department Responses

Proposed Regulations Implementing the Antibiotic Use in Food Animals Ordinance, City & County of San Francisco

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Background: Between March 19 and April 5, 2018, the SF Department of the Environment received written and oral public comments regarding proposed regulations implementing the Antibiotic Use in Food Animals Ordinance, No. 204-17. The following are the SF Department of the Environment's responses.

| Comment # | Type of Comment | Comment | Department's Response |
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| First deadline for reporting | | | |
| 1 | Written and oral | Collect data: 1) ASAP, by the end of 2018; or 2) prior to April 2019; or 3) by a deadline determined only after all regulations, forms, processes and reporting requirements are finalized, and after 2020 at the earliest; or 4) in 2021 at the earliest, to give producers a 3-5 year period to make changes to their plant operations so that data collected is specific to the meat/poultry sold to San Francisco. | The Department received requests to both hasten and delay the initial reporting date, but no commenters provided a compelling reason to do either. May 3, 2019, 18 months after the ordinance passed, is a reasonable reporting deadline because it gives Grocers sufficient time to gather the required information from their suppliers, while ensuring prompt implementation of the transparency measures required by the ordinance. The ordinance requires reporting by Product Group, and it is not necessary for Producers to increase the granularity of their tracking systems in order to provide the required information. In addition, the waiver process will provide adequate flexibility for Grocers unable to meet the reporting deadline for particular Product Groups. |
| Definition of Product Group | | | |
| 2 | Oral | Refine the definition of a product versus a product group to avoid excessive paperwork. | It is not clear how the commenter wishes the definition of Product Group to be refined. Grocers needing assistance filling out their reporting forms may reach out to the San Francisco Department of the Environment at abxordinance@sfgov.org . The regulations reflect the ordinance's requirement for reporting by Product Group and its definition of Product Group. A Product Group is akin to a product line (e.g., Store Brand Extra Healthy Label Chicken). Grocers are not required to complete a report form for each product within the product line (e.g., drumsticks), except in the case of Product Groups that include only one product. |
| Waivers | | | |
| 3 | Written and oral | Remove regulation section D.2.3 to prohibit waivers that cover multiple grocers in order to ensure waiver requests are specific to individual situations and not overly broad. | Waiver petitions will be reviewed on a case-by-case basis. Where multiple petitioners file a joint petition, the Director has discretion to grant a waiver to each petitioner who meets the waiver requirements. |
| 4 | Written and oral | Add provision requiring the Department to notify stakeholders on AUIFA mailing list by email when the Department receives waiver petitions. | The Department will inform stakeholders on its email list whenever new petitions have been filed and uploaded to its website. |
| 5 | Written and oral | Add a one-year maximum waiver duration to regulations section D.2.4 since the ordinance (at (§2703(b)) requires a specific time period for waivers. | Setting a maximum time period for all waivers is not necessary. The ordinance only requires that each waiver be granted for a specific period ("Director may exercise reasonable discretion to waive reporting of the relevant information for a period of time specified by the Director") and petitions will be approved on a case-by-case basis. |
| 6 | Written and oral | Require grocers to provide documentation of their attempts to collect the required information before granting a waiver. | The regulations, at section D.2.1, require a Grocer to demonstrate why it would not be feasible to provide the required information without significant hardship, as well as any supporting documentation that the Grocer relies upon. This requirement ensures that the Department will be able to consider a wide range of evidence. |
| 7 | Written and oral | Add a provision to make fines mandatory for violations. | The Department has enforcement discretion and will exercise that discretion on a case-by-case basis to ensure that the ordinance is implemented effectively. |
| 8 | Written and oral | Allow waivers to be filed based on Product Group, rather than for individual Grocers, since Grocers do not currently have any data being requested. | The ordinance provides for waiver petitions to be filed by a "Grocer." Grocers may petition for waivers if they meet the criteria established in the regulations and may petition for waivers for specific Product Groups. |
| 9 | Written | Make granted waivers public to allow retailers to have same benefit of the waiver based on significant hardship. | The Department may post on its website the waivers that have been approved. The ordinance requires the Department to post waiver petitions on its website for a minimum of 30 days and provide a written public comment period. Petitions will be reviewed on a case-by-case basis, and decisions will be based on factors, evidence and public comments specific to each petition. |
| 10 | Written | Clarify what may be considered "significant hardship" for an impacted grocer, taking into consideration that a Grocer might be left with no options for compliance through a waiver if the information simply cannot be determined or does not exist (ie, Grocer's reason for facing hardship is not one recognized by the regulations). | The extent of hardship will be reviewed on a case-by-case basis, and decisions will be based on factors, evidence and public comments specific to each petition. |

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| 11 | Written | Provide an expectation of confidentiality for Grocers or Producers when filing for a waiver, as section D.2.2 of the regulations, considerations for petition, includes defining the hardship being claimed and "terms of a contract" as decision points, but without a reassurance that these details will be confidential, Grocers may be dissuaded from reporting or filing for a waiver. | The ordinance requires that all waiver petitions be posted publicly on the Department's website for a minimum of 30 days. Grocers may choose to redact irrelevant information or submit only relevant portions of contracts or other documents used to demonstrate significant hardship. Grocers with concerns regarding confidentiality issues should contact the Department before submitting documents. The Department will work with petitioners to address concerns, while complying with the ordinance and other relevant laws. |
| 12 | Written and oral | Provide more options for exemptions and ways to broaden the conversation. | The ordinance only allows the Department to grant a waiver if a Grocer shows, based on substantial evidence, that reporting certain information is not feasible without significant hardship, and it requires the Department to craft waivers as narrowly as possible. The ordinance does not give the Department discretion to provide additional exceptions. |
| Contents of Reporting Form (Appendix A to Regulation SFE-18-01-AUIFA) | | | |
| 13 | Written | Remove Q'1 of Part 3 as administration of antibiotics for the purpose of growth promotion is already prohibited nationwide (thus the question is unnecessary). | Even though the administration of antibiotics to food animals is prohibited for growth promotion within the United States, it is still allowed in other countries. |
| 14 | Written | Remove Q'3(a) and 3(b) of Part 3 as it is impracticable or impossible to expect Grocers to know the answers to these questions. | Grocers should work with their Producers to get this information. Where it is not feasible for a Grocer to secure this information without significant hardship, the Grocer may request a waiver. |
| 15 | Written | Remove Q'4 of Part 3 as it asks if store policies require whoever administers antibiotics to follow the law. | Federal law does not require veterinary oversight for use of all antibiotics. Where a Grocer is unable to confirm that a policy is in place, the Grocer may answer 'No'. |
| 16 | Written | Remove Q'1(c) of Part 4 as Grocer will not likely have access to information regarding the number of animals raised by its producers, nor will many Producers have it. | Grocers should work with their Producers to get this information. Where it is not feasible for a Grocer to secure this information without significant hardship, the Grocer may request a waiver. |
| 17 | Written | Clarify in Q'1(c) of Part 4 if Grocer needs to report total number of animals raised by Producer nationwide, statewide, or to SF. | The information requested in Part 4 is not geographical. The regulation requires general Producer information for each Product Group. Where a Product Group has multiple Producers, the regulations provide two options for reporting: Grocers may provide, for each Producer, either 1) the total number of animals raised and volume of medically important antibiotics used for the particular Product Group, or 2) the total number of animals raised and volume of medically important antibiotics used by that Producer's entire operation for animals of the same type as the Product Group. The Department understands that this is the least burdensome approach available to meet the requirements of the ordinance. |
| 18 | Written | Add "steers" to definition of cattle in the text box of Part 4. | "Bullock" is synonymous with "steer". However for clarity the Department has updated the regulations to include "steers" in the definition of cattle in the text box of Part 4. |
| 19 | Written | Define/distinguish "young cattle" from "calves" in the text box of Part 4. | Young cattle and calves are grouped together, and should include young animals 12 months old or younger. |
| 20 | Written | Define "sheep" in the text box of Part 4. | For clarity, the heading has been revised to "lamb, mutton, and other sheep products." |
| 21 | Written | Clarify whether Grocers need to report antibiotic data for sows or other live animals. Explain in the text box of Part 4 why the number of living sows or living sheep is relevant. The Grocer/slaughter plant could only guesstimate these numbers. | The Department is using the European Union's metric for measuring antibiotic use in animal production, which is the most widely-used approach endorsed by experts and leading health and medical groups. The information required by the text box in Part 4 mirrors the categories used in the European Union's approach. Thus Grocers are required to report antibiotic data for their Producers' sows and living sheep. |
| 22 | Written | Remove the last paragraph of Part 4 as the Grocer/packer will not have the ability to access the specific number of animals raised and volume of medically important antibiotics used for a particular Product Group, nor the alternative, which requests the total number of animals raised and the volume of medically important antibiotics used by Producer. | Grocers should work with their Producers to get this information. Where it is not feasible for a Grocer to secure this information without significant hardship, the Grocer may request a waiver. |
| 23 | Written | Explain in the last paragraph in Part 4 how the weighted average will be calculated (e.g., by species, live weight, carcass dressed weight, or pound of meat sold?). | The Department expects to adopt the European Union's metric for measuring antibiotic use in animal production, which is the most widely-used approach endorsed by experts and leading health and medical groups. This methodology relies on average weights at treatment for different species. |

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| 24 | Written | Remove Q'2 of Part 5 as it unnecessarily complicates the form by asking about non-medically important antibiotics. | The ordinance requires reporting to distinguish between medically important antibiotics and non-medically important, but grants the Department discretion to determine the appropriate level of reporting in each category. In response to stakeholder input, the Department has determined that it should prioritize medically important antibiotics. Accordingly, the Department has removed Part 5, Questions 2(a)-(c), and only requires reporting on medically important antibiotics at this time. However, the Department may determine that reporting on non-medically important antibiotics is necessary and appropriate in the future. |
| 25 | Written | Part 5 requires grocers to report the kilograms of antibiotic used. In-feed antibiotics are measured in grams or kilograms, but injectable antibiotics are measured in mg/mL, and are administered by the mL. Are grocers going to be required to report the number of <i>milligrams</i> of antibiotic administered? | Yes, Grocers are required to report the amount of antibiotics administered in milligrams (mg) or kilograms (kg). Generally antibiotic products list the weight of an active ingredient present in the product. |
| How reported information will be published | | | |
| 26 | Written | Explain how the Department intends to publish the information collected, how the information will be communicated to the SF consumer, and answer the following questions regarding its plan to publish: 1. Does the Department plan to explain FDA guidance documents 209 and 213 and changes to federal policy implemented? 2. Does the Department plan to educate consumers about how FDA establishes maximum residue limits (MRLs) for ABX used in food producing animals? 3. Does the Department intend to explain withdrawal times for ABX and how they are developed? 4. Does the Department intend to provide info to consumers about residue testing by USDA and inform consumers that 99.9% of meat/poultry residue tests do not violate MRLs set by FDA? | The ordinance directs the Department to analyze the information collected and report its findings. The content of the Department's reports will reflect the information collected: antibiotic use policies and quantities of antibiotics used. The ordinance does not address federal rules or guidance or antibiotic residues, so the Department is not required to include this information in its reports. The Department may provide additional context in its reports to inform the public's purchasing decisions. |
| 27 | Written | Provide a public comment period on how the Department plans to publish the information collected. | The Department is not required to provide a public comment period on the Department's plans to publish information collected, and the Department has determined that it is not necessary to solicit public comments on this issue. However, the Department continues to welcome public input on an ongoing basis; questions and suggestions may be emailed to abxordinance@sfgov.org at any time. |
| 28 | Written | Clarify how the city will confirm that the information collected by the ordinance is accurate or factual. | Grocers are legally required to respond accurately and factually. The reporting form includes a declaration of accuracy. The Department has the authority to apply fines and reexamine permits. Grocers and Producers may be held jointly and severally liable for failure to respond accurately or factually. |
| 29 | Written | Clarify how we intend to educate SF consumers regarding the published data. | The ordinance directs the Department to analyze the information collected and report its findings. The content of the Department's reports will reflect the information collected: antibiotic use policies and quantities of antibiotics used. The Department may provide additional context in its reports to inform the public's purchasing decisions. |
| 30 | Written and oral | Separate reporting data by retail chain and brand when the Department publishes information regarding the data obtained from the reports. | At this time, the Department plans to report data by Grocer and Product Group, to inform the public's purchasing decisions. |
| Concerns about confidentiality and competition | | | |
| 31 | Written | Explain the value in collecting data regarding the amounts and types of antibiotics used. | The ordinance requires reporting on the amounts and purposes of antibiotics used to inform the public's purchasing decisions. Granular reporting will allow for more meaningful comparisons across Product Groups. |
| 32 | Written | Explain what policy measures will be implemented to protect private and proprietary business information, such as the specifications that grocers have for their suppliers, that could be used by competitors. | The ordinance requires that all waiver petitions be posted publicly on the Department's website for a minimum of 30 days. Grocers may choose to redact irrelevant information or submit only relevant portions of contracts or other documents used to demonstrate significant hardship. Grocers with concerns regarding confidentiality issues should contact the Department before submitting documents. The Department will work with petitioners to address concerns, while complying with the ordinance and other relevant laws. |
| Concerns about liability | | | |
| 33 | Written and oral | Allow Producers (in addition to Grocers) to report to the Department, request and obtain waivers, and maintain documentation regarding their own and their Grocers' products since Producers may be held jointly and severally liable. | The ordinance places responsibility to report on Grocers. Grocers may work with their Producers to collect this data. |

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| 34 | Written | Consider a corporate-level reporting requirement rather than store-level reporting. This would allow compliance at a corporate level (and avoid needing an individual in a grocery store to take on legal responsibility for providing accurate data). | A Grocer may be "a person, firm, corporation, partnership, or other entity that owns and/or operates in the City a grocery store". The proposed regulations allow reporting to be done at a corporate level on behalf of one or more stores, with the caveat that a Grocer must report separately for each of its distinct retail banners. |
| Documentation | | | |
| 35 | Written | Require documentation be maintained by grocers for only 1 year, instead of 5, similar to USDA's Final Rule, "Records to be kept by official establishments and retail stores that grind raw beef products", that requires retail stores to keep records for 1 year. | To reduce the burden on Grocers, the regulations do not require Grocers to submit all supporting documentation with their reports. Accordingly, it is necessary to ensure that documents remain available for review on an as-needed basis. Five years is a reasonable retention period to ensure accountability and will not impose an undue burden on Grocers. Documents may be maintained digitally. |
| 36 | Written | Clarify what type of documentation may be used to show a Grocer's storewide policy prohibits medically important antibiotics use. For example, the Department could offer a template to retailers to ensure they understand expectations for corporate-wide policy. | The ordinance, at section 2703(e), allows for a variety of documentation to be submitted to evidence the Grocer's storewide or Product Group policy. In addition to this documentation evidencing the policy, the Grocer must also provide "the process, in writing, by which the Grocer enforces the policy, including any Third-Party Certification used, written statements from Producers, purchasing specifications, or equivalent information that demonstrates enforcement of the store-wide policy. For a Product Group for which there has been no change to the Antibiotic Use Policy from the previous year, the Grocer shall retain documentation establishing that there has been no change." This requirement also eases the reporting burden for those companies that have considered this issue. |
| The ordinance | | | |
| 37 | Written and oral | Several comments suggested changes to the ordinance or questioned its rational. | The regulations cannot change requirements established by the ordinance. |