

May 18, 2020

U.S. Environmental Protection Agency
EPA Docket Center
Office of Research and Development Docket
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460.

RE: EPA-HQ-OA-2018-0259 for comment on Supplemental notice of proposed rulemaking on the Strengthening Transparency in Regulatory Science Proposed Rulemaking.

Keep Antibiotics Working (KAW) recommends that the U.S. Environmental Protection Agency (EPA) not move forward with proposed rules that would limit the agency's ability to use the best science available. KAW is particularly concerned with provisions in the proposed rule that would lead EPA to discount studies where all study data is not made public.

KAW is a coalition of 18 public health, environment, consumer protection and animal protection organizations that are working together to ensure that untreatable superbugs resulting from the overuse of antibiotics on farms do not reverse the medical advances of the past century.

Our interest in this EPA action is primarily related to the Agency's regulation of antibiotics used in vegetable and fruit production under the Federal Insecticide, Fungicide, and Rodenticide Act. KAW has engaged with EPA around the regulation of antibiotics since at least 2006. Our concern is that the use of antibiotics in food production can contribute to the urgent public health crisis of antibiotic resistance through the selection of antibiotic resistant bacteria that can impact human, animal, and environmental health. KAW is concerned about the safety of workers applying antibiotic pesticides, the safety of consumers who eat fruits and vegetables from plants that have been administered antibiotic pesticides, and concerned about both people and animals exposed to antibiotics and antibiotic-resistant bacteria that occur in the environment because of their use in agriculture.

While KAW strongly supports greater transparency in EPA actions around the use of antibiotics in animal agriculture, we do not believe that this proposed rule actually provides the needed transparency and it may make it more difficult for EPA to properly take into consideration some of the limited information that is available related to use of antibiotics in vegetable and fruit production. In the realm of crop use of antibiotics, there is very limited data available and the data that is available covers mainly apples and pears not other crops such as citrus fruits.¹ Because approvals for citrus use in the U.S. are

¹ FAO and WHO. 2019. Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance: Role of the Environment, Crops and Biocides – Meeting report. Microbiological Risk Assessment Series no. 34. Rome. Available from: <http://www.fao.org/3/ca6724en/ca6724en.pdf>

fairly recent, studies on antibiotic use in citrus are primarily available from researchers in other countries, which increases the risk that the underlying data will not be available. Raw data from studies on impacts of worker exposure to antibiotic pesticides might not be available both due to the confidentiality of medical records and due to the need to protect workers from retaliation by crop production companies.² Despite these limitations, this type of data is often the best available. Given the low number of studies related to crop use of antibiotics and the real risk that underlying data will not be available for studies published in the peer reviewed literature for the reasons described above, it is inappropriate for EPA to move forward with the proposed rule.

Specific responses to changes in the supplemental proposed rulemaking:

1) KAW opposes the language in the proposed rule to extend provisions in the 2018 proposed rule that covered only dose-response data and dose-response models to all data and models. Like the majority of commenters on the 2018 proposed rule, KAW opposes those provisions when only applying to dose-response data and dose-response models so do not support their extension to even wider use.

2) KAW opposes extending the scope of the rule making to apply to “influential scientific information” as well as “significant regulatory action.” In the realm of antimicrobial resistance where the KAW groups have expertise, the core set of scientific ideas that guide policy are not based on a limited number of studies but instead by a synthesis of a wide range of studies illustrating the role of antimicrobial use in the selection of antimicrobial resistance. Given the complexity created by the interactions between the environment, farming systems, microbial communities, and resistance determinants, individual studies on antimicrobial resistance provide very little information to guide policy and can only be interpreted in the context of the broader set of studies. For this reason both the U.S. Food and Drug Administration and EPA rely on qualitative methods to address risks of antibiotic resistance. Since the spread of antimicrobial resistance is based on interactions between living organisms, it is much more complex to address than risks related to toxins. Any attempt to rely only on studies where the underlying data is readily available with respect to the core science behind antimicrobial resistance would preclude the type of synthesis that is needed for policy making. In addition, there is already a lack of data on the impacts of antibiotics in crop systems, so further limiting the type of data that can be considered would make decision making almost impossible. Given that KAW opposes the extension of the rule to “influential scientific information,” we also oppose the modifications to rule language and associated definitions related to the extension. More generally, KAW views the rule making itself as misguided so opposes all of the text.

3) KAW opposes the provision to “only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation.” As we have described above, this provision is completely unworkable in the context of antimicrobial use in agriculture. This would eliminate much of the already

² Prado J., Mulay P. et al. 2017. Acute Pesticide-Related Illness Among Farmworkers: Barriers to Reporting to Public Health Authorities. *J Agromedicine*. 2017;22(4):395-405. doi: 10.1080/1059924X.2017.1353936.

limited scientific information that is available and also is contrary to the normal practice of science and the peer-review process.

4) KAW does not accept that allowing the EPA administrator to arbitrarily waive the data requirements in cases where there are “technological barriers” to data sharing resolves the issues related to using the best science available, and may actually makes it worse. The proposed rule states that the administrator may waive the data requirements if releasing the data conflicts with laws governing privacy, but not that he shall do so. Independent of whether or not there is a technological barrier, EPA rule making should not conflict with existing laws protecting privacy and confidentiality. In addition, the result of allowing the waiver to be tied to technological barriers may further bias the EPA toward accepting only industry data and not data from long term health studies which are the most relevant for determining public health risks from pesticide use.

Antimicrobial resistance is a growing and very complex public health crisis that leads to the illness of millions and the deaths of tens of thousands of people in the US each year. Addressing this threat requires access to the best scientific information available. This proposed rule would obligate EPA to throw out much of the available scientific information and thus hinder the Agency’s ability to make needed decisions with respect to public and environmental health. For this reason, KAW and its allies oppose the proposed rule in whole including these supplemental proposals.