

**Comments from the United States of America on Proposed Draft  
Guidelines for the Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance**

**GENERAL COMMENTS**

- The United States thanks the eWG for the opportunity to submit comments on the draft Guidelines for Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance.
- Regarding questions posed to the eWG, much of the document from Section 9 onward is pasted in from the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) One Health document so it seems redundant and potentially misleading to. Selectively excerpt from the AGISAR document into this draft, and it makes it difficult to do line-by-line editing. We suggest very broad paragraphs making reference to existing OIE and WHO AGISAR documents. We believe addressing sample sizes and locations is too prescriptive and detailed for this document. We have addressed through our comments those areas where the language could be more realistic and practical. In particular, taking the tone of the OIE texts which describe what a surveillance system looks like instead of statements such as “countries should do this or that” would help alleviate the directive/prescriptive nature of the document and facilitate the ability of the TFAMR to more quickly reach consensus.
- We note “bacteria” are referenced for the first time in paragraph 8. To be microbiologically appropriate for the topic of surveillance “AMR” should in virtually every instance be followed by the ~~word-phrase~~ “bacteria or resistance determinants or genes” throughout the document. The reason this nuance is mentioned is because it is relevant to the concept of surveillance. In this document, without continually specifying the entity to be monitored or surveilled (i.e., “bacteria or resistance determinants or genes”) the potential for confusion is high during ~~oral-verbal~~ discussion and in written formats.

The document discusses foodborne bacteria but does not make it clear which bacteria are of most relevance until section 10.6. The “Core Four” of bacteria that all countries should test will be the ones OIE and AGISAR identified: *Salmonella*, *Campylobacter*, *Enterococci* and *Escherichia coli* (the latter two as reservoirs of resistance genes for Gram-positive and Gram-negative bacteria, respectively). *Staphylococcus aureus* is not appropriate for inclusion, as zoonotic *Staphylococcus* is not a common cause of foodborne disease and therefore not within the mandate of Codex. The Core Four are those that are of most global food safety significance, are easily grown, and are mature in methods development. Testing for resistance in some additional species of foodborne bacteria becomes problematic for reasons mentioned below. Gaining consensus on testing for the Core Four bacteria first and including the option to add others as resources allow, for advanced labs or reference or research labs, for surveillance and monitoring is a logical approach that has been taken by many developed countries. This is one way the surveillance document could be better focused to provide useful guidance without being prescriptive.

- The Step-wise implementation section 9 is impractical. Implementation in LMICs has to start with fundamentals as outlined in the World Bank report (See part IV p. 38). Step 1 here would really be more like Step 10 for those countries. Even for countries like the US and EU countries, Step 3 is impossible because not all listed items are achievable with available resources. For example, wastewater surveillance seems more appropriate within a research framework. The World Bank Report offers specific examples and country-level case studies of how to create a laboratory, the operating budget and other information for LMICs. See Annexes 5, 6 and 10. <https://openknowledge.worldbank.org/bitstream/handle/10986/26707/114679-REVISED-v2-Drug-Resistant-Infections-Final-Report.pdf?sequence=1&isAllowed=y>
- With regards to antimicrobial susceptibility testing methods for foodborne bacteria from human cases, food animal samples, or retail foods (the Core Four bacteria are mentioned above) there are standardized and quality-controlled methods for only those that grow easily, but very few such methods for those that are fastidious. For foodborne bacteria derived from crops we are unaware of any standardized antimicrobial susceptibility test methods and do not believe there are any interpretive categories for such bacteria. This is an area that would require significant investment to generate methods and data comparable to that of CLSI or EUCAST.

Commented [RM1]: E. by itself could refer to Enterococcus.

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- It should be flagged that pan-susceptible or even non-MDR strains still cause foodborne illness in humans that will require antibiotic treatment in a sub-population of ill persons. No resistance is detected to approximately 80% of *Salmonella* isolated from human cases according to the US CDC's National Antimicrobial Resistance Monitoring System (<https://www.cdc.gov/narms/pdf/2014-Annual-Report-narms-508c.pdf>). Thus, the document needs to include direction to countries, laboratories, and food safety agencies on where to go to address all bacteria, including susceptible bacteria by referencing Codex food hygiene documents such as the Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013). Codex food safety is all about reduction in contamination of all microorganisms and is covered in many other Codex and FAO documents on microbiological food safety, food hygiene and HACCP aspects.

#### SPECIFIC COMMENTS

#### SECTION 1 INTRODUCTION

Much of the language in the introduction is repetitive. We propose the following language to describe a program that is succinct, but also provide edits if our proposal is not taken.

An integrated monitoring and surveillance program:

- **Tracks changes in the antimicrobial susceptibility of foodborne bacteria,**
- **Combined with data on the use of antimicrobials in humans and animals, and epidemiological data on various sources of resistance, provides information for the risk analysis process and is an essential component of a comprehensive national food control system.**
- **Promotes and protects public health by providing information to risk managers about emerging bacterial resistance, how AMR bacteria differ from susceptible bacteria, and the impact of interventions designed to limit the spread of resistance.**

*Rationale* The description for integrated surveillance is aspirational but not practical. Codex should give countries advice on what can realistically be achieved. Even high-resource countries cannot achieve integrated monitoring and surveillance as described. It is much too simplistic to set the goal of aggregating data from all sources to inform risk management advice across ALL sectors.

Paragraph 5: An integrated monitoring and surveillance program **strives to include** ~~includes~~ the coordinated and systematic sampling, testing, analysis and reporting of AMR and AMU along the food chain, including ~~the alignment and harmonization~~ **collaboration of various sectors in public health and agriculture to interpret results, of sampling, testing, analysis and reporting methodologies and practices in humans, animals, foods, plants and the environment to the greatest extent practical.**

*Rationale* The sentence is not practical as written. Different pathogens from different products, species, etc. require different methodologies and sample collection approaches. There is no clear guidance in this statement.

Paragraph 6: Delete. It is repetitive of paragraph 5-rewritten above.

Paragraph 8: Suggest combining with 7 and edit to read as: "It provides information to risk managers about bacterial resistance trends, how ~~resistant infections~~ **AMR bacteria** differ from susceptible ~~bacteria infections~~ **bacteria**, and the impact of interventions designed to limit the spread of resistance.

*Rationale* Improve accuracy and consistency of terminology

Paragraph 9 – This sentence should be written in a less prescriptive way-see paragraph 10 or OIE chapters. ~~Each country should design and implement a~~ **An ideal** program for monitoring and surveillance of foodborne AMR and AMU "along the food chain" that is appropriate to national circumstances. ~~This should be~~ **would be** informed by all available knowledge on priority foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries and sectors.

*Rationale* Statements such as these which are so aspirational that there are no current examples of countries with such programs in place cause concerns for trade barriers. Rewriting the whole paper to be more like paragraph 10 versus paragraph 9 will allow the TFAMR to come to consensus sooner.

Paragraph 10 – Edit as: "Monitoring and surveillance information on foodborne AMR and AMU along the food chain provides an essential input to risk assessment and decisions by risk managers on control measures to minimize ~~any~~ public health risks due to exposure from foodborne ~~this~~ **pathways for AMR bacteria** and ~~their~~ resistance determinants.

~~**Incorporating** new scientific knowledge should be incorporated in monitoring and surveillance programs as it becomes available so as to **to improve design and implementation will** enhance the utility of existing information and data. Design and implementation of programs should also evolve as AMR policies change at the national and international level.~~

*Rationale* *Rewritten to be less prescriptive and accurate. The last sentence is repetitive of the one before.*

Paragraph 11

- Bullet 2 – Edit as: “• Setting **public food safety** goals related to AMR bacteria”

*Rationale* *To keep within scope of Codex*

- Bullet 5- Delete

*Rationale* *Outside the scope of Codex*

- Bullet 6- Edit as: “**Providing data for** Guiding and evaluating **informing** risk management decisions on more effective or new control measures, either regulatory or non-regulatory”

*Rationale* *The risk managers, not the surveillance administrators should be guiding and evaluating risk management decisions.*

- Bullet 7 – Edit as: “**Provide data to** assessing the impact of control measures at different parts of the food chain in mitigating foodborne risks to consumers

*Rationale* *The risk assessors, not the surveillance system, assess risk*

Paragraph 12 – The guidelines provided in this document will contribute to the ~~development and~~ implementation of National Action Plans (NAP) on AMR that make the best use of available resources at the national level, with the goal of ongoing enhancement as more scientific knowledge, technical capability, data and funding become available.

*Rationale* *Many countries have already developed NAPs*

Combine Paragraphs 14 and 15 to read as: “these guidelines should ~~also be used in conjunction~~ **be read in conjunction** with **Codex Guideline 77 - Risk Analysis for Foodborne Antimicrobial Resistance, and other relevant Codex texts and relevant Chapters of the OIE Terrestrial and Aquatic Animal Health Codes. In addition,** those already developed by other international standard setting organisations and international bodies especially the WHO-AGISAR **guideline**, “Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria; Application of a One Health Approach” **should also be considered,** and relevant chapters of the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code”.

*Rationale* *Codex texts should be read in **conjunction** with other standards developed through transparent processes of review and consensus by Member Countries such as those recognized under the World Trade Organization (WTO) SPS agreement [i.e. Codex, OIE, and International Plant Protection Council (IPPC)]. Expert-derived technical recommendations may also be **considered** where relevant. The WHO relies on an expert group without Member State review, so Codex guidelines, which carry trade implications, should not make the WHO document legally binding, but rather note that the information can be considered.*

Paragraph 16 – Strike “adequacy of human health care infrastructure and reporting” and delete “human data”

*Rationale* *Human health care infrastructure is beyond the scope of Codex. Human data is repeated.*

#### SECTION 4: SCOPE

Paragraph 1 – Delete the added text “and the environment” to read: “These guidelines cover the design and implementation of an integrated monitoring and surveillance program for **foodborne** AMR bacteria and resistance genes, and AMU along the food chain, including animals crops and the environment.”

*Rationale* *The scope of work for the Task Force (and Codex) is foodborne AMR. We are unaware of any country with national surveillance guidelines for foodborne AMR bacteria in crops or the environment. How is Codex to provide guidance for something that no country is doing? If a country is currently conducting national AMR bacteria surveillance in crops please provide the information.*

Paragraph 2 – Revise as: “The microorganisms covered by these guidelines are those bacteria of **public health food safety**-relevance.

*Rationale* *To stay within the scope of Codex*

Paragraph 5 – Modify as: “A monitoring and surveillance programme for AMR and AMU along the food chain within the context of overall risk management of foodborne AMR bacteria (One Health approach) will include design elements, analysis of data and reporting that are common to, and integrated with, **as appropriate**, AMR monitoring and surveillance systems for human and animal health, as well as **relevant** environmental monitoring.”

*Rationale* The focus of this TFAMR should be to give advice on building foodborne AMR surveillance. It is too simplistic to state everything can be integrated. “As appropriate” and “relevant” are added because there are different samples, methodologies, and bacteria to appropriately test in the environment, different animal species, and people. Everything is not comparable and capable of integration, but all data needs to be put in context and considered.

Paragraph 6 – Delete: These guidelines will provide for utilization of appropriate AMR and AMU data, as applicable, from humans, animals, crops, food and environment in order to conduct integrated analysis of all these data.

*Rationale* The sentence is aspirational and not realistic. What country has a national program to conduct integrated surveillance and analysis of food, crops, animals, humans, and the environment?

## SECTION 5: DEFINITIONS

One Health approach – Suggest replacing existing definition with the following (US Centers for Disease Control and Prevention definition): ~~An internationally recognised approach to designing and implementing programmes, policies, legislation and research on AMR in which multiple sectors communicate and work together to achieve better public health outcomes~~ **A collaborative, multi-sectoral, and trans-disciplinary approach — working at the local, regional, national, and global levels — with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.**

*Rationale* The existing definition does not specify the sectors of One Health and mentions terms such as “legislation” which may not be appropriate for all countries.

Medically important antimicrobial agents – Suggest modification as: “Antimicrobial agents prioritized as being **of concern to public health**. e.g. **National lists or** the WHO list of critically important antimicrobials<sup>3</sup>.

*Rationale* To stay within Codex scope..

Risk-based approach – Please provide clarification on the source of the definition.

~~“For the purpose of these guidelines, a fully integrated approach to the design and implementation of a monitoring and surveillance system includes:~~

- ~~☐ The coordinated and systematic sampling, testing, analysis and reporting of AMR along the food chain~~
- ~~☐ Alignment and harmonisation of sampling, testing, analysis and reporting methodologies and practices in humans, animals, plants and the environment to the greatest extent practical~~
- ~~☐ Integrated analysis of all monitoring and surveillance data and other information on AMR, and AMU so as to inform effective risk management across all sectors~~

Monitoring of AMR and Surveillance of AMR - It is unclear where the definition for “monitoring of AMR and surveillance of AMR originates. The US suggests consistency with other international forums and providing references.

## SECTION 6: PRINCIPLES

Paragraph 1 – Revise sentence as: “These principles should be read in conjunction with the Codex guidelines for risk analysis of foodborne AMR (CAC/GL 77-2011) **and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes.**”

*Rationale* The OIE Codes have very pertinent information that Codex does not need to duplicate or be in conflict with.

Bullet 1 – Strike “AMU” to read “Monitoring and surveillance programs for AMR ~~and AMU~~ should be a core component of a national food safety system;

*Rationale* AMR surveillance is the core mission of the surveillance guidelines to address the Codex mandate of foodborne AMR risk. It is important to help countries prioritize, and determine their foodborne AMR status as a priority core component need. AMU occurs on-farm and should be within OIE’s mandate, rather than a core component in this document, though AMU can be referenced later in the document.

Bullet 7 - Edit "to extend practical" to "to the extent practical, the"

*Rationale* Syntax, editorial

Bullet 2 – Strike the bullet: "Monitoring and surveillance programmes should include data on development of AMR and patterns of use in all relevant sectors so as to support risk analysis and policy initiatives;

*Rationale* The statement is not realistic or practical and does not belong in a document with trade implications.

Bullet 4 – Suggest editing bullet 4 as: "Programmes for monitoring and surveillance of AMR should aspire to incorporate an integrated One Health approach within the mission of Codex for food safety."

*Rationale* It may not be immediately possible, effective or efficient to combine data from human, animal and environmental sources, however the aspiration to include all relevant information could be described.

Bullet 6 – Suggest revising bullet 6 as: "In using a step-wise approach, priority should be given to the most relevant elements/risks from a public health perspective (e.g. combinations of bacterial species/ food to be analysed/ food commodity, the AMR bacteria, resistance determinants, and the antimicrobial agent(s) to which resistance is expressed.)"

*Rationale* The language provided is from Principle 6 CAC/GL 71 for consistency

Suggest adding the following principles:

- **Public communication of the results of monitoring and surveillance should be based on Codex risk communication working principles, include the scientific basis for food-borne risks, and provide complete transparency on use of methodology and interpretive categories, and differences in historical reporting to provide context when comparisons to historical data or between countries/regions are made.**
- **Programs should follow a science-based design approach, focus on the analysis and interpretation of data trends rather than simply collecting and reporting bulk data, and exhibit transparency in all aspects of the program.**
- **Programs should inform with science-based data for outcomes-based actions to reduce the risk of foodborne AMR development.**

Bullet 9 – Suggest revising bullet 9 as: "• **Countries** A national monitoring and surveillance system should **strive to** harmonize laboratory methodology, data collection, analysis and reporting ~~should be aligned and harmonized across all sectors in national AMR systems as part of an integrated approach.~~ Use of **as appropriate using to the extent possible,** internationally recognized, standardized and validated AST methods and harmonized interpretative ~~criteria~~ **categories** to facilitate comparable data at national and international levels;"

*Rationale* This is an aspirational goal in practice. Methods are internationally recognized by ISO, but other groups like European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical & Laboratory Standards Institute (CLSI) have closer connections to laboratories and diagnostic companies. Harmonized interpretive categories (criteria is no longer used) are problematic because they relate to patient treatment regimens which vary considerably).

Bullet 11 - National programmes should strive to harmonise components, methodologies and interpretative categories/criteria with **according to applicable** internationally recognized, **consensus-based surveillance guidelines such as CAC/GL 77 and OIE codes** guidance so as to enhance an integrated approach to **inform risk assessment and risk** information management at the international level;

*Rationale* References are provided for other consensus-based surveillance guidance and clarifying language is provided as to why the harmonization is needed.

Bullet 12 – Strike and edit as: "All monitoring/surveillance data (not just AMR bacteria on imported food), taken as a whole, help illustrate trends, identify priority risks, and are inputs to inform the overall risk analysis process, and are not meant to be individual points to be used as barriers to trade." "Data generated from national monitoring and surveillance programmes of AMR in imported foods should not be used to inappropriately generate barriers to trade."

*Rationale* The statement as written is vague as "inappropriately" can mean different things to different people.

## SECTION 7: Risk-based approach

Paragraph 4: Revise and move information as a bullet to 10.1.3: Hazard identification should include ~~human~~ microbiological foodborne pathogens and bacterial commensals bacteria in or on food commodities that may compromise human therapy due to AMR likely to transmit AMR to humans.

*Rationale* This paragraph seems more appropriate where Risk Assessment is discussed, since Risk Profiles are one of the first things to be done. Why not Section 10.1.3?

## SECTION 8: REGULATORY FRAMEWORK AND ROLES

8.1 First paragraph – Revise second sentence as: “~~The~~ Competent Authorities responsible for food safety should ~~provide~~ develop an...”

*Rationale* The language is too prescriptive to identify the authority-maybe it's a mix of medicines agency, food safety and animal health-let countries decide this as appropriate to their national situation

8.2 Suggest deleting this section

*Rationale* This information is covered under CAC/RCP 61 and OIE and does not belong in this surveillance document.

## SECTION 9: A STEPWISE APPROACH TO INTEGRATED MONITORING AND SURVEILLANCE PROGRAMME OF AMR BACTERIA

Paragraph 2 - The stepwise approach ~~to~~ on the monitoring and surveillance of AMR bacteria and the use of AMs that is presented in these guidelines ~~references WHO AGISAR Guidelines for integrated surveillance of AMR in foodborne bacteria~~ 4 should be read in conjunction with Codex Guideline 77 - Risk Analysis for Foodborne Antimicrobial Resistance and relevant Chapters of the OIE Terrestrial (6.7, 6.8) and Aquatic Animal Health Codes (6.3, 6.4) including reporting options of OIE Guidance for the collection of data on antimicrobial agents used in animals 5). In addition, the WHO-AGISAR guideline, "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria: Application of a One Health Approach"-should also be considered.

*Rationale* Codex texts should be read in **conjunction** with other standards developed through transparent processes of review and consensus by Member Countries such as those recognized under the World Trade Organization (WTO) SPS agreement [i.e. Codex, OIE, and International Plant Protection Council (IPPC)]. Expert-derived technical recommendations may also be **considered** where relevant. The WHO uses an expert group without Member State review, so Codex guidelines, which carry trade implications, should not make legally binding what is in the WHO document, but rather make reference that the information can be considered.

*Rationale* The WHO AGISAR Guidelines are not consensus-based but rather formed by expert groups.

### Pre-requisites

Add new paragraph - **An informed gap analysis process presents a significant component of the proposed work. Countries should identify challenges that they currently face in collecting and reporting AMU and AMR data. The challenges may be related to data management; data security; resources available for establishing a monitoring and surveillance program, as well as the willingness and ability of stakeholders to contribute to the NAP.**

Paragraph 1 - Revise first sentence as: “Monitoring and surveillance should focus on ~~priority bacterial species and/or determinants of AMR, priority AMs~~ the food commodity, the AMR bacteria and the antimicrobial agent(s) to which resistance is expressed as described in CAC/GL 77. e.g. WHO list of critically important antimicrobials for human medicine (reference6) and a range of sample sources as determined at the national level.

*Rationale* Revised to be consistent with CAC/GL 77

Step 1 bullet 1 – Revise as: “Monitoring of foodborne AMR bacteria to a range of priority AMs that have been ranked as ~~highest priority~~ critically important for human health [as defined by ~~Consideration can be given to national lists, consensus-based guidelines, or the~~ WHO in the list of CIAs for human medicine, reference].”

*Rationale* If a country has a national list that can take precedence and the WHO CIA list was generated by an expert group and not consensus-driven. “Critically” was chosen over “priority” because the language is directly out of the WHO CIA list and could cause some confusion if users are looking for highest priority agents (this is another category in addition to critically important in the latest WHO list).

Step 1 – Add a Bullet—Scope and design elements informed by identified hazards/risks.

*Rationale* This added bullet gives consistency with steps 2 and 3

Step 1 bullet 4 – Revise as: “**Consider sources for antibiotic use data as described in OIE chapters 6.3 and 6.8. Data from veterinary medicinal product registration authorities, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and pharmaceutical industry associations can be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration. The use of a variety of surveillance vehicles may be considered in the development of national systems, including public-private partnerships for data collection. Such supplemental and innovative surveillance approaches may facilitate better resource management and ultimately enhance the development of more accurately based data collection processes.**

*Rationale* Sources of data will vary from country to country. This language is consistent with OIE 6.8 and gives the reader practical information tying it to vet registrations, which some countries have not put into practice.

Step 2 bullet 2 – Revise as: “Monitoring and surveillance of foodborne AMR bacteria to a broader range of priority AMs that have been ranked as critically and highly important for human health [**Consideration can be given to national lists or consensus-based guidelines, or the WHO** in the list of CIAs for human medicine, reference].”

*Rationale* Language aligned with scope of TFAMR work. Highly struck to be consistent with Step 1 bullet 1 above. Critically important AM’s gives countries an important place to start that everyone can agree on. If a country has a national list, that can take precedence. The WHO CIA list was generated by an expert group and not consensus-driven.

Step 2 bullet 5 - Pro-active surveillance activities as informed by monitoring and human **foodborne AMR illness** epidemiology.

*Rationale* Language added to stay within scope of Task Force work and Codex

Step 2 bullet 6 Delete “~~Alignment of food chain methodologies and practices with those used in other sectors.~~”

*Rationale* This statement is too aspirational and does not give countries any guidance.

Step 2 bullet 7: Revise as: “Develop a national program for estimating antimicrobial sales and/or use data with appropriate metrics in appropriate agriculture commodities where the greatest estimated use is occurring.” Strike: “~~Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group.~~”

*Rationale* Directing collection of sales data is too prescriptive to belong in a document that could be used for addressing trade concerns. Many developing countries have not even achieved this level of detailed data collection.

*Rationale* Sources of data will vary from country to country. This language is consistent with OIE 6.8 and gives the reader practical information tying it to vet registrations, which some countries don’t even have yet.

Step 3 bullet 2 – Revise as: “Monitoring and surveillance of foodborne AMR bacteria to a broad range of priority AMs that are important for human health [as defined by **national lists or consensus-based guidelines** WHO in the list of CIAs for human medicine, reference].”

*Rationale* If a country has a national list, then that can take precedence. The WHO CIA list was generated by an expert group and not consensus-driven.

Step 3 bullet 5 - Pro-active surveillance activities as informed by monitoring and human **foodborne AMR illness** epidemiology.

*Rationale* Language added to stay within scope of Task Force work

Step 3 bullet 6 Delete “~~Alignment of food chain methodologies and practices with those used in other sectors.~~”

*Rationale* This statement does not appear appropriate to include in a trade document. Most high resource countries have not even determined how to do this.

Step 3 bullet 7: Revise as: “Implement a national program for estimating antimicrobial sales and/or use data with appropriate metrics in appropriate agriculture commodities where the greatest estimated use is occurring.” Strike: “~~Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group and route of administration.~~”

Step 3 bullet 8: Revise the bullet to read: “Integrated analysis and reporting of data from the food chain ~~and other sectors~~ **to evaluate with animal, human and relevant environmental aspects for a (“One Health” approach).**”

*Rationale* Animal, human and environmental sectors are outside Codex scope but an integrated approach is one that should be added to other data streams, not be duplicative of them. The Codex component should complement the other pieces so the integration would include Codex, OIE, WHO, FAO, etc. Codex does not have to encompass everything.

Step 3 bullet 9: Change “period” to “periodic” to read: “**Periodic** review and resetting of the risk analysis cycle as monitoring and surveillance data, together with new technology, is analysed and reported.

#### Table 1: Description of Steps

Step 1 – Scope: Revise as: “Priority ~~AMs and foods~~ **food commodity, the AMR bacteria, resistance determinants, and the antimicrobial agent(s) to which resistance is expressed as defined at national level as hazards or risks to health**”.

*Rationale* – Provide consistency with GL77 and clarity from text to table

Step 2 – Design: Revise “~~Alignment of Harmonize methodologies across sectors- for sample types in human, animal and retail meats to the extent possible~~”

*Rationale* It is not possible to harmonize methodologies across all sectors. It is better to be specific and give some guidance to countries on what is achievable.

Step 2 – Scope: Revise as: “Priority AMs and representative foods as determined by risk profile.”

*Rationale* – Provide clarity from text to table

Step 3 – Design: Revise “~~Alignment of Harmonize methodologies across sectors- for sample types in human, animal and retail meats to the extent possible~~”

*Rationale* It is not possible to harmonize methodologies across all sectors. It is better to be specific and give some guidance to countries on what is achievable.

Commented [RM2]: Revise to say, “... for sample types from retail meat products, domestic animals, and human exposures, to the extent possible.” My first reading of the statement conjured up revolting thoughts of cannibalism. See step 3 below, also.

#### SECTION 10: DESIGN OF MONITORING AND SURVEILLANCE PROGRAMMES

References to crops should await scientific advice. New text if proposed below ONLY if incoming scientific advice requested at TFAMR5 supports inclusion of crops. This language should be left bracketed.

[There is limited information regarding the impact to foodborne illness from AMR human pathogens or genes originating from crops. For surveillance of foodborne bacteria derived from crops, standardized antimicrobial susceptibility test methods and interpretive categories for such bacteria would require significant investment to generate methods and data comparable to that of CLSI or EUCAST. Ideally, competent authorities determine with crop experts and stakeholders, the research gaps, food safety priorities, and needs for monitoring for AMR bacteria and/or genes in crops as applicable to national circumstances. As methodology and data collection are refined, food safety priorities are identified, and resources allow, multi-year, region-specific monitoring of AMR bacteria and/or genes can help assess the extent and distribution of AMR bacteria and/or genes in the region to support risk assessments for foodborne AMR bacterial].

Paragraph 1 – Add third sentence and revise the existing third sentence to read as: “The design will be primarily determined by the resources available and the technical capability of the Competent Authority. **Prioritization of design elements (e.g. bacteria, food products, and antimicrobial agents) is typically a function of the risk manager, rather than the surveillance system administration.** An ability to change the design in response to new ~~policy~~ **risk management** objectives, scientific knowledge and risk assessment is a key attribute.

*Rationale* It should be clarified here that the prioritization of the AMR bacteria/food/antimicrobial is a function of the risk manager, and not the surveillance system administration. Codex is a risk management body so policy is edited to risk. Here is a place we can give countries guidance in how systems work.

Edits suggested as below:

- o 10.1 1 - A stepwise approach is key to ensuring continuous enhancement of the monitoring and surveillance programme, **however it is essential as enhancements are made to consider the**



**importance of historical data to determine trends.** The following aspects should be **factored to** taken into account in arriving at an appropriate step for the design and implementation of a programme:

- Bullet 2 – Revise as: “Veterinary Infrastructure, to include veterinary access, level of available veterinary care and regulatory structure for veterinary medicine.”

*Rationale* Frame the term veterinary infrastructure for a global audience.

- Bullet 3 - Pharmaceutical infrastructure **to include drug manufacturing capacity, innovation/development and distribution of veterinary drugs**

*Rationale* Frame the term pharmaceutical infrastructure for a global audience.

- Add the following bullets to the existing list in 10.1.1:
  - **Capacity of the Food Safety Control System**
  - **Other relevant national circumstances**

*Rationale* As methods and data interpretation change, it is important to give proper context. Additional bullets help add contextual information.

- 10.1 2 -
  - Bullet 2 – Type and use of **medically important** AMs along the food chain
  - Add: **Relevant research publications**

*Rationale* Focus on antimicrobials important for therapeutic use in human medicine and additional information from research for consideration.

- 10.4 Sample sources

Paragraph 1 – Modify first sentence to read: “Member Countries may wish to consider, for reasons of cost and administrative efficiency, collecting human and agricultural AMR data in a single programme while addressing confidentiality needs to facilitate data collection. A consolidated programme would also facilitate comparisons of bacteria, and phenotypic and genotypic data as available for risk analysis purposes.

Strike: ~~Data from the samples can be integrated from other sources, e.g. human isolate.~~

*Rationale* Provide more clarity.

Paragraph 2 - Modify third sentence to: “Samples collected from food-producing animals ~~should can~~ be taken from the same animal species as retail meat food samples in an integrated programme; **however, one cannot assume that there is a relationship between what is found on farm and at retail because of the many processing steps that occur between the farm and retail levels.**”

*Rationale* The statement as written appears to assume that what is found on farm will correlate with what is found at retail and that is not scientifically supportable.

Last Paragraph – Strike “vegetables” to read: “The types of food samples include meat (beef, chicken, turkey, pork, etc.), fish, dairy product, other edible tissues (liver, kidney, etc.), **vegetables**, and processed food **of animal origin.**”

*Rationale* Need to await scientific advice for support to include crops in this surveillance document.

Last sentence – Delete ~~Food samples should reflect the purchasing habits of the consumer (e.g. in open markets or chain stores).~~

*Rationale* Too many samples above to break down into such categories. Food samples are not static. They are here today, eaten tomorrow and vary seasonally. Great for research projects but if this is the expectation for countries, it is aspirational and not practical. This is NOT doable in the US.

- 10.8 1
  - Revise header to Methods and interpretive **categories criteria**
  - Paragraph 2 – Revise as “...from EUCAST **or CLSI.**”

*Rationale* Editorial

- Paragraph 3 – Revise as: “...as well as the categorization of the isolate (**susceptible, intermediate, resistant, wild-type or non-wild type.**)”

*Rationale* Since both clinical breakpoints and/or epidemiological cut-off values may be appropriate for use in any given program, additional clarity is needed.

- Paragraph 6 - Revise as: “The use of epidemiological cut-off values, rather than clinical breakpoints, as **the** interpretive **category** criteria **may should** allow for optimum sensitivity for detection of acquired resistance.”

*Rationale* The statement needs to be less definitive as there are several factors to consider. For some resistance mechanisms, the MIC shift is more pronounced and either Epidemiologic Cut-Off Value (ECOFF)s or clinical breakpoints would suffice. Which one to use depends on the goals of the surveillance system—detect emerging resistance (ECOFFs) or inform on resistance trends and patient care (clinical breakpoints). In the case of foodborne AMR bacteria, human clinical breakpoints may be the most important. Clinical breakpoints and ECOFFs are not interchangeable.

## 11. SURVEILLANCE OF NATIONAL ANTIMICROBIAL SALES AND USE DATA FOR USE IN ANIMALS AND CROPS

- 11.1 Paragraph 4: Delete

*Rationale* Metrics for use methodology have taken high resource countries many years to develop and appropriate metrics are still under consideration and not agreed to within many countries. Metrics should be further developed within OIE with appropriate animal health experts to consider use rather than be debated within Codex whose role is to address food safety rather than debate on-farm metrics calculations.

- 11.2: Strike all existing text under 11.2 and replace existing text with:

**The antimicrobial agents, classes or sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.**

**Nomenclature of antimicrobial agents should comply with international standards where available.**

**The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic or non-therapeutic).**

*Rationale* The existing language is duplicative of Section 9 (see suggested edits above) and this proposed language offers clarity and is harmonized with OIE Ch. 6.8

11.3 and 11.4 should be deleted (see text above under Section 10 for crops) and await scientific advice.

## SECTION 12: IMPLEMENTATION OF THE MONITORING AND SURVEILLANCE PROGRAMMES

### 12.4 Analysis and reporting of results

Paragraph 6 – Suggested rewrite of existing sentence: Information provided from monitoring and surveillance of AMR should be analyzed ~~combined with information on~~ **viewed through a One Health lens that includes not only the amounts of antimicrobial agents that are used AMU in primary production in national settings, especially with regard to direct use associated with the food chain. Sources of such data include human and veterinary medicine, but also the many pathways among people, animals, and their shared environment connecting resident bacterial populations.**

*Rationale* Collecting national AMU data from farms is resource intensive. And connecting information regarding what antimicrobials were used in animals on the farm, what resistance developed, what resistance may have already been present, what resistance survived the process of slaughter and processing, and what resistance may have contaminated food products derived from the animal that was found through a surveillance system must consider the ecology of resistance and other external sources that could have contaminated animal products. The development and spread of AMR does not just involve the use of antimicrobial drugs. There are many pathways among people, animals, and the environment connecting resident bacterial populations in one population or setting to those in other populations or settings. The ability of bacteria to move from one setting to another, sometimes over large geographic distances and among the different populations, makes it difficult to know with certainty where resistant strains of bacteria originated. Bacteria have the ability to share genetic material in a variety of ways.

12.4, Last sentence of paragraph 6: Add appropriate data source or delete.

*Rationale* The sentence is incomplete as written.

## SECTION 13 REVIEW

### Section 13.1 Integrated analysis of results

Paragraph 1 – Revise as: “Combined analysis of results and data from a programme of integrated surveillance of **AMR** in foodborne bacteria comprises the ~~bringing together~~ **synthesis** of antimicrobial use **AMU** in humans and animals and antimicrobial resistance **AMR** data across all sectors including humans, food-producing animals, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system **and epidemiological context.**”

*Rationale* The statement does not include anything beyond resistance AMR and AMU. See rationale provided above for 12.4.

Paragraph 2 – Revise first sentence as: “Data from relevant human isolates should include data from those **more relevant** foodborne pathogens ~~more relevant~~ according to national epidemiological information (e.g. *Salmonella*, *Campylobacter*) and whenever possible, commensal flora such as *E. coli* and potentially ~~also~~ *Enterococcus* spp. ~~from healthy humans.~~”

*Rationale* Countries are looking for guidance on where to utilize scarce resources. Collecting isolates from healthy humans does not appear to be a priority area on which to spend resources designated for foodborne AMR surveillance.

### Section 13.3 Ineffective use

This section should be deleted.

*Rationale* Pharmacovigilance is duplicative of what is being revised in CAC/RCP 61 and OIE Ch. 6.9.

## SECTION 14: RISK COMMUNICATION

Paragraph 2 - Value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce **inappropriate** use of AMs and preserve the effectiveness of AMs in humans and animals.

*Rationale* With changes in animal populations and disease conditions, the goal should be to reduce inappropriate use rather than total quantity used. Considerations might include an increase in animal population or high disease incidence.,

New Paragraph 3 - **Antimicrobial susceptibility testing methods, emerging genotypic approaches, and interpretive categories used in surveillance should be clearly described, and differences transparently explained to show where data may and may not be directly comparable.**

## SECTION 15: TRAINING

Paragraph 1 – The first sentence should be revised as: “A **Competent authorities should undertake training using** a tiered approach to implementation at the national level ~~is required~~, proportional to each step.”

*Rationale* The statement is too prescriptive for a Codex document that has trade implications.

**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** CLA/RISE Regulatory Conference  
**Date:** Wednesday, April 18, 2018 1:44:35 PM

---

Sheryl- thanks for reaching out regarding the session on lessons learned. We are getting some pushback and do now plan to rework a different session.

Thank you for agreeing originally but don't want to put any of you in the position of having to discuss these issues publicly now.

You are off the hook- but we will bring you back in.

Janet

(b) (6) (direct)

(b) (6) (mobile)

**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Ethan Mathews](#)  
**Subject:** Re: WPS  
**Date:** Thursday, June 14, 2018 3:10:20 PM

---

I will call shortly. One task to complete and I will call your cell.  
Sheryl

Sent from my iPad

On Jun 14, 2018, at 2:08 PM, Ethan Mathews [\(b\) \(6\) @croplifeamerica.org](#) wrote:

Sheryl –

Could you give me a ring when you have a moment? Cell is best: [\(b\) \(6\)](#)

Ethan Mathews  
Director of Government Affairs  
CroLife America  
[\(b\) \(6\) @croplifeamerica.org](#)  
[\(b\) \(6\)](#) (o)  
[\(b\) \(6\)](#) (m)

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Rachel Lattimore](#)  
**Subject:** Re: CLA/ABA Event May 8  
**Date:** Wednesday, May 2, 2018 7:21:44 PM

---

Thanks! I shared with a couple of folks and encouraged them to attend!  
Sheryl

Sent from my iPhone

On May 2, 2018, at 5:35 PM, Rachel Lattimore (b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)> wrote:

Sheryl,

It was a pleasure to see you earlier today. Here's a copy of the event agenda I mentioned then. The event is open to the public and free of charge. It may be of interest to you or your staff.

Best regards,

Rachel

Rachel G. Lattimore  
Senior Vice President, General Counsel, Secretary  
CropLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005  
(b) (6) – direct  
(202) 296-1585 – main  
(b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
[www.croplifeamerica.org](http://www.croplifeamerica.org)

<ABA CLA 2018 Event Agenda.pdf>

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Ethan Mathews](#)  
**Subject:** Re: PPC meeting  
**Date:** Friday, June 15, 2018 6:59:19 PM

---

You, too!

Sent from my iPhone

On Jun 15, 2018, at 5:03 PM, Ethan Mathews (b) (6) [@croplifeamerica.org](mailto:@croplifeamerica.org) wrote:

Perfect! We look forward to it! Hope you are able to enjoy this great weather :)

Ethan

On Jun 15, 2018, at 4:47 PM, Kunickis, Sheryl - OSEC  
<[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

Absolutely. I am hoping the meeting won't go too long and I can leave from there directly.

Sent from my iPhone

On Jun 15, 2018, at 4:35 PM, Ethan Mathews (b) (6) [@croplifeamerica.org](mailto:@croplifeamerica.org) wrote:

The meeting lasts from 10:30 to noon. Do you think you could make it there by 1130?

On Jun 15, 2018, at 4:32 PM, Kunickis, Sheryl - OSEC  
<[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

Hi Ethan,  
I am in a meeting with an Under Secretary until 10:30. Can this be pushed out to a little later as I will need time to travel to your offices?  
Thanks,  
Sheryl

Sent from my iPhone

On Jun 15, 2018, at 3:44 PM, Ethan Mathews  
(b) (6) [@croplifeamerica.org](mailto:@croplifeamerica.org) wrote:

Sheryl –

Thank you for the conversation yesterday.

I wanted to extend an invite to you and Elizabeth to speak to members of the Pesticide Policy Coalition at our upcoming meeting on Thursday, June 21, from 10:30-noon at CLA offices. We are hoping that you could address the section 10109 language in the Senate Farm Bill and perhaps a report on progress on Administrative improvements around ESA/FIFRA.

Ethan Mathews  
Director of Government Affairs  
CroLife America

(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)

(b) (6) (o)

(b) (6) (m)

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**From:** [Fajardo, Julius](#)  
**To:** (b) (6) @croplifeamerica.org; (b) (6) @syngenta.com; (b) (6) @dow.com; (b) (6) @dupont.com; (b) (6) @bayer.com; (b) (6) @basf.com; (b) (6) @basf.com; (b) (6) @iskbc.com; (b) (6) @fmc.com; (b) (6) @adama.com; (b) (6) @valent.com; Gilberto Olaya  
**Cc:** [Sundin, George](#); [Anandaraman, Neena - OSEC](#); [Jim, Janet Collins](#); [Barron, Jim](#); [Greg Mattern](#); (b) (6) @nufarm.com; [Charlotte Sanson](#); (b) (6) @adama.com  
**Subject:** RE: [Caution: Suspicious Attachment]Re: Crop language regarding antimicrobial use  
**Date:** Monday, June 11, 2018 6:55:39 AM

Ray,  
 My initial thoughts below.

**From:** Ray McAllister [mailto:(b) (6) @croplifeamerica.org]  
**Sent:** Saturday, June 09, 2018 10:57 AM  
**To:** (b) (6) @syngenta.com; (b) (6) @dow.com; (b) (6) @dupont.com; (b) (6) @bayer.com; (b) (6) @basf.com; (b) (6) @basf.com; (b) (6) @iskbc.com; (b) (6) @fmc.com; (b) (6) @adama.com; (b) (6) @valent.com; Gilberto Olaya (b) (6) @syngenta.com>  
**Cc:** [Sundin, George](#) (b) (6) @msu.edu>; [Anandaraman, Neena - OSEC](#) (b) (6) @osec.usda.gov>; [Fajardo, Julius](#) <Julius.Fajardo@ARS.USDA.GOV>; [Jim](#) <(b) (6) @ccqc.org>; [Janet Collins](#) (b) (6) @croplifeamerica.org>; [Barron, Jim](#) (b) (6) @arysta.com>; [Greg Mattern](#) (b) (6) @nufarm.com>; (b) (6) @nufarm.com; [Charlotte Sanson](#) (b) (6) @adama.com>; (b) (6) @adama.com  
**Subject:** [Caution: Suspicious Attachment]Re: Crop language regarding antimicrobial use

FRAC, et al.:

Neena Anandaraman of USDA has sent an updated draft of the proposed language (attached).

I'd like to raise a few concerns, based on my profound ignorance of antibiotic use:

- There are only three antibiotics registered for crop use in the US (streptomycin, kasugamycin, and oxytetracycline).

Do they have different modes of action?

Based on the 2018 FRAC Code List, below is a detailed comparison of the three registered antibiotics for crop use. Different FRAC codes would entail different modes of action.

<u>TARGET SITE AND CODE</u>	<u>GROUP NAME</u>	<u>CHEMICAL</u>	
<u>GROUP</u>	<u>COMMON NAME</u>	<u>COMMENTS</u>	
	<u>FRAC CODE</u>		
<b>D3</b> protein synthesis (ribosome, initiation step)	hexopyranosyl antibiotic	hexopyranosyl antibiotic	kasugamycin
			Resistance known in fungal and bacterial ( <i>P.</i> <i>glumae</i> ) pathogens. Medium risk. Resistance management required.
			<b>24</b>

**D4**

protein synthesis (ribosome, initiation step)	glucopyranosyl antibiotic	glucopyranosyl antibiotic	streptomycin	Bactericide. Resistance known. High risk. Resistance management required.	<b>25</b>
---	------------------------------	------------------------------	--------------	--	-----------

**D5**

protein synthesis (ribosome, elongation step)	tetracycline antibiotic	tetracycline antibiotic	oxytetracycline	Bactericide. Resistance known. High risk. Resistance management required.	<b>41</b>
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Are they registered for the same crop uses? If the answers to these questions are no, it does not bode well for resistance management strategies based on rotation of treatments. Guidance based on impractical or impossible approaches loses credibility.

The table below summarizes the MRLs in key crops to which antibiotics are applied. All three antibiotics are registered for apples and pears.

Antibiotic	Crop	MRL
Streptomycin	Apples / Pears	0.25 ppm
	Citrus Group 10-10	2.00 ppm*
Kasugamycin	Apples / Pears	0.20 ppm
	Walnuts	0.04 ppm
	Cherries	0.60 ppm
Oxytetracycline	Apples / Pears	0.35 ppm
	Peaches / Nectarines	0.35 ppm
	Citrus Group 10-10	0.40 ppm*

\*Under a Section 18 emergency exemption

- How much difference will it mak to prohibit the use of animal manure as fertilizer or prohibit grazing of livestock? Does this consign manure to hazardous waste? Grazing may be a practical means of weed control and maintenance of cover crops.

~~~~~

THINK Before You Open!

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**From:** [CropLife America & RISE](#)  
**To:** [Elizabeth Hill](#)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Tuesday, March 27, 2018 7:58:03 AM

Header\_2.15.18



Dear Elizabeth:

Your registrat on has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

| Registration Information: |                                                                                                      |                      |
|---------------------------|------------------------------------------------------------------------------------------------------|----------------------|
| Registration Items        |                                                                                                      |                      |
| Elizabeth Hill            | CLA & RISE 2018 Regulatory Conference                                                                |                      |
| Sessions                  |                                                                                                      |                      |
| Elizabeth Hill            | Networking Breakfast                                                                                 | 26-Apr-2018 7:00 AM  |
| Elizabeth Hill            | General Session                                                                                      | 26-Apr-2018 8:00 AM  |
| Elizabeth Hill            | Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process                      | 26-Apr-2018 10:30 AM |
| Elizabeth Hill            | Networking Lunch                                                                                     | 26-Apr-2018 12:00 PM |
| Elizabeth Hill            | Series II - Charting a Path Forward for the Use of Population Modeling in Ecological Risk Assessment | 26-Apr-2018 1:15 PM  |
| Elizabeth Hill            | Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome    | 26-Apr-2018 3:00 PM  |
| Elizabeth Hill            | Networking Reception                                                                                 | 26-Apr-2018 4:45 PM  |
| Elizabeth Hill            | Networking Breakfast                                                                                 | 27-Apr-2018 7:00 AM  |
| Elizabeth Hill            | General Session                                                                                      | 27-Apr-2018 8:00 AM  |
| Elizabeth Hill            | Series IV - Challenges and Recommendations for Generating and Utilizing Higher-Tier Data in Ecologic | 27-Apr-2018 9:45 AM  |
| Additional Information    |                                                                                                      |                      |
| Elizabeth Hill            | When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee       |                      |

[Click here for the event agenda](#)

[Add to Calendar](#)

**Event Registration Confirmation number: FXNT8DXHKQV**

We look forward to seeing you in April!

CropLife America & RISE

[Share on Twitter](#)

[Book your group hotel for CropLife America & RISE Regulatory Conference](#) until April 6!

Footer\_2.15.18



**Content**

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Having trouble with the link? Simply copy and paste the entire address listed below into your web browser [http://www.cvent.com/d/Vs\\_T8II780-EV08tiikv5Q/lnw8/P1/OR?](http://www.cvent.com/d/Vs_T8II780-EV08tiikv5Q/lnw8/P1/OR?)

\*\*\*\*\*

If you no longer want to receive emails from Francesca Purcell please click the link below. [Opt-Out](#)



**From:** [Courtney DeMarco](#)  
**To:** [Ray McAllister](#); [Sci Reg](#); [Amy Asmus](#)  
**Cc:** [Ashlea Rives Frank](#); [George Sabbagh](#); [Doreen Manchester](#); [Underwood Russell USGR](#); [Charlotte Sanson](#); [Courtney Demarco](#); [\(b\) \(6\)](#); [Mike Kellogg](#); [Gus Zieske](#); [Lisa Nichols](#); [Tessa Scown](#); [JACKSON - GHEISSARI](#); [AMELIA ELIZABETH TAG/1920](#); [LEOPOLD, VINCENT A \[AG/1005\]](#); [Carrie Tackema](#); [John Carbone](#); [John M Brausch](#); [Bob Mann](#); [Jeff Giddings](#); [Catherine M Holmes](#); [Green, Charles](#); [Jonynas, Ann](#); [Layton, Ray](#); [Mark Trostle](#); [Cain, Jack](#); [Laurent Oger](#); [Trish Sheehy](#); [Daniel Eugene Edwards](#); [Steven D. Bennett](#); [Holt, Doug](#); [Shari Long](#); [Ann Blacker](#); [Alan Samel](#); [Faith Kee](#); [Naq, Jayanta](#); [Matt McCoole](#); [Jackson, Scott](#); [Turnbough, Anne](#); [Ephi Gur](#); [Linda Mitchell](#); [Greg Wuthnow](#); [Seibert, Nicholas](#); [Patti Turner](#); [Khalid Akkari](#); [Zeller, Samuel](#); [Nicole O'Loughlin](#); [Douglas Hines](#); [Christian Picard](#); [Thatcher Mary Kay USWS](#); [Adriana M Doi](#)  
**Subject:** Pre-PPDC Breakfast Meeting - NEW LOCATION  
**Attachments:** [Final Agenda for May 2018 PPDC Meeting 4 18 18.docx](#)

Update on Location 4/30/18:

Renaissance Capital View, 2800 South Potomac Avenue, Arlington VA 22202, Studio A (from front door, go to your left and up the main staircase to the second floor, the room is to the right of the staircase on the opposite side).

If you have any questions the day of the breakfast, feel free to call or text Courtney @ [\(b\) \(6\)](#).

Please RSVP again to the calendar invite whether you plan to attend or cannot attend the breakfast.

Thank you,

Courtney DeMarco and Ray McAllister

TO: [CLA Members, Friends and Allies](#) (on BCC: line)

FROM: [Ray McAllister & Courtney DeMarco](#), [CLA](#)

The next Pesticide Program Dialogue Committee meeting takes place on Wednesday and Thursday, May 2 and 3. CLA invites you to our customary breakfast sessions for those attending each day's PPDC session in Crystal City, VA. The locale is the Renaissance Capital View, 2800 South Potomac Avenue, Arlington VA 22202 Cinnabar Restaurant, level 2 of the Hyatt Regency Crystal City Hotel (2799 Jefferson Davis Highway, Arlington, VA 22202), across the street from the OPP headquarters where the PPDC meeting takes place. These are opportunities to compare notes on the coming agenda items for the day, and the discussion of the day before. EPA's final agenda for the PPDC meeting is attached. We welcome your contributions to notes on agenda topics for ag allies serving on the PPDC (By Monday April 30), which we will share at the breakfast sessions.

This invitation is going to Ag allies serving on the PPDC, Members of the Pesticide Policy Coalition, CLA committees, and other ag allies. If there are others you would like us to invite, or you are not certain if they are already included, please let us know, and we will invite them directly (rather than forwarding this message).

Please respond promptly, as attendance may be limited by the space available. We need a separate RSVP for each day you plan to attend the breakfast. Unfortunately, call-in participation will not be possible for the breakfast discussion.



## PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA

Conference Line: 1-866-299-3188; Conference Code: (b) (6)

### Wednesday, May 2, 2018

- 9:00-9:20**      **Welcome and Opening Remarks**  
*Charlotte Bertrand, Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention*  
*Rick Keigwin, Director, Office of Pesticide Programs*
- 9:20-9:30**      **Introductions by PPDC Members**
- 9:30-10:30**     **1. Pesticide Registration Improvement Act (PRIA) Update**  
**Session Chair:** *Steve Schaible, OPP PRIA Coordinator*  
 9:30 – 10:10    EPA  
 10:10-10:30    PPDC Discussion
- 10:30-10:45**   **Break**
- 10:45-11:45**   **2. Smart Label Project/e-CSF**  
**Session Chair:** *Patricia Parrott, Senior Advisor, Field and External Affairs Division*  
 10:45-11:15    EPA  
 11:15-11:45    PPDC Discussion
- 11:45-1:15**     **Lunch**
- 1:15-2:00**     **3. 21st Century Toxicology: OPP's Efforts on Non-Animal Alternative Testing for the Acute 6-Pack**  
**Session Chairs:** *Anna Lowit, Senior Science Advisor, OPP*  
*Garland Waleko, Pesticide Re-Evaluation Division*  
 1:15-1:35      EPA  
 1:35-2:00      PPDC Discussion
- 2:00-3:00**     **4. 21st Century Toxicology: OPP's Efforts on Reduced Animal Testing for Ecological Risk Assessment - New Approach Methodologies and Retrospective Analyses**  
**Session Chair:** *Kimberly Nesci, Deputy Director, Environmental Fate and Effects Division*  
 2:00-2:30      EPA  
 2:30-3:00      PPDC Discussion
- 3:00-3:15**     **Break**



- 3:15-4:30**     **5. Regulatory Updates**  
**Session Chairs: OPP Senior Leadership Team**  
*a. Novel Mosquito Products*  
*b. Biopesticides*  
*c. Registration Review Update*
- 4:30-4:45**     **Public Comment**
- 4:45**            **Meeting Adjourns**

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**Thursday, May 3, 2018**

- 9:00-10:00**    **6. Endangered Species Act (ESA) Work**  
**Session Chair: Marietta Echeverria, Director, Environmental Fate and Effects Division**  
9:00-9:30        EPA  
9:30-10:00     PPDC Discussion
- 10:00-10:45**   **7. Communication Plan on Resistance Management**  
**Session Chair: Wynne Miller, Director, Biological and Economic Analysis Division**  
10:00-10:25    EPA  
10:25-10:45   PPDC Discussion
- 10:45-11:00**   **Break**
- 11:00-11:30**   **8. Status Update from the Public Health Workgroup**  
**Session Chairs: Arnold E. Layne, Deputy Director, OPP**  
**Susan Jennings, Senior Advisor on Public Health, OPP**  
11:00-11:15    EPA  
11:15-11:30   PPDC Discussion
- 11:30-11:45**   **Discussion Topics for Next PPDC Meeting**  
**Session Chair: Rick Keigwin, Director, OPP**
- 11:45-12:00**   **Public Comment**
- 12:00**            **Meeting Adjourns**



**From:** [Ray McAllister](#)  
**To:** [Chao, Julie - Fas](#); [Doherty, Julia M. EOP/USTR](#); [Rasmussen, Mark - FAS](#); [Miller.DavidJ@epa.gov](#); [Herndon, George](#); [Kunickis, Sheryl - OSEC](#); [julie\\_e\\_callahan@ustr.eop.gov](#)  
**Cc:** [Janet Collins](#)  
**Subject:** Fw: Revised Commission Policy Document on Handling of Import Tolerances for substances triggering EU hazard cut-offs in Reg 1107/2009  
**Date:** Wednesday, May 23, 2018 8:45:30 AM  
**Attachments:** [Handling of import tolerances for active substances falling under the cut-off criteria.docx](#)

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Julie, et al.:

Has this document come to your attention? Does it trigger WTO notification? How will USG respond?

Ray McAllister  
 CropLife America

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**From:** Peter Day [\(b\) \(6\)](#) @ecpa.eu>  
**Sent:** Tuesday, May 22, 2018 7:11 PM  
**To:** Christoph Neumann; [\(b\) \(6\)](#) @croplife.org; Janet Collins; Ray McAllister  
**Cc:** [\(b\) \(6\)](#) @croplife.org; Stuart Rutherford; Graeme Taylor  
**Subject:** Revised Commission Policy Document on Handling of Import Tolerances for substances triggering EU hazard cut-offs in Reg 1107/2009

Dear Colleagues

FYI attached the revised Commission policy document on ITs received **informally** today, this should be discussed at the SCOPAFF residues meeting in June. There is no formal vote needed or expected as this is a policy document not legislation, but obviously the Commission would like to ensure as many member states as possible support the policy.

The document has been sent to the third country missions here in Brussels, and several food chain partners are aware. The document provides the long sought clarity but it's not the direction we wanted. If you have any queries on the text let us know. We still need to discuss what advocacy options we have.

Kind regards  
 Peter

*This note has not been endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

## **Handling of import tolerances for active substances falling under hazard-based criteria of Regulation (EC) No 1107/2009**

Regulation (EC) No 1107/2009<sup>1</sup> introduced hazard-based criteria related to human health for the approval of active substances used in plant protection products. Following these cut-off criteria laid down in points 3.6.2, 3.6.3, 3.6.4, and 3.6.5 of Annex II to the Regulation, active substances cannot in principle be approved or renewed if they are classified under certain hazard classes in accordance with Regulation (EC) No 1272/2008 unless a derogation from complying with these criteria applies.

Regulation (EC) No 396/2005<sup>2</sup> provides rules for the setting of maximum residue levels (MRLs) in food and feed. These MRLs apply to domestic and imported products. For the latter, it is also possible to set specific import tolerances (ITs) on request of a third country provided they are supported by data and are considered safe for consumers. When an active substance is not approved under Regulation (EC) 1107/2009, its MRLs are set to the limit of determination (LOD) under Regulation (EC) No 396/2005, and existing ITs are automatically revoked. This can lead to restrictions for trade in food and feed as such substances could still be used in third countries, who might then submit requests for ITs. Regulation (EC) No 396/2005 does not mention the cut-off criteria referred to above since it was adopted prior to Regulation (EC) No 1107/2009 and it is therefore necessary to decide how existing ITs and new IT requests will be handled for active substances that have not been approved as a consequence of the application of the cut-off criteria.

### **Initial approach**

The initial approach for the handling of existing ITs and new IT requests consisted in deleting existing ITs and refusing new IT requests for active substance falling under the cut-off criteria

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<sup>1</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, ([OJ L 309, 24.11.2009, p. 1](#)).

<sup>2</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, ([OJ L 70, 16.3.2005, p. 1](#)).

of Regulation (EC) No 1107/2009<sup>3</sup>, but only when the non-compliance is specifically recognised in an EU legal act, like a non-renewal decision. From a procedure point of view, the rejection of new IT requests by Member States without any risk assessment was envisaged.

This approach was presented and discussed at the PAFF Committee meetings in September and November 2017. It was also discussed with stakeholders and third countries.

These discussions pointed to issues of compliance with the legal requirements laid down in Regulation (EC) No 396/2005 regarding the management of IT requests and highlighted the risk of litigation before WTO panels for fixing restrictions on trade not based on a risk assessment, as required by the SPS agreement.

### **Revised approach**

Taking into account these concerns, the following revised approach was developed.

#### *Existing ITs for active substances falling under the cut-off criteria*

MRLs, including ITs, for substances falling under the cut-off criteria the approval of which is not renewed will be deleted on the basis of Article 17 of Regulation (EC) No 396/2005. This legal basis allows for deletion of MRLs without seeking the opinion of EFSA for active substances present in plant protection products the authorisations of which have been revoked when the approval of an active substance is not renewed or simply expires (irrespective of the reasons).

- When the active substance is not renewed, the non-compliance with the cut-off criteria is explicitly referred to in a legal act based on Regulation (EC) 1107/2009, i.e. the non-renewal decision, which is based on EFSA conclusions. Following the adoption of the non-renewal decision, Member States will have to revoke authorisations, which will trigger Article 17 of Regulation (EC) No 396/2005.
- When the approval of the substance expires and no renewal procedure is initiated, the same approach will be applied. Even if the non-compliance with the cut-off criteria is not explicitly referred to in a legal act based on Regulation (EC) 1107/2009, the revocation of existing authorisations by Member States (which is a consequence of the expiry of the approval) will trigger Article 17 of Regulation (EC) No 396/2005.

This similar treatment for non-renewed approvals and expired approvals ensures that applicants will not deliberately choose to not submit a dossier (or withdraw a dossier when it becomes apparent that the cut-off criteria will not be complied with) in order to arrive at an

---

<sup>3</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, ([OJ L 309, 24.11.2009, p. 1](#)).

expiration of approval route rather than an explicit decision on non-renewal of approval in order to maintain existing ITs.

*Handling of IT requests for active substances falling under the cut-off criteria*

IT requests submitted for imports from 3<sup>rd</sup> countries will undergo systematically the procedures laid down in Regulation (EC) No 396/2005, including a risk assessment by a rapporteur Member State and a peer-review and opinion by EFSA.

Consequently, the granting of the IT will be considered on a case-by-case basis following a risk assessment, taking into account the EFSA opinion and also, where appropriate, other legitimate factors<sup>4</sup> as well as the precautionary principle.

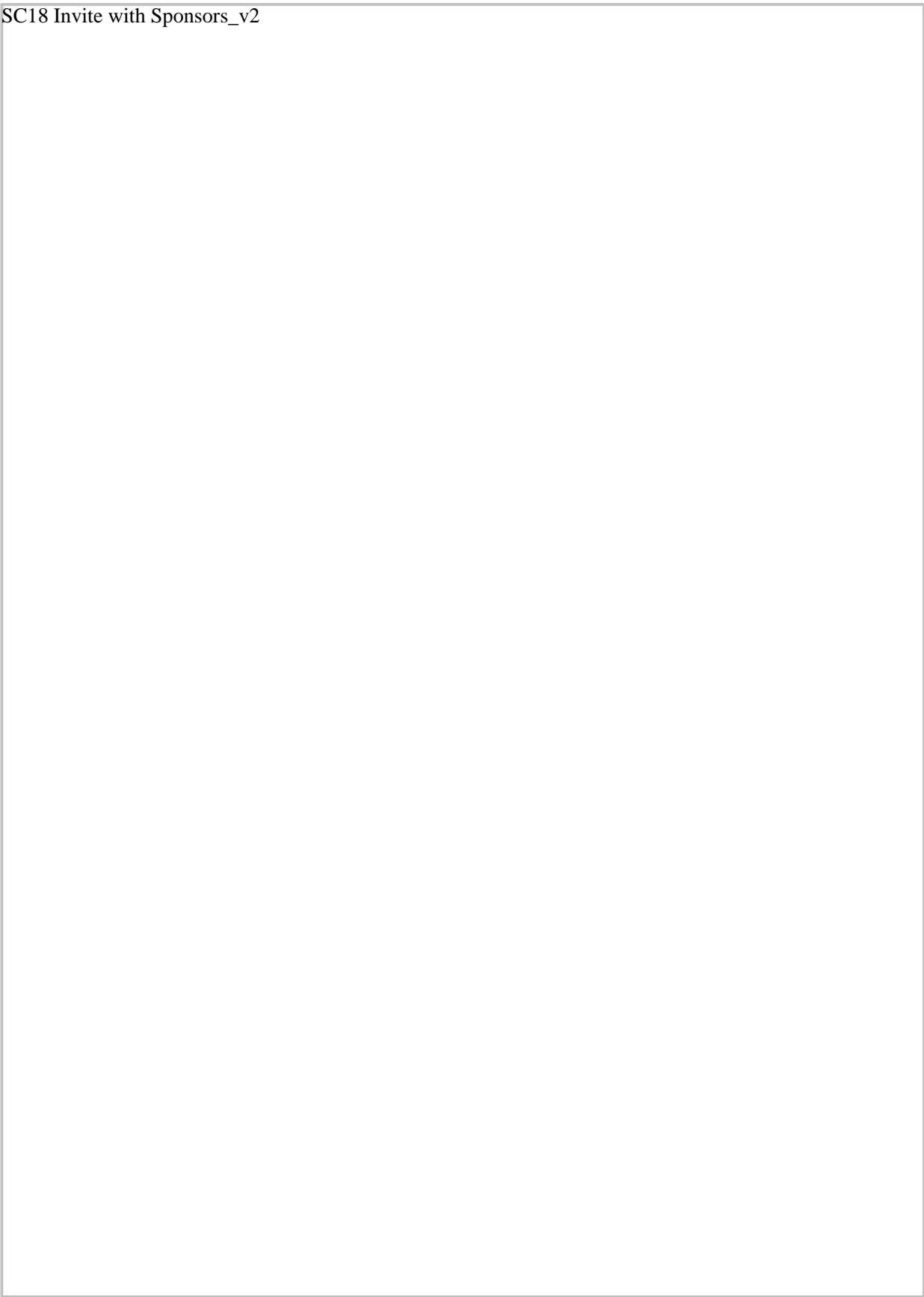
---

<sup>4</sup> Article 14(2)(f) of Regulation (EC) No 396/2005 specifically refers to such factors to be taken into account.

**From:** [CropLife America & RISE](#)  
**To:** [Rosalind James](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:52 PM

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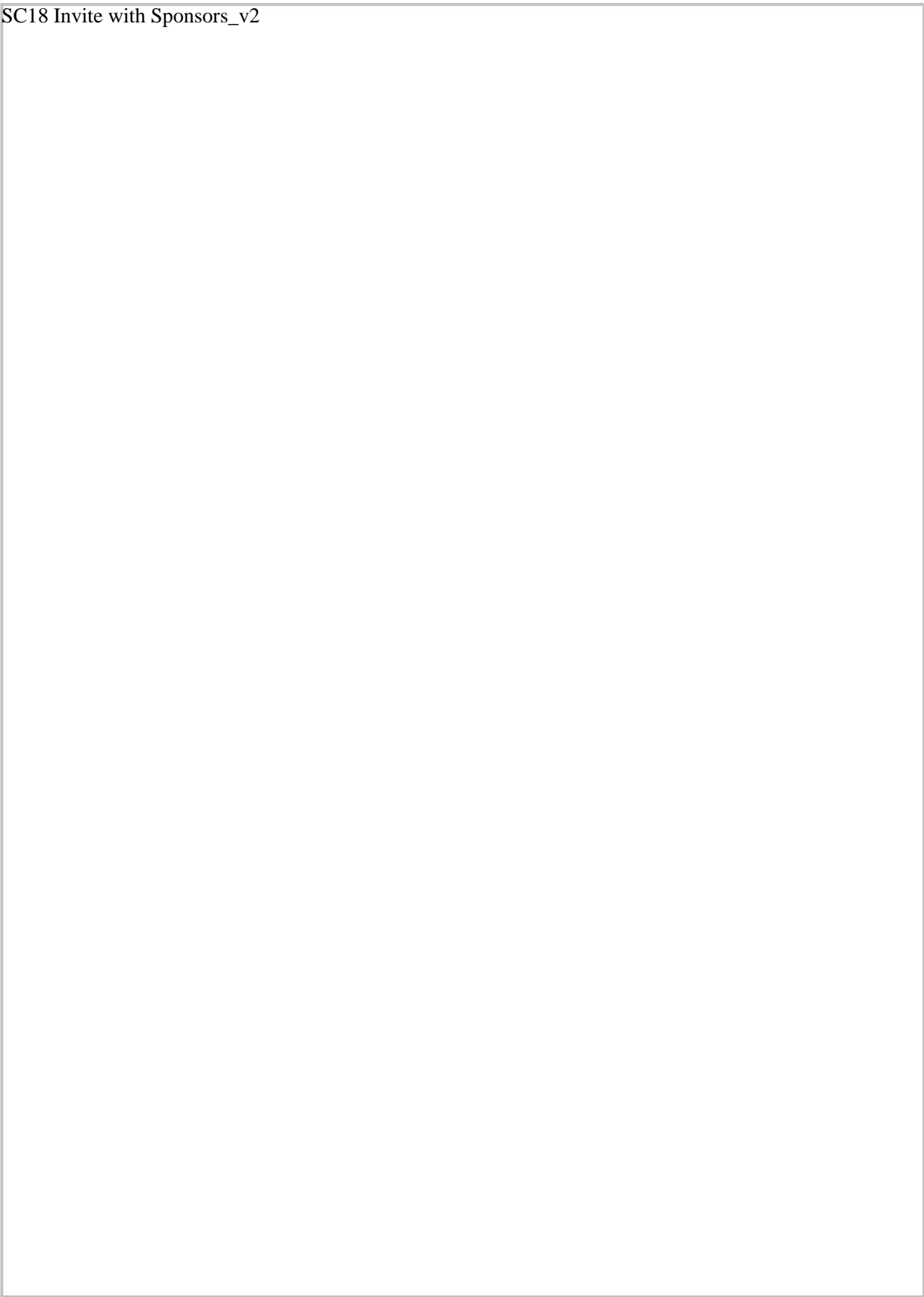


**From:** [CropLife America & RISE](#)  
**To:** [Elizabeth Hill](#)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
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**To:** [Alexander Domesle](#)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:55 PM

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**From:** [Ray McAllister](#)  
**To:** [Sheryl Kunickis](#); [David Epstein](#)  
**Bcc:** [david.epstein@oce.usda.gov](mailto:david.epstein@oce.usda.gov)  
**Subject:** Fwd: [Ext] Diana Haynes Info  
**Date:** Tuesday, August 21, 2018 11:44:10 AM

---

Sheryl & David:

Can you answer this question?

Ray S. McAllister, PhD  
Senior Director, Regulatory Policy  
CropLife America

(b) (6) (office)  
(b) (6) (cell)  
(b) (6) [@croplife.us](mailto:>@croplife.us)

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**From:** Angela Klemens (b) (6) [@fmc.com](mailto:>@fmc.com)>  
**Date:** August 21, 2018 at 11:38:03 AM EDT  
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**Subject:** [Ext] Diana Haynes Info

(b) (6)

Thanks, Ray.

Angela

Angela S Klemens, PhD  
Consumer Safety Assessment  
FMC Agricultural Solutions  
Stine Research Center S300/428  
1090 Elkton Road, Newark, DE 19711  
office: (b) (6)  
email: (b) (6) [@fmc.com](mailto:>@fmc.com)  
[www.fmc.com](http://www.fmc.com)

**From:** [Fajardo, Julius](#)  
**To:** [Jim Cranney \(b\) \(6\) @croplifeamerica.org](#)  
**Subject:** Draft AMR Document  
**Date:** Friday, February 16, 2018 10:40:10 AM  
**Attachments:** [Antibiotics in Crops 4\\_11\\_2017.docx](#)

---

Per discussion, please find attached draft for review. Thanks and best regards.

\*\*\*\*\*

**Julius E. Fajardo, Ph.D.** | *Plant Pathologist* | *USDA-Office of Pest Management Policy* | 1400 Independence Ave SW,  
Rm 3861-South Bldg (MS 0314) | Washington, DC 20250 | Tel. 202-720-3186 | Fax 202-720-3191 | Cell (b) (6)  
| [julius.fajardo@ars.usda.gov](mailto:julius.fajardo@ars.usda.gov) | <http://www.ars.usda.gov/opmp>

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## Practices that Minimize the Development of Antibiotic Resistance in Agricultural Crops

Technical experts from universities, government agencies, agriculture extension workers, distributors, and farmers can develop region-specific resistance management guidelines to inform labeling and use of specific antimicrobial agents.

- Only authorized antimicrobial agents labeled for specific use should be used. For example, key practices to implement could include:
  - Specifying a Grouping or Code in the label based on the region or country's technical committee recommendations
  - To reduce the likelihood of bacteria developing resistance, alternation of bactericides with a different mode of action
  - No more than two consecutive applications of the same antibiotic code or group
  - Resistance management strategies involving the implementation of integrated pest management, use of crop varieties resistant to the pathogen of concern, use of disease forecasting models, and sanitation
  - Consultation with a local extension specialist or certified crop consultant, State agricultural advisor, or manufacturer when necessary
- Label restrictions and precautions to minimize AMR could include:
  - Not applying antimicrobial agents in orchards where the soil has been fertilized with animal waste or manure.
  - Prohibiting animal grazing in treated areas and public notification through posting restriction signs along the perimeter of the treatment area.
  - Restricting the conditions of use such as the number of times an antimicrobial agent can be used through label requirements.
  - Limit consumer exposure by requiring a pre-harvest interval (PHI) which specifies the timing of the last antibiotic application relative to the harvest of the treated crops.

| Antibiotic      | Crop                 | PHI     |
|-----------------|----------------------|---------|
| Streptomycin    | Apples               | 50 days |
|                 | Pears                | 30 days |
| Kasugamycin     | Apples / Pears       | 90 days |
|                 |                      |         |
| Oxytetracycline | Apples / Pears       | 60 days |
|                 | Peaches / Nectarines | 21 days |

- Limit consumer exposure to AMR by the establishment of permissible antibiotic residues and legal tolerances or maximum residue levels (MRL) on raw agricultural commodities and processed products.



- Research regarding alternatives to antibiotics that reduce the selection of antibiotic-resistant strains as well as the decrease the need for the number of treatments should be encouraged. Examples of alternatives that are currently being tested for efficacy under laboratory and field conditions include:
  - biological control (e.g. *Pseudomonas fluorescens* strain A506)
  - antimicrobial peptides
  - induced systemic resistance (e.g. acibenzolar-s-methyl)
  - durable host plant resistance
  - targeting bacterial biofilms (e.g. 2-aminoimidazole)
  - effector proteins
  - targeting quorum sensing
  - nanoparticles
  - innovations in delivery systems (e.g. endotherapy and thermotherapy)
- Access to University-based agriculture extension specialists and disease forecasting models can help optimize the timing of applications to target disease control and minimize the number of applications. Examples include:
  - Cougarblight, Maryblyt, Billing's system are few examples of [disease predictive models for fire blight in pome fruit](#) that evaluate weather factors to predict if conditions are favorable for the disease and if antibiotics should be sprayed (<http://ipm.ucanr.edu/DISEASE/DATABASE/fireblight.html>).
  - Maryblyt predicts specific infection events and symptom development for the different phases of fire blight epidemics in apples and pears. Maryblyt is used by growers and in research, extension and teaching programs in 32 U.S. states and in at least 36 countries.

Specific examples of how regional guidelines and models can be used include:

- The Cooperative Extension of Cornell University developed guidelines for apple production regions in New York where streptomycin resistance has never been detected. In addition, the guidelines cover antibiotic management for high risk regions where streptomycin resistance has been detected and confirmed. Below is an excerpt of the guidelines:
  - If streptomycin resistance has been confirmed:
    - a. When the first blossom infection is forecast, apply kasugamycin at 64 fl oz. /acre in 100 gallons of water. Do not spray alternate row middles. Do not apply after petal fall. Consider including the penetrating surfactant Regulaid (1 pt/100 gal of spray solution) to enhance the effectiveness of kasugamycin.
    - b. At the 2nd high risk period, apply a tank mix of streptomycin at 24 oz. /acre in combination with either oxytetracycline at 32 oz. /acre, or a bloom time rate of a registered copper product.
    - At the 3rd or 4th high risk periods, repeat steps 'a' and 'b', respectively.
  - If streptomycin resistance has not been confirmed, but is present in the region:

- a. When the first blossom infection is forecast, apply a tank mix of streptomycin at 24 oz. /acre in combination with either oxytetracycline at 32 oz. /acre, or a bloom time rate of a registered copper product.
- b. At the 2nd high risk period, apply kasugamycin at 64 fl oz. /acre in 100 gallons. Consider including the penetrating surfactant Regulaid (1 pt/100 gal of spray solution) to enhance the effectiveness of kasugamycin.
- At the 3rd or 4th high risk period, repeat steps 'a' or 'b' depending on concerns about the effectiveness of streptomycin.
- Prohexadione-Calcium (Apogee) sprays should be applied at 6-12 oz/100 gal (3-6 oz/100 gal for tree <5 years) at 1-3 inches shoot growth. A second treatment should be made 14-21 days later. Apogee will not be effective if applied after you see fire blight symptoms.

### **Surveillance and Monitoring of Antibiotic Resistance in Agricultural Crops**

- Competent authorities and stakeholders should determine research gaps and needs of monitoring for antibiotic resistance in plants
- Region-specific monitoring of AMR from specific antimicrobial agent use in the region should be conducted to address data gaps. For example, isolation and identification of total bacterial populations isolated from flower, leaf and soil samples from apple orchards applied with antimicrobial agents can be monitored.
- Multi-year, region-specific monitoring of AMR can help assess the extent and distribution of AMR to help determine effectiveness of the antimicrobial agent in the region.
- Genetic analysis of isolates to understand the origins and diversity of AMR in bacteria can be explored for utility in bacterial disease management, bacterial strain tracking and limiting the AMR spread in a region.

**From:** [Mary Jo Tomalewski](#)  
**To:** [Jay Vroom](#); [Janet Collins](#); [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Cc:** [Courtney DeMarco](#)  
**Subject:** Meeting with Sheryl Kunickis

---

**From:** [Francesca Purcell](#)  
**To:** [Teung Chin](#)  
**Bcc:** [teung.chin@oce.usda.gov](mailto:teung.chin@oce.usda.gov)  
**Subject:** Registration Confirmed - CropLife America 2018 Holiday Open House  
**Date:** Tuesday, November 20, 2018 10:08:39 AM

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Dear Teung:

Your registration has been confirmed. Please save this email for future reference.

Event: CropLife America 2018 Holiday Open House

Attending: Teung Chin

Time: 5:30 pm

Date: Tuesday, December 11, 2018

Confirmation Number: (b) (6)

[Click here to view the event summary.](#)

We look forward to seeing you there.

Sincerely,  
Francesca Purcell  
CropLife America  
(b) (6) @croplifeamerica.org

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Rachel Lattimore](#)  
**Subject:** Re: January 31, 2018 Memorandum of Agreement Implementation  
**Date:** Friday, February 22, 2019 9:51:02 AM

---

Thanks, Rachel!  
 Sheryl

---

**From:** "Rachel Lattimore" <(b) (6)@croplifeamerica.org>  
**Date:** Friday, February 22, 2019 at 9:36:33 AM  
**To:** "Andrew Wheeler" <[Wheeler.Andrew@Epa.gov](mailto:Wheeler.Andrew@Epa.gov)>, "David Bernhardt " <[exsec@ios.doi.gov](mailto:exsec@ios.doi.gov)>, "Mary Neumayr" <[Mary.B.Neumayr@ceq.eop.gov](mailto:Mary.B.Neumayr@ceq.eop.gov)>, "Perdue, Sonny - OSEC, Washington, DC" <[Sonny.Perdue@osec.usda.gov](mailto:Sonny.Perdue@osec.usda.gov)>, "Wilbur Ross" <[WLRoss@doc.gov](mailto:WLRoss@doc.gov)>  
**Cc:** "Alexandra Dapolito Dunn" <[Dunn.alexandra@epa.gov](mailto:Dunn.alexandra@epa.gov)>, "Chris Oliver" <[Chris.W.Oliver@noaa.gov](mailto:Chris.W.Oliver@noaa.gov)>, "Chris Prandoni" <[Christopher.D.Prandoni@ceq.eop.gov](mailto:Christopher.D.Prandoni@ceq.eop.gov)>, "Margaret Everson " <[Margaret\\_Everson@fws.gov](mailto:Margaret_Everson@fws.gov)>, "Michael J. Hickey" <[mhickey@omb.eop.gov](mailto:mhickey@omb.eop.gov)>, "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Subject:** January 31, 2018 Memorandum of Agreement Implementation

Dear Secretaries Ross and Perdue, Acting Secretary Bernhardt, Acting Administrator Wheeler and Chairwoman Neumayr:

Please see the attached letter.

Best regards,

Rachel Lattimore

Rachel G. Lattimore  
 Senior Vice President, General Counsel, Secretary  
 CroLife America  
 1156 15<sup>th</sup> Street, NW  
 Suite 400  
 Washington, DC 20005  
 (b) (6) – direct  
 (202) 296-1585 – main  
 (b) (6)@croplifeamerica.org  
[www.croplifeamerica.org](http://www.croplifeamerica.org)

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [\(b\) \(6\)@croplifeamerica.org](#); [Boswell, Kristi - OSEC, Washington, DC](#)  
**Cc:** [Bachmann, Peter - OCR, Washington, DC](#); [Ruthann Anderson](#); [Stephanie Regagnon](#);  
[\(b\) \(6\)@croplifeamerica.org](#); [Jeff Case](#); [Janet Collins](#); [Kellie Bray](#); [Epstein, David - OCE](#)  
**Bcc:** [Epstein, David](#)  
**Subject:** Re: Bee Health and USDA!  
**Date:** Tuesday, October 16, 2018 7:34:16 PM

---

Good Evening!

Very timely message! Our office via Dr. David Epstein was in touch with Stephanie re: Fieldwatch last week about hosting a meeting at USDA as there is interest. Glad to help move this forward per your direction. Let me know how we can assist.

Cheers,  
Sheryl

---

**From:** "Jay Vroom" <[\(b\) \(6\)@croplifeamerica.org](#)>  
**Date:** Tuesday, October 16, 2018 at 5:39:43 PM  
**To:** "Boswell, Kristi - OSEC, Washington, DC" <[Kristi.Boswell@osec.usda.gov](#)>  
**Cc:** "Bachmann, Peter - OCR, Washington, DC" <[Peter.Bachmann@osec.usda.gov](#)>, "Ruthann Anderson" <[\(b\) \(6\)@capca.com](#)>, "Stephanie Regagnon" <[\(b\) \(6\)@fieldwatch.com](#)>, "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](#)>, <[\(b\) \(6\)@croplifeamerica.org](#)> <[\(b\) \(6\)@croplifeamerica.org](#)>, "Jeff Case" <[\(b\) \(6\)@croplifeamerica.org](#)>, "Janet Collins" <[\(b\) \(6\)@croplifeamerica.org](#)>, "Kellie Bray" <[\(b\) \(6\)@croplifeamerica.org](#)>  
**Subject:** Re: Bee Health and USDA!

Thanks Kristi,

I'm sure Sheryl will have some ideas. Also there's no particular rush so take some time and then we can figure out how to best connect all the parties — maybe with a conference call supported by some PPT slides.

Jay

Sent from my iPhone

On Oct 16, 2018, at 3:36 PM, Boswell, Kristi - OSEC, Washington, DC <[Kristi.Boswell@osec.usda.gov](#)> wrote:

Jay,

Great to meet you. Let me do some tracking and figure out who the right agency folks are to loop in. I'll be in touch!

Thanks,  
Kristi Boswell



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**From:** Bachmann, Peter - OCR, Washington, DC  
**Sent:** Tuesday, October 16, 2018 12:56:46 PM  
**To:** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC;  
(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray; Boswell, Kristi - OSEC, Washington, DC  
**Subject:** Re: Bee Health and USDA!

No worries, Jay. My colleague, Kristi Boswell, is the Secretary's Senior Advisor with the Research/Pesticide Portfolio. She should be able to assist!

Peter

---

**From:** Jay Vroom (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
**Sent:** Tuesday, October 16, 2018 12:51:39 PM  
**To:** Bachmann, Peter - OCR, Washington, DC  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC;  
(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray  
**Subject:** Bee Health and USDA!

Hi Peter,

I just spoke at the annual meeting of the California Association of Pest Control Advisors (CAPCA) — their CEO Ruthann Anderson is copied here, as is Fieldwatch CEO Stephanie Regagnon.

CAPCA and Fieldwatch are teaming up to implement what I think may be the most comprehensive bee tracking and transparency program I've seen yet— and in the state with the highest pollination services demand. They want it operational for 2019.

I'm not sure you are the right political lead person at USDA to connect with but I know you'll get us connected in all the right places at USDA ! In addition to those (like Dr Kunickis) who track pesticide issues at the intersection with bee health I think those who oversee bee loss info including emergency livestock loss payments to beekeepers all need to know about this new initiative in California!

Let me know how else I can help connect the dots?

I'll Also Share his with EPA!

Jay

Sent from my iPhone

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**From:** [CropLife America & RISE](#)  
**To:** [David Epstein](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** Last week for Early Bird Rates! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Tuesday, April 3, 2018 1:47 06 PM

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**From:** [Ray McAllister](#)  
**To:** [Fajardo, Julius](#); [Jim Cranney](#)  
**Subject:** RE: Follow-up  
**Date:** Wednesday, March 14, 2018 1:14:27 PM

---

I'll pull together what I have received.

Ray S. McAllister, PhD  
Senior Director Regulatory Policy  
Croplife America

O: (b) (6) C: (b) (6)  
(b) (6)@croplife.us

---

**From:** Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>  
**Sent:** Tuesday, March 13, 2018 3:04 PM  
**To:** Ray McAllister (b) (6)@croplifeamerica.org>; Jim Cranney (b) (6)@ccqc.org>  
**Subject:** Follow-up

Just to follow-up on your comments about the attached document. Neena will be needing the revised language by early next week. Thanks and best regards.

Julius

\*\*\*\*\*

**Julius E. Fajardo, Ph.D.** | *Plant Pathologist* | *USDA-Office of Pest Management Policy* | 1400 Independence Ave SW, Rm 3861-South Bldg (MS 0314) | Washington, DC 20250 | Tel. 202-720-3186 | Fax 202-720-3191 | Cell (b) (6) | [julius.fajardo@ars.usda.gov](mailto:julius.fajardo@ars.usda.gov) | <http://www.ars.usda.gov/opmp>

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Kellie Bray](#)  
**Subject:** Call received  
**Date:** Wednesday, March 14, 2018 11:03:27 AM

---

Hi Kelly,  
I am (b) (6) back Monday. How can I help?  
Sheryl

Sent from my iPhone

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [\(b\) \(6\) @croplifeamerica.org](#); [Epstein, David - OCE](#)  
**Bcc:** [Epstein, David](#)  
**Subject:** Re: [Ext] Diana Haynes Info  
**Date:** Tuesday, August 21, 2018 11:52:01 AM

---

I have two emails and will forward them to you. I do not know info yet.

Sheryl H. Kunickis, Ph.D., Director  
U.S. Department of Agriculture - Office of Pest Management Policy  
South Building, Room 3871; 1400 Independence Ave., SW;  
Washington, D.C. 20250-0314  
(202 720-5375 Desk phone - [\(b\) \(6\)](#) Cell phone  
[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Ray McAllister [\(b\) \(6\) @croplifeamerica.org](#)>  
**Sent:** Tuesday, August 21, 2018 11:44:06 AM  
**To:** Kunickis, Sheryl - OSEC; Epstein, David - OCE  
**Subject:** Fwd: [Ext] Diana Haynes Info

Sheryl & David:

Can you answer this question?

Ray S. McAllister, PhD  
Senior Director, Regulatory Policy  
CropLife America  
[\(b\) \(6\)](#) (office)  
[\(b\) \(6\)](#) (cell)  
[\(b\) \(6\) @croplife.us](#)

Begin forwarded message:

**From:** Angela Klemens <[\(b\) \(6\) @fmc.com](#)>  
**Date:** August 21, 2018 at 11:38:03 AM EDT  
**To:** [\(b\) \(6\) @croplifeamerica.org](#)" <[\(b\) \(6\) @croplifeamerica.org](#)> Ray McAllister  
**Subject:** [Ext] Diana Haynes Info

[\(b\) \(6\)](#)

Thanks, Ray.

Angela

Angela S Klemens, PhD  
Consumer Safety Assessment

FMC Agricultural Solutions  
Stine Research Center S300/428  
1090 Elkton Road, Newark, DE 19711  
office: (b) (6)  
email: (b) (6)@fmc.com  
[www.fmc.com](http://www.fmc.com)



**From:** [Fajardo, Julius](mailto:Fajardo_Julius)  
**To:** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Subject:** RE: Need help from FRAC  
**Date:** Tuesday, March 20, 2018 5:26:23 AM

---

Hi Ray,

I'm familiar with the paper of McManus. I did not have the other paper. Thanks for sharing.

---

**From:** Ray McAllister [mailto:(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]  
**Sent:** Monday, March 19, 2018 5:03 PM  
**To:** Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>  
**Subject:** FW: Need help from FRAC

Julius:

Are you familiar with the attached papers? I am just passing them along without having read or critiqued them.

Ray S. McAllister, PhD  
 Senior Director Regulatory Policy  
 CropLife America

O: (b) (6) C: (b) (6)

(b) [@croplife.us](mailto:(b)@croplife.us)

---

**From:** Olaya Gilberto USVB (b) (6) [@syngenta.com](mailto:(b) (6)@syngenta.com)>  
**Sent:** Wednesday, February 21, 2018 9:48 PM  
**To:** Hermann Dietrich CHBS (b) (6) [@syngenta.com](mailto:(b) (6)@syngenta.com)>; Klaus Stenzel (b) (6) [@bayer.com](mailto:(b) (6)@bayer.com)>; Sierotzki Helge CHST <(b) (6) [@syngenta.com](mailto:(b) (6)@syngenta.com)>; Martin Semar (b) (6) [@basf.com](mailto:(b) (6)@basf.com)>; (b) (6) [@basf.com](mailto:(b) (6)@basf.com); Andreas Mehl <(b) (6) [@bayer.com](mailto:(b) (6)@bayer.com)>; Juergen Derpmann (b) (6) [@bayer.com](mailto:(b) (6)@bayer.com)>  
**Cc:** (b) (6); Ray McAllister <(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>; Andrew Duncan McKenzie Ward <(b) (6) [@croplife.org](mailto:(b) (6)@croplife.org)>  
**Subject:** RE: Need help from FRAC

Dear colleagues,

Attached are 2 papers I found about the subject of antibiotic use in agriculture and that could be very useful. One with more focus in the use of antibiotic to control *Erwinia amylovora* (fire blight on pears and apples) and written by Patricia McManus that have a long history of research work on this area. The other paper with more focus on the impact of antibiotic use in animal production.

Regards,

Gilberto

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Rachel Lattimore](#)  
**Subject:** Re: January 31, 2018 Memorandum of Agreement Implementation  
**Date:** Tuesday, April 10, 2018 4:48:46 PM

---

Thank you!

Sent from my iPhone

On Apr 10, 2018, at 3:51 PM, Rachel Lattimore (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)> wrote:

Secretary Zinke, Secretary Ross, Secretary Purdue and Administrator Pruitt:

Please see the attached letter.

Sincerely,

Rachel G. Lattimore  
Senior Vice President, General Counsel, Secretary  
CroLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005  
(b) (6) - direct  
(b) (6) - main  
(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
[www.croplifeamerica.org](http://www.croplifeamerica.org)

<ESA FIFRA MOA Letter 041018.pdf>

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**From:** [CropLife America & RISE](#)  
**To:** [Sheryl Kunickis](#)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 21, 2018 4:16:29 PM

Header\_2.15.18



Dear Sheryl:

Your registration has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

| Registration Information: |                                                                                                   |                      |
|---------------------------|---------------------------------------------------------------------------------------------------|----------------------|
| Registration Items        |                                                                                                   |                      |
| Sheryl Kunickis           | CLA & RISE 2018 Regulatory Conference                                                             |                      |
| Sessions                  |                                                                                                   |                      |
| Sheryl Kunickis           | Welcome Reception                                                                                 | 25-Apr-2018 5:30 PM  |
| Sheryl Kunickis           | Networking Breakfast                                                                              | 26-Apr-2018 7:00 AM  |
| Sheryl Kunickis           | General Session                                                                                   | 26-Apr-2018 8:00 AM  |
| Sheryl Kunickis           | Series I - Application of Environmental Epidemiology in Risk Assessment and Decision-Making       | 26-Apr-2018 10:30 AM |
| Sheryl Kunickis           | Networking Lunch                                                                                  | 26-Apr-2018 12:00 PM |
| Sheryl Kunickis           | Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome | 26-Apr-2018 3:00 PM  |
| Sheryl Kunickis           | Networking Breakfast                                                                              | 27-Apr-2018 7:00 AM  |
| Sheryl Kunickis           | General Session                                                                                   | 27-Apr-2018 8:00 AM  |
| Sheryl Kunickis           | Series IV - Tox Testing & Risk Assessment for Human Health: How Should We Approach Globalization? | 27-Apr-2018 9:45 AM  |
| Additional Information    |                                                                                                   |                      |
| Sheryl Kunickis           | When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee    |                      |

[Click here for the event agenda](#)

[Add to Calendar](#)

[Event Registration Confirmation number: MDN5J9RB3G8](#)

We look forward to seeing you in April!

CropLife America & RISE

[Share on Twitter](#)

[Book your group hotel for CropLife America & RISE Regulatory Conference](#) until April 6!

Footer\_2.15.18



**Content**

\*\*\*\*\*

Having trouble with the link? Simply copy and paste the entire address listed below into your web browser <http://www.cvent.com/d/58ZODR5pa0CYH1fM-ZdFA/lnw8/P1/OR?>

\*\*\*\*\*

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**From:** [CropLife America & RISE](#)  
**To:** [Alexander Domesle](#)  
**Subject:** Early Bird Rates still available! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 28, 2018 8:18:12 AM

---

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**From:** [CropLife America & RISE](#)  
**To:** [David Epstein](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** Early Bird Rates still available! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 28, 2018 8:17:56 AM

---

Sponsor Invite



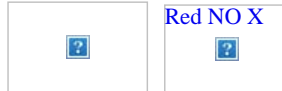
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**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Ray McAllister](#)  
**Subject:** [CAUTION: Suspicious Link]Re: [CAUTION: Suspicious Link]FW: USDA Reorganization - The Economic Research Service (ERS) will realign with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and t...  
**Date:** Thursday, August 9, 2018 7:58:59 PM

---

**PROCEED WITH CAUTION:** This message triggered warnings of **potentially** malicious web content. Evaluate this email by considering whether you are expecting the message, along with inspection for suspicious links.

Questions: [Spam.Abuse@wdc.usda.gov](mailto:Spam.Abuse@wdc.usda.gov)

Hear hear!

Glad to know that all is well.

Sent from my iPhone

On Aug 9, 2018, at 7:55 PM, Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

Hi Janet,  
 No changes for us. It gives Rob a whole lot more responsibility and people! I think he will be glad to let us keep doing our work! Quite an unexpected day on many fronts!  
 Sheryl

---

**From:** "Janet Collins" <(b) (6)@croplifeamerica.org>  
**Date:** Thursday, August 9, 2018 at 7:23:35 PM  
**To:** "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Cc:** "(b) (6)@croplifeamerica.org" <(b) (6)@croplifeamerica.org>  
**Subject:** [CAUTION: Suspicious Link]FW: USDA Reorganization - The Economic Research Service (ERS) will realign with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food ...

**PROCEED WITH CAUTION:** This message triggered warnings of **potentially** malicious web content. Evaluate this email by considering whether you are expecting the message, along with inspection for suspicious links.

Questions: [Spam.Abuse@wdc.usda.gov](mailto:Spam.Abuse@wdc.usda.gov)

Sheryl- hope all is well with you and with the work at USDA! Does this realignment have any impact on you, your offices and/or your staff?

Its hard to understand the structure given all the change!

My best,

Janet

(b) (6) (direct)

(b) (6) (mobile)

---

**From:** Jimmy Liu (b) (6) @fien.com>

**Sent:** Thursday, August 9, 2018 5:54 PM

**To:** (b) (6) @fien.com

**Subject:** USDA Reorganization - The Economic Research Service (ERS) will realign with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food and Agriculture (NIFA) will be...

**USDA Reorganization - The Economic Research Service (ERS), currently under USDA's Research, Education, and Economics mission area, will "... realign once again with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food and Agriculture (NIFA) will be relocated outside of the National Capital Region. The movement of the employees outside of Washington, DC is expected to be completed by the end of 2019 ... New locations have yet to be determined, and it is possible that ERS and NIFA may be co-located when their new homes are found ..."**

**Document Title:** The title of the August 9, 2018 USDA Press Release is "USDA to Realign ERS with Chief Economist, Relocate ERS & NIFA Outside DC"

**Organization:** USDA Press Office

**Source:** August 9, 2018 USDA Press Release

**Web site:** The August 9, 2018 USDA Press Release is posted at <http://www.usda.gov/media/press-releases/2018/08/09/usda-realign-ers-chief-economist-relocate-ers-nifa-outside-dc>

**Summary:** The text of the August 9, 2018 USDA Press Release follows: (Washington, D.C., August 9, 2018) – U.S. Secretary of Agriculture Sonny Perdue today announced further reorganization of the U.S. Department of Agriculture (USDA), intended to improve customer service, strengthen offices and programs, and save taxpayer dollars. The Economic Research Service (ERS), currently under USDA’s Research, Education, and Economics mission area, will realign once again with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food and Agriculture (NIFA) will be relocated outside of the National Capital Region. The movement of the employees outside of Washington, DC is expected to be completed by the end of 2019.

“It’s been our goal to make USDA the most effective, efficient, and customer-focused department in the entire federal government,” Perdue said. “In our Administration, we have looked critically at the way we do business, with the ultimate goal of ensuring the best service possible for our customers, and for the

taxpayers of the United States. In some cases, this has meant realigning some of our offices and functions, or even relocating them, in order to make more logical sense or provide more streamlined and efficient services.”

#### Realigning ERS with OCE

Moving ERS back together with OCE under the Office of the Secretary simply makes sense because the two have similar missions. ERS studies and anticipates trends and emerging issues, while OCE advises the Secretary and Congress on the economic implications of policies and programs. These two agencies were aligned once before, and bringing them back together will enhance the effectiveness of economic analysis at USDA.

#### Relocating ERS and NIFA outside National Capital Region

New locations have yet to be determined, and it is possible that ERS and NIFA may be co-located when their new homes are found. USDA is undertaking the relocations for three main reasons:

1. To improve USDA’s ability to attract and retain highly qualified staff with training and interests in agriculture, many of whom come from land-grant universities. USDA has experienced significant turnover in these positions, and it has been difficult to recruit employees to the Washington, DC area, particularly given the high cost of living and long commutes.
2. To place these important USDA resources closer to many of stakeholders, most of whom live and work far from the Washington, DC area.
3. To benefit the American taxpayers. There will be significant savings on employment costs and rent, which will allow more employees to be retained in the long run, even in the face of tightening budgets.

No ERS or NIFA employees will be involuntarily separated. Every employee who wants to continue working will have an opportunity to do so, although that will mean moving to a new location for most. Employees will be offered relocation assistance and will receive the same base pay as before, and the locality pay for the new location. For those who are interested, USDA is seeking approval from the Office of Personnel Management and the Office of Management and Budget for both Voluntary Early Retirement Authority and Voluntary Separation Incentive Payments.


“None of this reflects on the jobs being done by our ERS or NIFA employees, and in fact, I frequently tell my Cabinet colleagues that USDA has the best workforce in the federal government,” Perdue said. “These changes are more steps down the path to better service to our customers, and will help us fulfill our informal motto to ‘Do right and feed everyone.’”

Perdue previously announced other significant changes at USDA. In May 2017, USDA created the first-ever Undersecretary for Trade and Foreign Agricultural Affairs (<http://www.usda.gov/media/press-releases/2017/05/11/secretary-perdue-announces-creation-undersecretary-trade>) and reconstituted and renamed the new Farm Production and Conservation mission area, among other realignments. In addition, in September 2017, Perdue realigned a number of offices (<http://www.usda.gov/media/press-releases/2017/09/07/secretary-perdue-announces-usda-improvements-customer-service>) to improve customer service and maximize efficiency. Those actions involved innovation, consolidation, and the rearrangement of certain offices into more logical organizational reporting structures.

#####

This article (#44053) was distributed by e-mail on August 9, 2018 to those whose

names are on the FIEN, LLC Subject Matter Distribution Lists for Agricultural Research; Alternative Crop Uses and Waste Utilization; Analytical Methods; Animal Welfare; Biobased Products; Biotechnology; Citrus; Crop Protection; Dairy; Economics and Statistics; Energy Efficiency and Renewable Energy; Fats and Oils; Fisheries; Food Quality, Product Development and Marketing (Ag Commodities and Processed Food); Food Safety; Food Waste; Fruits, Vegetables and Nuts; Global Climate Change; Government Administrative Actions; Grains; International Trade; Invasive Species; Meat, Poultry and Eggs; Nutrition - General; Organic Food; Plant Variety Protection; Risk Assessment and Communication; Sustainable Development; Tobacco; Veterinary Medicine  
-end-

The above information was sent to you by Jimmy Liu of the Food Industry Environmental Network, LLC --- <http://www.fien.com> --- mobile: 240 476 5958 --- e-mail @fien.com

\* Messages prefaced with [SFM] are FIEN Shortened Messages which are distinguished from FIEN Traditional Messages as described at <http://www.fien.com/SFM.php>

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**From:** [CropLife America & RISE](#)  
**To:** [Alexander Domesle](#)  
**Subject:** Last week for Early Bird Rates! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Tuesday, April 3, 2018 1:47:29 PM

---

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**From:** [Ray McAllister](#)  
**To:** [Kunickis, Sheryl - OSEC](#); [Epstein, David](#)  
**Cc:** [Janet Collins](#); [Jay Vroom](#)  
**Bcc:** [Epstein, David](#)  
**Subject:** FAO - News Article: FAO launches guide to tackle Fall Armyworm in Africa head-on  
**Date:** Tuesday, March 13, 2018 12:08:36 PM

---

Sheryl & David:

Have you folks followed the FAO work on fall armyworm in Africa? In mid-February, FAO released “Integrated management of the Fall Armyworm on maize: A guide for Farmer Field Schools in Africa” (132 pp., see link below). I haven’t had a chance to review it, but I understand that the approaches it espouses would deny to African farmers the modern effective tools that are used in the US to keep the pest in check.

The Acknowledgements claim input from, among others, “... entomologists and other researchers from the Americas with sound experience on FAW management.” Among the 50+ people listed in the acknowledgements, the only US contributor is “Robert Meagher (USDA-Agriculture Research Service, Gainesville, Florida).” Do you have contact information for Dr. Meagher? I’d be interested in his impression of the guide.

<http://www.fao.org/news/story/en/item/1100355/icode/>

Ray S. McAllister, PhD  
Senior Director, Regulatory Policy  
CropLife America

(b) (6) [REDACTED] (office)

(b) (6) [REDACTED] (cell)

(b) (6) [REDACTED] [@croplife.us](mailto:[REDACTED]@croplife.us)

**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Courtney DeMarco](#)  
**Cc:** [Janet Collins](#)  
**Subject:** Re: 2018 CLA & RISE Regulatory Conference - Speaker Invitation  
**Date:** Saturday, March 17, 2018 2:12:41 AM

---

Hi Courtney,  
I do not recall any invitation. I have been out of the country and back on Monday and can follow up! ☺  
Sheryl

Sent from my iPhone  
<image002.jpg>

On Mar 16, 2018, at 7:16 PM, Courtney DeMarco (b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)> wrote:

<!--[if !vml]--><!--[endif]-->

March 16, 2018

Dear Sheryl Kunickis,

Croplife America and RISE are delighted to confirm your participation as a guest speaker at our 2018 Regulatory Conference, April 25-27, 2018. It will be held at the Renaissance Arlington Capital View Hotel, located at 2800 S Potomac Avenue, Arlington, Virginia, 22202. This year's Conference will highlight ongoing regulatory science and policy issues currently engaging our industry, including ESA and FIFRA risk assessments and risk management; inerts and mixtures; alternative methods for human health assessment; use of precision agriculture tools; and many other timely topics. We also have confirmed participation of speakers and EPA's Office of Pesticide Programs leadership across sessions that we think will provide valuable input and expertise.

We welcome your participation as a session speaker, you will address what you've learned about the consultation process to date and what they still need to develop going forward, during our session, What We've Learned, What We Need: The FIFRA/ESA Consultation Process on April 26, at 10:30 AM. The session goal is session goal, and the session will include other speakers with expertise in this area. Panel presentations will be followed by an audience Q&A session.

You are asked to forward your biography as soon as possible, and all presentation materials including PowerPoint presentations to Courtney DeMarco at (b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>, no later than April 16<sup>th</sup>. If you have any questions about the Conference, please don't hesitate to contact Courtney by email or by phone



at (b) (6). We look forward to seeing you at our 2018 CLA/RISE Regulatory Conference!

Respectfully,  
<!--[if !vml]-->

<image006.jpg>

<image005.jpg>

<!--[endif]-->

Janet E. Collins  
Hobbs  
Executive Vice President, Science and Regulatory Affairs  
CropLife America

Aaron  
President  
RISE

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**From:** [Jay Vroom](#)  
**To:** [Osama A. El-Lissy](#)  
**Cc:** [Janet Collins](#); [Sheryl Kunickis Ph.D.](#)  
**Bcc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Soy Systems Task Force  
**Date:** Wednesday, January 31, 2018 4:59:27 PM

---

Good afternoon!

It was great to talk with you today at lunch. Janet Collins and I will be in touch with you about the soy systems task force you mentioned.

Jay

**Jay Vroom**

President & CEO

CroLife America

1156 15th Street, NW

Suite 400

Washington, DC 20005

**Direct Dial** (b) (6)

**Main Switchboard** (202) 296-1585

**Mobile** (b) (6)

**Fax** (202) 466-5832

**Email** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)

**Executive Assistant** Mary Jo Tomalewski (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org), (b) (6) o,

(b) (6) m)

**Web** [www.croplifeamerica.org](http://www.croplifeamerica.org)

**From:** [Sarah Macedo](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: Jay Vroom Video Project - TOP SECRET and Revised Upload Link  
**Date:** Friday, July 20, 2018 3:32:34 PM

---

Hi Sheryl,

I just wanted to let you know there is still time to send me a quick video for Jay! Please let me know if you need any assistance.

Thanks,  
Sarah

---

**From:** Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>  
**Sent:** Friday, June 22, 2018 11:14 AM  
**To:** Sarah Macedo (b) (6) @croplifeamerica.org>  
**Subject:** Re: Jay Vroom Video Project - TOP SECRET and Revised Upload Link

Will do! Thanks!

Sent from my iPhone

On May 25, 2018, at 12:08 PM, Sarah Macedo <(b) (6) @croplifeamerica.org> wrote:

Good Afternoon,

I wanted to send a friendly reminder of the project outlined below before the holiday weekend and pass along a **revised link** to upload your short video message:

(b) (6)

Please do not hesitate to let me know if you have any questions!

Best,  
Sarah

---

**From:** Sarah Macedo  
**Sent:** Thursday, May 17, 2018 2:05 PM  
**To:** 'sheryl.kunickis@osec.usda.gov' <sheryl.kunickis@osec.usda.gov>  
**Subject:** Jay Vroom Video Project - TOP SECRET

Good Afternoon,

After 30 years leading CropLife America, President and CEO Jay Vroom is retiring and we would like you to be a part of this significant milestone! We are reaching out to those who have worked with Jay over the years to help us create a short video to air during our 2018 Annual Meeting.

We encourage you to send us a 10 – 20 second video message for Jay – it may contain your well wishes, a brief story, congratulations – just be sure to make it your own!

Please upload your video to the following DropBox link **by July 2:**

(b) (6)

After your video is uploaded to DropBox, our video editors will make your contribution look great! Rest assured, if you don't understand the technical stuff, just give me a call and I'm happy to walk you through it.

Finally, your discretion is of utmost importance! **We would love to keep this a surprise as much as we possibly can - please do not let anyone know.**

Do not hesitate to let me know of any questions and thank you for helping us celebrate Jay's life and career!

Best,  
Sarah

**Sarah Macedo**

Manager, New Media Content

CropLife America

1156 15th Street N.W., Suite 400

Washington, D.C. 20005

Office: (b) (6)

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<image001.png>

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**From:** [Ray McAllister](#)  
**To:** [Anandaraman, Neena - OSEC](#)  
**Cc:** [Fajardo, Julius - OCE](#)  
**Bcc:** [Fajardo, Julius](#)  
**Subject:** RE: Codex TFAMR for Comments CoP2  
**Date:** Monday, July 30, 2018 4:54:21 PM

---

I'm confused by the WHO list of "[Critically Important Antimicrobials for Human Medicine](#)". I find tetracycline and streptomycin listed there, but I can't tell if they are the same compounds as those used in crop production.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CroLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) @croplife.us

---

**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Sent:** Monday, July 30, 2018 4:13 PM  
**To:** Ray McAllister <(b) (6) @croplifeamerica.org>  
**Cc:** Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>  
**Subject:** RE: Codex TFAMR for Comments CoP2

Julius Fajardo is working up comments for the crop side too if it's easier for you two to touch base on comments

Office: (b) (6)  
 Cell: (b) (6)

---

**From:** Ray McAllister [[mailto:\(b\) \(6\) @croplifeamerica.org](mailto:(b) (6) @croplifeamerica.org)]  
**Sent:** Monday, July 30, 2018 3:57 PM  
**To:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Subject:** RE: Codex TFAMR for Comments CoP2

I will need more time. How much can you give me.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CroLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) @croplife.us

---

**From:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Sent:** Monday, July 30, 2018 8:22 AM

**To:** Ray McAllister (b) (6) @croplifeamerica.org>

**Subject:** FW: Codex TFAMR for Comments CoP2

Hi Ray-I didn't get to run the webinar question by Don yet, but did want to make sure the crop folks saw this and are commenting on it.

If you all need more time, please let me know, but there's crop language in here and our most immediate need is for you all to review and provide edits.

Office: (b) (6)

Cell: (b) (6)

---

**From:** Lowery, Kenneth - FSIS

**Sent:** Monday, July 16, 2018 8:09 AM

**To:** Allison Phibbs (b) (6) @chickenusa.org>; Anjulen ANDERSON (b) (6) @elanco.com>; (b) (6) @chickenusa.org; Barbara Madden (b) (6) @nwhort.org>; Bob Bruss (b) (6) @nufarm.com>; Brian Ronholm (b) (6) @arentfox.com>; Clint Nesbitt (b) (6) @bio.org>; Courtney Knupp (b) (6) @nppc.org>; Dan Botts (b) (6) @ffva.com>; Daniella Taveau (b) (6) @kslaw.com>; Danielle Larochelle (b) (6) @nufarm.com>; Dave White <dwhite25@utk.edu>; Dick White (b) (6) ; Ed Ruckert (b) (6) @mwe.com>; George Sundin <sundin@msu.edu>; Heidi Irrig (b) (6) @syngenta.com>; (b) (6) @nmpf.org; Janet Collins (b) (6) @croplifeamerica.org>; Jay Pscheidt <pscheidj@science.oregonstate.edu>; Jean Halloran (b) (6) @consumer.org>; Jeff Watts (b) (6) @zoetis.com>; Jim Adaskaveg <jim.adaskaveg@ucr.edu>; Jim Cranney (b) (6) @ccqc.org>; Joel Newman (b) (6) @afia.org>; (b) (6) @beef.org; Kerik Cox <kdc33@cornell.edu>; (b) (6) @dtbassociates.com; Laura MacCleery (b) (6) @cspinet.org>; (b) (6) @afia.org; Lisa Efferts - CSPI (b) (6) @cspinet.org>; (b) (6) @turkeyfed.org; (b) (6) @nppc.org; Mallory L. Gage (b) (6) >; Mano Basu (b) (6) @gmaonline.org>; Margaret Malkoski (b) (6) @nfi.org>; Maria Del Mar Jimenez-Gasco <Jimenez-gasco@psu.edu>; Mark Trimmer (b) (6) @TrimmerConsulting.com>; Michael HANSEN (b) (6) @consumer.org>; Mike MCGOWAN (b) (6) @zoetis.com>; Nick Gardner (b) (6) @gmaonline.org>; Patricia McManus <psm@plantpath.wisc.edu>; Phyllis Marquitz (b) (6) @effem.com>; Quan Zeng <Quan.zeng@ct.gov>; Rachel Cumberbatch (b) (6) @ahi.org>; Randy Singer <rsinger@umn.edu>; (b) (6) @croplifeamerica.org; Richard CARNEVALE (b) (6) @ahi.org>; Rodney Akers (b) (6) @arysta.com>; Sarah Sorscher (b) (6) @cspinet.org>; Stephanie Slinski (b) (6) @citrusrdf.org>; Steve Suppan <(b) (6) @iatp.org>; Steven ROACH (b) (6) @foodanimalconcerns.org>; Taw Richardson <(b) (6) @agrosource.net>; Thomas Shryock <(b) (6) >; Tim Wilson (b) (6) @arysta.com>; Green, Alice - FSIS <Alice.Green@fsis.usda.gov>; Andrew Chi Yuen Yeung <Andrew.Yeung@fda.hhs.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bennett, Patty - AMS <Patty.Bennett@ams.usda.gov>; McCluskey, Brian J - APHIS <brian.j.mccluskey@aphis.usda.gov>; Canavan, Jeff - FSIS <Jeff.Canavan@fsis.usda.gov>; Caroline De Waal <Caroline.DeWaal@fda.hhs.gov>; Jackson, Charlene <Charlene.Jackson@ARS.USDA.GOV>; Charles Pixley <Charles.Pixley@fsis.usda.gov> <Charles.Pixley@fsis.usda.gov>; Daniel Folmer <Daniel.Folmer@cfsan.fda.gov>; McChesney, Daniel <daniel.mcchesney@fda.hhs.gov>; David A Dargatz <David.A.Dargatz@aphis.usda.gov>; David Edwards <David.Edwards@fda.hhs.gov>; David

Ingram <[David.Ingram@fda.hhs.gov](mailto:David.Ingram@fda.hhs.gov)>; David Miller <[Miller.Davidj@epa.gov](mailto:Miller.Davidj@epa.gov)>; Dawn Sievert <[dsievert@cdc.gov](mailto:dsievert@cdc.gov)>; Evans, Don - FAS <[Don.Evans@fas.usda.gov](mailto:Don.Evans@fas.usda.gov)>; LaFond, Dorian - AMS <[Dorian.LaFond@ams.usda.gov](mailto:Dorian.LaFond@ams.usda.gov)>; Felicia B. Billingslea <[Felicia.Billingslea@fda.hhs.gov](mailto:Felicia.Billingslea@fda.hhs.gov)>; Herndon.George-FASContact <[herndon.george@epa.gov](mailto:herndon.george@epa.gov)>; Goldman, David - Commissioned Corps - FSIS <[David.Goldman@fsis.usda.gov](mailto:David.Goldman@fsis.usda.gov)>; Gregory Noonan <[Gregory.Noonan@fda.hhs.gov](mailto:Gregory.Noonan@fda.hhs.gov)>; Heather Tate <[Heather.tate@fda.hhs.gov](mailto:Heather.tate@fda.hhs.gov)>; Henry Kim <[henry.kim@fda.hhs.gov](mailto:henry.kim@fda.hhs.gov)>; Jean Whichard <[zyr3@cdc.gov](mailto:zyr3@cdc.gov)>; Jenny Scott <[Jenny.Scott@fda.hhs.gov](mailto:Jenny.Scott@fda.hhs.gov)>; Hain, Joe - FAS <[Joe.Hain@fas.usda.gov](mailto:Joe.Hain@fas.usda.gov)>; Clifford, John R - APHIS <[John.Clifford@aphis.usda.gov](mailto:John.Clifford@aphis.usda.gov)>; Greifer, John K - APHIS <[John.K.Greifer@aphis.usda.gov](mailto:John.K.Greifer@aphis.usda.gov)>; John Sheehan <[John.Sheehan@fda.hhs.gov](mailto:John.Sheehan@fda.hhs.gov)>; Frye, Jonathan <[Jonathan.Frye@ars.usda.gov](mailto:Jonathan.Frye@ars.usda.gov)>; Julia\_Doherty@ustr.eop.gov; Julie Callahan <[Julie\\_E\\_Callahan@ustr.eop.gov](mailto:Julie_E_Callahan@ustr.eop.gov)>; Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>; Schwegel, Justin - FAS <[Justin.Schwegel@fas.usda.gov](mailto:Justin.Schwegel@fas.usda.gov)>; Bjork, Kathe E - APHIS <[Kathe.E.Bjork@aphis.usda.gov](mailto:Kathe.E.Bjork@aphis.usda.gov)>; Granger, Larry M - APHIS <[Larry.M.Granger@aphis.usda.gov](mailto:Larry.M.Granger@aphis.usda.gov)>; Larry Kerr <[Larry.Kerr@hhs.gov](mailto:Larry.Kerr@hhs.gov)>; Lauren Robin <[lauren.robin@fda.hhs.gov](mailto:lauren.robin@fda.hhs.gov)>; Lesley V. D'Anglada <[DAnglada.Lesley@epa.gov](mailto:DAnglada.Lesley@epa.gov)>; Leslie Yang <[Leslie\\_Yang@ustr.eop.gov](mailto:Leslie_Yang@ustr.eop.gov)>; Wanida Lewis-FASContact <[LewisWE@state.gov](mailto:LewisWE@state.gov)>; Durso, Lisa <[Lisa.Durso@ARS.USDA.GOV](mailto:Lisa.Durso@ARS.USDA.GOV)>; Lynn Filpi <[Lynn.Filpi@hhs.gov](mailto:Lynn.Filpi@hhs.gov)>; McKinnell, Cathy - FAS <[Cathy.McKinnell@fas.usda.gov](mailto:Cathy.McKinnell@fas.usda.gov)>; Rosenblum, Micah - FAS <[Micah.Rosenblum@fas.usda.gov](mailto:Micah.Rosenblum@fas.usda.gov)>; Michael Choi <[ChoiMI@state.gov](mailto:ChoiMI@state.gov)>; David, Michael J - APHIS <[Michael.J.David@aphis.usda.gov](mailto:Michael.J.David@aphis.usda.gov)>; Moreau, Robert <[Robert.Moreau@ARS.USDA.GOV](mailto:Robert.Moreau@ARS.USDA.GOV)>; McCluskey, Patrick - AMS <[Patrick.J.McCluskey@ams.usda.gov](mailto:Patrick.J.McCluskey@ams.usda.gov)>; Paul S. Honigfort <[Paul.Honigfort@fda.hhs.gov](mailto:Paul.Honigfort@fda.hhs.gov)>; Paul South <[Paul.South@fda.hhs.gov](mailto:Paul.South@fda.hhs.gov)>; Moreau, Robert <[Robert.Moreau@ARS.USDA.GOV](mailto:Robert.Moreau@ARS.USDA.GOV)>; Robinson, Brandi <[Brandi.Robinson@fda.hhs.gov](mailto:Brandi.Robinson@fda.hhs.gov)>; Hammond, Rose <[Rose.Hammond@ARS.USDA.GOV](mailto:Rose.Hammond@ARS.USDA.GOV)>; Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>; Stanley, Mary - FSIS <[Mary.Stanley@fsis.usda.gov](mailto:Mary.Stanley@fsis.usda.gov)>; Steven Wilson <[Steven.Wilson@noaa.gov](mailto:Steven.Wilson@noaa.gov)>; Susan Jennings <[Jennings.Susan@epa.gov](mailto:Jennings.Susan@epa.gov)>; Dutko, Terry - FSIS <[Terry.Dutko@fsis.usda.gov](mailto:Terry.Dutko@fsis.usda.gov)>; Thompson, Christopher D - AMS <[Christopher.D.Thompson@ams.usda.gov](mailto:Christopher.D.Thompson@ams.usda.gov)>; Norden, Timothy - AMS <[Timothy.D.Norden@ams.usda.gov](mailto:Timothy.D.Norden@ams.usda.gov)>; Vito Su <[suv@state.gov](mailto:suv@state.gov)>; William Jones <[William.Jones@fda.hhs.gov](mailto:William.Jones@fda.hhs.gov)>

**Cc:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; USA - Ron Miller <[Ron.Miller@fda.hhs.gov](mailto:Ron.Miller@fda.hhs.gov)>; 'Ruby.Singh@fda.hhs.gov' <[Ruby.Singh@fda.hhs.gov](mailto:Ruby.Singh@fda.hhs.gov)>; Kishore, Rita - FSIS <[Rita.Kishore@fsis.usda.gov](mailto:Rita.Kishore@fsis.usda.gov)>

**Subject:** Codex TFAMR for Comments CoP2

Dear TFAMR Stakeholders,

Please see attached a new version of the revised text for the Code of Practice to Minimize and Contain Antimicrobial Resistance from the Electronic Working Group Chair and Co-chairs.

Please send comments by July 30, 2018 to [Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov) , [Ron.Miller@fda.hhs.gov](mailto:Ron.Miller@fda.hhs.gov) ; [Ruby.Singh@fda.hhs.gov](mailto:Ruby.Singh@fda.hhs.gov) ; [Kenneth.Lowery@fsis.usda.gov](mailto:Kenneth.Lowery@fsis.usda.gov) for consideration in drafting of U.S. Comments. When sending comments, please provide text for suggested revision and justification as much as possible. The Electronic Working Group Chair and Co-chairs will next review comments submitted to prepare a report including further revised text for submission to the Codex Secretariat. Our understanding is that the report will be circulated ahead of the next meeting of the TFAMR in December 2018 for further comment by Member States and

Observers.

Neena Anandaraman, DVM, MPH, DACVPM  
Veterinary Science Policy Advisor  
Office of the Chief Scientist  
United States Department of Agriculture  
Office: (b) (6)  
Cell: (b) (6)

*Ken*

Kenneth Lowery  
International Issues Analyst  
U.S. Codex Office  
Office of the Under Secretary  
Trade and Foreign Agricultural Affairs  
Room 4861-S  
1400 Independence Avenue SW  
Washington DC 20250-3700  
[Kenneth.lowery@fsis.usda.gov](mailto:Kenneth.lowery@fsis.usda.gov)  
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**From:** [CropLife America & RISE](#)  
**To:** [Teung Chin](#)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Monday, March 19, 2018 8:39:34 AM

Header\_2.15.18



Dear Teung:

Your registration has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

| Registration Information: |                                                                                                      |                      |
|---------------------------|------------------------------------------------------------------------------------------------------|----------------------|
| Registration Items        |                                                                                                      |                      |
| Teung Chin                | CLA & RISE 2018 Regulatory Conference                                                                |                      |
| Sessions                  |                                                                                                      |                      |
| Teung Chin                | Networking Breakfast                                                                                 | 26-Apr-2018 7:00 AM  |
| Teung Chin                | General Session                                                                                      | 26-Apr-2018 8:00 AM  |
| Teung Chin                | Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process                      | 26-Apr-2018 10:30 AM |
| Teung Chin                | Networking Lunch                                                                                     | 26-Apr-2018 12:00 PM |
| Teung Chin                | Series II - Charting a Path Forward for the Use of Population Modeling in Ecological Risk Assessment | 26-Apr-2018 1:15 PM  |
| Teung Chin                | Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome    | 26-Apr-2018 3:00 PM  |
| Teung Chin                | Networking Breakfast                                                                                 | 27-Apr-2018 7:00 AM  |
| Teung Chin                | General Session                                                                                      | 27-Apr-2018 8:00 AM  |
| Teung Chin                | Series IV - Challenges and Recommendations for Generating and Utilizing Higher-Tier Data in Ecologic | 27-Apr-2018 9:45 AM  |
| Additional Information    |                                                                                                      |                      |
| Teung Chin                | When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee       |                      |

[Click here for the event agenda](#)

[Add to Calendar](#)

[Event Registration Confirmation number: P5N5YVN5LYJ](#)

We look forward to seeing you in April!

CropLife America & RISE

[Share on Twitter](#)

[Book your group hotel for CropLife America & RISE Regulatory Conference](#) until April 6!

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**Content**

\*\*\*\*\*

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\*\*\*\*\*

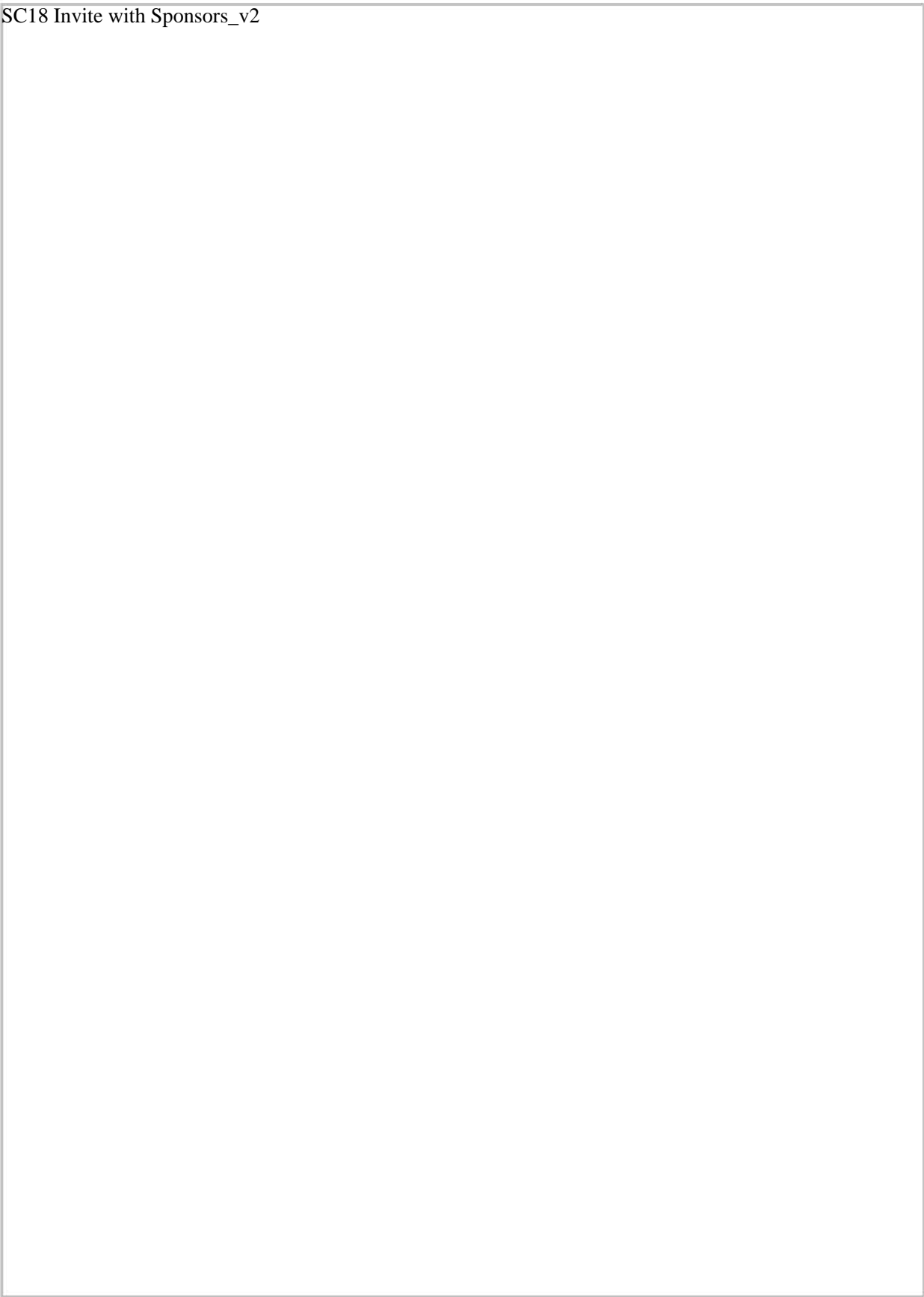
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**From:** [CropLife America & RISE](#)  
**To:** [David Epstein](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:53 PM

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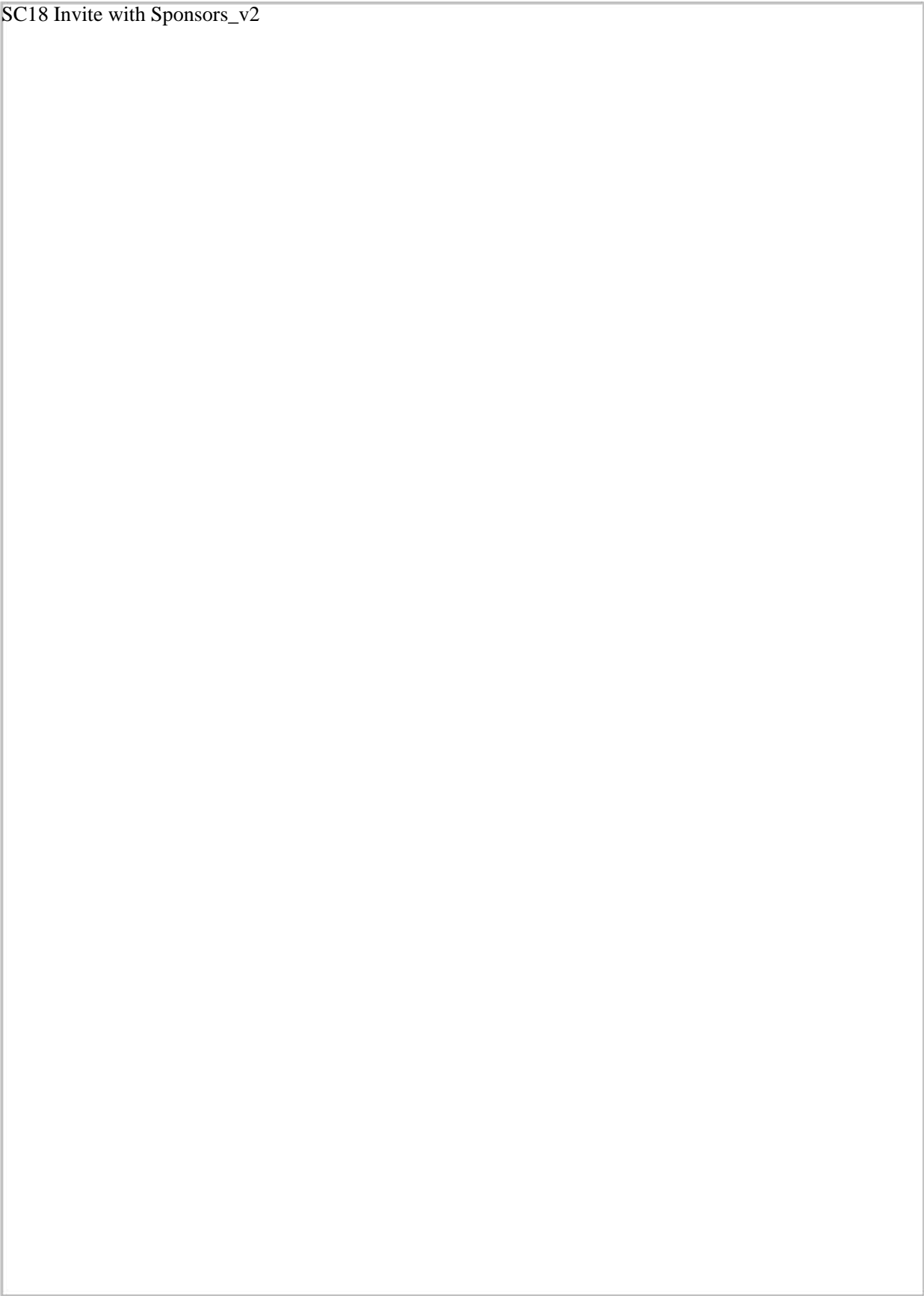
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**From:** [CropLife America & RISE](#)  
**To:** [Jill Schroeder](#)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:56 PM

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [\(b\) \(6\)@croplifeamerica.org](#); [Boswell, Kristi - OSEC, Washington, DC](#)  
**Cc:** [Bachmann, Peter - OCR, Washington, DC](#); [Ruthann Anderson](#); [Stephanie Regagnon](#);  
[\(b\) \(6\)@croplifeamerica.org](#); [Jeff Case](#); [Janet Collins](#); [Kellie Bray](#); [Epstein, David - OCE](#)  
**Subject:** Re: Bee Health and USDA!  
**Date:** Tuesday, October 16, 2018 7:34:21 PM

---

Good Evening!

Very timely message! Our office via Dr. David Epstein was in touch with Stephanie re: Fieldwatch last week about hosting a meeting at USDA as there is interest. Glad to help move this forward per your direction. Let me know how we can assist.

Cheers,  
 Sheryl

---

**From:** "Jay Vroom" <[\(b\) \(6\)@croplifeamerica.org](#)>  
**Date:** Tuesday, October 16, 2018 at 5:39:43 PM  
**To:** "Boswell, Kristi - OSEC, Washington, DC" <[Kristi.Boswell@osec.usda.gov](#)>  
**Cc:** "Bachmann, Peter - OCR, Washington, DC" <[Peter.Bachmann@osec.usda.gov](#)>, "Ruthann Anderson" <[\(b\) \(6\)@capca.com](#)>, "Stephanie Regagnon" <[\(b\) \(6\)@fieldwatch.com](#)>, "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](#)>, [\(b\) \(6\)@croplifeamerica.org](#) <[\(b\) \(6\)@croplifeamerica.org](#)>, "Jeff Case" <[\(b\) \(6\)@croplifeamerica.org](#)>, "Janet Collins" <[\(b\) \(6\)@croplifeamerica.org](#)>, "Kellie Bray" <[\(b\) \(6\)@croplifeamerica.org](#)>  
**Subject:** Re: Bee Health and USDA!

Thanks Kristi,

I'm sure Sheryl will have some ideas. Also there's no particular rush so take some time and then we can figure out how to best connect all the parties — maybe with a conference call supported by some PPT slides.

Jay

Sent from my iPhone

On Oct 16, 2018, at 3:36 PM, Boswell, Kristi - OSEC, Washington, DC <[Kristi.Boswell@osec.usda.gov](#)> wrote:

Jay,

Great to meet you. Let me do some tracking and figure out who the right agency folks are to loop in. I'll be in touch!

Thanks,  
 Kristi Boswell

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---



**From:** Bachmann, Peter - OCR, Washington, DC  
**Sent:** Tuesday, October 16, 2018 12:56:46 PM  
**To:** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC;  
(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray; Boswell, Kristi - OSEC, Washington, DC  
**Subject:** Re: Bee Health and USDA!

No worries, Jay. My colleague, Kristi Boswell, is the Secretary's Senior Advisor with the Research/Pesticide Portfolio. She should be able to assist!

Peter

---

**From:** Jay Vroom (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
**Sent:** Tuesday, October 16, 2018 12:51:39 PM  
**To:** Bachmann, Peter - OCR, Washington, DC  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC;  
(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray  
**Subject:** Bee Health and USDA!

Hi Peter,

I just spoke at the annual meeting of the California Association of Pest Control Advisors (CAPCA) — their CEO Ruthann Anderson is copied here, as is Fieldwatch CEO Stephanie Regagnon.

CAPCA and Fieldwatch are teaming up to implement what I think may be the most comprehensive bee tracking and transparency program I've seen yet— and in the state with the highest pollination services demand. They want it operational for 2019.

I'm not sure you are the right political lead person at USDA to connect with but I know you'll get us connected in all the right places at USDA ! In addition to those (like Dr Kunickis) who track pesticide issues at the intersection with bee health I think those who oversee bee loss info including emergency livestock loss payments to beekeepers all need to know about this new initiative in California!

Let me know how else I can help connect the dots?

I'll Also Share his with EPA!

Jay

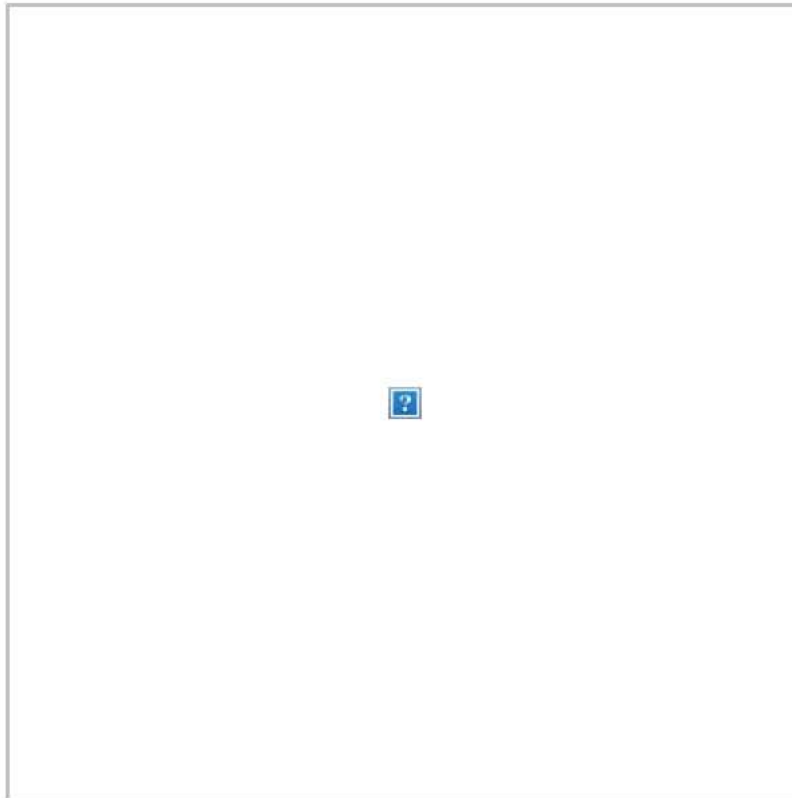
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**From:** [CropLife America & RISE](#)  
**To:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Bcc:** [dianne.fowler@oce.usda.gov](mailto:dianne.fowler@oce.usda.gov)  
**Subject:** Invitation to the CropLife America & RISE 2019 Regulatory Conference  
**Date:** Tuesday, February 19, 2019 7:19:15 AM

---



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Please respond by clicking **Yes** or **No**

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For more conference details, please email: [Francesca Purcell](#)

If you no longer want to receive emails from CropLife America & RISE, please [Opt-Out](#).

Please note you will be opted out of ALL event-related emails and will not receive event invitations in the future.



**From:** [Ray McAllister](#)  
**To:** [Jim Cranney](#); [Neena Anandaraman](#)  
**Cc:** [Julius Fajardo](#); [Lowery, Kenneth - FSIS](#); [Edward Ruckert](#); [Dan Botts](#); [Phil Korson](#); [Terry Humfeld](#); [Jim Adaskaveg](#)  
**Subject:** RE: IPPC and NAPPO Updates for U.S. Stakeholders  
**Date:** Friday, May 18, 2018 10:42:03 AM

---

Let's get the opinions of George Sundin and Jim Adaskaveg on the IPPC approach. (I don't have George's email address.)

Ray S. McAllister, PhD  
 Senior Director Regulatory Policy  
 CropLife America  
 O: (b) (6) C: (b) (6)  
 (b) (6)@croplife.us

---

**From:** Jim Cranney <(b) (6)@ccqc.org>  
**Sent:** Friday, May 18, 2018 10:36 AM  
**To:** Neena Anandaraman <Neena.Anandaraman@osec.usda.gov>; Ray McAllister <(b) (6)@croplifeamerica.org>  
**Cc:** Julius Fajardo <Julius.Fajardo@ARS.USDA.GOV>; Lowery, Kenneth - FSIS <Kenneth.Lowery@fsis.usda.gov>; Edward Ruckert <(b) (6)@mwe.com>; Dan Botts <(b) (6)@ffva.com>; Phil Korson <(b) (6)>; Terry Humfeld <(b) (6)@cranberryinstitute.org>; Jim Adaskaveg <jim.adaskaveg@ucr.edu>  
**Subject:** Re: IPPC and NAPPO Updates for U.S. Stakeholders

Hello Neena,

Yes, George is a great guy and excellent representative for this issue. We will continue to collaborate with him and Jim Adaskaveg on this issue.

Regarding the IPPC, there is also some risk that special interests could hijack the issue there as well. As you know, the EU is poised to promote its view of the world at the IPPC and all international venues. However, it could be a counterweight to Codex.

I'll talk to some people at APHIS and ask their opinion.

We'll consider it. Thanks for the suggestion.

Regards,  
 Jim

James Cranney  
 California Citrus Quality Council  
 Mobile: (b) (6)  
 (b) (6)@ccqc.org

On May 18, 2018, at 5:58 AM, "Anandaraman, Neena - OSEC" <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)> wrote:

Hi Jim and Ray,

Hope you are well! I had the good fortune of meeting George Sundin through an intro from Julius, at our AMR Advisory Council mtng on Wednesday. He did a SPECTACULAR job educating the Council on AB use in crops. The Council very much appreciated his presentation and got a lot from it. I understand he will be going to the FAO Expert meeting in June that will advise the Codex Task Force, which is very encouraging.

I saw the announcement below, and just wondered whether it may be worth the industry asking IPPC to take a more active role on antibiotic use guidelines. It seems like a more appropriate place to develop best management practices for crops than Codex, and if IPPC is not engaged, Codex will continue to try to address the gap. Likely they won't drop it as they will say they have a food safety mandate, but at least we'd have the experts at IPPC addressing GL's for use of AB's in crops, instead of food/animal experts at Codex, just as we have OIE engaged on the animals side. Of course, it may become another contentious venue to consider AMR, but just a thought for your consideration.

Thanks,  
Neena

Office: (b) (6)  
Cell (b) (6)

---

**From:** APHIS Stakeholder Registry [<mailto:aphis@subscribers.usda.gov>]  
**Sent:** Thursday, May 17, 2018 11:16 AM  
**To:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Subject:** IPPC and NAPPO Updates for U.S. Stakeholders

USDA-APHIS GovDelivery Header



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## **IPPC and NAPPO News: Updates from USDA APHIS Plant Protection and Quarantine**

### **IPPC Call for Topics: Standards and Implementation**

The International Plant Protection Convention (IPPC) has issued a call for topics. The call period is May 1 to August 31, 2018. Specifically, the IPPC is seeking proposals for new plant health standards and new tools that support the implementation of existing standards. IPPC standards play a critical role in safeguarding plant resources and creating new export opportunities for producers and exporters. Priority will be given to proposals that have the largest potential global impact, contribute to the purpose of the IPPC, can be implemented at the global level, clearly identify problems that need to be resolved through the development or implementation of standards, and for which there is adequate technical information available to support the proposed initiative. Visit the [IPPC web site](#) to view the criteria for proposals, download the submission forms, and read about other requirements.

Please send your proposals no later than July 30, 2018, to Dr. Marina Zlotina, PPQ's IPPC Technical Director: [marina.a.zlotina@aphis.usda.gov](mailto:marina.a.zlotina@aphis.usda.gov).

If you have any questions about the IPPC call for proposals, please email [Dr. Zlotina](#). We look forward to

receiving your ideas and suggestions for future IPPC work that may be a priority for your industry or organization.

### Draft Standards and Specifications for Consultation

In July, the IPPC will make several draft International Standards for Phytosanitary Measures (ISPMs) and draft specifications documents available for consultation (review and commenting). APHIS is inviting all interested stakeholders to participate in 2018 Consultation starting July 1. We will publish a complete list of drafts available for consultation, deadlines for commenting, and instructions for submitting comments on the [Draft Standards page](#) on the APHIS web site on July 1.

### NAPPO 2018 Work Program

The North American Plant Protection Organization (NAPPO) recently announced its [2018 work program](#). This year's program includes three new priority projects related to implementing international standards for seed health ([ISPM 38](#)), laboratory accreditation ([RSPM 9](#)), and plants for planting ([RSPM 35](#)). The program also includes several carry-over projects from 2017, some of which are nearing the country consultation stage. The work program reflects APHIS priorities to advance regional safeguarding initiatives, trade harmonization goals, and aligns with PPQ's top strategic areas of focus, such as seed health, forest pests, and risk-based sampling. The program also includes ongoing activities that support IPPC initiatives or obligations, such as pest reporting and ePhyto. To view the list of NAPPO's [current projects](#) and active [expert groups](#), please visit the [NAPPO web site](#).

### Upcoming NAPPO Events

NAPPO will hold its annual meeting from October 22-25, 2018, in Tucson, Arizona. Interested stakeholders are encouraged to attend. Please visit the [NAPPO web site](#) for more information. For information on NAPPO initiatives and how APHIS is involved, contact PPQ's NAPPO Technical Director, Patricia Abad at [patricia.v.abad@aphis.usda.gov](mailto:patricia.v.abad@aphis.usda.gov), or the [NAPPO Secretariat](#).

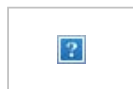
### Stay Involved!

U.S. stakeholders are vital to the work of the IPPC and NAPPO. Your input on proposed projects, review of draft standards and documents, and participation in IPPC and NAPPO events ensures we are developing relevant standards that advance U.S. harmonization goals. Standards facilitate the safe trade of plants, plant products and other regulated articles, harmonize plant protection policies and practices among and between trading partners in North America and internationally, and provide a critical framework for addressing phytosanitary trade issues and negotiating market access requests.

**Spread the Word!** If you represent a large organization or association, please distribute this message to your membership.

**Stay Connected!** To receive these updates in your inbox, please subscribe to the [APHIS Stakeholder Registry](#) and select the "International Phytosanitary Standards" topic.

---

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This email was sent to [neena.anandaraman@osec.usda.gov](mailto:neena.anandaraman@osec.usda.gov) using GovDelivery Communications Cloud on behalf of: USDA Animal and Plant Health Inspection Service · 4700 River Rd · Riverdale, MD 20737

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**From:** [Sarah Macedo](#)  
**To:** [sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)  
**Subject:** Jay Vroom Video Project - TOP SECRET  
**Date:** Thursday, May 17, 2018 2:05:29 PM  
**Attachments:** [image001.png](#)

---

Good Afternoon,

After 30 years leading CropLife America, President and CEO Jay Vroom is retiring and we would like you to be a part of this significant milestone! We are reaching out to those who have worked with Jay over the years to help us create a short video to air during our 2018 Annual Meeting.

We encourage you to send us a 10 – 20 second video message for Jay – it may contain your well wishes, a brief story, congratulations – just be sure to make it your own! Please upload your video to the following DropBox link **by July 2:**

(b) (6). After your video is uploaded to DropBox, our video editors will make your contribution look great! Rest assured, if you don't understand the technical stuff, just give me a call and I'm happy to walk you through it.

Finally, your discretion is of utmost importance! **We would love to keep this a surprise as much as we possibly can - please do not let anyone know.**

Do not hesitate to let me know of any questions and thank you for helping us celebrate Jay's life and career!

Best,  
Sarah

**Sarah Macedo**

Manager, New Media Content  
CropLife America  
1156 15th Street N.W., Suite 400  
Washington, D.C. 20005  
Office: (b) (6)

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**From:** [Ray McAllister](#)  
**To:** [Anandaraman, Neena - OSEC](#); [Jim Cranney](#); [Janet Collins](#)  
**Cc:** [Fajardo, Julius - OCE](#)  
**Bcc:** [Fajardo, Julius](#)  
**Subject:** RE: Codex question  
**Date:** Monday, October 29, 2018 10:39:52 AM

---

I would disagree with the APHIS comment. Large producers rely on crop advisors for far more than selection of crop varieties, including nutrient management, field scouting, crop protection, etc. The American Society of Agronomy established its Certified Crop Advisor program in 1992, covering the US and Canada. See <https://www.certifiedcropadviser.org/>. That said, "certified crop advisor" may not have the same meaning, or may not have any meaning in other countries.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CropLife America

(b) (6) (office)

(b) (6) (mobile)

(b) (6)@croplife.us

---

**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>

**Sent:** Monday, October 29, 2018 9:32 AM

**To:** Jim Cranney (b) (6)@ccqc.org; Ray McAllister <(b) (6)@croplifeamerica.org>; Janet Collins (b) (6)@croplifeamerica.org

**Cc:** Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>

**Subject:** Codex question

Hi All,

We got a comment from APHIS that "crop advisors" help you with what to plant each year, but have little plant health expertise. Julius suggested "certified crop advisors and consultants" instead of "crop advisors and consultants".

Any concerns?

Thanks,  
 Neena

Neena Anandaraman, DVM, MPH, DACVPM  
 Veterinary Science Policy Advisor  
 Office of the Chief Scientist  
 United States Department of Agriculture  
 Office: (b) (6)  
 Cell (b) (6)

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Janet Collins](#)  
**Cc:** [\(b\) \(6\) @croplifeamerica.org](#)  
**Subject:** Re: [CAUTION: Suspicious Link]FW: USDA Reorganization - The Economic Research Service (ERS) will realign with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of F...  
**Date:** Thursday, August 9, 2018 7:55:15 PM

---

Hi Janet,  
 No changes for us. It gives Rob a whole lot more responsibility and people! I think he will be glad to let us keep doing our work! Quite an unexpected day on many fronts!  
 Sheryl

---

**From:** "Janet Collins" [\(b\) \(6\) @croplifeamerica.org](#)>  
**Date:** Thursday, August 9, 2018 at 7:23:35 PM  
**To:** "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Cc:** [\(b\) \(6\) @croplifeamerica.org](#) <[\(b\) \(6\) @croplifeamerica.org](#)>  
**Subject:** [CAUTION: Suspicious Link]FW: USDA Reorganization - The Economic Research Service (ERS) will realign with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food ...

**PROCEED WITH CAUTION:** This message triggered warnings of **potentially** malicious web content. Evaluate this email by considering whether you are expecting the message, along with inspection for suspicious links.

Questions: [Spam.Abuse@wdc.usda.gov](mailto:Spam.Abuse@wdc.usda.gov)

Sheryl- hope all is well with you and with the work at USDA! Does this realignment have any impact on you, your offices and/or your staff?

Its hard to understand the structure given all the change!

My best,

Janet

[\(b\) \(6\)](#) (direct)

[\(b\) \(6\)](#) (mobile)

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**From:** Jimmy Liu [\(b\) \(6\) @fien.com](#)>  
**Sent:** Thursday, August 9, 2018 5:54 PM  
**To:** [\(b\) \(6\) @fien.com](#)  
**Subject:** USDA Reorganization - The Economic Research Service (ERS) will realign with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food and Agriculture (NIFA) will be...

**USDA Reorganization - The Economic Research Service (ERS), currently under USDA's Research, Education, and Economics mission area, will "... realign once again with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food and Agriculture (NIFA) will be relocated outside of the National Capital Region. The movement of the employees outside of Washington, DC is expected to be completed by the end of 2019 ... New locations have yet to be determined, and it is possible that ERS and NIFA may be co-located when their new homes are found ..."**

**Document Title:** The title of the August 9, 2018 USDA Press Release is "USDA to Realign ERS with Chief Economist, Relocate ERS & NIFA Outside DC"

**Organization:** USDA Press Office

**Source:** August 9, 2018 USDA Press Release

**Web site:** The August 9, 2018 USDA Press Release is posted at

<http://www.usda.gov/media/press-releases/2018/08/09/usda-realign-ers-chief-economist-relocate-ers-nifa-outside-dc>

**Summary:** The text of the August 9, 2018 USDA Press Release follows:

(Washington, D.C., August 9, 2018) – U.S. Secretary of Agriculture Sonny Perdue today announced further reorganization of the U.S. Department of Agriculture (USDA), intended to improve customer service, strengthen offices and programs, and save taxpayer dollars. The Economic Research Service (ERS), currently under USDA's Research, Education, and Economics mission area, will realign once again with the Office of the Chief Economist (OCE) under the Office of the Secretary. Additionally, most employees of ERS and the National Institute of Food and Agriculture (NIFA) will be relocated outside of the National Capital Region. The movement of the employees outside of Washington, DC is expected to be completed by the end of 2019.

"It's been our goal to make USDA the most effective, efficient, and customer-focused department in the entire federal government," Perdue said. "In our Administration, we have looked critically at the way we do business, with the ultimate goal of ensuring the best service possible for our customers, and for the taxpayers of the United States. In some cases, this has meant realigning some of our offices and functions, or even relocating them, in order to make more logical sense or provide more streamlined and efficient services."

**Realigning ERS with OCE**

Moving ERS back together with OCE under the Office of the Secretary simply makes sense because the two have similar missions. ERS studies and anticipates trends and emerging issues, while OCE advises the Secretary and Congress on the economic implications of policies and programs. These two agencies were aligned once before, and bringing them back together will enhance the effectiveness of economic analysis at USDA.

**Relocating ERS and NIFA outside National Capital Region**

New locations have yet to be determined, and it is possible that ERS and NIFA may be co-located when their new homes are found. USDA is undertaking the relocations for three main reasons:

1. To improve USDA's ability to attract and retain highly qualified staff with training and interests in agriculture, many of whom come from land-grant universities. USDA has experienced significant turnover in these positions, and it has been difficult to recruit employees to the Washington, DC area, particularly given the high cost of living and long commutes.
2. To place these important USDA resources closer to many of stakeholders, most of whom live and work far from the Washington, DC area.
3. To benefit the American taxpayers. There will be significant savings on employment costs and rent, which will allow more employees to be retained in the long run, even in the face of

tightening budgets.

No ERS or NIFA employees will be involuntarily separated. Every employee who wants to continue working will have an opportunity to do so, although that will mean moving to a new location for most. Employees will be offered relocation assistance and will receive the same base pay as before, and the locality pay for the new location. For those who are interested, USDA is seeking approval from the Office of Personnel Management and the Office of Management and Budget for both Voluntary Early Retirement Authority and Voluntary Separation Incentive Payments.

“None of this reflects on the jobs being done by our ERS or NIFA employees, and in fact, I frequently tell my Cabinet colleagues that USDA has the best workforce in the federal government,” Perdue said. “These changes are more steps down the path to better service to our customers, and will help us fulfill our informal motto to ‘Do right and feed everyone.’”

Perdue previously announced other significant changes at USDA. In May 2017, USDA created the first-ever Undersecretary for Trade and Foreign Agricultural Affairs (<http://www.usda.gov/media/press-releases/2017/05/11/secretary-perdue-announces-creation-undersecretary-trade> ) and reconstituted and renamed the new Farm Production and Conservation mission area, among other realignments. In addition, in September 2017, Perdue realigned a number of offices (<http://www.usda.gov/media/press-releases/2017/09/07/secretary-perdue-announces-usda-improvements-customer-service> ) to improve customer service and maximize efficiency. Those actions involved innovation, consolidation, and the rearrangement of certain offices into more logical organizational reporting structures.

#####

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-end-

The above information was sent to you by Jimmy Liu of the Food Industry Environmental Network, LLC --- <http://www.fien.com> --- mobile: (b) (6) --- e-mail: (b) (6)@fien.com

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**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Re: Call  
**Date:** Saturday, February 24, 2018 9:20:11 AM

---

After 11 I am good

> On Feb 24, 2018, at 9:04 AM, Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

>

> Anytime works! Just provide time and number!

>

> Sent from my iPhone

>

>> On Feb 24, 2018, at 8:52 AM, Jay Vroom <(b) (6)@croplifeamerica.org> wrote:

>>

>> Sheryl,

>>

>> By copy of this to Rachel, Janet and Kellie I'm checking their availability yet today. Hoping one or all of them might be able to join you and I on the phone.

>>

>> ..I'm busy between 9 and 9:45am and 11:30 am to 1pm....

>>

>> Jay

>>

>> Jay Vroom

>> President & CEO

>> CropLife America

>> Direct Dial: (b) (6)

>> Mobile: (b) (6)

>> Executive Assistant: Mary Jo Tomalewski <(b) (6)>, <(b) (6)>@croplifeamerica.org)

>>

>>

>> -----Original Message-----

>> From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]

>> Sent: Friday, February 23, 2018 10:19 PM

>> To: Jay Vroom <(b) (6)@croplifeamerica.org>

>> Subject: Re: Call

>>

>> Yes. Just let me know a time. Hope it was a lovely evening!

>>

>> Sent from my iPhone

>>

>>> On Feb 23, 2018, at 10:17 PM, Jay Vroom <(b) (6)@croplifeamerica.org> wrote:

>>>

>>> Hi Sheryl,

>>> Apologies— I've been in a dimmer meeting since 6 pm. Can I try to arrange a phone call with you tomorrow morning please?

>>> Jay

>>>

>>> Sent from my iPhone

>>>

>>>> On Feb 23, 2018, at 6:25 PM, Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

>>>>

>>>> Supper at 6:30. Anytime after 7 or let me know if Saturday or Sunday are better. Just home from Ag Outlook Forum.



>>>>

>>>> Sent from my iPhone

>>>>

>>>>

>>>>

>>>>

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** (b) [@croplifeamerica.org](#)  
**Subject:** Re: Sorry I could not answer your call—when can I call you back— maybe 8:45?  
**Date:** Monday, March 5, 2018 8:40:44 AM

---

No trouble. I was returning your call. Hope your survived the wind!!!

Sent from my iPad

On Mar 5, 2018, at 8:37 AM, Jay Vroom (b) (6) [@croplifeamerica.org](#)> wrote:

In a board meeting but can step out...

Sent from my iPhone

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Chao, Julie - FAS](#)  
**Cc:** [\(b\) \(6\) @croplifeamerica.org](#)  
**Subject:** Re: Neonics  
**Date:** Wednesday, May 2, 2018 1:18:07 PM

---

I feel so silly!

Sent from my iPad

On May 2, 2018, at 1:15 PM, Chao, Julie - FAS <[\(b\) \(6\) @fas.usda.gov](#)> wrote:

Hi Ray and Sheryl,

Glad we're all on the same page now. ☺

Ray, I am happy to share what we know about the EU's neonic ban. I'll send some more information this afternoon after I get back to my desk.

Thanks!

Julie

---

**From:** Ray McAllister [[mailto:\(b\) \(6\) @croplifeamerica.org](mailto:(b) (6) @croplifeamerica.org)]  
**Sent:** Wednesday, May 02, 2018 1:12 PM  
**To:** Kunickis, Sheryl - OSEC  
**Cc:** Chao, Julie - FAS  
**Subject:** Re: Neonics

Julie and I are well acquainted, but your message didn't mention me.

On May 2, 2018, at 1:09 PM, Kunickis, Sheryl - OSEC  
<[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

My error. I thought you knew one another! I should have made an electronic introduction. Julie is a terrific and valued honorary member of OPMP! Ray is with CropLife America and a valued partner.  
Sheryl

Sent from my iPad

On May 2, 2018, at 1:00 PM, Ray McAllister  
<[\(b\) \(6\) @croplifeamerica.org](#)> wrote:

Julie:

This is who Sheryl is talking about.

Ray S. McAllister, PhD  
 Senior Director, Regulatory Policy

CropLife America

(b) (6) (office)  
(b) (6) (cell)  
(b) (6) [@croplife.us](mailto:croplife.us)

On May 2, 2018, at 12:43 PM, Kunickis, Sheryl - OSEC  
<[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

Julie,  
Can you provide any info on the neonics and MRLs/trade in the EU?  
I told him you are more aware since it is EU?  
Thanks,  
Sheryl

Sent from my iPhone

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** (b) @croplifeamerica.org  
**Subject:** Re: Time for a phone call?  
**Date:** Friday, February 23, 2018 6:18:19 PM

---

7pm?

Sent from my iPhone

> On Feb 23, 2018, at 5:59 PM, Jay Vroom (b) (6) @croplifeamerica.org> wrote:  
>  
> Left you a voicemail message RE chance to talk before your data meeting Monday?  
> Jay  
>  
> Sent from my iPhone

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**From:** [Courtney DeMarco](#)  
**To:** [Courtney DeMarco](#)  
**Bcc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: Pre-PPDC Breakfast session - October 31, 2018  
**Date:** Thursday, October 25, 2018 2:30:50 PM  
**Importance:** High

---

All –

Just a reminder, please “accept” the calendar invitation for the breakfast, so we have a firm count to give to the hotel. If you need for me to re-send the invitation, I would be happy to do so.

Thank you,

Courtney DeMarco  
 Science and Regulatory Affairs  
 CropLife America  
 1156 15<sup>th</sup> Street, NW  
 Suite 400  
 Washington, DC 20005  
 (b) (6)

-----Original Appointment-----

**From:** Courtney DeMarco  
**Sent:** Wednesday, October 17, 2018 4:34 PM  
**Subject:** Pre-PPDC Breakfast session - October 31, 2018  
**When:** Wednesday, October 31, 2018 7:00 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** Cinnabar Restaurant; 2799 Jefferson Davis Highway, Arlington, Virginia, USA, 22202

TO: CLA Allies & Members

FROM: Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CropLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) @croplife.us

EPA has circulated the following announcement of the PPDC meeting on October 31 and November 1. Because of the different meeting format (seminar on day 2), we will hold our Pre-PPDC Breakfast session on the first day only. Please join us at 7:00 a.m. October 31 at the Cinnabar Restaurant, Hyatt Regency Hotel, 2799 Jefferson Davis Highway, Arlington, Virginia, USA, 22202. Accepting or declining this calendar invitation will constitute your RSVP for the breakfast meeting. We must wrap up shortly after 8:00 a.m., to allow time for clearing security before the earlier 8:30 a.m. start of the PPDC meeting across the street from the hotel.

Please do not forward this invitation. If there are others you think we should invite, please let me know so we can add them to the list.

---

**From:** U.S. EPA Office of Chemical Safety and Pollution Prevention <[oppt.epa@public.govdelivery.com](mailto:oppt.epa@public.govdelivery.com)>  
**Sent:** Saturday, October 13, 2018 1:25 AM  
**To:** Courtney DeMarco <(b) (6) @croplifeamerica.org>  
**Subject:** U.S. EPA Office of Chemical Safety and Pollution Prevention Daily Digest Bulletin

USAEPA Banner



## Pesticide Program Dialogue Committee Meeting October 31, 2018 and Biotechnology Seminar November 1, 2018

10/12/2018

U.S. EPA Office of Pesticide Programs Update Banner



## Pesticide Program Dialogue Committee Meeting October 31, 2018 and Biotechnology Seminar November 1, 2018

EPA's Office of Pesticide Programs (OPP) will hold a public meeting of the Pesticide Program Dialogue Committee (PPDC) on Wednesday, October 31, 2018, from 8:30 a.m. to 5:00 p.m. Additionally, on Thursday, November 1, from 8:30 a.m. to noon OPP will hold a Biotechnology Seminar. Both events will be held in EPA's first floor conference center at One Potomac Yard South, 2777 South Crystal Drive, Arlington, VA 22202. [Read the Federal Register notice announcing the PPDC meeting and biotechnology seminar.](#)

The agenda for the PPDC meeting will be available on the [PPDC webpage](#) by October 19, 2018. The PPDC provides advice and recommendations to EPA on issues associated with pesticide regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from use of pesticides. [Further information about the Pesticide Program Dialogue Committee.](#)

Both events are open to the public, and no advance registration is required. Please be aware of the ID requirements for visiting the Office of Pesticide Programs. [View additional information on the ID requirements, as well as information on the location of EPA's building and how to reach it by public transportation or car.](#) The ID requirements are under the Building Access tab and transportation information is under the HQ Buildings in Virginia tab.

For questions on these events, please contact Shannon Jewell at 703-347-0109 or [jewell\\_shannon@epa.gov](mailto:jewell_shannon@epa.gov).

EPA distributes its OPP Updates to external stakeholders and citizens who have expressed an interest in the Agency's pesticide program activities and decisions. This update service is part of EPA's continuing effort to improve public access to federal pesticide information.

For general questions about pesticides and pesticide poisoning prevention, contact the National Pesticide Information Center (NPIC) by email at [npic@ace.orst.edu](mailto:npic@ace.orst.edu) or by visiting the [NPIC website](#).

For information about ongoing activities in the Office of Pesticide Programs, [visit our homepage](#).

You can unsubscribe or update your subscriptions or e-mail address at any time on your [Subscriber Preferences Page](#). All you will need is your e-mail address. If you have any questions or problems, please e-mail [subscriberhelp.govdelivery.com](mailto:subscriberhelp.govdelivery.com) for assistance.

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This email was sent to [\[redacted\]@croplifeamerica.org](mailto:(b) [redacted]@croplifeamerica.org) using GovDelivery Communications Cloud on behalf of: U.S. EPA, Office of Chemical Safety and Pollution Prevention, 707 17th St, Suite 4000, Denver, CO 80202, 1-800-439-1420



**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Ruckert, Edward](#); [Dan Botts](#); [Glenn Barbara - FASContact](#); (b) (6) [@croplifeamerica.org](#)  
**Subject:** Re: Sad News  
**Date:** Tuesday, August 21, 2018 11:05:17 AM

You are so right, Ed. Folks around here and on USDA email are just devastated. She continued to work silently throughout her fight for life- she was truly a gem.  
 Sheryl

Sheryl H. Kunickis, Ph.D., Director  
 U.S. Department of Agriculture - Office of Pest Management Policy  
 South Building, Room 3871; 1400 Independence Ave., SW;  
 Washington, D.C. 20250-0314

(b) (6) Desk phone - (b) (6) Cell phone

[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

**From:** Ruckert, Edward (b) (6) [@mwe.com](#)>  
**Sent:** Tuesday, August 21, 2018 11:01:54 AM  
**To:** Kunickis, Sheryl - OSEC; Dan Botts; Glenn Barbara - FASContact; (b) (6) [@croplifeamerica.org](#)  
**Subject:** RE: Sad News

Sheryl,  
 Diana was a truly nice person, really devoted to public service. The news of her passing simply makes a dark day even darker. She will be missed. Thank you for the news. I will circulate it to MCFA. Regards, Ed

**Edward M. Ruckert**  
 Partner

**McDermott Will & Emery LLP** | The McDermott Building | 500 North Capitol Street, NW | Washington, DC 20001-1531  
 Tel + (b) (6) | Fax +1 202 756 8087

[Biography](#) | [Website](#) | [vCard](#) | [Email](#) | [Twitter](#) | [LinkedIn](#) | [Blog](#)

**From:** Kunickis, Sheryl - OSEC [mailto:[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)]  
**Sent:** Tuesday, August 21, 2018 9:21 AM  
**To:** Dan Botts; Ruckert, Edward; Glenn Barbara - FASContact; (b) (6) [@croplifeamerica.org](#)  
**Subject:** Fw: Sad News

Please see message.

**From:** AMS - data, amsmpo <[amsmpo.data@ams.usda.gov](mailto:amsmpo.data@ams.usda.gov)>  
**Sent:** Tuesday, August 21, 2018 8:58 AM  
**To:** [dkloss@cdpr.ca.gov](mailto:dkloss@cdpr.ca.gov); [barzin.moradi@cdfa.ca.gov](mailto:barzin.moradi@cdfa.ca.gov); Tu, Tiffany@CDFA ([tiffany.tu@cdfa.ca.gov](mailto:tiffany.tu@cdfa.ca.gov)); Aylesworth, Stacy@CDFA ([stacy.aylesworth@cdfa.ca.gov](mailto:stacy.aylesworth@cdfa.ca.gov)); sarvamangala.gunjur@cdfa.ca.gov; 'Gallegos - CDA, Don ([donz.gallegos@state.co.us](mailto:donz.gallegos@state.co.us))'; (b) (6) [@freshfromflorida.com](#); (b) (6) [@freshfromflorida.com](#); (b) (6) [@freshfromflorida.com](#); (b) (6) [@freshfromflorida.com](#); 'Parker, Gail' (b) (6) [@freshfromflorida.com](#); Saffold, Empress; [tom.phillips@maryland.gov](mailto:tom.phillips@maryland.gov); [kenneth.mcmanus@maryland.gov](mailto:kenneth.mcmanus@maryland.gov); [philip.davidson@maryland.gov](mailto:philip.davidson@maryland.gov); VanBuren, Craig (MDARD); Pruet, Jessica (MDARD); Barretta, Frank (MDARD); [regan9@michigan.gov](mailto:regan9@michigan.gov);



maria.ishida@agriculture.ny.gov; 'debra.oglesby@agriculture.ny.gov' (debra.oglesby@agriculture.ny.gov); 'karen.stephani@agriculture.ny.gov' (karen.stephani@agriculture.ny.gov); Akhtar, Saeed (AGRICULTURE); Joscelyn.Moseley@agriculture.ny.gov; Grant, Teresa M; 'ronald.willett@ncagr.gov' (ronald.willett@ncagr.gov); stephanie.moore@ncagr.gov; Beverly.Byrum@Agri.ohio.gov; Matthew.Brittain@agri.ohio.gov; 'amin@agri.ohio.gov' (amin@agri.ohio.gov); LKaminski@agri.ohio.gov; Milo, Dan (DMilo@agri.ohio.gov); Jodi.Taylor@agri.ohio.gov; 'leslie.smith@texasagriculture.gov'; 'Patrick Bizzell' (Patrick.Bizzell@texasagriculture.gov); 'hugh.robinson@texasagriculture.gov' (hugh.robinson@texasagriculture.gov); Dannis Tamplin (Dannis.Tamplin@TexasAgriculture.gov); 'barbara.sparkman@texasagriculture.gov'; BWHITE@AGR.WA.GOV; 'Mfirman@agr.wa.gov'; 'bholmes@agr.wa.gov'; nchambers@agr.wa.gov; stownsend@agr.wa.gov; Gu, Qingfen (AGR); Smith, KerryR - AMS; Simonds, Roger - AMS; Barber, Jonathan - AMS; Denski, Marie - AMS; Halmo, Karen - AMS; Guo, Ruihong - AMS; Rasmussen, Mark - FAS; Caldera, Mayra - FAS; Chao, Julie - FAS; Quan, Peter - NASS; Duan, Franklin - NASS; Rakola, Betsy - AMS; Kunickis, Sheryl - OSEC; nguyen.thuy@epa.gov; 'miller.davidj@epa.gov' (miller.davidj@epa.gov); 'hrdy.david@epa.gov' (hrdy.david@epa.gov); Chris.Sack@fda.hhs.gov; charlotte.Liang@fda.hhs.gov; Michael.Kelly@TexasAgriculture.gov

**Cc:** AMS–ST MPD

**Subject:** Sad News

We are deeply saddened to share that our beloved friend and colleague Diana Haynes passed away on August 20<sup>th</sup> (b) (6)

. We will provide details of the arrangements once they are finalized. In the meantime any cards of condolences for the family may be sent to MPD.

Diana has been with the Pesticide Data Program (PDP) since its inception. First at the Washington State Department of Agriculture laboratory in Yakima and then with the Monitoring Programs Division (MPD) as a chemist, Quality Assurance Officer, Deputy Director, and Director.

Diana's passing profoundly affects all of us. We will miss her leadership, technical knowledge, and most of all, her compassion. Her calm presence, supreme competence, and steadying influence were just part of what made her an effective leader and face of the program. If you have any questions regarding PDP operations, please feel free to contact MPD.

- Administrative – Ruihong Guo
- Financial – Dawn Fay
- Technical – Contact your laboratory liaison
- Sampling – Chris Pappas

Please be assured that MPD will carry on Diana's legacy of excellence and continue

to work with all PDP stakeholders to ensure the continued success of the program.

With deep sorrow,

The USDA's Monitoring Programs Division and Science & Technology Program

USDA, AMS, S&T, Monitoring Programs Division  
1400 Independence Ave SW  
Room 0611 South Stop 0276  
Washington DC 20250

*“The Power of Science with Quality Service”*

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\*\*\*\*\*

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**From:** [Janet Collins](#)  
**To:** [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov); [Cindy Baker-Smith \(b\) \[REDACTED\]](#) [@gowanco.com](mailto:[REDACTED]@gowanco.com); [Courtney DeMarco](#)  
**Subject:** Updates

---

**From:** Ray McAllister  
**To:** (b) (6) @synqenta.com; (b) (6) @synqenta.com; (b) (6) @dow.com; (b) (6) @dupont.com;  
 (b) (6) @bayer.com; (b) (6) @basf.com; (b) (6) @basf.com; (b) (6) @iskbc.com;  
 (b) (6) @fmc.com; (b) (6) @adama.com; (b) (6) @valent.com  
**Cc:** Sundin, George; Neena Anandaraman; Julius Fajardo; Jim; Janet Collins; Barron, Jim; Greg Mattern;  
 (b) (6) @nufarm.com; Charlotte Sanson; (b) (6) @adama.com  
**Subject:** Rop language regarding antimicrobial use  
**Date:** Friday, June 8, 2018 3:00:14 PM  
**Attachments:** [bmeps \(bactericides irc edits\).docx](#)  
**Importance:** High

---

FRAC Colleagues:

[cc: Nufarm, Arysta, Adama, & others]

We need your urgent help. George Sundin, plant pathologist at Michigan State University, is serving on an expert panel for the Codex Task Force on Antimicrobial Resistance (TFAMR). The work group is tasked with developing language for a Codex guidance document on *“Practices that Minimizes the Development of Antibiotic Resistance in Agricultural Crops”* (see attached). George will be meeting with the group next week and needs our input on the attached draft. Please let me know right away if this is within your area of expertise; are there other industry folks we should consult; do you have other approaches to recommend. I’m copying George to ask how we contact him with any feedback.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CropLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) @croplife.us

---

**From:** Anandaraman, Neena - OSEC [mailto:Neena.Anandaraman@osec.usda.gov]  
**Sent:** Friday, June 8, 2018 1:58 PM  
**To:** Jim Cranney (b) (6) @ccqc.org>; Ray McAllister (b) (6) @croplifeamerica.org>  
**Cc:** Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>  
**Subject:** crop language  
**Importance:** High

Hi Jim and Ray,

I spoke with Julius yesterday about getting back with you about language for crops that’s consistent with US practices that could be proposed for the Code of Practice. Julius had shared the attached with me. I believe Ray was going to get feedback from the FRAC Group?

Anyway, I’m circumventing Julius because I just spoke with Don about timing. He said that if you all could have language that reflects best practices of the US that you could ask George Sundin, to propose at the FAO expert meeting, he is attending this coming week, that would be ideal.

So we would need language ASAP to George.

I'm happy to talk with you all if you need further clarification.

Thanks,  
Neena

Neena Anandaraman, DVM, MPH, DACVPM  
Veterinary Science Policy Advisor  
Office of the Chief Scientist  
United States Department of Agriculture  
Office: (b) (6)  
Cell: (b) (6)

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**Practices that Minimizes the Development of Antibiotic Resistance in Agricultural Crops**

- Technical experts from universities, government agencies, agriculture extension workers, distributors, and farmers can develop region-specific resistance management guidelines to inform labeling and use of specific antimicrobial agents.
- Only authorized antimicrobial agents labeled for specific use should be used. For example, key practices to implement could include:
  - Specifying a Grouping or Code on the label, based on the region or country's technical committee recommendations
  - To reduce the likelihood that bacteria develop resistance, alternation of bactericides with a different mode of action
  - No more than two consecutive applications of the same antibiotic code or group
  - Implement resistance management strategies using involving the implementation of integrated pest management, consider use of crop varieties resistant to the pathogen of concern, use of disease forecasting models to determine application timing, and sanitation
  - Consultation with a local extension specialist or certified crop consultant, State agricultural advisor, or manufacturer when necessary
- Label restrictions and precautions- to minimize AMR could include:
  - Not applying antimicrobial agents in orchards where the soil has been fertilized with animal waste or manure.
  - Prohibiting animal grazing in treated areas and public notification through posting restriction signs along the perimeter of the treatment area.
  - Restricting the conditions of use such as the number of times an antimicrobial agent can be used through label requirements that are determined by research.
  - Limit consumer exposure by requiring a pre-harvest interval (PHI) which specifies the timing of the last antibiotic application relative to the harvest of the treated crops based on residue trials.

Commented [JRC1]: What does this mean?

| Antibiotic      | Crop                 | PHI     |
|-----------------|----------------------|---------|
| Streptomycin    | Apples               | 50 days |
|                 | Pears                | 30 days |
| Kasugamycin     | Apples / Pears       | 90 days |
|                 |                      |         |
| Oxytetracycline | Apples / Pears       | 60 days |
|                 | Peaches / Nectarines | 21 days |

Commented [JRC2]: I don't think it's necessary to include this table. Let each country determine PHIs based on their own research.

- Limit consumer exposure to AMR by the establishment of permissible antibiotic residues and legal tolerances or maximum residue levels (MRL) for bactericides on raw agricultural commodities and processed products.

- Research regarding alternatives to antibiotics that reduce the selection of antibiotic-resistant strains as well as the decrease the need for the number of treatments should be encouraged. Examples of alternatives that are currently being tested for efficacy under laboratory and field conditions include:
  - biological control (e.g. *Pseudomonas fluorescens* strain A506)
  - antimicrobial peptides
  - induced systemic resistance (e.g. acibenzolar-s-methyl)
  - durable host plant resistance
  - targeting bacterial biofilms (e.g. 2-aminoimidazole)
  - effector proteins
  - targeting quorum sensing
  - nanoparticles
  - innovations in delivery systems (e.g. endotherapy and thermotherapy)
  
- Access to University-based agriculture extension specialists and disease forecasting models can help optimize the timing of applications to target disease control and minimize the number of applications. Examples include:
  - Cougarblight, Maryblyt, Billing's system are few examples of [disease predictive models for fire blight in pome fruit](#) that evaluate weather factors to predict if conditions are favorable for the disease and if antibiotics should be sprayed (<http://ipm.ucanr.edu/DISEASE/DATABASE/fireblight.html>). [These models can then be used to communicate with growers about the best time to make effective applications.](#)
  - Maryblyt predicts specific infection events and symptom development for the different phases of fire blight epidemics in apples and pears. Maryblyt is used by growers and in research, extension and teaching programs in 32 U.S. states and in at least 36 countries.

**Commented [JRC3]:** I don't know that this should be included in a BMP document. It's understood that everyone would or should look for alternative to bactericides. These chemicals are more of a last resort, so research should be conducted to find alternatives, but this is not the place to mention it.

Specific examples of how regional guidelines and models can be used include:

- ~~The~~ Cooperative Extension [Leaders at](#) Cornell University developed guidelines for apple production regions in New York where streptomycin resistance has never been detected. In addition, the guidelines cover ~~antibiotic~~[bactericide](#) management for high risk regions where streptomycin resistance has been detected and confirmed. Below is an excerpt of the guidelines:
  - [If streptomycin resistance has been confirmed:](#)
    - a. When the first blossom infection is forecast, apply kasugamycin at 64 fl oz. /acre in 100 gallons of water. Do not spray alternate row middles. Do not apply after petal fall. Consider including the penetrating surfactant Regulaid (1 pt/100 gal of spray solution) to enhance the effectiveness of kasugamycin.
    - b. At the 2nd high risk period, apply a tank mix of streptomycin at 24 oz. /acre in combination with either oxytetracycline at 32 oz. /acre, or a bloom time rate of a registered copper product.

- At the 3rd or 4th high risk periods, repeat steps 'a' and 'b', respectively.
- If streptomycin resistance has not been confirmed, but is present in the region:
  - a. When the first blossom infection is forecast, apply a tank mix of streptomycin at 24 oz. /acre in combination with either oxytetracycline at 32 oz. /acre, or a bloom time rate of a registered copper product.
  - b. At the 2nd high risk period, apply kasugamycin at 64 fl oz. /acre in 100 gallons. Consider including the penetrating surfactant Regulaid (1 pt/100 gal of spray solution) to enhance the effectiveness of kasugamycin.
  - At the 3rd or 4th high risk period, repeat steps 'a' or 'b' depending on concerns about the effectiveness of streptomycin.
- Prohexadione-Calcium (Apogee) sprays should be applied at 6-12 oz/100 gal (3-6 oz/100 gal for tree <5 years) at 1-3 inches shoot growth. A second treatment should be made 14-21 days later. Apogee will not be effective if applied after you see fire blight symptoms.

**Commented [JRC4]:** In my opinion, this section should be deleted. This is a generic document meant to be used to develop global policy. This language doesn't belong in the document.

#### Surveillance and Monitoring of Antibiotic Resistance in Agricultural Crops

- ~~Competent~~Regulatory authorities and stakeholders should ~~determine~~identify research gaps and ~~whether there is a need~~ ~~of~~to monitoring for antibiotic resistance in plants
- Region-specific monitoring of AMR from specific antimicrobial agent use in the region should be conducted to address data gaps. For example, isolation and identification of total bacterial populations isolated from flower, leaf and soil samples from apple orchards applied with antimicrobial agents can be monitored.
- Multi-year, region-specific monitoring of AMR can help assess the extent and distribution of AMR to help determine effectiveness of the antimicrobial agent in the region.
- Genetic analysis of isolates to understand the origins and diversity of AMR in bacteria can be explored for utility in bacterial disease management, bacterial strain tracking and limiting the AMR spread in a region.

**Commented [JRC5]:** Plant host resistance is an efficacy issue. What is the relevance to human resistance.

**Commented [JRC6]:** What does this have to do with human resistance?

**Commented [JRC7]:** Will growers not know if bactericide applications are working or not? Do we want national or regional authorities telling growers when and when not to use a product? Regulators will be glad to participate here. We don't want them to. Ineffective products won't be used. Attentive researchers will know it.

**Commented [JRC8]:** Not sure about this. What's the human resistance impact?



**From:** [Ray McAllister](#)  
**To:** [Sundin, George](#)  
**Cc:** [Janis, Jonathan](#); [Akers, Rodney](#); [Neena Anandaraman](#); [Julius Fajardo](#)  
**Subject:** RE: Crop language regarding antimicrobial use  
**Date:** Monday, June 11, 2018 3:08:20 PM  
**Attachments:** [image002.png](#)

---

George:

Our Arysta colleagues confirm that the proposed crop language is consistent with their label for kasugamycin.

Ray S. McAllister, Ph.D.  
Senior Director, Regulatory Policy  
CropLife America  
(b) (6) (office)  
(b) (6) (mobile)  
(b) @croplife.us

---

**From:** Akers, Rodney [mailto:(b) (6)@arysta.com]  
**Sent:** Monday, June 11, 2018 11:35 AM  
**To:** Ray McAllister (b) (6)@croplifeamerica.org>  
**Cc:** Janis, Jonathan (b) (6)@arysta.com>  
**Subject:** FW: Crop language regarding antimicrobial use

Good Morning Ray,

Jim Barron forwarded your email to me. I am not sure what input you need from Arysta but the attached file for Crop Best Practices Guidelines is currently what Arysta has on its labels for Kasugamycin uses on Pome Fruit, Cherry and Walnuts. See response in RED below. Let me know what I can do to help. Thank you.

Best regards,  
Rodney

---

**From:** Barron, Jim  
**Sent:** Monday, June 11, 2018 9:20 AM  
**To:** Akers, Rodney (b) (6)@arysta.com>  
**Subject:** FW: Crop language regarding antimicrobial use



Jim Barron, Ph. D.  
Senior Regulatory Affairs Manager

North America



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 Cary, NC 27513  
 Office Telephone (b) (6)  
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 Email: (b) (6)@arysta.com

---

**From:** Ray McAllister [[mailto:\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]  
**Sent:** Saturday, June 09, 2018 10:57 AM  
**To:** (b) (6)@syngenta.com; (b) (6)@dow.com; (b) (6)@dupont.com;  
 (b) (6)@bayer.com; (b) (6)@basf.com; (b) (6)@basf.com; (b) (6)@iskbc.com;  
 (b) (6)@fmc.com; (b) (6)@adama.com; (b) (6)@valent.com; Gilberto Olaya  
 <(b) (6)@syngenta.com>  
**Cc:** Sundin, George <[sundin@msu.edu](mailto:sundin@msu.edu)>; Neena Anandaraman  
 <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; Julius Fajardo <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>; Jim  
 (b) (6)@ccqc.org; Janet Collins (b) (6)@croplifeamerica.org; Barron, Jim  
 <(b) (6)@arysta.com>; Greg Mattern <(b) (6)@nufarm.com>;  
 (b) (6)@nufarm.com; Charlotte Sanson <(b) (6)@adama.com>;  
 (b) (6)@adama.com  
**Subject:** Re: Crop language regarding antimicrobial use

FRAC, et al.:

Neena Anandaraman of USDA has sent an updated draft of the proposed language (attached).

I'd like to raise a few concerns, based on my profound ignorance of antibiotic use:

- There are only three antibiotics registered for crop use in the US (streptomycin, kasugamycin, and oxytetracycline). Do they have different modes of action? **Yes - Kasugamycin Group 24 , Streptomycin Group 25, and Oxytetracycline Group 41** Are they registered for the same crop uses? **All are registered for use on Pome Fruit but differ on other crops.** If the answers to these questions are no, it does not bode well for resistance management strategies based on rotation of treatments. Guidance based on impractical or impossible approaches loses credibility.
- How much difference will it mak to prohibit the use of animal manure as fertilizer or prohibit grazing of livestock? **Not a problem in the US with this restriction; manures can be used in other areas just not in orchards.** Does this consign manure to hazardous waste? Grazing may be a practical means of weed control and maintenance of cover crops.

---

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**From:** [Fajardo, Julius](#)  
**To:** [Anandaraman, Neena - OSEC](#); [Jim Cranney](#); (b) (6) [@croplifeamerica.org](#)  
**Subject:** RE: crop language  
**Date:** Monday, June 11, 2018 7:43:50 AM  
**Attachments:** [CropBestPracticeGuidelines\\_JEF Comments.docx](#)

---

Please find attached additional comments. Cheers.

---

**From:** Anandaraman, Neena - OSEC  
**Sent:** Friday, June 08, 2018 9:09 PM  
**To:** Jim Cranney <(b) (6) [@ccqc.org](#)>; (b) (6) [@croplifeamerica.org](#)  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** RE: crop language

Apologies! Please use this version instead

Office: (b) (6)  
 Cell (b) (6)

---

**From:** Anandaraman, Neena - OSEC  
**Sent:** Friday, June 8, 2018 9:06 PM  
**To:** 'Jim Cranney' (b) (6) [@ccqc.org](#); (b) (6) [@croplifeamerica.org](#)  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** RE: crop language

Hi Jim-I took a crack at this by just deleting everything questionable. Also, we don't need the surveillance piece since that's not covered in the Code of Practice.  
 Please see if the attached works and please feel free to make any other changes.

Office: (b) (6)  
 Cell (b) (6)

---

**From:** Jim Cranney [[mailto:\(b\) \(6\) @ccqc.org](mailto:(b) (6) @ccqc.org)]  
**Sent:** Friday, June 8, 2018 7:35 PM  
**To:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>;  
 (b) (6) [@croplifeamerica.org](#)  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** RE: crop language

Hello Neena,

We've already commented on the document, so all we need is Ray to sign off on it. I'll wait

to hear back from Ray. Meanwhile, can you please send me the latest edited version. I can send it out to the registrants that I know of that have antibiotic registrations.

Regards,  
Jim

James R. Cranney, Jr.  
California Citrus Quality Council  
853 Lincoln Way  
Auburn, California 95603  
Tel: (530) 885-1894  
Mobile: (b) (6)  
(b) (6) @ccqc.org

---

**From:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Sent:** Friday, June 08, 2018 10:58 AM  
**To:** Jim Cranney (b) (6) @ccqc.org; (b) (6) @croplifeamerica.org  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** crop language  
**Importance:** High

Hi Jim and Ray,

I spoke with Julius yesterday about getting back with you about language for crops that's consistent with US practices that could be proposed for the Code of Practice. Julius had shared the attached with me. I believe Ray was going to get feedback from the FRAC Group?

Anyway, I'm circumventing Julius because I just spoke with Don about timing. He said that if you all could have language that reflects best practices of the US that you could ask George Sundin, to propose at the FAO expert meeting, he is attending this coming week, that would be ideal.

So we would need language ASAP to George.

I'm happy to talk with you all if you need further clarification.

Thanks,  
Neena

Neena Anandaraman, DVM, MPH, DACVPM  
Veterinary Science Policy Advisor  
Office of the Chief Scientist  
United States Department of Agriculture  
Office: (b) (6)  
Cell: (b) (6)

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### Practices that Minimize the Development of Antibiotic Resistance in Agricultural Crops

- Technical experts from universities, government agencies, agriculture extension workers, distributors, and farmers can develop region-specific resistance management guidelines to inform labeling and use of specific antimicrobial agents.
- Only authorized antimicrobial agents labeled for specific use should be used. For example, key practices to implement could include:
  - To reduce the likelihood that bacteria develop resistance, alternate bactericides with a different mode of action
  - No more than two consecutive applications of the same antibiotic code or group
  - Implement resistance management strategies using integrated pest management, consider use crop varieties resistant to the pathogen of concern, use of disease forecasting models to determine application timing
  - Consultation with a local extension specialist or certified crop consultant, State agricultural advisor, or manufacturer when necessary
- Label restrictions and precautions to minimize AMR could include:
  - Not applying antimicrobial agents in orchards where the soil has been fertilized with animal waste or manure
  - Prohibiting animal grazing in treated areas and public notification through posting restriction signs along the perimeter of the treatment area.
  - Restricting the conditions of use such as the number of times an antimicrobial agent can be used through label requirements that are determined by research.
  - Limit consumer exposure by requiring a pre-harvest interval (PHI) which specifies the timing of the last antibiotic application relative to the harvest of the treated crops based on GLP-residue trials.
  - Establish legal tolerances or maximum residue levels (MRL) for antibacterials on raw agricultural commodities and processed products.
- Access to university-based agriculture extension specialists and disease forecasting models can help optimize the timing of applications to target disease control and minimize the number of applications. Examples include:
  - Cougarblight, Maryblyt, Billing's system are few examples of [disease predictive models for fire blight in pome fruit](#) that evaluate weather factors to predict if conditions are favorable for the disease and if antibiotics should be sprayed (<http://ipm.ucanr.edu/DISEASE/DATABASE/fireblight.html>). These models can then be used to communicate with growers about the best time to make effective applications.
  - Maryblyt predicts specific infection events and symptom development for the different phases of fire blight epidemics in apples and pears. Maryblyt is used by growers and in research, extension and teaching programs in 32 U.S. states and in at least 36 countries.

**Commented [USDA OPMP1]:** Re-phrase: Label restrictions and precautions to minimize the potential for AMR could include:

Add bulleted items such as:

- Not to be used for medical, veterinary or human purposes
- Apply only at specified and labelled rates of application.
- Applicators and other handlers must wear the required Personal Protective Equipment (PPE) as stated and specified in the label
- Do not enter or allow worker entry into treated areas during the specified Restricted-Entry Interval (REI) as stated in the label

**Commented [USDA OPMP2]:** Include also human biosolids in addition to animal waste or manure

Specific examples of how regional guidelines and models can be used include:

- Cooperative Extension Leaders at Cornell University developed guidelines for apple production regions in New York where streptomycin resistance has never been detected. In addition, the guidelines cover bactericide management for high risk regions where streptomycin resistance has been detected and confirmed. Below is an excerpt of the guidelines:

DRAFT



**From:** [Courtney DeMarco](#)  
**To:** [Ray McAllister](#)  
**Subject:** Pre-PPDC Breakfast Meeting  
**Attachments:** [Final Agenda for May 2018 PPDC Meeting 4 18 18.docx](#) Attachment withheld as duplicate

---

TO: CLA Members, Friends and Allies (on BCC: line)

FROM: Ray McAllister & Courtney DeMarco, CLA

The next Pesticide Program Dialogue Committee meeting takes place on Wednesday and Thursday, May 2 and 3. CLA invites you to our customary breakfast sessions for those attending each day's PPDC session in Crystal City, VA. The locale is the Cinnabar Restaurant, level 2 of the Hyatt Regency Crystal City Hotel (2799 Jefferson Davis Highway, Arlington, VA 22202), across the street from the OPP headquarters where the PPDC meeting takes place. These are opportunities to compare notes on the coming agenda items for the day, and the discussion of the day before. EPA's final agenda for the PPDC meeting is attached. We welcome your contributions to notes on agenda topics for ag allies serving on the PPDC (By Monday April 30), which we will share at the breakfast sessions.

This invitation is going to Ag allies serving on the PPDC, Members of the Pesticide Policy Coalition, CLA committees, and other ag allies. If there are others you would like us to invite, or you are not certain if they are already included, please let us know, and we will invite them directly (rather than forwarding this message).

Please respond promptly, as attendance may be limited by the space available. We need a separate RSVP for each day you plan to attend the breakfast. Unfortunately, call-in participation will not be possible for the breakfast discussion.

**From:** [Courtney DeMarco](#)  
**To:** [Ray McAllister](#); [Sci Reg](#); [Amy Asmus](#)  
**Cc:** [Mike Kellogg](#); [Gus Zieske](#); [Lisa Nichols](#); [Tessa Scown](#); [JACKSON - GHEISSARI, AMELIA ELIZABETH \[AG/1920\]](#); [LEOPOLD, VINCENT A \[AG/1005\]](#); [Carrie Tackema](#); [John Carbone](#); [John M Brausch](#); [Bob Mann](#); [Jeff Giddings](#); [Catherine M Holmes](#); [Green, Charles](#); [Jonynas, Ann](#); [Layton, Ray](#); [Mark Trostle](#); [Cain, Jack](#); [Laurent Oger](#); [Trish Sheehy](#); [Daniel Eugene Edwards](#); [Steven D. Bennett](#); [Holt, Doug](#); [Shari Long](#); [Ann Blacker](#); [Alan Samel](#); [Faith Kee](#); [Nag, Jayanta](#); [Matt McCoole](#); [Jackson, Scott](#); [\(b\) \(6\)](#); [Turnbough, Anne](#); [Ephi Gur](#); [Linda Mitchell](#); [Greg Wuthnow](#); [Seibert, Nicholas](#); [Patti Turner](#); [Khalid Akkari](#); [Zeller, Samuel](#); [Nicole O'Loughlin](#); [Douglas Hines](#); [Christian Picard](#); [Charlotte Sanson](#); [Thatcher Mary Kay USWS](#); [Adriana M Doi](#) **Courtney Demarco**  
**Subject:** Pre-PPDC Breakfast Meeting - NEW LOCATION  
**Attachments:** [Final Agenda for May 2018 PPDC Meeting 4 18 18.docx](#) Attachment withheld as duplicate  
**Importance:** High

Update on Location 4/30/18:

Renaissance Capital View, 2800 South Potomac Avenue, Arlington VA 22202, Studio A (from front door, go to your left and up the main staircase to the second floor, the room is to the right of the staircase on the opposite side).

If you have any questions the day of the breakfast, feel free to call or text Courtney @ [\(b\) \(6\)](#).

Please RSVP again to the calendar invite whether you plan to attend or cannot attend the breakfast.

Thank you,

Courtney DeMarco and Ray McAllister

TO: CLA Members, Friends and Allies (on BCC: line)

FROM: Ray McAllister & Courtney DeMarco, CLA

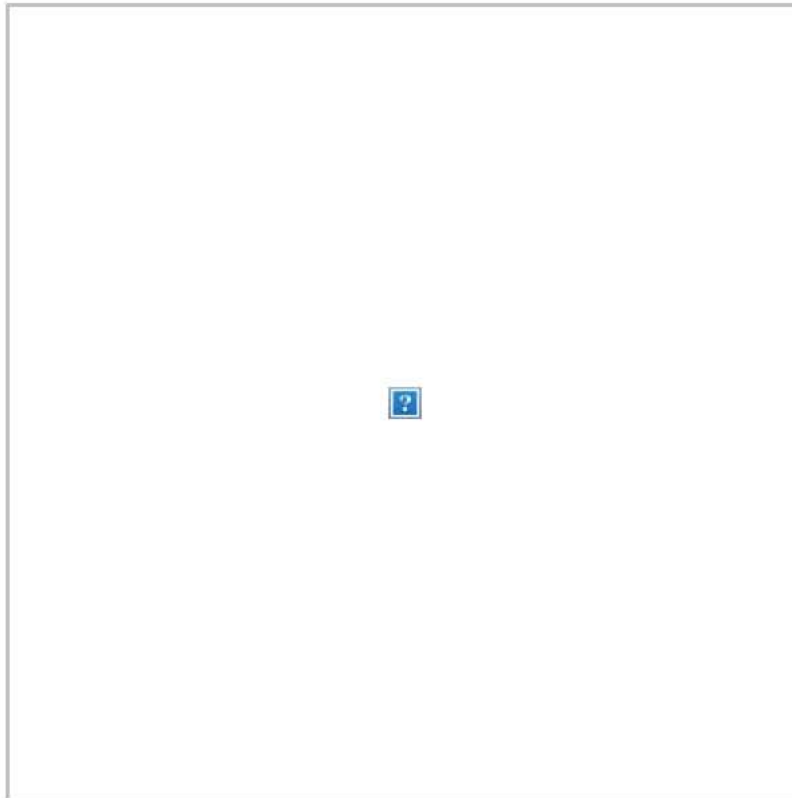
The next Pesticide Program Dialogue Committee meeting takes place on Wednesday and Thursday, May 2 and 3. CLA invites you to our customary breakfast sessions for those attending each day's PPDC session in Crystal City, VA. The locale is the Renaissance Capital View, 2800 South Potomac Avenue, Arlington VA 22202 Cinnabar Restaurant, level 2 of the Hyatt Regency Crystal City Hotel (2799 Jefferson Davis Highway, Arlington, VA 22202), across the street from the OPP headquarters where the PPDC meeting takes place. These are opportunities to compare notes on the coming agenda items for the day, and the discussion of the day before. EPA's final agenda for the PPDC meeting is attached. We welcome your contributions to notes on agenda topics for ag allies serving on the PPDC (By Monday April 30), which we will share at the breakfast sessions.

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Please respond promptly, as attendance may be limited by the space available. We need a separate RSVP for each day you plan to attend the breakfast. Unfortunately, call-in participation will not be possible for the breakfast discussion.

**From:** [CropLife America & RISE](#)  
**To:** [teung.chin@ars.usda.gov](mailto:teung.chin@ars.usda.gov)  
**Bcc:** [teung.chin@oce.usda.gov](mailto:teung.chin@oce.usda.gov)  
**Subject:** Invitation to the CropLife America & RISE 2019 Regulatory Conference  
**Date:** Tuesday, February 19, 2019 7:19:16 AM

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13, 2019

**Ready to RSVP?**

Please respond by clicking **[Yes](#)** or **[No](#)**

We look forward to seeing you!

For more conference details, please email: [Francesca Purcell](#)

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Please note you will be opted out of ALL event-related emails and will not receive event invitations in the future.



**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Karen Cain](#)  
**Cc:** [Hamilton, Robert \(b\) \(6\) \[REDACTED\]@valent.com](#); [\(b\) \(6\) \[REDACTED\]@croplifeamerica.org](#)  
**Subject:** Re: guest at March 20 CLA Registration Cmt meeting?  
**Date:** Wednesday, March 7, 2018 4:53:11 PM

---

Thanks, Karen! These are excellent questions. I look forward to meeting with the committee.  
Sheryl

Sent from my iPhone

On Mar 7, 2018, at 1:29 PM, Karen Cain <[\(b\) \(6\) \[REDACTED\]@bayer.com](#)> wrote:

Sheryl – let’s schedule your discussion w/ CLA on March 20 right after lunch (1:00 – 2:00). You are welcome to join us for lunch.

I have already collected the following questions/topics for discussion. I will forward you additional questions that come in during the next 2 days (I will send them to your gmail account since you will be traveling).

1. You have been successful in recently hiring new additions to your team during the past year or two. Are these newly created positions or filling of previously existing positions? Can you provide an organizational chart for your Dept and clarity on the work being done by each?
2. There are a significant number of registration review dockets opened and in various stages in the process. How does your team keep aware of these dockets and when comment periods are open? Do you comment on all dockets? If not, how do you determine which dockets/uses to comment on? What is your internal process in preparing comments prior to posting? Do you share them with EPA prior to posting?
3. Under the EPA Reduced risk process, I believe EPA is required to consult with USDA. Is this correct and, if so, does this happen? If yes, how and when does this occur? Similarly, EPA has put more emphasis on a benefits assessment related to new active ingredients and uses. What, if any role, is OPMP providing in this process?
4. How does OPMP view its role in the PPDC meetings and process?
5. Does OPMP play a role in SAPs, particularly when they are related to new or existing technologies for growers eg Bt for insect control?
6. How much time and activity is spent on ESA type activities by your team. What type of information is most helpful to your team in this area? What type of information can you provide registrants as they are working with EPA to mitigate risks resulting from ESA?
7. Does your Agency/department have a formal MOA with EPA – what does that look like?

Thanks again for your willingness to meet w/ CLA Registration Committee members.

Freundliche Grüße / Best regards,

**Karen Cain**

**Sr Regulatory Manager**

////////////////////

Bayer U.S. LLC  
Crop Science, Crop Science  
Registrations  
2 TW Alexander Drive  
Durham NC 27709  
United States

Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6) @bayer.com  
Web: <http://www.bayer.us>

---

**From:** Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
**Sent:** Tuesday, March 06, 2018 8:43 AM  
**To:** Karen Cain  
**Cc:** Hamilton, Robert (b) (6) @valent.com; (b) (6) @croplifeamerica.org  
**Subject:** Re: guest at March 20 CLA Registration Cmt meeting?

Hi Karen,

I am glad to join the meeting. The entire day is meeting free, so choose the best time.

Note I will be overseas from March 8 and back on March 19. If you send the questions, send them to (b) (6) Sheryl Kunickis

Thanks,  
Sheryl

Sent from my iPad

On Mar 5, 2018, at 10:35 AM, Karen Cain (b) (6) @bayer.com> wrote:

Sheryl – as Chair of the CLA Registration Committee, I would like to invite you to attend the March 20<sup>th</sup> meeting for a discussion with committee members on recent activities within USDA’s Office of Pest Management Policy. It has been several months (a couple of years in fact) since the CLA Reg Committee has had the opportunity to meet with you. If you are available, I will provide a list of questions by end of this week so you can be prepared.

Our schedule is flexible anytime between 9:30 – 2:30 and we meet at the CLA Offices (1156 15<sup>th</sup> St NW, Suite 400). Please let me know if you would be available to meet with us for an hour during this time.  
Thanks!

Freundliche Grüße / Best regards,

**Karen Cain**

**Sr Regulatory Manager**



Bayer U.S. LLC  
Crop Science, Crop Science  
Registrations  
2 TW Alexander Drive  
Durham NC 27709  
United States

Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6) @bayer.com  
Web: <http://www.bayer.us>

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---

**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Francesca Purcell](#)  
**Subject:** Re: Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 21, 2018 3:04 02 PM

Clayton is my new employee I was looking thru the site so that I could give him details about registering I plan to register I wondered why I received a copy of his registration, but figured he referenced me!

Sent from my iPad

On Mar 21, 2018, at 2:56 PM, Francesca Purcell (b) [redacted] @croplifeamerica.org wrote:

Hi Sheryl,

This registration is for Clayton Myers (email [clayton.myers@ars.usda.gov](mailto:clayton.myers@ars.usda.gov)) - Was this sent to you or did you mean to forward to someone else? I see you've visited the site but NOT registered.

Thank you,

Francesca Purcell  
 CropLife America  
 RISE (Responsible Industry for a Sound Environment)  
 Meetings & Events  
<http://pestfacts.net/risemember/events/calendar/>  
<https://www.croplifeamerica.org/events/>

1156 15<sup>th</sup> Street, NW  
 Suite 400  
 Washington DC 20005

(b) (6) (d)  
 (b) (6) (m)

---

**From:** Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
**Sent:** Wednesday, March 21, 2018 2:39 PM  
**To:** Francesca Purcell (b) [redacted] @croplifeamerica.org  
**Subject:** Re: Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference

:)

Sent from my iPad

On Mar 21, 2018, at 2:33 PM, CropLife America & RISE (b) [redacted] @croplifeamerica.org wrote:



Dear Clayton:

Your registration has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time  
**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA  
**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

| Registration Information: |                                                                                             |                      |
|---------------------------|---------------------------------------------------------------------------------------------|----------------------|
| Registration Items        |                                                                                             |                      |
| Clayton Myers             | CLA & RISE 2018 Regulatory Conference                                                       |                      |
| Sessions                  |                                                                                             |                      |
| Clayton Myers             | Networking Breakfast                                                                        | 26-Apr-2018 7:00 AM  |
| Clayton Myers             | General Session                                                                             | 26-Apr-2018 8:00 AM  |
| Clayton Myers             | Series I - Application of Environmental Epidemiology in Risk Assessment and Decision-Making | 26-Apr-2018 10:30 AM |

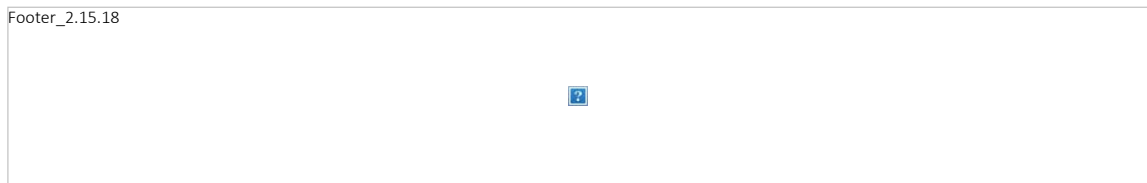


|                               |                                                                                                      |                      |
|-------------------------------|------------------------------------------------------------------------------------------------------|----------------------|
| Clayton Myers                 | Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process                      | 26-Apr-2018 10:30 AM |
| Clayton Myers                 | Networking Lunch                                                                                     | 26-Apr-2018 12:00 PM |
| Clayton Myers                 | Series II - Charting a Path Forward for the Use of Population Modeling in Ecological Risk Assessment | 26-Apr-2018 1:15 PM  |
| Clayton Myers                 | Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome    | 26-Apr-2018 3:00 PM  |
| Clayton Myers                 | Networking Reception                                                                                 | 26-Apr-2018 4:45 PM  |
| Clayton Myers                 | Networking Breakfast                                                                                 | 27-Apr-2018 7:00 AM  |
| Clayton Myers                 | General Session                                                                                      | 27-Apr-2018 8:00 AM  |
| Clayton Myers                 | Series IV - Challenges and Recommendations for Generating and Utilizing Higher-Tier Data in Ecologic | 27-Apr-2018 9:45 AM  |
| Clayton Myers                 | Series IV - Pollinator Protection Priorities                                                         | 27-Apr-2018 9:45 AM  |
| Clayton Myers                 | Series V - Other Ingredients and Their Roles in Crop Protection                                      | 27-Apr-2018 11:15 AM |
| <b>Additional Information</b> |                                                                                                      |                      |
| Clayton Myers                 | When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee       |                      |

[Click here for the event agenda](#)  
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[Event Registration Confirmation number: K3NEBH2ZGWL](#)

We look forward to seeing you in April!

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[Content](#)

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**From:** [CropLife America & RISE](#)  
**To:** [Rosalind James](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** Early Bird Rates still available! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 28, 2018 8:18:10 AM

---

Sponsor Invite



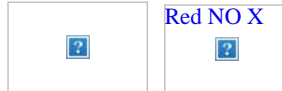
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Ready to RSVP? Respond by clicking one of the buttons below!



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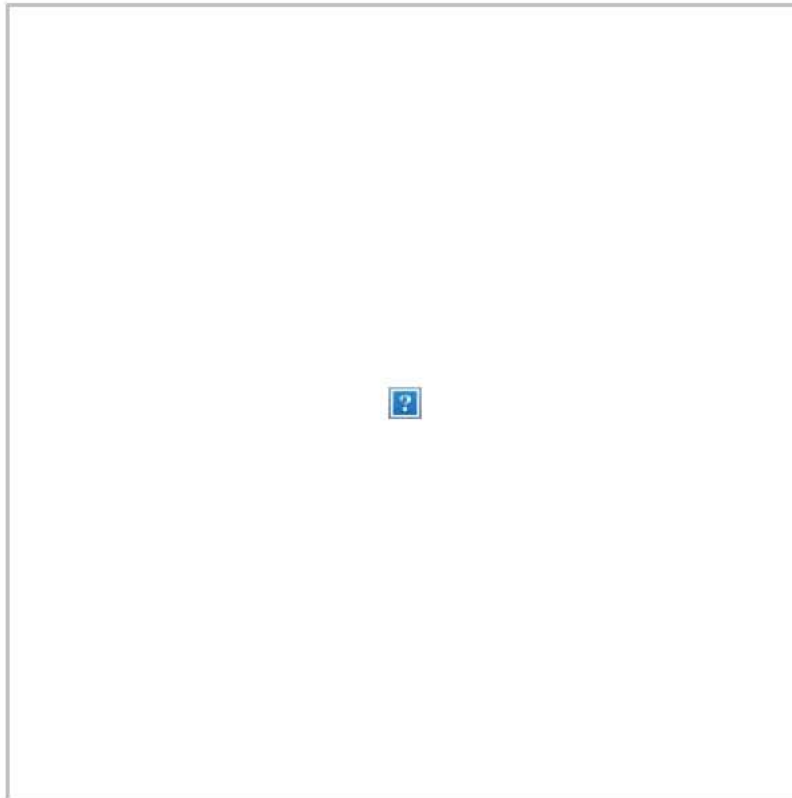


**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Mary Jo Tomalewski](#)  
**Subject:** Accepted: Meeting with Sheryl Kunickis

---

**From:** [CropLife America & RISE](#)  
**To:** [teung.chin@ars.usda.gov](mailto:teung.chin@ars.usda.gov)  
**Bcc:** [teung.chin@oce.usda.gov](mailto:teung.chin@oce.usda.gov)  
**Subject:** Invitation to the CropLife America & RISE 2019 Regulatory Conference  
**Date:** Monday, February 11, 2019 2:55:47 PM

---



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13, 2019

**Ready to RSVP?**

Please respond by clicking [Yes](#) or [No](#)

We look forward to seeing you!

For more conference details, please email: [Francesca Purcell](#)

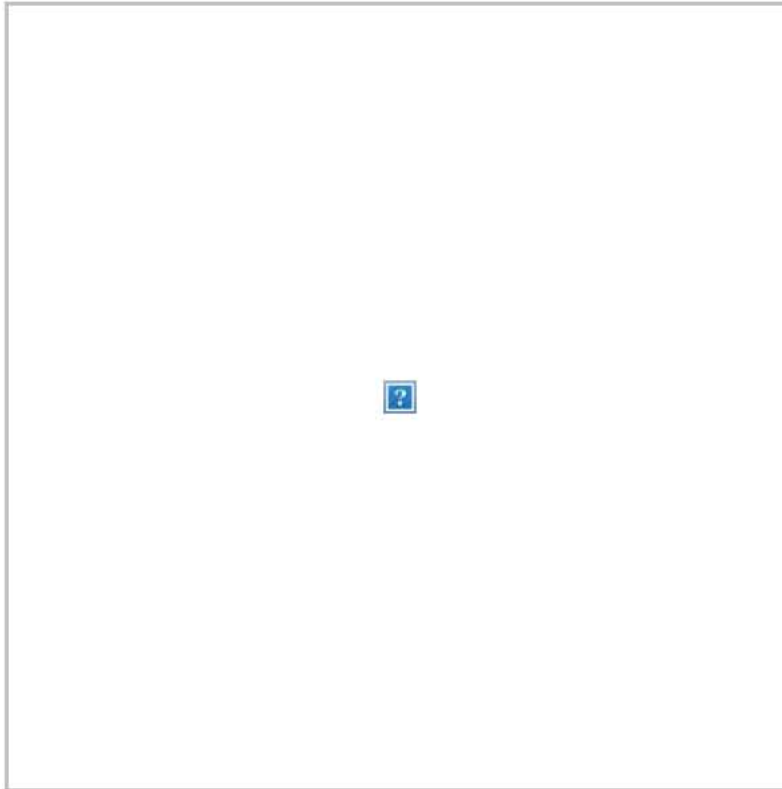
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**From:** [Francesca Purcell](#)  
**To:** [Teung Chin](#)  
**Bcc:** [teung.chin@oce.usda.gov](mailto:teung.chin@oce.usda.gov)  
**Subject:** Registration Confirmed - CropLife America & RISE 2019 Regulatory Conference  
**Date:** Tuesday, February 19, 2019 8:13:43 AM

---



Dear Teung,

Your registration has been confirmed. Please save this email for future reference.

**Event:** CropLife America & RISE 2019 Regulatory Conference

**Attending:** Teung Chin

**Date:** April 3, 2019 - Apr 5, 2019

**Confirmation Number:** P6ND59NDPY4

[Add to calendar](#)

**Current Registration:**

|                                  |                    |             |
|----------------------------------|--------------------|-------------|
| <b>Registration Information:</b> |                    |             |
| <b>Registration Items</b>        |                    |             |
| Teung<br>Chin                    | Event Registration |             |
| <b>Sessions</b>                  |                    |             |
| Teung                            | Welcome Reception  | 03-Apr-2019 |

|               |                                                                                                      |                         |
|---------------|------------------------------------------------------------------------------------------------------|-------------------------|
| Chin          |                                                                                                      | 5:00 PM                 |
| Teung<br>Chin | Series I - Science Policy Activities for Endangered Species Risk Assessment                          | 04-Apr-2019<br>10:30 AM |
| Teung<br>Chin | Series II - Expert Panel: Application of Use and Usage Data in an Endangered Species Risk Assessment | 04-Apr-2019<br>1:15 PM  |
| Teung<br>Chin | Series III - Water, Water, Everywhere: Methods to Estimate Concentrations of Pesticides...           | 04-Apr-2019<br>3:00 PM  |
| Teung<br>Chin | Networking Reception                                                                                 | 04-Apr-2019<br>5:00 PM  |
| Teung<br>Chin | General Session - EPA Office of Pesticide Programs: Today, Tomorrow, and Beyond                      | 05-Apr-2019<br>8:00 AM  |
| Teung<br>Chin | Series IV - Part 1: Potential Options for Up-front Species Conservation and the Benefits of These... | 05-Apr-2019<br>9:45 AM  |
| Teung<br>Chin | Series V - Part 2: Potential Options for Up-front Species Conservation and the Benefits of These...  | 05-Apr-2019<br>11:15 AM |



We look forward to seeing you in April!

For more conference details, please email: [Francesca Purcell](#)

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**From:** [Courtney DeMarco](#)  
**To:** [Kunickis, Sheryl - OSEC](#); [Janet Collins](#); [Ray McAllister](#)  
**Subject:** RE: Monday?  
**Date:** Monday, November 5, 2018 9:13:30 AM

---

(b) (6)

---

**From:** Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Sent:** Monday, November 5, 2018 8:45 AM  
**To:** Janet Collins <(b) (6)@croplifeamerica.org>; Ray McAllister <(b) (6)@croplifeamerica.org>  
**Subject:** Re: Monday?

Let me know when you have availability and the best phone number. I have meetings from 10-11 and 1-2:30 pm.

Cheers,

Sheryl

Sheryl H. Kunickis, Ph.D., Director  
U.S. Department of Agriculture - Office of Pest Management Policy  
South Building, Room 3871; 1400 Independence Ave., SW;  
Washington, D.C. 20250-0314  
(202 720-5375 Desk phone - (b) (6) Cell phone  
[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Janet Collins <(b) (6)@croplifeamerica.org>  
**Sent:** Friday, November 2, 2018 5:39:06 PM  
**To:** Kunickis, Sheryl - OSEC; (b) (6)@croplifeamerica.org  
**Subject:** Re: Monday?

Of course

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---

**From:** Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Sent:** Friday, November 2, 2018 5:38:21 PM  
**To:** Ray McAllister; Janet Collins  
**Subject:** Monday?

Missed your call. (b) (6). Can we talk Monday morning?  
Sheryl

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Boswell, Kristi - OSEC, Washington, DC](#); (b) (6) [@croplifeamerica.org](#)  
**Subject:** Fw: Bee Health and USDA!  
**Date:** Thursday, October 18, 2018 2:54:32 PM

---

Hi Kristi and Jay,

David and I met with Stephanie by phone today. We are tentatively looking at a date in January to host FieldWatch at USDA. Once we figure out schedules, etc. , I will let you know more.

Cheers,  
 Sheryl

Sheryl H. Kunickis, Ph.D., Director  
 U.S. Department of Agriculture - Office of Pest Management Policy  
 South Building, Room 3871; 1400 Independence Ave., SW;  
 Washington, D.C. 20250-0314  
 (202 720-5375 Desk phone - (b) (6) Cell phone  
[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Stephanie Regagnon (b) (6) [@fieldwatch.com](#)>  
**Sent:** Thursday, October 18, 2018 2:32 PM  
**To:** Kunickis, Sheryl - OSEC; Epstein, David - OCE  
**Subject:** RE: Bee Health and USDA!

Dave and Sheryl –

So nice to chat with you today! I look forward to working with you!

Stephanie

---

**From:** Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Sent:** Tuesday, October 16, 2018 6:34 PM  
**To:** (b) (6) [@croplifeamerica.org](#); Boswell, Kristi - OSEC, Washington, DC  
 <[Kristi.Boswell@osec.usda.gov](mailto:Kristi.Boswell@osec.usda.gov)>  
**Cc:** Bachmann, Peter - OCR, Washington, DC  
 <[Peter.Bachmann@osec.usda.gov](mailto:Peter.Bachmann@osec.usda.gov)>; Ruthann Anderson  
 (b) (6) [@capca.com](#)>; Stephanie Regagnon (b) (6) [@fieldwatch.com](#)>;

(b) (6) @croplifeamerica.org; Jeff Case <(b) (6)@croplifeamerica.org>; Janet Collins (b) (6) @croplifeamerica.org; Kellie Bray (b) (6) @croplifeamerica.org; Epstein, David - OCE <David.Epstein@OCE.USDA.GOV>

**Subject:** Re: Bee Health and USDA!

Good Evening!

Very timely message! Our office via Dr. David Epstein was in touch with Stephanie re: Fieldwatch last week about hosting a meeting at USDA as there is interest. Glad to help move this forward per your direction. Let me know how we can assist.

Cheers,  
Sheryl

---

**From:** "Jay Vroom" <(b) (6)@croplifeamerica.org>  
**Date:** Tuesday, October 16, 2018 at 5:39:43 PM  
**To:** "Boswell, Kristi - OSEC, Washington, DC" <Kristi.Boswell@osec.usda.gov>  
**Cc:** "Bachmann, Peter - OCR, Washington, DC" <Peter.Bachmann@osec.usda.gov>, "Ruthann Anderson" <(b) (6)@capca.com>, "Stephanie Regagnon" (b) (6) @fieldwatch.com>, "Kunickis, Sheryl - OSEC" <Sheryl.Kunickis@osec.usda.gov>, (b) (6) @croplifeamerica.org" (b) (6) @croplifeamerica.org>, "Jeff Case" <(b) (6)@croplifeamerica.org>, "Janet Collins" (b) (6) @croplifeamerica.org>, "Kellie Bray" <(b) (6)@croplifeamerica.org>  
**Subject:** Re: Bee Health and USDA!

Thanks Kristi,

I'm sure Sheryl will have some ideas. Also there's no particular rush so take some time and then we can figure out how to best connect all the parties — maybe with a conference call supported by some PPT slides.

Jay

Sent from my iPhone

On Oct 16, 2018, at 3:36 PM, Boswell, Kristi - OSEC, Washington, DC  
<[Kristi.Boswell@osec.usda.gov](mailto:Kristi.Boswell@osec.usda.gov)> wrote:

Jay,

Great to meet you. Let me do some tracking and figure out who the right agency folks are to loop in. I'll be in touch!

Thanks,  
Kristi Boswell

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---

**From:** Bachmann, Peter - OCR, Washington, DC  
**Sent:** Tuesday, October 16, 2018 12:56:46 PM  
**To:** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC; (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray; Boswell, Kristi - OSEC, Washington, DC  
**Subject:** Re: Bee Health and USDA!

No worries, Jay. My colleague, Kristi Boswell, is the Secretary's Senior Advisor with the Research/Pesticide Portfolio. She should be able to assist!

Peter

---

**From:** Jay Vroom <(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
**Sent:** Tuesday, October 16, 2018 12:51:39 PM  
**To:** Bachmann, Peter - OCR, Washington, DC  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC; (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray

**Subject:** Bee Health and USDA!

Hi Peter,

I just spoke at the annual meeting of the California Association of Pest Control Advisors (CAPCA) — their CEO Ruthann Anderson is copied here, as is Fieldwatch CEO Stephanie Regagnon.

CAPCA and Fieldwatch are teaming up to implement what I think may be the most comprehensive bee tracking and transparency program I've seen yet— and in the state with the highest pollination services demand. They want it operational for 2019.

I'm not sure you are the right political lead person at USDA to connect with but I know you'll get us connected in all the right places at USDA ! In addition to those (like Dr Kunickis) who track pesticide issues at the intersection with bee health I think those who oversee bee loss info including emergency livestock loss payments to beekeepers all need to know about this new initiative in California!

Let me know how else I can help connect the dots?

I'll Also Share his with EPA!

Jay

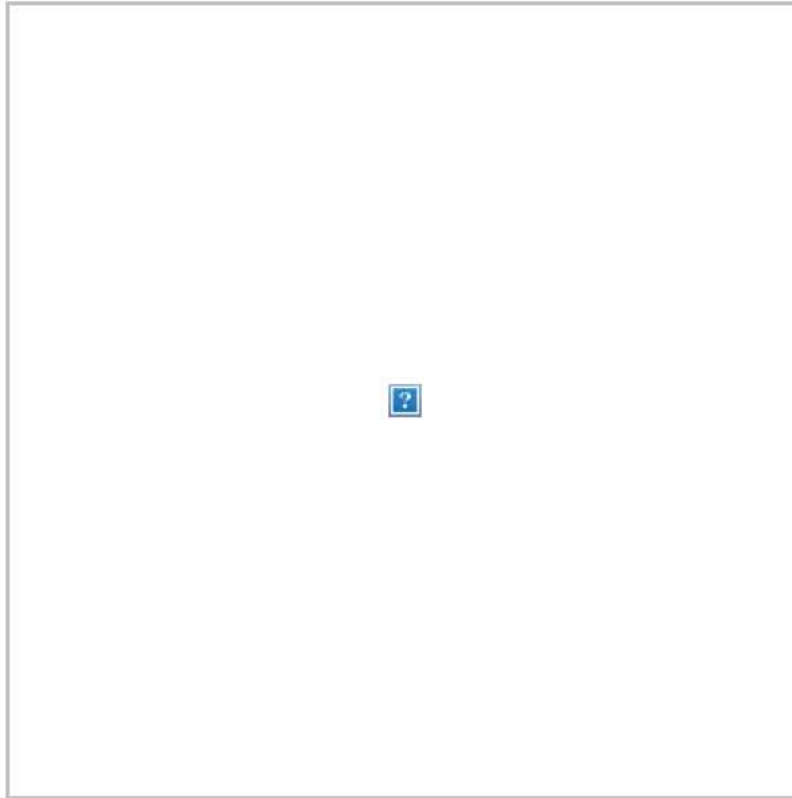
Sent from my iPhone

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**From:** [CropLife America & RISE](#)  
**To:** [sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)  
**Subject:** Invitation to the CropLife America & RISE 2019 Regulatory Conference  
**Date:** Monday, February 11, 2019 2:55:47 PM

---



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We look forward to seeing you!



For more conference details, please email: [Francesca Purcell](#)

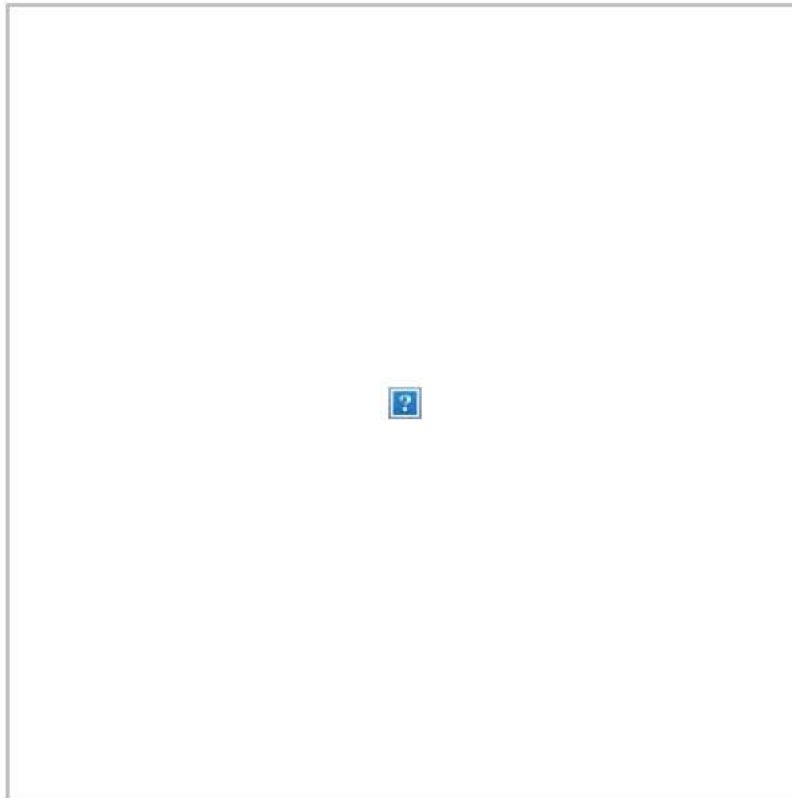
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**From:** [CropLife America & RISE](#)  
**To:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Bcc:** [dianne.fowler@oce.usda.gov](mailto:dianne.fowler@oce.usda.gov)  
**Subject:** Invitation to the CropLife America & RISE 2019 Regulatory Conference  
**Date:** Monday, February 11, 2019 2:55:47 PM

---



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We look forward to seeing you!

For more conference details, please email: [Francesca Purcell](#)

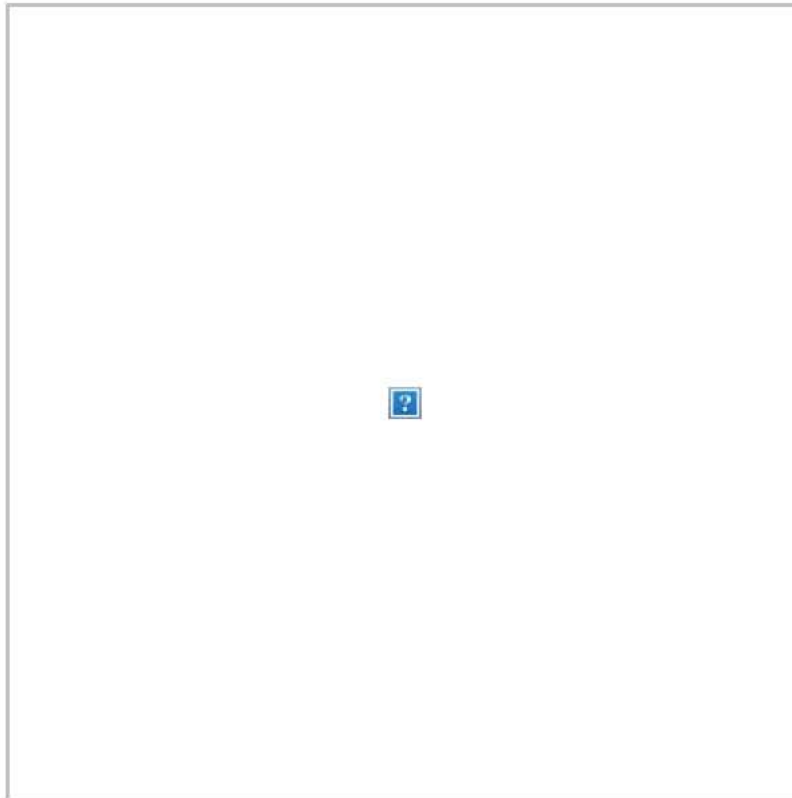
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**From:** [CropLife America & RISE](#)  
**To:** [jill.schroeder@ars.usda.gov](mailto:jill.schroeder@ars.usda.gov)  
**Bcc:** [jill.schroeder@oce.usda.gov](mailto:jill.schroeder@oce.usda.gov)  
**Subject:** Invitation to the CropLife America & RISE 2019 Regulatory Conference  
**Date:** Monday, February 11, 2019 2:55:48 PM

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Group room rates are available at the Renaissance Capital View Hotel until March  
13, 2019

**Ready to RSVP?**

Please respond by clicking **[Yes](#)** or **[No](#)**

We look forward to seeing you!

For more conference details, please email: [Francesca Purcell](#)

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**From:** [Rachel Lattimore](#)  
**To:** [exsec@ios.doi.gov](mailto:exsec@ios.doi.gov); [WLRoss@doc.gov](mailto:WLRoss@doc.gov); [Pruitt.scott@epa.gov](mailto:Pruitt.scott@epa.gov); [Sonny.Purdue@osec.usda.gov](mailto:Sonny.Purdue@osec.usda.gov)  
**Cc:** (b) (6) [@who.eop.gov](mailto:@who.eop.gov); [mhickey@omb.eop.gov](mailto:mhickey@omb.eop.gov); [Christopher.D.Prandoni@ceq.eop.gov](mailto:Christopher.D.Prandoni@ceq.eop.gov); [Gregory\\_Sheehan@fws.gov](mailto:Gregory_Sheehan@fws.gov); [Chris.W.Oliver@noaa.gov](mailto:Chris.W.Oliver@noaa.gov); [Bertrand.Charlotte@epa.gov](mailto:Bertrand.Charlotte@epa.gov); [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Subject:** January 31, 2018 Memorandum of Agreement Implementation  
**Date:** Tuesday, April 10, 2018 3:51:18 PM  
**Attachments:** [ESA FIFRA MOA Letter 041018.pdf](#)

---

Secretary Zinke, Secretary Ross, Secretary Purdue and Administrator Pruitt:

Please see the attached letter.

Sincerely,

Rachel G. Lattimore  
Senior Vice President, General Counsel, Secretary  
CroLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005  
(b) (6) – direct  
(202) 296-1585 – main  
(b) (6) [@croplifeamerica.org](mailto:@croplifeamerica.org)  
[www.croplifeamerica.org](http://www.croplifeamerica.org)

April 10, 2018

The Honorable Ryan Zinke  
Secretary  
U.S. Department of the Interior  
1849 C Street, N.W.  
Washington, D.C. 20240  
[exsec@ios.doi.gov](mailto:exsec@ios.doi.gov)

The Honorable Wilbur Ross  
Secretary  
U.S. Department of Commerce  
1401 Constitution Avenue, N.W.  
Washington, D.C. 20230  
[WLRoss@doc.gov](mailto:WLRoss@doc.gov)

The Honorable Scott Pruitt  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
[Pruitt.scott@Epa.gov](mailto:Pruitt.scott@Epa.gov)

The Honorable Sonny Perdue  
Secretary  
U.S. Department of Agriculture  
1400 Independence Ave S.W.  
Washington, D.C. 20250  
[Sonny.Purdue@osec.usda.gov](mailto:Sonny.Purdue@osec.usda.gov)

Via Electronic Mail

Re: January 31, 2018 Memorandum of Agreement Implementation

Secretaries Perdue, Ross and Zinke and Administrator Pruitt:

We write to present a unified voice on the opportunity to address one of the most challenging issues facing the intersection of federal pesticide regulation and endangered species conservation: the need for an efficient regulatory process for aligning federal pesticide registration decisions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with the requirements of the Endangered Species Act (ESA). We believe these thoughts are both specific and timely as you implement the January 31, 2018 Memorandum of Agreement on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review (MOA), which we support. For too long, this issue has been marked by divisiveness and conflict as to possible product effects on endangered species and regulatory uncertainty for pesticide manufacturers, farmers, and other users. Your agencies can redouble their efforts from the last four years to move past these conflicts by prioritizing a series of administrative improvements to how pesticides are evaluated. The recent MOA can further this goal considerably.

As a group of diverse stakeholders who care deeply about harmonizing endangered species conservation with agriculture and pest control, we believe that your agencies can and should make further administrative improvements, consistent with the collaborative approaches they have announced, and with their engagement with stakeholders during recent years. There are numerous ways to improve the process of assessing potential impacts to endangered species associated with pesticide registrations. The recommendations here are ones that we mutually support, that we believe are feasible to implement, and that can meaningfully improve the

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Page 2

process. And in pursuing these recommendations, we urge you to engage stakeholders in an open and transparent manner, as contemplated by the MOA.

**1. Develop interagency processes on pesticide consultations that enable the EPA, Services, and USDA to make the best use of each agency's expertise and limited resources**

The expertise needed to complete robust pesticide consultations already exists within the agencies and should be leveraged to its fullest extent. The U.S. Environmental Protection Agency (EPA) has expertise in ecological risk assessments for pesticides, including risk assessment methods needed to evaluate the potential risks of pesticides to non-target wildlife, such as exposure modeling and probabilistic tools, and requires significant amounts of data for pesticide registrations. The U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively, the Services) have substantial expertise on threatened and endangered species, including species biology, distribution, threats, and recovery needs. And the U.S. Department of Agriculture (USDA) has expertise on how pesticides are used in agriculture, including the timing and location of pesticide applications. This use information can be shared with other agencies in ways that do not compromise landowner privacy or specific species locations.

To make better use of limited agency resources, EPA should play a larger role in assessing the potential effects of pesticides on endangered species, including at the population and species levels. For the EPA to play such a role, and other agencies to leverage their existing data and resources, your agencies should start by assessing the effectiveness of existing interagency agreements and guidance on how to complete pesticide consultations. This effort should help ensure that all four agencies have a common understanding of their own responsibilities, the key scientific and policy assumptions that underlie an ESA pesticide consultation, including risk-assessment endpoints, and the data and analyses needed to achieve those endpoints. This assessment would also provide stakeholders with the transparency and accountability that should allow them to support this proposed approach.

New guidance could identify clearer roles for each agency based on expertise and available and reliable data. For example, USDA could be relied on for the cropping and pesticide use data it already collects; EPA for quantitative risk assessment tools and uncertainty analysis; and the Services for defining species ranges and evaluating effects at the species level. At the same time, guidance could also identify ways for the agencies to continue improving collaboration so that one agency is not “handing off” its analysis to another agency, but rather coordinating with that agency throughout the consultation process. An improved approach could also allow stakeholders to provide more information and data during the process, similar to how other endangered species reviews under the ESA are completed.

Your agencies can build additional guidance today and implement it as a living document that can be updated easily to reflect improved methods your agencies develop in the future. If successful, the guidance will help ensure that capable agency scientists—whether sitting at the



April 10, 2018

Page 3

EPA or the Services—can share and implement a common understanding of how to perform pesticide consultations, facilitating their collaboration.

## **2. Use more refined species location maps and better pesticide use data**

By using more refined data on where species are likely to occur, the EPA and the Services can improve the occurrence maps of many species compared to some of the maps the Services currently use, many of which are county-level. Refined range maps, which could be produced using species distribution models and other robust scientific approaches, would more accurately depict the true distribution of species and may result in fewer overlaps with areas affected by pesticide use, allowing for a better understanding of potential exposure to those species. This should expedite endangered species review for pesticides, improving the EPA's and the Services' ability to meet statutory timeframes under FIFRA and the ESA.

By further involving pesticide registrants and the public, and considering available data, your agencies can make use of more realistic information on when and how pesticides are applied, thus enabling a more refined assessment. This information, when combined with refined species range maps, may enable the EPA and the Services to identify more instances where pesticide use does not overlap with species habitat. We see promising opportunities to work with USDA, state agencies, species expert organizations, growers, and registrants to improve data on pesticide use patterns.

## **3. Adopt better endangered species exposure assessments**

Better exposure assessments can help the Services and EPA make defensible, science-based conclusions that pesticide exposure is low or absent. One approach is to develop and implement an interagency plan to refine hydrological and other exposure models that adopt more accurate assumptions about endangered species exposure to pesticides. We see opportunities to further refine commonly used models to distinguish between realistic and improbable exposure scenarios. More realistic scenarios would help ensure that conservation efforts focus on the species that are most likely to be affected by potential pesticide exposure.

## **4. Take advantage of avoidance and minimization opportunities to improve the efficiency and effectiveness of pesticide consultations**

EPA's registration of pesticides currently includes requirements to avoid and minimize impacts to non-target organisms. To enhance endangered species review, pesticide registrants could choose to voluntarily adopt additional site-specific avoidance and minimization measures for endangered species as part of EPA's registration process or during consultations. Refined species occurrence data are important to these efforts because they may allow pesticide registrants, farmers, and other users to target protective measures to areas where species and their habitats are likely to occur. They may also result in more pesticide consultations being expeditiously resolved. Such an outcome would represent a win for conservation and for

regulated entities: fewer species potentially exposed to pesticides that could pose a risk to them, and quicker and more predictable pesticide registration decisions.

## **5. Support opportunities to use voluntary conservation in pesticide evaluations**

In addition to avoidance and minimization, a pesticide registrant may choose to consider voluntary conservation efforts as an option to expedite, supplement, or simplify endangered species review for a pesticide. This type of conservation effort (similar to a concept known as compensatory mitigation in other contexts and referred to as “mitigation” below) can also conserve species while expediting or simplifying pesticide consultations. This approach has not played a prominent role in pesticide consultations to date. But if registrants choose to pursue this option, effective and timely conservation efforts consistent with mitigation goals could lead to more efficient consultations in some circumstances.

We urge your agencies to devote resources to help interested stakeholders establish voluntary conservation projects and to integrate those projects into pesticide consultations at the request of registrants. Specifically, we encourage the agencies to work with stakeholders to develop a regulatory framework that further incentivizes voluntary conservation to improve or increase habitat for endangered species.

## **6. Prioritize species-use combinations for formal consultation**

We recommend that your agencies consider developing decision systems to help distinguish among situations that pose low, medium, and high likelihood of jeopardy or adverse modification (JAM) in formal consultation. In developing this system, your agencies could consider both species and pesticide use factors. For example, species factors could include abundance, biological status, and prey base. And use factors could include mode of action, route of entry, and areas of use.

Identifying low, medium, and high-risk scenarios will help your agencies apply the most efficient methods to complete JAM analyses. For many scenarios, proxy measures or general principles of conservation biology and ecotoxicology may be adequate to inform the JAM analysis. For other, higher-risk scenarios, more detailed species- and pesticide-specific analyses may be warranted. The goal should be to complete the JAM analysis for low risk scenarios using efficient yet defensible methods, so that agency staff can focus their limited resources on higher risk scenarios that required more detailed, resource-intensive methods.

We believe that these recommendations for managing endangered species review of pesticides will provide for a more efficient approach to species conservation while providing a sound basis for decisionmaking. We also understand that your agencies would need additional resources and funding to implement the recommendations effectively and expeditiously. We ask for a commitment at the highest levels within your agencies to prioritize these improvements to endangered species review of pesticides. With that commitment, we believe an enduring

April 10, 2018  
Page 5

solution is possible to the current concerns with the adequacy of endangered species assessments in pesticide consultations.

Sincerely,

CropLife America  
Defenders of Wildlife  
American Soybean Association  
Minor Crop Farmer Alliance  
National Association of Corn Growers  
National Association of Wheat Growers

cc: Mr. Ray Starling  
Special Assistant to the President for Agriculture, Trade and Food Assistance  
(b) (6) [\[REDACTED\]@who.eop.gov](mailto: [REDACTED]@who.eop.gov)

Mr. Michael J. Hickey  
Chief, Environment Branch, Office of Management and Budget  
[mhickey@omb.eop.gov](mailto:mhickey@omb.eop.gov)

Mr. Chris Prandoni  
Associate Director for Natural Resources, Council on Environmental  
Quality [Christopher.D.Prandoni@ceq.eop.gov](mailto:Christopher.D.Prandoni@ceq.eop.gov)

Mr. Greg Sheehan  
Principal Deputy Director, U.S. Fish and Wildlife Service  
[Gregory\\_sheehan@fws.gov](mailto:Gregory_sheehan@fws.gov)

Mr. Chris Oliver  
Assistant Administrator for Fisheries, NOAA Fisheries  
[Chris.W.Oliver@noaa.gov](mailto:Chris.W.Oliver@noaa.gov)

Ms. Charlotte Bertrand  
Acting Principal Deputy Assistant Administrator, EPA Office of Chemical Safety and  
Pollution Prevention  
[Bertrand.Charlotte@epa.gov](mailto:Bertrand.Charlotte@epa.gov)

Dr. Sheryl Kunickis  
Director of Office of Pest Management, U.S. Department of Agriculture  
[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)

**From:** [Mary Jo Tomalewski](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Jay Vroom](#)  
**Subject:** RE: Brief phone call?  
**Date:** Wednesday, April 18, 2018 9:36:19 AM

---

Hi, Sheryl,

Those email addresses are below.

MJ

Mary Jo Tomalewski  
 Executive Assistant to the President & CEO  
 CropLife America  
 Direct Dial (b) (6)  
 Mobile (b) (6)  
 Email (b) (6)@croplifeamerica.org

-----Original Message-----

From: Jay Vroom  
 Sent: Wednesday, April 18, 2018 9:05 AM  
 To: Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>  
 Cc: Mary Jo Tomalewski (b) (6)@croplifeamerica.org; Beau Greenwood (b) (6)@croplifeamerica.org; Rachel Lattimore (b) (6)@croplifeamerica.org; Kellie Bray <(b) (6)@croplifeamerica.org>  
 Subject: Re: Brief phone call?

Sheryl

Good to talk. As soon as Mary Jo can get to her computer I'll ask her to send you the names and titles are email addresses for the ESA letter signatories—

Jamie Clark for Defenders (b) (6)@defenders.org  
 Jay Vroom for CLA (b) (6)@croplifeamerica.org  
 Chris Novak for Corn (b) (6)@ncga.com  
 Ryan Findlay for Beans (b) (6)@soy.org  
 Chandler Goule for Wheat (b) (6)@wheatworld.org  
 Ed Ruckert for Minor Crops Alliance (b) (6)@mwe.com

Jay

Sent from my iPhone

> On Apr 18, 2018, at 8:58 AM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>

> Need to ask you a question this morning if possible. If you are available, let me know the time and

best number.

> Thanks,

> Sheryl

>

> Sent from my iPad

>

>

>

>

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**From:** [Rachel Lattimore](#)  
**To:** [Andrew Wheeler](#); [David Bernhardt](#) ; [Mary Neumayr](#); [Sonny Perdue](#); [Wilbur Ross](#)  
**Cc:** [Alexandra Dapolito Dunn](#); [Chris Oliver](#); [Chris Prandoni](#); [Margaret Everson](#) ; [Michael J. Hickey](#); [Sheryl Kunickis](#)  
**Subject:** January 31, 2018 Memorandum of Agreement Implementation  
**Date:** Friday, February 22, 2019 9:36:30 AM  
**Attachments:** [FIFRA ESA Priority Letter 022219.pdf](#)  
[ESA FIFRA MOA Letter 041018.pdf](#) Attachment withheld as duplicate

---

Dear Secretaries Ross and Perdue, Acting Secretary Bernhardt, Acting Administrator Wheeler and Chairwoman Neumayr:

Please see the attached letter.

Best regards,

Rachel Lattimore

Rachel G. Lattimore  
Senior Vice President, General Counsel, Secretary  
CroLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005

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February 22, 2019

The Honorable Wilbur Ross  
Secretary  
U.S. Department of Commerce  
1401 Constitution Avenue, N.W.  
Washington, D.C. 20230  
[WLRoss@doc.gov](mailto:WLRoss@doc.gov)

The Honorable Sonny Perdue  
Secretary  
U.S. Department of Agriculture  
1400 Independence Ave, S.W.  
Washington, D.C. 20250  
[Sonny.Perdue@osec.usda.gov](mailto:Sonny.Perdue@osec.usda.gov)

The Honorable Andrew Wheeler  
Acting Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
[Wheeler.Andrew@Epa.gov](mailto:Wheeler.Andrew@Epa.gov)

The Honorable David Bernhardt  
Acting Secretary  
U.S. Department of the Interior  
1849 C Street, N.W.  
Washington, D.C. 20240  
[exsec@ios.doi.gov](mailto:exsec@ios.doi.gov)

Ms. Mary Neumayr  
Chairwoman  
Council on Environmental Quality  
730 Jackson Place, N.W.  
Washington, DC 20503  
[Mary.B.Neumayr@ceq.eop.gov](mailto:Mary.B.Neumayr@ceq.eop.gov)

Via Electronic Mail

Re: January 31, 2018 Memorandum of Agreement on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review; Priority Administrative Improvement Proposals

Dear Secretaries Ross and Perdue, Acting Secretary Bernhardt, Acting Administrator Wheeler and Chairwoman Neumayr:

We write to thank the Council on Environmental Quality (CEQ) for its work in implementing the January 31, 2018 Memorandum of Agreement on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review (MOA) and to follow up on a letter several of the organizations below sent on April 10 to the U.S. Department of Agriculture (USDA), the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency (EPA) in support of the MOA. A copy of that April 10 letter is enclosed for your reference.

As organizations representing stakeholders with keen interests in the work being done under the MOA, we continue to work together to develop ideas and suggestions for the MOA's Interagency Working Group to address the need for an efficient regulatory process for aligning federal pesticide registration decisions under the Federal Insecticide, Fungicide, and Rodenticide

Act (FIFRA) with the requirements of the Endangered Species Act (ESA). As set out in the letter of April 10, we believe that the Interagency Working Group and its member agencies can and should find ways to improve the process of assessing potential impacts to endangered species associated with pesticide registrations. We included general recommendations we mutually support, that we believe are feasible to implement, and that can meaningfully improve the process.

Our intent in this letter is to refine and prioritize our recommendations, furthering what we hope will be increased shareholder outreach and exchange of ideas. We recognize both the limited resources available to the federal agencies and the complexities of the task ahead. With that in mind, we hope that you will accept these suggestions, with their accompanying suggested timelines and lead organizations, in the spirit in which they are intended – to help frame discussions between stakeholders and CEQ in its role overseeing the Interagency Working Group. Further, we believe that Section 10115 of the 2018 Farm Bill, titled “FIFRA Interagency Working Group,” will encourage these discussions and underscore the value for the Working Group to periodically report its progress in improving the consultation process. We would be happy to build out the ideas in this letter more fully and discuss them with you as your internal discussions continue, and thank you for your continued commitment to the ideas of outreach with stakeholders outlined in the MOA.

### **PRIORITY ADMINISTRATIVE IMPROVEMENT PROPOSALS**

For your consideration, below is a working list of the highest priority proposals for administrative improvements to the ESA pesticide consultation process. The proposals are organized into three categories:

- Category 1: Those that will immediately improve the efficiency of the consultation process within the next year;
- Category 2: Those that will improve the efficiency over the next several years; and
- Category 3: Those that will improve transparency and stakeholder engagement, irrespective of timing.

### **CATEGORY 1: IMMEDIATE EFFICIENCY IMPROVEMENTS**

#### **Develop and use refined species distribution maps**

The U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively the Services) could continue (a) generating refined distribution maps for certain species that are considered the best available scientific data and (b) developing a process to receive those types



of maps from the public for all other ESA-listed species, store them in a central database, and share them with the public. Both steps, however, might require several years to complete. In the interim, the Services could expeditiously adopt a method for finalizing refined maps specifically for pesticide consultations based on *currently available* data and working with others actively developing such maps. Those interim refined maps could be evaluated, finalized, shared, and used as early as 2019. The Services could also develop guidance, such as a standard operating protocol, on how the public should produce and submit refined maps to the agencies.

By taking the above actions, the Services and EPA should be able to increase the number of species with refined distribution maps and to significantly focus the risk assessment process. This would reduce the number of erroneous overlaps between species occurrence and pesticide use, and may identify currently unrecognized areas of overlap, resulting in more accurate and efficient ESA effects findings.

Proposed timeframe: We propose the Services finalize the interim maps for pesticide consultations and the mapping guidance by the summer of 2019, while continuing to work on the longer-term strategy of obtaining and sharing maps that are even more refined.

Lead organization: Services career staff could publish this guidance, which will encourage knowledgeable stakeholders to submit refined species distribution maps to the Services. There are non-government organizations and/or task forces that could conduct mapping projects under the guidance of and in collaboration with the Services.

### **Consider updating Interim Approaches document**

When EPA and the Services published the ESA-FIFRA Interim Approaches document in November 2013, they explained that the document would be updated in the future. The agencies could now consider updating the document in light of their experience on pesticide consultations since 2013.

Proposed timeframe: EPA and the Services could begin soliciting public feedback on updates to the Interim Approaches by the spring of 2019.

Lead organization: EPA and the Services, with oversight from the Interagency Working Group.

### **Apply refined pesticide use data**

This proposal has two components. First, the Services and EPA could clarify the role of actual use data in defining the scope of pesticide consultations, especially in light of the Services past practice of assuming maximum allowable label use. Without this clarification, it remains unclear exactly how the efforts to gather refined use data will improve consultation outcomes.

Second, USDA, EPA, and the Services could identify potential sources of better pesticide use data, including governmental (state/federal) and private/commercial data sets. In doing so, they could better understand and tap the extensive agricultural data expertise within the service divisions of USDA (NASS, ARS, ERS). The three agencies could also collectively identify specific geographical areas where improved use data could potentially refine the risk assessment for certain species.

Proposed timeframe: Complete survey of data sources by the summer of 2019.

Lead organization: USDA, EPA, and the Services, with input from stakeholders and oversight from the Interagency Working Group. Additionally, non-government organizations or a task force could conduct pesticide use assessment projects under the guidance and supervision of USDA, EPA, and the Services.

### **Prioritize species-pesticide combinations for consultations**

The Services and EPA, with input from USDA, could develop a decision system to prioritize species-pesticides within informal and formal consultations. The system would distinguish between low, medium, and high potential likelihood of species and habitat effects. Lower likelihood situations could receive a simplified assessment, thus freeing up agency resources to focus on higher likelihood situations. The system would consider both species factors (*e.g.*, data availability, temporal and spatial overlap of species habitat and pesticide use, abundance, biological status, prey base, etc.) and pesticide use factors (*e.g.*, target pest, route of entry, timing and areas of use, label use restrictions, etc.). This improvement would increase regulatory efficiency by reducing the amount of time and analysis spent on risk assessments for the low and medium priority scenarios.

The agencies could start with a simple prioritization system for informal consultations, using existing data and processes. For example, when initiating informal consultation, agencies could identify species that will clearly not be affected (*e.g.*, listed whales for a limited use herbicide). This type of simplified prioritization scheme could be developed into a full-fledged system to prioritize pesticide-species combinations.

Proposed timeframe: The Services, EPA, and USDA could begin developing a simplified system in the spring of 2019 and complete the process by that winter.

Lead organization: The Interagency Working Group could initiate and monitor the process; the Services and EPA could develop the system with input from stakeholders. Additionally, non-government organizations or a task force could demonstrate a prioritization approach, such as through a pilot project or hypothetical consultation, under the guidance and supervision of the Services.

## **CATEGORY 2: MEDIUM- OR LONG-TERM EFFICIENCY IMPROVEMENTS**

### **Propose consultation processes tailored to pesticides, including consideration of optional conservation actions**

The current consultation process is not optimized to handle the volume and complexity of pesticide consultations in a timely manner, nor to incentivize voluntary conservation measures to offset the potential effects of pesticide use. A consultation process tailored to the complexities of pesticide consultations and established through new regulations, policies, and/or Section 7 Handbook revisions could help address these issues. Potential components of this tailored process include (1) taking advantage of the resources and expertise of EPA, USDA, and stakeholders to help the Services with formal consultation; (2) expedited consultation on pesticides that pose a low risk of a jeopardy/adverse modification finding (*e.g.*, where the Services have not identified pesticides as a primary or likely stressor); and (3) using voluntary conservation actions to facilitate “not likely to adversely affect” and no jeopardy/adverse modification findings by offsetting potential adverse effects associated with pesticide use. Our proposal is consistent with the Services’ recent regulatory proposal to create “optional collaborative consultation” processes with action agencies to improve the efficiency of those consultations.

To make progress on this approach, the Service and EPA could begin developing a joint procedure document that describes how the agencies will conduct pesticide consultations as efficiently and defensibly as possible. The document would describe key science, legal, and policy assumptions that underlie all pesticide consultations, and be updated periodically to reflect best practices.

Proposed timeframe: The Services and EPA could begin seeking stakeholder input on a tailored consultation process by the spring of 2019 (*e.g.*, through an advance notice of proposed rulemaking). The agencies could also begin developing the joint procedures in the fall of 2019.

Lead organization: The Interagency Working Group could initiate and monitor the process, and work with the Services and EPA to jointly develop a tailored consultation process. Stakeholders could provide ideas and other input on such a process.

### **Improve exposure assessments**

Current terrestrial and aquatic exposure models often over-predict exposure when one considers pesticide use, the agricultural setting, and distribution of species on a landscape scale. Better exposure assessments can help the Services and EPA make defensible, science-based conclusions that put pesticide exposure into its proper context across the landscape. More accurate exposure models will significantly focus the assessment by reducing the number of

erroneous “may affect” determinations. EPA and the Services could work with stakeholders to refine exposure modeling to distinguish between realistic and improbable exposures estimates, where monitoring data are abundant and contradict modeling data. A high-priority task is to develop consistent methods for aquatic exposure modeling (for both marine/estuary and freshwater environments).

Proposed timeframe: We propose the Interagency Working Group, Services, and EPA plan to convene an official stakeholder forum to address terrestrial and aquatic exposure by the summer of 2019.

Lead organization: EPA could lead the effort with the participation of the Services, USDA, and stakeholders. The Interagency Working Group would monitor the process to assure progress is made to refine/update terrestrial and aquatic exposure models.

### **Linking the risk assessment to ESA conservation goals**

Current risk assessments are not tailored to the ESA conservation goals for listed species. For example, the assessments are typically based on individual level endpoints but the ESA conservation goals may be described in a recovery plan in terms of species population numbers or distribution or conservation of specific habitat. As a result, the endpoints require additional translation before they are directly relevant to the jeopardy/adverse modification analysis. Improving the risk characterization so that it is directly relevant to the ESA conservation goals should reduce the complexity of consultations and improve species conservation outcomes (*e.g.*, improved targeting of any voluntary conservation measures that clearly benefit recovery).

Proposed timeframe: The Services and EPA could work with stakeholders and experts, to begin improving the the risk characterization by the summer of 2019, completing the process by that winter.

Lead organization: The Services and EPA could develop the system with input from stakeholders. Additionally, non-government organizations or a task force could develop a proposed framework or demonstrate the proposal through a hypothetical risk assessment, under the guidance and supervision of the Services.

### **Reduce the resource deficits at the Services, EPA, USDA by enabling stakeholders to help with discrete projects that will improve the pesticide risk assessment process**

A significant bottleneck in the ESA-FIFRA process arises from inadequate resources for this work at the Services, EPA, and USDA. There are multiple strategies to address this challenge. One that has never been broadly discussed is for one or more stakeholders to voluntarily fund or provide in-kind support for specific projects completed by the Services, EPA, or USDA that

would improve the pesticide consultation process. Examples include the drafting of guidance on refined species distribution mapping, the refinement of pesticide use data, or any number of other initiatives that the agencies currently lack the resources to carry out. The agencies would need to ensure against any conflicts of interest between the funded work and the outcomes of a risk assessment.

A related proposal is for the Secretaries of the Interior, Commerce, and USDA, and the Administrator of EPA to jointly direct the Services, EPA, and USDA to identify opportunities for stakeholders to help fund initiatives within their agencies to improve the pesticide consultation process.

At the same time, stakeholders can seek Congressional appropriations if necessary to help the agencies fund these discrete projects.

Proposed timeframe: The agencies could begin creating the opportunities described above in the spring of 2019.

Lead organization: EPA and the Services, with oversight from the Interagency Working Group.

### **CATEGORY 3: IMPROVING TRANSPARENCY AND ENGAGEMENT**

#### **Stakeholder engagement**

There are several opportunities to better engage stakeholders, especially registrants, in helping to provide data and analyses to inform pesticide consultations. One is to develop forums to engage stakeholders periodically under the Interagency MOA. Two is to continue periodic interagency public workshops (the last one was in the summer of 2016). Three is for the Services, working with EPA, to establish direct lines of communication with registrants (as “applicants” under section 7) to more seamlessly address questions and data needs during development of the biological evaluations and consultations. In doing so, the Services could create a protocol for registrants to directly supply the agencies with additional data and analysis needed to complete consultations. Fourth is to explicitly adopt the position that transparent processes (*e.g.*, range map development or improving exposure assessments) are preferred, to allow for a range of stakeholder input in a complex situation.

Proposed timeframe: The Interagency Working Group, Services, and EPA could convene an official stakeholder forum by the spring of 2019.

Lead organization: The Interagency Working Group could chair forums under the MOA. The Services, EPA, and USDA could take the lead on any interagency public workshops. Stakeholders could be engaged to help coordinate forums for engagements, similar to past

workshops by Minor Crop Farmer Alliance or North Carolina State University's Center for Regulatory Excellence.

### **Risk documentation**

EPA and the Services could jointly issue guidance describing how they will properly document best practices and other key aspects of the endangered species risk assessment, including use of a robust weight of evidence framework and more comprehensive uncertainty analysis. The goal is to create a more focused, streamlined set of documents (*e.g.*, BEs, BiOps) that facilitate faster and more effective consultation and create a better record for each pesticide action. The guidance could also summarize case studies where these principles have been properly applied.

Proposed timeframe: EPA and the Services could begin developing the guidance by the summer of 2019.

Lead organization: The Services and EPA could complete the documentation with oversight from the Interagency Working Group. Additionally, non-government organizations or a task force could help with this project under the guidance and supervision of the Services.

\* \* \*

Again, we appreciate your commitment to this important work and stand ready to assist. We continue to believe an enduring solution is possible to address concerns with the adequacy of endangered species assessments in pesticide consultations.

Sincerely,

American Soybean Association  
 CropLife America  
 Defenders of Wildlife  
 Environmental Policy Innovation Center  
 Minor Crop Farmer Alliance  
 National Corn Growers Association  
 National Association of Wheat Growers

cc: Mr. Michael J. Hickey  
 Chief, Environment Branch  
 Office of Management and Budget  
[mhickey@omb.eop.gov](mailto:mhickey@omb.eop.gov)

Mr. Chris Prandoni  
Associate Director for Natural Resources  
Council on Environmental Quality  
[Christopher.D.Prandoni@ceq.eop.gov](mailto:Christopher.D.Prandoni@ceq.eop.gov)

Ms. Margaret Everson  
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Mr. Chris Oliver  
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NOAA Fisheries  
[Chris.W.Oliver@noaa.gov](mailto:Chris.W.Oliver@noaa.gov)

Ms. Alexandra Dapolito Dunn  
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EPA Office of Chemical Safety and Pollution Prevention  
[Dunn.alexandra@epa.gov](mailto:Dunn.alexandra@epa.gov)

Dr. Sheryl Kunickis  
Director of Office of Pest Management Policy  
U.S. Department of Agriculture  
[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)

**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Mary Jo Tomalewski](#)  
**Subject:** Re: CLA April Regulatory Conference  
**Date:** Thursday, March 29, 2018 12:37:09 PM

---

Hi Mary Jo,  
 Best date is Tuesday, April 10 at 9:00 a.m.  
 Second best is April 9, ~ 3:30 pm - I can stop at the office on my way to VA.  
 Third is April 13 before 10:30 a.m.  
 Sheryl

Sent from my iPad

On Mar 29, 2018, at 9:06 AM, Mary Jo Tomalewski <(b) (6)@croplifeamerica.org> wrote:

Sheryl,

Jay and Janet would be available:

- Monday, April 9 – after 3:30p
- Tuesday, April 10 – 9:00a
- Friday, April 13 – before 10:30a, 3:00 or after

Let me know what works for you and I'll send a calendar appointment.  
 MJ

Mary Jo Tomalewski  
 Executive Assistant to the President & CEO  
 CropLife America  
 Direct Dial (b) (6)  
 Mobile (b) (6)  
 Email (b) (6)@croplifeamerica.org

-----Original Message-----

**From:** Jay Vroom  
**Sent:** Thursday, March 29, 2018 8:22 AM  
**To:** [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Cc:** Janet Collins (b) (6)@croplifeamerica.org; Mary Jo Tomalewski <(b) (6)@croplifeamerica.org>; Courtney DeMarco <(b) (6)@croplifeamerica.org>  
**Subject:** CLA April Regulatory Conference

Hi Sheryl!

Could Janet and I find some  
 Time To Come Over and brief you and your team about our April conference and  
 get any additional suggestions for things we Might add —And talk about how we  
 Could go about seeking lots of USDA participation?



AndWhile there we. Might check in on a few other issues?

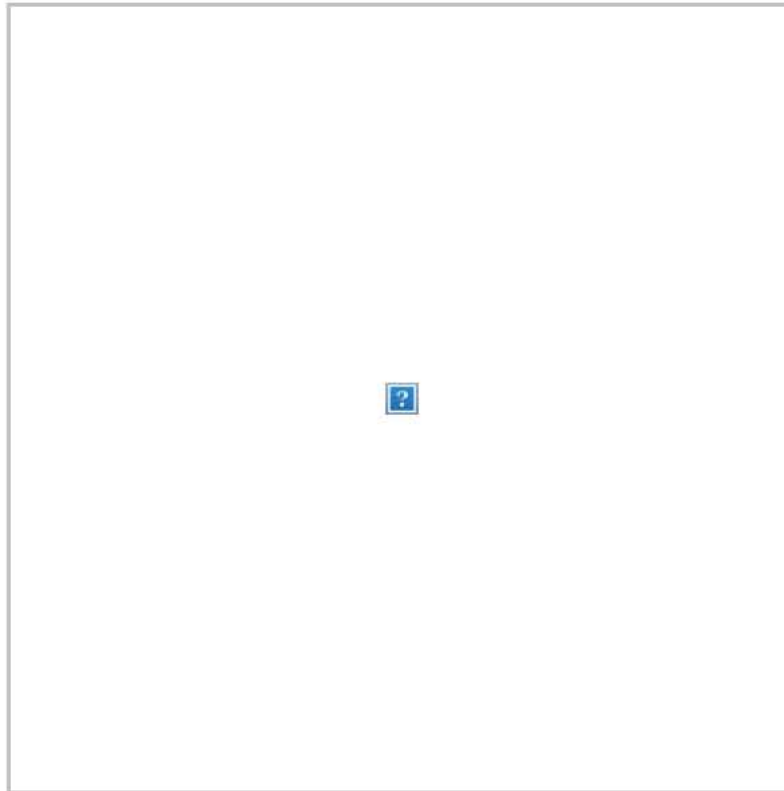
Jay

Sent from my iPhone

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**From:** [Francesca Purcell](#)  
**To:** [Sheryl Kunickis](#)  
**Subject:** Registration Confirmed - CropLife America & RISE 2019 Regulatory Conference  
**Date:** Friday, February 15, 2019 8:48:37 AM

---



Dear Sheryl,

Your registration has been confirmed. Please save this email for future reference.

**Event:** CropLife America & RISE 2019 Regulatory Conference

**Attending:** Sheryl Kunickis

**Date:** April 3, 2019 - Apr 5, 2019

**Confirmation Number:** N6N4MJZCCLW

[Add to calendar](#)

**Current Registration:**

| Registration Information: |                    |                        |
|---------------------------|--------------------|------------------------|
| Registration Items        |                    |                        |
| Sheryl Kunickis           | Event Registration |                        |
| Sessions                  |                    |                        |
| Sheryl Kunickis           | Welcome Reception  | 03-Apr-2019<br>5:00 PM |

|                    |                                                                                                      |                         |
|--------------------|------------------------------------------------------------------------------------------------------|-------------------------|
| Sheryl<br>Kunickis | General Session - The Role of Regulation in Product Innovation and Sustainability                    | 04-Apr-2019<br>8:00 AM  |
| Sheryl<br>Kunickis | Series I - Good Epidemiology Practices for Pesticide Exposure Assessment: The Time Has Come          | 04-Apr-2019<br>10:30 AM |
| Sheryl<br>Kunickis | Series I - Science Policy Activities for Endangered Species Risk Assessment                          | 04-Apr-2019<br>10:30 AM |
| Sheryl<br>Kunickis | Series II - Expert Panel: Application of Use and Usage Data in an Endangered Species Risk Assessment | 04-Apr-2019<br>1:15 PM  |
| Sheryl<br>Kunickis | Series III - Social Media Success: How Influencers Create Buzz                                       | 04-Apr-2019<br>3:00 PM  |
| Sheryl<br>Kunickis | Networking Reception                                                                                 | 04-Apr-2019<br>5:00 PM  |
| Sheryl<br>Kunickis | General Session - EPA Office of Pesticide Programs: Today, Tomorrow, and Beyond                      | 05-Apr-2019<br>8:00 AM  |
| Sheryl<br>Kunickis | Series IV - How to Weave Scientific Information into Persuasive Narratives                           | 05-Apr-2019<br>9:45 AM  |
| Sheryl<br>Kunickis | Series IV - Part 1: Potential Options for Up-front Species Conservation and the Benefits of These... | 05-Apr-2019<br>9:45 AM  |
| Sheryl<br>Kunickis | Series V - Part 2: Potential Options for Up-front Species Conservation and the Benefits of These...  | 05-Apr-2019<br>11:15 AM |



We look forward to seeing you in April!

For more conference details, please email: [Francesca Purcell](#)

If you no longer want to receive emails from CroLife America & RISE, please [Opt-Out](#).

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**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Updates  
**Date:** Wednesday, April 25, 2018 11:11:43 AM

---

Sheryl- would it be possible for CLA to get a roster of participants in the MoA meetings?

Also- would you be able to give our CLA group a brief 10 minute update on the weekly meetings- even over the phone today? Our technical group is meeting today and beyond curious!

Thank you.

Janet

(b) (6) [REDACTED] (direct)  
[REDACTED] (mobile)

**From:** [Ray McAllister](#)  
**To:** (b) (6) @syngenta.com; (b) (6) @dow.com; (b) (6) @dupont.com; (b) (6) @bayer.com;  
 (b) (6) @basf.com; (b) (6) @basf.com; (b) (6) @iskbc.com; (b) (6) @fmc.com;  
 (b) (6) @adama.com; (b) (6) @valent.com; [Gilberto Olaya](#)  
**Cc:** [Sundin, George](#); [Neena Anandaraman](#); [Julius Fajardo](#); [Jim](#); [Janet Collins](#); [Barron, Jim](#); [Greg Mattern](#);  
 (b) (6) @nufarm.com; [Charlotte Sanson](#); (b) (6) @adama.com  
**Subject:** [Caution: Suspicious Attachment]Re: Crop language regarding antimicrobial use  
**Date:** Saturday, June 9, 2018 10:56:51 AM  
**Attachments:** [CropBestPracticeGuidelines.docx](#)  
[ATT00001.htm](#)

---

FRAC, et al.:

Neena Anandaraman of USDA has sent an updated draft of the proposed language (attached).

I'd like to raise a few concerns, based on my profound ignorance of antibiotic use:

- There are only three antibiotics registered for crop use in the US (streptomycin, kasugamycin, and oxytetracycline). Do they have different modes of action? Are they registered for the same crop uses? If the answers to these questions are no, it does not bode well for resistance management strategies based on rotation of treatments. Guidance based on impractical or impossible approaches loses credibility.
- How much difference will it mak to prohibit the use of animal manure as fertilizer or prohibit grazing of livestock? Does this consign manure to hazardous waste? Grazing may be a practical means of weed control and maintenance of cover crops.

~~~~~  
 THINK Before You Open!

This message has an HTML attachment that may display **possibly spoofed** web content. Pages like these are used in phishing attacks.

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Questions: Contact Client Technology Services (CTS) via email at (Spam.Abuse@wdc.usda.gov)

## Practices that Minimize the Development of Antibiotic Resistance in Agricultural Crops

- Technical experts from universities, government agencies, agriculture extension workers, distributors, and farmers can develop region-specific resistance management guidelines to inform labeling and use of specific antimicrobial agents.
- Only authorized antimicrobial agents labeled for specific use should be used. For example, key practices to implement could include:
  - To reduce the likelihood that bacteria develop resistance, alternate bactericides with a different mode of action
  - No more than two consecutive applications of the same antibiotic code or group
  - Implement resistance management strategies using integrated pest management, consider use crop varieties resistant to the pathogen of concern, use of disease forecasting models to determine application timing
  - Consultation with a local extension specialist or certified crop consultant, State agricultural advisor, or manufacturer when necessary
- Label restrictions and precautions to minimize AMR could include:
  - Not applying antimicrobial agents in orchards where the soil has been fertilized with animal waste or manure.
  - Prohibiting animal grazing in treated areas and public notification through posting restriction signs along the perimeter of the treatment area.
  - Restricting the conditions of use such as the number of times an antimicrobial agent can be used through label requirements that are determined by research.
  - Limit consumer exposure by requiring a pre-harvest interval (PHI) which specifies the timing of the last antibiotic application relative to the harvest of the treated crops based on residue trials.
  - Establish legal tolerances or maximum residue levels (MRL) for antibacterials on raw agricultural commodities and processed products.
- Access to university-based agriculture extension specialists and disease forecasting models can help optimize the timing of applications to target disease control and minimize the number of applications. Examples include:
  - Cougarblight, Maryblyt, Billing's system are few examples of [disease predictive models for fire blight in pome fruit](#) that evaluate weather factors to predict if conditions are favorable for the disease and if antibiotics should be sprayed (<http://ipm.ucanr.edu/DISEASE/DATABASE/fireblight.html>). These models can then be used to communicate with growers about the best time to make effective applications.
  - Maryblyt predicts specific infection events and symptom development for the different phases of fire blight epidemics in apples and pears. Maryblyt is used by growers and in research, extension and teaching programs in 32 U.S. states and in at least 36 countries.

Specific examples of how regional guidelines and models can be used include:

- Cooperative Extension Leaders at Cornell University developed guidelines for apple production regions in New York where streptomycin resistance has never been detected. In addition, the guidelines cover bactericide management for high risk regions where streptomycin resistance has been detected and confirmed. Below is an excerpt of the guidelines:

DRAFT

**From:** [Fajardo, Julius](#)  
**To:** (b) (6) @croplifeamerica.org; [Jim Cranney](#)  
**Subject:** Follow-up  
**Date:** Tuesday, March 13, 2018 3:03:53 PM  
**Attachments:** [Antibiotics in Crops Draft Feb 2018.docx](#) Attachment withheld as duplicate

---

Just to follow-up on your comments about the attached document. Neena will be needing the revised language by early next week. Thanks and best regards.

Julius

\*\*\*\*\*

**Julius E. Fajardo, Ph.D.** | *Plant Pathologist* | *USDA-Office of Pest Management Policy* | 1400 Independence Ave SW, Rm 3861-South Bldg (MS 0314) | Washington, DC 20250 | Tel. 202-720-3186 | Fax 202-720-3191 | Cell (b) (6) | [julius.fajardo@ars.usda.gov](mailto:julius.fajardo@ars.usda.gov) | <http://www.ars.usda.gov/opmp>

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** (b) @croplifeamerica.org  
**Cc:** [Hill2, Elizabeth - OCE](#); [Myers, Clayton - OCE](#)  
**Subject:** Re: Registration Confirmed - CropLife America 2018 Holiday Open House  
**Date:** Tuesday, November 20, 2018 9:04:51 AM

---

Hi Francesca,

I attempted to register two of my staff along with my registration, but there was no place that I could locate to insert their names and Email addresses. I have cc'd them on this message.

Could you please send them invitations? Elizabeth Hill is the OPMP Agricultural Economist and Dr. Clayton Myers is our new Ecological Risk Assessor.

Thanks,  
Sheryl

---

**From:** "Francesca Purcell" (b) (6) @croplifeamerica.org>  
**Date:** Tuesday, November 20, 2018 at 8:57:53 AM  
**To:** "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Subject:** Registration Confirmed - CropLife America 2018 Holiday Open House

[View in browser](#)

CLA HOH Header

Dear Sheryl:

Your registration has been confirmed. Please save this email for future reference.

Event: CropLife America 2018 Holiday Open House

Attending: Sheryl Kunickis

Time: 5:30 pm

Date: Tuesday, December 11, 2018

Confirmation Number: (b) (6)

[Click here to view the event summary.](#)

We look forward to seeing you there.

Sincerely,

Francesca Purcell

CropLife America

(b) (6) @croplifeamerica.org

CLA HOH Footer



[Unsubscribe](#) | [Opt Out](#)

Your payment for the CropLife America 2018 Holiday Open House event has been successfully processed. Please save this email for your records.

#### Transaction Information

Item	Transaction Information	Quantity	Amount
\$100 SOME + Open House RSVP	\$100.00	1	\$100.00
<b>Transaction Total</b>			<b>\$100.00</b>

Registration Confirmation Number: ZZN26NWQLCH

[Click here](#)

If you have any questions about this transaction or email, please contact Francesca Purcell directly at (b) (6) @croplifeamerica.org.



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**From:** [Courtney DeMarco](#)  
**To:** [Ray McAllister](#); [Sci Reg](#); [Amy Asmus](#)  
**Cc:** [Ashlea Rives Frank](#); [George Sabbagh](#); [Kristin Brugger](#); [Doreen Manchester](#); [Patty Vandierendonck](#); [Underwood Russell USGR](#); [Charlotte Sanson](#); [Mike Kelloqg](#); [Gus Zieske](#); [Lisa Nichols](#); [Tessa Scown](#); [JACKSON - GHEISSARI](#); [AMELIA ELIZABETH \[AG/1920\]](#); [LEOPOLD, VINCENT A \[AG/1005\]](#); [Carrie Tackema](#); [John Carbone](#); [John M Brausch](#); [Bob Mann](#); [Jeff Giddings](#); [Catherine M Holmes](#); [Green, Charles](#); [Jonynas, Ann](#); [Layton, Ray](#); [Mark Trostle](#); [Cain, Jack](#); [Laurent Oger](#); [Trish Sheehy](#); [Daniel Eugene Edwards](#); [Steven D. Bennett](#); [Holt, Doug](#); [Shari Long](#); [Ann Blacker](#); [Alan Samel](#); [Faith Kee](#); [Naq, Jayanta](#); [Matt McCoole](#); [Jackson, Scott](#); [\(b\) \(6\)](#); [Turnbough, Anne](#); [Ephi Gur](#); [Linda Mitchell](#); [Greg Wuthnow](#); [Seibert, Nicholas](#); [Pati Turner](#); [Khalid Akkari](#); [Zeller, Samuel](#); [Nicole O'Loughlin](#); [Douglas Hines](#); [Christian Picard](#); [Thatcher Mary Kay USWS](#); [Adriana M Doj](#)  
**Subject:** Pre-PPDC Breakfast Meeting - NEW LOCATION  
**Attachments:** [Final Agenda for May 2018 PPDC Meeting 4 18 18.docx](#) Attachment withheld as duplicate

---

Update on Location 4/30/18:

Renaissance Capital View, 2800 South Potomac Avenue, Arlington VA 22202, Studio A (from front door, go to your left and up the main staircase to the second floor, the room is to the right of the staircase on the opposite side).

If you have any questions the day of the breakfast, feel free to call or text Courtney @ [\(b\) \(6\)](#)

Please RSVP again to the calendar invite whether you plan to attend or cannot attend the breakfast.

Thank you,

Courtney DeMarco and Ray McAllister

**TO:** CLA Members, Friends and Allies (on BCC: line)

**FROM:** Ray McAllister & Courtney DeMarco, CLA

The next Pesticide Program Dialogue Committee meeting takes place on Wednesday and Thursday, May 2 and 3. CLA invites you to our customary breakfast sessions for those attending each day's PPDC session in Crystal City, VA. The locale is the Renaissance Capital View, 2800 South Potomac Avenue, Arlington VA 22202 Cinnabar Restaurant, level 2 of the Hyatt Regency Crystal City Hotel (2799 Jefferson Davis Highway, Arlington, VA 22202), across the street from the OPP headquarters where the PPDC meeting takes place. These are opportunities to compare notes on the coming agenda items for the day, and the discussion of the day before. EPA's final agenda for the PPDC meeting is attached. We welcome your contributions to notes on agenda topics for ag allies serving on the PPDC (By Monday April 30), which we will share at the breakfast sessions.

This invitation is going to Ag allies serving on the PPDC, Members of the Pesticide Policy Coalition, CLA committees, and other ag allies. If there are others you would like us to invite, or you are not certain if they are already included, please let us know, and we will invite them directly (rather than forwarding this message).

Please respond promptly, as attendance may be limited by the space available. We need a separate RSVP for each day you plan to attend the breakfast. Unfortunately, call-in participation will not be possible for the breakfast discussion.

**From:** [Francesca Purcell](#)  
**To:** [Sheryl Kunickis](#)  
**Subject:** Registration Confirmed - 2019 CropLife America Winter Board Meeting & Legislative Rally  
**Date:** Thursday, February 14, 2019 9:19:24 AM

---



Dear Sheryl,

Your registration has been confirmed. Please save this email for future reference.

Event: CropLife America Board & Allies dinner

Attending: Sheryl Kunickis

Number in Party: 1

Date: Tuesday, March 5

Time: 6:30 PM cocktails, 7:30 PM dinner

Salon I-II (2nd floor)

The Ritz-Carlton Pentagon City

1250 South Hayes Street, Arlington, Virginia, 22202

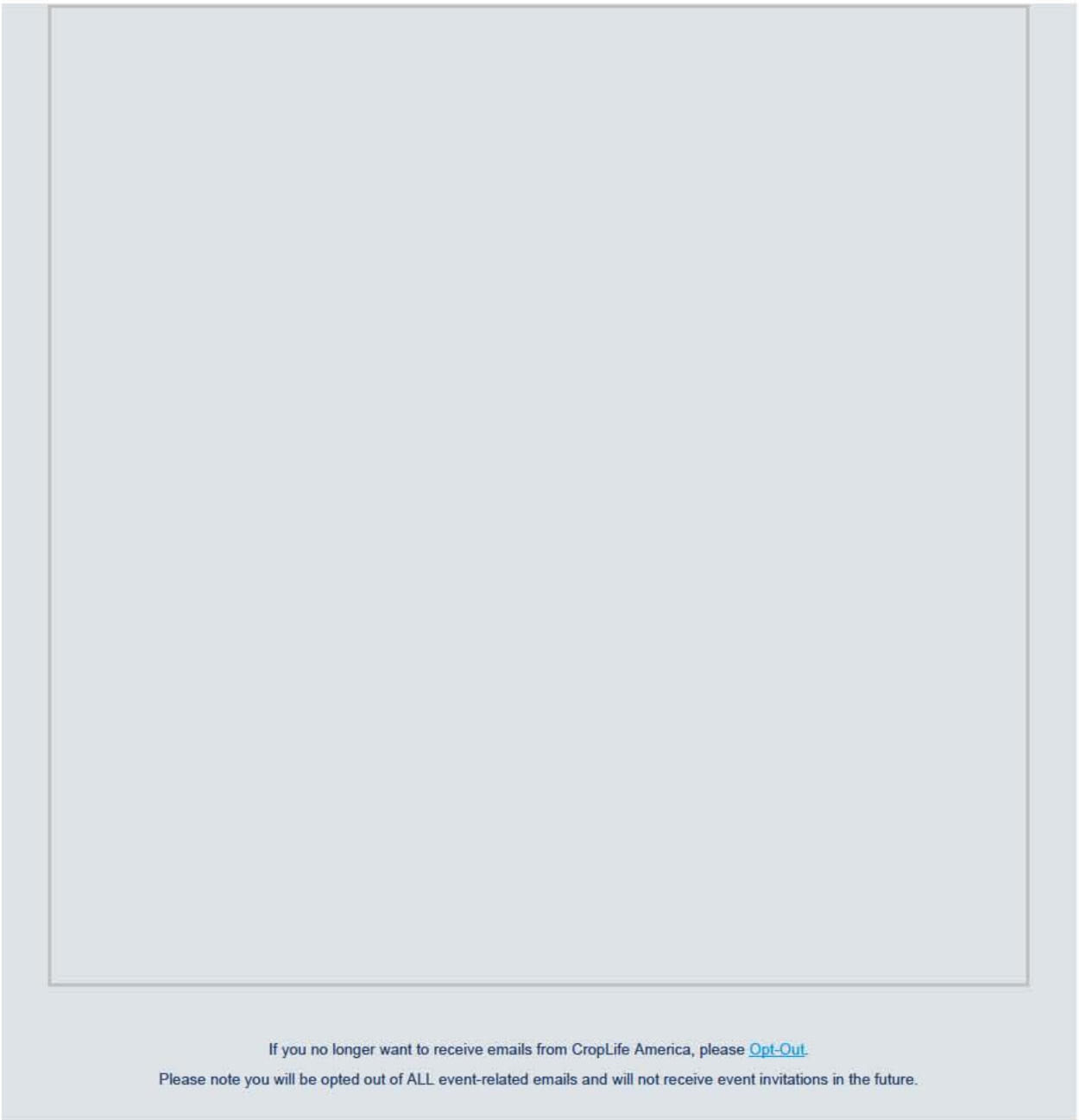
Confirmation Number: (b) (6)

We look forward to seeing you there.

Sincerely,

CropLife America

Need to email our event planner? Get in touch with Francesca at  
(b) (6)@croplifeamerica.org.



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**From:** [Fajardo, Julius](#)  
**To:** [Anandaraman, Neena - OSEC](#); (b) (6) [@croplifeamerica.org](#)  
**Cc:** [Jim Cranney](#)  
**Subject:** RE: Any time for a phone call?  
**Date:** Thursday, February 15, 2018 5:36:35 AM

---

I'm available.

---

**From:** Anandaraman, Neena - OSEC  
**Sent:** Wednesday, February 14, 2018 7:06 PM  
**To:** (b) (6) [@croplifeamerica.org](#)  
**Cc:** Jim Cranney (b) (6) [@ccqc.org](#); Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>  
**Subject:** Re: Any time for a phone call?

Great-will send an invite for 10am

Sent from my iPhone

On Feb 14, 2018, at 7:00 PM, Ray McAllister (b) (6) [@croplifeamerica.org](#) wrote:

On Friday, before 1:30 p.m. or 2:30 to 4 p.m.

Ray S. McAllister, PhD  
Senior Director, Regulatory Policy  
CropLife America

(b) (6) (office)

(b) (6) (cell)

(b) (6) [@croplife.us](#)

On Feb 14, 2018, at 6:30 PM, Jim Cranney <(b) (6) [@ccqc.org](#)> wrote:

Hi Neena,

Anytime after 9:30 a.m. PST I'm available all day.

Regards,  
Jim

James R. Cranney, Jr.  
California Citrus Quality Council  
853 Lincoln Way  
Auburn, California 95603  
Tel: (530) 885-1894  
Mobile: (b) (6)  
(b) (6) [@ccqc.org](#)

---

**From:** Anandaraman, Neena - OSEC [<mailto:Neena.Anandaraman@osec.usda.gov>]

**Sent:** Wednesday, February 14, 2018 3:27 PM  
**To:** Jim Cranney (b) (6) <[@ccqc.org](mailto:(b) (6)@ccqc.org)>; (b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** RE: Any time for a phone call?

ON Friday, I can rearrange most things except a meeting from 3-4pm

Office: (b) (6)  
Cell: (b) (6)

---

**From:** Anandaraman, Neena - OSEC  
**Sent:** Wednesday, February 14, 2018 6:26 PM  
**To:** 'Jim Cranney' (b) (6) <[@ccqc.org](mailto:(b) (6)@ccqc.org)>; (b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** RE: Any time for a phone call?

Happy to talk to each of you individually if we can't find a day.  
I can talk with you Jim tomorrow, Thursday, if there's a good time.

Is there a good time for you Friday, Ray?  
Thanks!

Office: (b) (6)  
Cell: (b) (6)

---

**From:** Jim Cranney [[mailto:\(b\) \(6\)@ccqc.org](mailto:(b) (6)@ccqc.org)]  
**Sent:** Wednesday, February 14, 2018 6:21 PM  
**To:** (b) (6) <[@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>; Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Cc:** Fajardo, Julius <[Julius.Fajardo@ARS.USDA.GOV](mailto:Julius.Fajardo@ARS.USDA.GOV)>  
**Subject:** RE: Any time for a phone call?

Thursday is better for me. I'm out of the office on Friday.

James R. Cranney, Jr.  
California Citrus Quality Council  
853 Lincoln Way  
Auburn, California 95603  
Tel: (530) 885-1894  
Mobile: (b) (6)  
(b) (6) <[@ccqc.org](mailto:(b) (6)@ccqc.org)>

---

**From:** Ray McAllister [[mailto:\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]  
**Sent:** Wednesday, February 14, 2018 1:27 PM  
**To:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; Jim Cranney

(b) (6) @ccqc.org>

Cc: Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>

Subject: RE: Any time for a phone call?

Friday and Wednesday would be the best days for me.

Ray S. McAllister, PhD

Senior Director Regulatory Policy

CropLife America

O: (b) (6) C: 202-577-6657

(b) (6) @croplife.us

---

**From:** Anandaraman, Neena - OSEC [<mailto:Neena.Anandaraman@osec.usda.gov>]

**Sent:** Wednesday, February 14, 2018 4:13 PM

**To:** Jim Cranney (b) (6) @ccqc.org>; Ray McAllister

(b) (6) @croplifeamerica.org>

**Cc:** Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>

**Subject:** Any time for a phone call?

Dear Jim and Ray,

I hope the New Year finds you well! It would be helpful to have a call as the electronic working group for Codex will get started soon. I would like to run some thoughts by you.

Would you have 30-45 minutes for a call this Thursday (2/15), Friday (2/16), next Tuesday (2/20) or Wednesday (2/21)?

We could go into the next weeks if not.

Thanks,

Neena

Neena Anandaraman, DVM, MPH, DACVPM

Veterinary Science Policy Advisor

Office of the Chief Scientist

United States Department of Agriculture

Office: (b) (6)

Cell: (b) (6)

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**From:** [CropLife America & RISE](#)  
**To:** [Rosalind James](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** Last week to register - join us at the CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, April 18, 2018 7:47:08 AM

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FINAL-INVITE-NO-HOTEL



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If you no longer want to receive emails from Francesca Purcell please click this link: [Opt-Out](#)



**From:** [Ray McAllister](#)  
**To:** [Fajardo, Julius](#)  
**Subject:** FW: Need help from FRAC  
**Date:** Monday, March 19, 2018 5:03:17 PM  
**Attachments:** [McManus,P.2014.Antibiotics use on plants.pdf](#)  
[Durso et al.2014.Antibiotics in Agriculture.pdf](#)

---

Julius:

Are you familiar with the attached papers? I am just passing them along without having read or critiqued them.

Ray S. McAllister, PhD  
 Senior Director Regulatory Policy  
 CropLife America  
 O: (b) (6) C: (b) (6)  
 (b) (6) @croplife.us

---

**From:** Olaya Gilberto USVB (b) (6) @syngenta.com>  
**Sent:** Wednesday, February 21, 2018 9:48 PM  
**To:** Hermann Dietrich CHBS <(b) (6) @syngenta.com>; Klaus Stenzel (b) (6) @bayer.com>; Sierotzki Helge CHST (b) (6) @syngenta.com>; Martin Semar (b) (6) @basf.com>; (b) (6) @basf.com>; Andreas Mehl (b) (6) @bayer.com>; Juergen Derpmann (b) (6) @bayer.com>  
**Cc:** (b) (6); Ray McAllister (b) (6) @croplifeamerica.org>; Andrew Ward (b) (6) @croplife.org>  
**Subject:** RE: Need help from FRAC

Dear colleagues,

Attached are 2 papers I found about the subject of antibiotic use in agriculture and that could be very useful. One with more focus in the use of antibiotic to control *Erwinia amylovora* (fire blight on pears and apples) and written by Patricia McManus that have a long history of research work on this area. The other paper with more focus on the impact of antibiotic use in animal production.

Regards,

Gilberto

# Does a drop in the bucket make a splash? Assessing the impact of antibiotic use on plants

Patricia S McManus



Antibiotics are applied to plants to prevent bacterial diseases, although the diversity of antibiotics and total amounts used are dwarfed by antibiotic use in animal agriculture. Nevertheless, the release of antibiotics into the open environment during crop treatment draws scrutiny for its potential impact on the global pool of resistance genes. The main use of antibiotics on plants is application of streptomycin to prevent fire blight, a serious disease of apple and pear trees. A series of recent studies identified and quantified antibiotic resistance genes and profiled bacterial communities in apple orchard plots that were or were not sprayed with streptomycin. While the specific objectives and methods varied, the results of these studies suggest that streptomycin application for fire blight control does not influence bacterial community structure or increase the abundance of resistance genes in orchards.

#### Addresses

Department of Plant Pathology, University of Wisconsin Madison, United States

Corresponding author: McManus, Patricia S ([psm@plantpath.wisc.edu](mailto:psm@plantpath.wisc.edu))

Current Opinion in Microbiology 2014, 19:76–82

This review comes from a themed issue on Ecology and industrial microbiology

Edited by Kornelia Smalla and James M Tiedje

For a complete overview see the [Issue](#) and the [Editorial](#)

Available online 5th July 2014

<http://dx.doi.org/10.1016/j.mib.2014.05.013>

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## Introduction

Most cultivated crops are plagued by dozens of fungal pathogens and several viruses, while any given crop species suffers just a few bacterial diseases. However, the relatively small number of bacterial diseases of plants is offset by the fact that they are often highly destructive and notoriously difficult to control. Commercially desirable crop varieties often lack genetic resistance to bacterial diseases, and the slate of bactericides available for use on plants is limited mostly to copper compounds, and on a few crops in some parts of the world, the antibiotics streptomycin, oxytetracycline, gentamicin, oxolinic acid, and kasugamycin. Estimates of the amount of antibiotics used in animal and plant agriculture worldwide are not available, but in 2011 in the USA, 13 542 metric tons of

antibiotics were sold for use in food animal production (U.S. Food and Drug Administration; <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf>), while 36 metric tons of antibiotics were applied to crops (U.S. Department of Agriculture National Agricultural Statistics Service; <http://quickstats.nass.usda.gov/results/109EEE67-BC97-3720-87DC-EFF1B7D98DA5#0293B483-DFB4-3C5A-90F5-B76C5C8C5B84>). Assuming that the antibiotics sold for animal use were consumed, then use of antibiotics on crops accounted for just 0.26% of total agricultural use

a proverbial drop in the bucket (Figure 1). However, antibiotics are usually applied to crop canopies in a fine mist, some of which settles to the soil or drifts off-site. The environment and soil in particular are widely regarded as repositories for antibiotic resistance genes important in clinical medicine [1–6], heightening concerns that the seemingly trivial amount of antibiotics used on crops could have a disproportionate impact on the global pool of resistance genes. Likewise, it has been hypothesized that fresh produce harboring antibiotic resistant bacteria could bridge the gap between the environmental and human gut niches [7,8]. Such concerns have resulted in tighter restrictions on the use of streptomycin in plant agriculture in Europe [9] and the banning of antibiotics in organic crop production in the USA (<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5104932>) and many other countries.

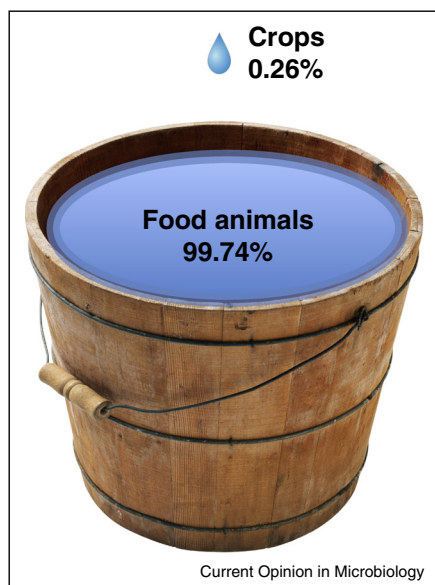
The practice of using antibiotics on plants, and initial findings on antibiotic resistance in plant-associated bacteria, have been described previously [10,11,12]. The introduction of antibiotics and resistance genes into plants and the food chain via animal manure used as fertilizer for crops [13–16] is an important and timely subject but is beyond the scope of this short review. The focus here is recent work that has assessed the impact of antibiotics used for plant disease control on bacterial communities and antibiotic resistance genes in cropping ecosystems.

## Effects of antibiotics in cropping ecosystems

A primary impetus for studies on the impact of antibiotics in plant agriculture has been the concern that antibiotics intended to control bacterial diseases might select for resistant bacteria and mobile antibiotic resistance genes in the environment and on edible produce. However, many studies also encompass the effect of antibiotics on bacterial community membership and diversity, which could have implications for resistance reservoirs, food



Figure 1



Agricultural use of antibiotics in the USA. The amount used on crops in 2011 was 36 metric tons, or 0.26% of the total agricultural use. Data from United States Department of Agriculture National Agricultural Statistics Service.

safety, and plant health. Rodríguez *et al.* [17] sampled iceberg lettuce from nine farms in Costa Rica where unknown amounts of gentamicin, oxytetracycline, and streptomycin had been sprayed and one unexposed farm. There were no trends suggesting an influence of antibiotics on bacterial community diversity, the proportion of cultured bacteria resistant to gentamicin, or the presence of tetracycline resistance genes and broad-host-range plasmids in the IncP-1 and IncQ incompatibility groups, which have been implicated in the horizontal transfer of resistance genes [18,19]. In further work in Costa Rica [20], spraying oxytetracycline combined with gentamicin on coriander five times over a 16-month period did not affect the proportion of culturable bacteria resistant to those antibiotics. Likewise, detection of resistance genes and IncP-1 and IncQ plasmids in total DNA isolated directly from soil was similar in antibiotic treated and untreated control plots.

The main use of antibiotics on plants in temperate zones has been application of streptomycin to manage fire blight, a highly destructive disease of apple, pear, and related plants caused by the Gram-negative, enteric bacterium *Erwinia amylovora*. The pathogen first infects flowers, and then invades its host systemically, leading to death of branches and in some cases, entire trees (Figure 2). This one disease is the target of 80–90% of antibiotics applied to plants, at least in countries where such records are readily obtained [10,11\*]. When conditions are favorable for infection, growers spray

Figure 2



A young apple orchard killed by fire blight, a disease caused by the bacterium *Erwinia amylovora*. Fire blight accounts for 80–90% of antibiotic use on plants [10,11\*]. Photo by Mark Longstroth, Michigan State University.

streptomycin or alternative antibiotics where streptomycin-resistant strains of *E. amylovora* have emerged to susceptible apple and pear varieties to prevent multiplication of *E. amylovora* on floral stigmata [10,11\*,21,22]. Early studies on the effects of streptomycin on bacterial communities in orchards were contradictory. For example, Tolba *et al.* [23] found that soil from an apple orchard treated with streptomycin and untreated soil from the same research station in Germany did not differ in the proportion of streptomycetes resistant to streptomycin, but the incidence of the streptomycin resistance genes *strA* and *strB* was greater in streptomycete isolates from treated soil. However, van Overbeek *et al.* [24], who sampled the same apple orchard as Tolba *et al.* [23], reported that the abundance of *strA*, *strB*, and additional streptomycin resistance genes, was not greater in bulk soil and grass rhizosphere soil from the treated apple orchard than in untreated soil from the same site or from diverse agricultural, pristine, or polluted environments throughout Europe (Table 1).

In an effort to identify novel antibiotic resistance genes, Donato *et al.* [25] constructed metagenomic libraries from total soil DNA from an apple orchard with a history of streptomycin exposure, and then screened the libraries on streptomycin and 10 other antibiotics. Thirteen clones were resistant to various beta-lactams, aminoglycosides, and tetracyclines, but there were no streptomycin resistant clones. However, *strA* and *strB* were detected in the libraries by PCR, suggesting that at least some resistance genes were present but not functional in their *Escherichia coli* host. Popowska *et al.* [26] used quantitative PCR to measure the levels of streptomycin and tetracycline

Table 1

Aminoglycoside and tetracycline resistance genes detected in apple orchards treated (T) or not treated (C) with streptomycin<sup>a</sup>

Sample type	Antibiotic resistance genes								Study
	<i>aph</i> (3'') <sup>b</sup>	<i>aph</i> (6) Id <sup>b</sup>	<i>aph</i> (6) Ic	<i>ant</i> (3'')	<i>ant</i> (6)	<i>tetB</i>	<i>tetM</i>	<i>tetW</i>	
Soil	T C	T C	<i>nt</i> <sup>c</sup>	<i>nt</i>	<i>nt</i>	<i>nt</i>	<i>nt</i>	<i>nt</i>	23
	T C	T C	T C	T C	T	<i>nt</i>	<i>nt</i>	<i>nt</i>	24
	T C	T C	<i>nt</i>	<i>nt</i>	<i>nt</i>	T C	T C	T C	30
Flowers	T C	T C	<i>nt</i>	<i>nt</i>	<i>nt</i>	T C	T C	T C	30
Leaves	T C	T C	<i>nt</i>	<i>nt</i>	<i>nt</i>	T C	T C	T C	30
Fruit	T C	T C	<i>nt</i>	<i>nt</i>	<i>nt</i>	T C	T C	T C	30

<sup>a</sup> Only those studies in which there was a direct comparison of treated and control samples are included.

<sup>b</sup> *aph* (3'') and *aph* (6) Id are also referred to in the literature as *strA* and *strB*, respectively.

<sup>c</sup> *nt*: not tested.

resistance genes in soils from apple and mixed fruit orchards treated with unspecified amounts of these antibiotics, manured vegetable garden soil, forest soil, and composted plant residues. While the experimental design did not allow statistical comparisons, the apple orchard soil contained relatively high levels of the streptomycin-resistance gene *aadA* and *Paenbacillus* spp. resistant to greater than 1024 µg/ml streptomycin. Levels of other streptomycin and tetracycline resistance genes, and sensitivity of bacteria, were unrelated to soil use history.

The literature summarized above shed light on bacterial communities in cropping systems, revealed resistance genes similar to those described in clinically important bacteria, and described possible mechanisms for horizontal transfer of resistance genes. However, field studies were limited by a lack of replicated control and treatment sites, making it impossible to account for site-to-site variability unrelated to antibiotic use. In most cases they lacked replicated sampling within sites, preventing any sort of statistical analysis. Further, the amounts of antibiotics and spray timing relative to sample collection were generally not well described. More recently researchers have paid closer attention to experimental design, and in doing so have more directly evaluated the impact of streptomycin use in apple orchards, as described below.

To assess the long-term effect of streptomycin use in commercial apple orchards, bacterial communities on mature leaves collected from four orchards where streptomycin had been applied most of the 10 years leading up to the study were compared with communities from four orchards that had not been sprayed with streptomycin [27\*\*]. Relatively shallow sequencing of 16S rRNA gene clone libraries (169 335 sequences per orchard site) revealed no differences in community membership that could be attributed to streptomycin use. Indices of alpha diversity (Shannon, Simpson's, and Pielou's evenness) were similar among orchards, regardless of streptomycin exposure. Likewise, analysis of similarity indicated that the variability in community structure among orchards was not linked to streptomycin use. Surprisingly, the

average proportion of cultured bacterial colonies resistant to streptomycin was significantly greater in orchards that had not been sprayed (65%) than in sprayed orchards (50%). This result could not be ascribed to a greater abundance of *Sphingomonas* or *Pseudomonas*, genera known to have a high frequency of intrinsic resistance to streptomycin even in the absence of selection [28,29]. The authors provided no further explanation for the unexpected result, but they concluded that springtime streptomycin use over several years did not increase the frequency of resistant bacteria on apple leaves in middle to late summer.

Duffy *et al.* [30\*\*] used quantitative PCR to measure the levels of streptomycin resistance genes *addA*, *strA*, and *strB*, tetracycline resistance genes *tetB*, *tetM* and *tetW*, and *IS1133*, an insertion sequence associated with transposon-borne *strA* and *strB* [10,19], on leaves, flowers, mature fruits, and in soil from streptomycin treated and untreated orchard plots at three locations. Streptomycin was applied at concentrations and times in line with the practices of commercial apple growers. Streptomycin and tetracycline resistance genes were detected in samples regardless of exposure to streptomycin (Table 1). Comparison of water-treated samples with streptomycin-treated samples showed significant increases in abundance in streptomycin resistance genes or *IS1133* in 11 of 216 comparisons, but the increases were not consistently associated with any particular resistance gene, sample type (i.e. soil, leaf, flower, or fruit), or location, nor were the increases reproducible over years. Significant increases in abundance of tetracycline resistance genes were detected in nine of 162 comparisons, but they also were not consistently tied to a particular sampling or orchard variable. From a statistical standpoint, chance alone might account for these results [31]. Taken together, the data suggest that streptomycin treatment does not select for genes conferring resistance to streptomycin or tetracycline in bacteria that inhabit apple tissues or orchard soil.

Soil bacterial communities are widely recognized as a reservoir for antibiotic resistance genes [1,4,5]. In two

recent works, the unintended exposure of soil to streptomycin during fire blight treatment was hypothesized to alter the membership and diversity of soil bacteria in apple orchards [32\*\*,33\*\*]. The authors of these studies posited that streptomycin exposure might select for multidrug-resistant bacteria with resistance mechanisms similar to those of human pathogens, or disrupt bacterial communities involved in functions related to plant health such as nutrient cycling and protection of roots from pathogens. Using tag pyrosequencing of 16S rRNA genes, Shade *et al.* [32\*\*] profiled bacterial communities in soil before and after spraying streptomycin to apple trees, and in orchard soil that had never been treated with streptomycin. For each treatment and sampling time, three types of communities were analyzed: total cultured bacteria; bacteria cultured on a medium containing streptomycin (15 µg/ml); and bacteria represented in total DNA isolated directly from soil (i.e. culture-independent community). Shannon diversity and Pielou's evenness indices, as well as hypothesis tests (analysis of similarity, multiple-response permutation procedure, permuted analysis of variance, and permuted analysis of dispersion) performed on a suite of resemblance metrics (Bray-Curtis, modified Gower, Sørensen's, and Morisita-Horn), were applied to the data sets, but none revealed community differences that could be associated with streptomycin treatment. These findings were corroborated by Walsh *et al.* [33\*\*] who applied several statistical tests to compare culture-independent bacterial communities from apple orchard soil beneath trees sprayed with streptomycin or water. They reported no influence of streptomycin on the abundance of major bacterial taxa in apple orchard soil, including *Pseudomonas*, *Burkholderia*, and *Stenotrophomonas*, genera that are intrinsically resistant to many antibiotics and related to important multidrug-resistant bacteria in hospitals.

Application of streptomycin to apple and pear flowers inhibits growth of *E. amylovora* on the floral stigma and thereby prevents fire blight [21,22]. However, when stigmata and leaves were sampled one and two weeks, respectively, after streptomycin application, the populations of cultured, non-target bacteria were not different from populations isolated from tissues treated with water [21]. In a study focused on bacterial community succession on apple flowers [34], streptomycin treatment slightly reduced phylogenetic diversity of bacterial communities but did not affect overall community structure or succession.

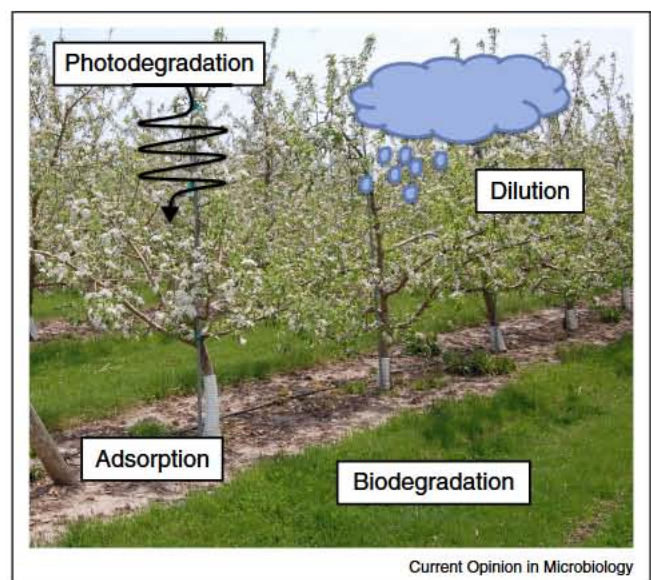
In summary, these recent apple orchard studies have focused on different tissues and soil sampled at different times of the year relative to streptomycin use. The research employed a range of culture-dependent and culture-independent methods to identify bacteria and resistance genes, varied in the depth of sequencing performed to identify members of the community, and

differed in the statistical hypothesis tests used to compare communities. While the specific objectives of each study were unique, the general conclusions are the same: streptomycin application for fire blight control does not appear to influence bacterial community structure or increase the abundance of resistance genes in orchards.

### Why no splash?

The lack of impact of antibiotics on non-target bacteria and resistance genes in various cropping ecosystems is counterintuitive. Antibiotics inhibit growth of *E. amylovora* on apple and pear flowers [21,22], and the emergence of streptomycin resistant strains of *E. amylovora* indicates that selection does occur in agricultural settings [10,11\*]. While the reasons for non-target bacterial community resilience in the face of antibiotic exposure have not been well investigated, an explanation put forth by some researchers [32\*\*] is that the amount of streptomycin that reaches the soil in a treated apple orchard is insufficient to exert selection pressure on bacteria. However, Walsh *et al.* [33\*\*] calculated that under conditions used for fire blight control, the average concentration in the top 10 cm of soil would be as high as 12 µg/ml, with higher concentrations near the soil surface. In theory, this would be enough to select for clinically relevant levels of resistance to some human pathogens. However, in an agricultural setting, the availability, stability, and activity of antibiotics are potentially influenced by adsorption to soil, dilution by rain or dew, photodegradation, and microbial degradation [35–38] (Figure 3). In Costa Rica, oxytetracycline was not detected in soil four days after it was applied to coriander [20]. This result might be explained by adsorption of

Figure 3



Processes that potentially influence the availability, stability, and activity of antibiotics applied to plants.

oxytetracycline to soil, a process that was shown to neutralize tetracycline in soil [37]. Antibiotics are also apparently non-persistent on aerial plant parts. For example, growth of *E. amylovora* on pear flowers was suppressed for just four days following application of streptomycin or oxytetracycline [22], perhaps because both antibiotics are susceptible to photodegradation [35,36]. Similarly, in the absence of rain, oxytetracycline levels were reduced to near the detection limit on peach leaves seven days after spraying, a result attributed to photodegradation [38].

### Does antibiotic use on plants pose a risk to human health?

Studies to date suggest that antibiotic use on crops will not enrich consumers' diets with resistant bacteria or resistance genes, a concern that has been raised, but not fully substantiated, with the nontherapeutic use of antibiotics in animal feed [39]. None of the plant studies, however, has addressed the possible direct risk to humans of antibiotic residues on produce. This concern was raised in a letter to the editor of a prominent microbiology journal [9], but the scant data provided did not support the authors' assertion that streptomycin residues on apple fruit select for antibiotic resistance in the human body.

The population at greater risk for exposure to antibiotics used on crops is not consumers of fresh produce but rather workers who mix and apply antibiotics, although exposure is mitigated by wearing personal protection equipment, which is required by law in some countries [10,11\*]. To date, no studies have monitored the bacterial flora of orchardists who apply antibiotics. However, Scherer *et al.* [40\*] used sheep as a model to assess the effect of streptomycin applied to pasture grass on multidrug resistance in fecal and nasal bacteria of mammals. While the intent was to simulate conditions in orchards being treated for fire blight, the timing of sprays was not consistent with practices used in modern commercial apple production. Four sprays were applied over a five-week period, whereas apple growers typically apply streptomycin zero to three times over a one-week to two-week period while trees are in bloom [10,11\*]. The percentage of streptomycin resistant *E. coli* isolated from feces of sheep that had grazed in treated pastures was significantly greater than in the control group a few days after the third and fourth sprays. Similarly, the percentage of streptomycin resistant *Staphylococcus* spp. isolated from nasal cavities of sheep in the treatment group was greater than in the control group after the third spray. Multidrug-resistant strains of *E. coli* were recovered more frequently from the treatment than control group. Thus, streptomycin exposure was associated with an increase in antibiotic resistant bacteria, which could have implications for livestock grazing in or near treated orchards. However, relating the results of this study to orchard worker health is problematic, because workers take measures to avoid

contact with antibiotics and do not graze on pasture grass. Farming practices and regulations that minimize exposure of farmers to antibiotics, as well as the relationship between antibiotic residues and the concentrations required to exert selection pressure, are covered elsewhere [10,11\*].

### Emerging trends in antibiotic use on plants

The controversy surrounding antibiotic use in agriculture, the emergence of streptomycin resistant plant pathogens, and the ongoing challenge of controlling bacterial diseases of plants have spurred research into alternative methods of control. Among the most promising developments is the rediscovery of kasugamycin for controlling plant pathogenic bacteria, especially *E. amylovora* [41,21]. Introduced in the 1960s and used as a fungicide for control of the rice blast fungus, kasugamycin was tested for fire blight control in the 1980s but was abandoned due to its phytotoxicity [42]. In trials on apple [21] and pear [41], a less phytotoxic formulation of kasugamycin was as effective or better than streptomycin and oxytetracycline in controlling fire blight. The recent registration of kasugamycin in Canada and imminent registration in the USA have been facilitated by the fact that this antibiotic is not used in human or veterinary medicine. Ahead of the widespread deployment of kasugamycin for fire blight control, researchers have identified resistance mechanisms and potential reservoirs of resistance genes in orchards [21]. The isolation of bacteria resistant to both kasugamycin and streptomycin from apple flowers and leaves [21] presents the possibility of selecting for streptomycin resistance through application of kasugamycin.

The economic devastation wrought by Huanglongbing (HLB) disease of citrus has prompted a re-evaluation of injecting antibiotics into tree trunks for disease control [43,44]. Combinations of penicillin + streptomycin or kasugamycin + oxytetracycline reduced titers of the HLB pathogen *Candidatus Liberibacter asiaticus* in citrus leaf mid veins [43]. The labor and expense of tree injection has curtailed this practice in agriculture. However, this method efficiently and directly delivers antibiotics to the vascular tissues of woody plants where the HLB bacterium and related pathogens reside, without creating controversial spray drift.

### Conclusions

The preponderance of data published in the past decade suggests that antibiotic use on plants is in fact a 'drop in the bucket' with negligible 'splash.' While far from exhaustive, this research has the potential to greatly alleviate the concerns surrounding antibiotic use for plant disease control. Thus, antibiotics are likely to see use on crops in the foreseeable future. However, we may witness a shift in the antibiotics used and how they are applied, motivated in part by growers' desire to preserve the

efficacy of these valuable tools and as dictated by government regulations.

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# Impacts of antibiotic use in agriculture: what are the benefits and risks?<sup>☆</sup>

Lisa M Durso<sup>1</sup> and Kimberly L Cook<sup>2</sup>



Antibiotic drugs provide clear benefits for food animal health and welfare, while simultaneously providing clear risks due to enrichment of resistant microorganisms. There is no consensus, however, on how to evaluate benefits and risks of antibiotic use in agriculture, or the impact on public health. Recent soil resistome work emphasizes the importance of environmental reservoirs of antibiotic resistance (AR), and provides a starting point for distinguishing AR that can be impacted by agricultural practices from AR naturally present in a system. Manure is the primary vehicle introducing antibiotic drugs, AR bacteria and AR genes from animals into the environment. Manure management, therefore, impacts the transfer of AR from agricultural to human clinical settings via soil, water, and food. Ongoing research on the ecology of naturally occurring and anthropogenically derived AR in agroecosystems is necessary to adequately quantify the benefits and risks associated with use of antibiotics in food animals.

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disease, which are among the ‘five freedoms’ accorded to livestock by contemporary animal husbandry [1]. Antibiotics also improve feed efficiency, which allows the same amount of meat to be produced with a smaller number of animals. Greater efficiency results in less cropland area necessary to grow animal feed, decreased manure production, and concomitant economic benefits for both consumers (e.g. lower prices) and producers (e.g. greater profits).

There is a broad consensus that antibiotic use enriches bacteria carrying antibiotic resistance genes (AR genes), and that antibiotic resistant bacteria (AR bacteria) and AR genes from agricultural settings can be physically transferred to humans. However many of the applied details of how, and at what rate bacteria and genes move from animals to humans through agricultural systems (soil, water, wildlife, insects, dust, food,) remain to be determined [2–8] (Figure 1). This review will focus on cattle, swine and poultry systems. Antibiotic use in aquaculture was recently reviewed elsewhere [9].

There are three main components to any discussion on AR: the antibiotic drugs, the AR bacteria, and the AR genes. The World Health Organization (WHO) list of antimicrobials of importance to human medicine contains 32 drug classes (260 individual drugs) listed as important, highly important, or critical for human medicine [WHO, [http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf?ua=1)]. Which drugs, bacteria, and genes are most relevant in the discussion of clinical consequences [10<sup>☆</sup>]? Of the 260 drugs on the WHO list of antimicrobial agents important for human medicine, only 39 are recommended or registered for use in cattle, swine, and poultry in the U.S [11,12] [Food Animal Residue Avoidance Database (FARAD), United States Department of Agriculture, <http://www.farad.org/vetgram/search.asp>] (Table 1). This includes drugs administered to individual animals and groups of animals to maintain animal health, and drugs used for growth promotion. The drugs available for use in animal agriculture vary by country, and the U.S. data are not necessarily representative of other countries. Recent U.S. Food and Drug Administration guidance regarding the labeling of over the counter antibiotics in food animals will also change how antibiotic drugs are used in cattle, swine and poultry.

To determine which agricultural antibiotics have a real possibility to impact clinical outcomes, veterinary drug information needs to be combined with information from

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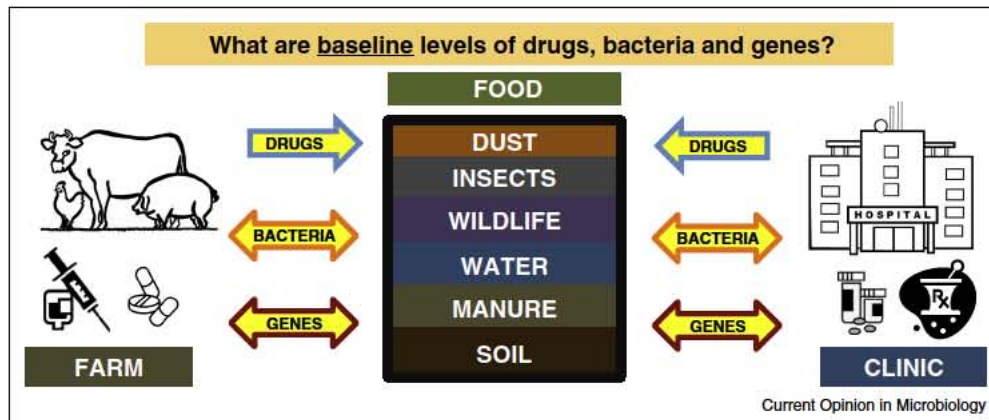
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## Introduction: which drugs, bacteria and genes should be measured in agroecosystems?

The use of antibiotics in animal production entwines ethics, economics, and environmental concerns. Antibiotics are critical for minimizing pain and treating

<sup>☆</sup> Mention of trade names or commercial products in this article is solely for the purpose of providing specific information and does not imply recommendation or endorsement by the U.S. Department of Agriculture. USDA is an equal opportunity provider and employer.

Figure 1



Movement of antibiotic resistance between farm and clinic. The environment is a reservoir of resistance, and a conduit of resistance between farm and clinic. The specific mechanisms by which antibiotic resistant bacteria and their genes are transported through the 'black box' of the environment remain uncertain. In order to accurately assess benefits and risks of antibiotic use in agriculture, it is essential to measure baseline levels of antibiotic drugs, resistant bacteria, and resistance genes when working with agriculturally impacted samples.

the Centers for Disease Control and Prevention (CDC) prioritized list of bacteria posing antibiotic resistance threats [CDC Threat Report, <http://www.cdc.gov/drugresistance/threat-report-2013/>], and with information regarding the ecology of pathogens [3,13] (Table 2). For example, tetracycline-resistant *Neisseria gonorrhoeae* is a pathogen listed as an Urgent Threat by CDC (the top category), and the antibiotic tetracycline is listed by CDC as a 'resistance of concern' for this pathogen. Although tetracycline is widely used in agricultural applications including over the counter sales of products added to feed and water, the fact that *N. gonorrhoeae* is a sexually transmitted disease with no known foodborne or environmental transmission suggests that agricultural use of the drug has limited impact on total burden of tetracycline resistance for *N. gonorrhoeae*. In contrast, tetracycline resistance is not listed by CDC as a 'resistance of concern' for *Campylobacter*, and is not generally recommended for treatment of *Campylobacter*. However, given its significance as a foodborne pathogen, any tetracycline resistant *Campylobacter* present in food animals would be more likely to impact human health. In a third example, multi-drug-resistant *Acinetobacter* inhabits soil, water, foods and arthropods and causes outbreaks associated with natural disasters [14]. Even though none of the drugs recommended for treatment [15] are used in food animals, the fact that *Acinetobacter* lives in the soil suggests that it has the theoretical potential to acquire resistance from agroecosystems.

For each antibiotic drug, there are a suite of genes that code for resistance. Resistance to tetracycline, for instance, can occur by three different mechanisms, encoded by over 25 different genes [16]. If the goal is to measure or track tetracycline resistance how much is on a farm, and how much is it reduced over time when a specific management

strategy is implemented which combination of these 25 different genes should be monitored, and in which types of bacteria? Different strains of the same organism may carry numerous AR genes [17], while the same AR genes may be carried by multiple taxa [18,19,20\*,21]. Taxa that survive well outside of the animal may have a greater potential to impact clinical disease due to the likelihood of surviving harsh environmental conditions until reaching an acceptable host [18,22\*,23]. These taxa would, therefore, provide better targets for measuring and tracking clinically relevant antibiotic resistance. Complicating the measurement of agricultural AR (agAR) and its potential for impacting human health are the physical, chemical, spatial, temporal and biological complexities of natural systems, and the 'many ecologies' of resistance [24–30]. As a result it can be expected that there will be different strategies and targets for the reduction of resistance in beef, dairy, swine, and poultry, operations [FAO/WHO/OIE, Expert Meeting on Critically Important Antimicrobials Report, Rome, Italy, November 2007].

### Defining baseline levels of drugs, bacteria and genes

The second challenge for evaluating benefits and risks of agricultural antibiotic use is that AR occurs naturally in the environment. A quantitative understanding of resistance transmission can be confounded by naturally occurring and baseline levels of resistance [31]. AR genes have been found in samples that pre-date the dawn of agriculture [32], and are ubiquitous in food, animal, human, and environmental samples [4,10\*\*,20\*,33\*\*,34,35,36\*]. For example, soil is a natural source of antibiotic-producing bacteria and a reservoir of resistance across the globe [10\*\*,34,35]. To understand the ecology and evolution of AR in agroecosystems and to accurately evaluate the



Table 1

World Health Organization (WHO) drugs of importance used in U.S. cattle, swine, and poultry.<sup>a</sup>

WHO drug classes	Number of drugs on list	Number given to agricultural animals <sup>b</sup>	Number available over the counter <sup>c</sup>	Number administered to animals orally <sup>d</sup>	Animal type <sup>e</sup>
<b>ALL</b>	260	39	19	17	CSP
<b>CRITICAL WHO DRUGS</b>					
Aminoglycosides	17	6	4	4	CSP
Carbapenems	7	1	0	0	CS
Cephalosporins (3rd and 4th generation)	26	2	0	0	CSP
Cyclic Esters	1	0	0	0	na
Drugs for mycobacterial diseases and tuberculosis	13	0	0	0	na
Fluoro and Other Quinolones	33	2	0	0	CS
Glycopeptides	6	0	0	0	na
Glycylcyclines	1	0	0	0	na
Lipopeptides	1	0	0	0	na
Macrolides and ketolides	21	8	4	4	CSP
Monobactams	2	0	0	0	na
Oxazolidinones (antibacterial)	1	0	0	0	na
Penicillins (natural, aminopenicillins and antipseudomonal)	26	3	0	0	CSP
Polymyxins	2	1	1	0	C
Rifamycins	5	1	0	0	C
<b>HIGHLY IMPORTANT WHO DRUGS</b>					
Aminopenicillins	2	0	0	0	na
Amphenicols	3	1	0	0	CS
Cephalosporins (1st and 2nd generation) and Cephamycins	27	1	0	0	C
Lincosamides	3	2	1	1	CSP
Penicillins (Antistaphylococcal)	5	1	0	0	C
Pleuromutilins	1	0	0	0	na
Pseudomonic acids	1	0	0	0	na
Riminofenazines	1	0	0	0	na
Steroid antibacterials	1	0	0	0	na
Streptogramins	3	1	1	1	CSP
Sulfonamides, Dihydrofolate reductase inhibitors and combos	28	3	3	2	CSP
Sulfones	2	0	0	0	na
Tetracyclines	11	3	3	3	CSP
<b>IMPORTANT WHO DRUGS</b>					
Aminocyclitols	1	1	1	1	CSP
Cyclic polypeptides	1	1	1	1	CSP
Nitrofurantoin	5	0	0	0	na
Nitroimidazoles	3	1	0	0	C

Note: The information in this list is not comprehensive, and is presented as an example of the *types* of information that need to be integrated. The data presented is based solely on information from the cited references, and is not intended to suggest consensus among veterinary or human medical practitioners regarding recommended treatment options.

<sup>a</sup> WHO List of Critically Important Antimicrobials, 3rd Revision ([http://www.who.int/foodborne\\_disease/resistance/cia/en/](http://www.who.int/foodborne_disease/resistance/cia/en/)). A full list of drugs is available in supplementary data.

<sup>b</sup> All drugs were listed for animal use in [11,12] or (<http://www.farad.org>, accessed December 13, 2013).

<sup>c</sup> Classified as over the counter by (<http://www.farad.org>, accessed December 13, 2013).

<sup>d</sup> Recommended for oral administration in feed or water (<http://www.farad.org>, accessed December 13, 2013).

<sup>e</sup> Dosages for Cattle (C), Swine (S), Poultry (P), or no dose given (na) [11,12] or (<http://www.farad.org>, accessed December 13, 2013).

impact and effectiveness of any intervention strategies it is, therefore, essential to collect baseline and control data when quantifying AR bacteria or AR genes in agricultural settings [28 30,37 39].

Since a critical component of the agricultural antibiotic hypothesis is that resistance genes enriched by agricultural antibiotic use travel to humans through food, soil, water, insects, dust, and wildlife [8,40<sup>\*</sup>], it is not sufficient to only measure resistance in zoonotic organisms.

Environmental bacteria and genes also need to be assessed [35]. Culture-based and culture independent methods can also be combined in order to measure resistance in a bacterial community at both the isolate and at the gene level [23,36<sup>\*</sup>,41].

Regardless of whether AR is naturally occurring or anthropogenic [42], efforts to reduce the impact of agricultural antibiotic use should focus on determining which types of agAR are most important to human health, and which can

Table 2

Integrating information on drugs, bacteria, and genes<sup>a</sup>

CDC Threat List 2013	Drugs of concern in human medicine that are also used in food animals WHO level of Concern: Critical (C), Highly Important (H), or Important (I)	Location of resistance gene <sup>b</sup>
<b>Urgent Threats</b>		
<i>Clostridium difficile</i>	Metronidazole <sup>UTD</sup> (C)	PTC
Carbapenem resistant Enterobacteriaceae	None: Carbapenems are not recommended/approved for ag use	
Drug Resistant <i>Neisseria gonorrhoeae</i>	Azithromycin <sup>CDC and UTD</sup> (C); Tetracycline <sup>CDC</sup> (H)	PTC
<b>Serious Threats</b>		
Multidrug resistant <i>Acinetobacter</i>	Ampicillin <sup>UTD</sup> (C); Polymyxin B <sup>UTD</sup> (C)	PTCG
Drug resistant <i>Campylobacter</i>	All Fluoroquinolones <sup>UTD</sup> (C); All Macrolides <sup>UTD</sup> (C)	C
Fluconazole resistant <i>Candida</i>	Anti fungal	
Extended Spectrum beta lactamase producing Enterobacteriaceae	All Cephalosporins <sup>CDC</sup> (C,H); All Penicillins <sup>CDC</sup> (C,H)	PTCG
Vancomycin resistant <i>Enterococcus</i>	None: Glycopeptides are not recommended/approved for ag use	
Multidrug resistant <i>Pseudomonas aeruginosa</i>	All Aminoglycosides <sup>CDC</sup> (C); All Cephalosporins <sup>CDC</sup> (C,H); All Fluoroquinolones <sup>CDC</sup> (C); Polymyxin B <sup>UTD</sup> (C)	PTCG
Drug resistant Non typhoidal <i>Salmonella</i>	Amikacin <sup>UTD</sup> (C); Azithromycin <sup>UTD</sup> (C)	PTCG
Drug resistant <i>Salmonella typhi</i>	Azithromycin <sup>CDC and UTD</sup> (C)	C
Drug resistant <i>Shigella</i>	Azithromycin <sup>CDC and UTD</sup> (C)	C
Methicillin resistant <i>Staphylococcus aureus</i>	All Cephalosporins <sup>CDC</sup> (C,H); Gentamycin <sup>UTD</sup> (C); Rifampicin <sup>UTD</sup> (C)	PTCG
Drug resistant <i>Streptococcus pneumonia</i>	Azithromycin <sup>CDC</sup> (C); Erythromycin <sup>CDC</sup> (C); All Penicillins <sup>CDC</sup> (C,H)	PTCG
Drug resistant tuberculosis	Amikacin <sup>CDC</sup> (C); All Fluoroquinolones <sup>CDC</sup> (C); Rifampicin <sup>CDC and UTD</sup> (C)	PTCG
<b>Concerning Threats</b>		
Vancomycin resistant <i>Staphylococcus aureus</i>	None: Glycopeptides are not recommended/approved for ag use	
Erythromycin resistant Group A <i>Streptococcus</i>	Erythromycin <sup>CDC</sup> (C); All Tetracyclines <sup>CDC</sup> (H)	PTC
Clindamycin resistant Group B <i>Streptococcus</i>	Erythromycin <sup>CDC</sup> (C)	C

<sup>CDC</sup> Listed as a 'resistance of concern' in CDC 2013 Threat Report ([http://www.cdc.gov/drugresistance/threat\\_report\\_2013/](http://www.cdc.gov/drugresistance/threat_report_2013/)).

<sup>UTD</sup> Recommended for treatment in UpToDate clinical diagnostic support tool (UpToDate, Basow DS (Ed), UpToDate, Waltham, MA. (Accessed on January 3, 2014)).

<sup>a</sup> The information provided in this table is for illustrative purposes only, as an example of the types of information that need to be integrated when assessing benefits and risks. The data presented is based solely on the cited references, and is not intended to suggest consensus among veterinary or human medical practitioners regarding recommended treatment options. Animal data is for drugs used in cattle, swine, and poultry in the U.S. that are also recommended for treatment of the threat organism in humans, or listed as a 'resistance of concern' by CDC. All veterinary drugs have published dosages for cattle, swine, or poultry in [11,12] or (<http://www.farad.org>, accessed December 13, 2013) (WHO List of Critically Important Antimicrobials, 3rd Revision ([http://www.who.int/foodborne\\_disease/resistance/cia/en/](http://www.who.int/foodborne_disease/resistance/cia/en/))).

be impacted by agricultural best management practices (Ag BMPs), including manure management. This includes defining both theoretical and applied mechanisms of AR transfer, clarifying the environmental conditions mediating that exchange [43] and quantifying bacteria and genes in applied manure-impacted substrates [28,37]. There is a need to develop robust, validated assays and consistent quality control standards that are specifically designed for diverse, complex, and inhibitor-laden agricultural samples [32,37].

### Connecting agriculture and clinic: manure management and the environment

In addition to its role as a reservoir and source of AR bacteria and AR genes [2,10<sup>\*\*</sup>,25,43,44,45<sup>\*</sup>], the environment is a critical conduit connecting agricultural systems to human health outcomes [3,8,33<sup>\*\*</sup>]. Manure (feces and urine) is the vehicle by which AR bacteria and AR genes first enter the environment. It is, therefore, an important point for monitoring AR levels, and a critical control point for isolating and remediating AR before it is transported

more broadly in agroecosystems [46<sup>\*\*</sup>]. A recent epidemiological study has demonstrated an association between direct exposure to fields where swine manure was applied to crops and methicillin resistant *Staphylococcus aureus* (MRSA) infection in people, though the humans did not have the MRSA clonal complex associated with swine [47<sup>\*</sup>]. Although most American consumers do not have direct contact with farm animals or their concentrated manures, this example highlights the important role that animal manure, and manure management can have on public health. More specifically, the concern is over the direct transfer of foodborne pathogens with clinically relevant resistances, and the indirect transfer (via environmental bacteria) of clinically relevant resistance encoding mobile genetic elements such as plasmids, transposons and bacteriophages.

Manure management can impact the persistence, survival and distribution of drugs, bacteria and genes in agroecosystems [26,48,49]. Manure is commonly applied to agricultural soils where it is a valuable resource for crop

fertilization and soil conditioning. The soil appears to have a great buffering capacity for antibiotic drugs and AR bacteria [23,50,51]. Studies suggest that AR bacteria and AR genes introduced to manured soils often have no effect on and/or are unable to compete with the existing soil communities [22\*,39,52]. Other research suggests that the AR in applied manure can be remediated by existing microbial populations [30] or manure management. In fact, manure treatments designed for control of nutrients and pathogens may also reduce antibiotic drugs, AR bacteria, and AR genes. For example, a woodchip bio-reactor system used to control nutrients from manure can retain 70–90% of some manure-borne antibiotics [53], and various composting systems can reduce both antibiotic drugs and AR genes [49,54,55]. Results depend on the specific bacteria or gene being measured, as well as the physical and chemical properties of the substrate (manure, compost, soil). It is clear that more field-based data are needed to clarify how manure treatment and Ag BMPs affect survival of AR bacteria and associated genes.

Feces is the focus of many monitoring programs [56], and the fecal-oral route of contamination is the fundamental mechanism for infection with foodborne pathogens. The commonly held perception that food is directly contaminated with feces spilled from the gastrointestinal tract during slaughter is an oversimplification. In cattle, for instance, the primary source of contamination on meat comes from the hide, not the lower gastrointestinal tract [57,58]. Even though the original source of the zoonotic bacteria was feces, the actual meat contamination event, where the individual bacterial cell of concern was physically deposited onto the food product, was from an indirect transfer via an environmental source.

Food has historically been considered the main vehicle for transmission of AR from food animals to consumers. It is a proven route by which zoonotic bacteria, and any AR genes they contain, can be transferred to humans. The specific route by which zoonotic pathogens are physically transferred to food products needs to be re-examined in light of the complex network of ecological relationships present for any given agricultural product (i.e. beef, dairy, swine, poultry, fish, produce) [43,59,60]. Non-pathogenic bacteria that harbor AR genes and AR genes that persist in the environment after the death of the host cell also need to be considered, as does directionality of transfer [28].

In the context of agAR the specific concern is not just the zoonotic agent itself, but the potential for the organisms to acquire resistance genes from agricultural settings that make standard treatment options ineffective. As such, it is the AR gene that should be considered the 'infectious disease entity' of concern when modeling agAR, though it is acknowledged that the carriage of AR genes does not mean that they are expressed. In many instances, the gene is spread horizontally via mobile genetic elements

(MGEs), which can be exceptionally stable once acquired, even in the absence of the target antibiotic drug [64]. Each type of MGE has its own ecology, and individual bacterial strains and species can have multiple types of MGEs that move AR genes both within and between cells. While laboratory-based and animal experiments clearly show the potential for the transfer of MGEs [3,10\*\*,65], there is little information available regarding the actual frequencies at which specific categories and types of MGE/AR gene combinations are transferred in agricultural environments [66]. Once acquired, MGEs and the AR genes they carry can be spread clonally (vertically) as well as horizontally. Individual MGE/AR gene combinations do not act in isolation, and the ways in which they interact need to be considered when looking at the potential for agAR to be transferred to humans. For example, an A/C plasmid was identified in a *Salmonella newport* clone where integration of a cephalosporin resistance gene knocked out the genes responsible for the A/C plasmid's conjugative ability [67]. However, despite this the clone (and therefore also the gene) was broadly distributed [67]. Surveillance and characterization of clinical and agricultural AR bacteria is needed in order to correlate specific resistances of concern to individual MGEs, and determine which gene/MGE/bacteria combinations may contribute the most to agAR-related human clinical disease.

There is no doubt that AR bacteria and AR genes can be transferred between animals and humans [60], but assumptions that identical gene sequences found in animals and humans originated in animals should not be made without supporting microbiological evidence [8,25]. In the words of the late Dr. Salyers, 'What this sequence information does not tell us is the direction of transfer, nor does it tell us whether a third, or fourth, or fifth party was involved. All the sequence data proves is that there is some genetic conduit open between the two organisms in which the same gene was found' [28].

What needs to be done? In order to accurately assess benefits and risks of antibiotic use in agriculture, it is imperative that studies in agroecosystems include information on baseline and natural levels of resistance. There is a critical need for research on the ecology of antibiotic resistance so that we can identify the types of resistance that are ecologically relevant to particular agricultural production systems, microbiologically relevant based on carriage of likely pathogens and clinically relevant based on the kinds of drugs used for human infections.

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## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.mib.2014.05.019>.

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Janet Collins](#)  
**Subject:** Accepted: Updates

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Cindy Smith](#); [Janet Collins](#)  
**Subject:** Re: Call  
**Date:** Thursday, August 30, 2018 6:48:29 AM

---

Thanks! Is it FedEx, UPS, or?

---

**From:** "Cindy Smith" <(b) (6)@gowanco.com>  
**Date:** Wednesday, August 29, 2018 at 8:28:16 PM  
**To:** "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>, "Janet Collins" <(b) (6)@croplifeamerica.org>  
**Subject:** RE: Call

You will have a delivery tomorrow and then let's try and schedule a call or meeting to talk live - next week to discuss –thanks very much Cindy

---

**From:** Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Sent:** Tuesday, August 28, 2018 8:25 AM  
**To:** Janet Collins <(b) (6)@croplifeamerica.org>  
**Cc:** Cindy Smith <(b) (6)@gowanco.com>  
**Subject:** Re: Call

Anytime until 4:30. Just provide a time and number. Look forward to our call!

Thanks,  
 Sheryl

Sheryl H. Kunickis, Ph.D., Director  
 U.S. Department of Agriculture - Office of Pest Management Policy  
 South Building, Room 3871; 1400 Independence Ave., SW;  
 Washington, D.C. 20250-0314  
 (202 720-5375 Desk phone - (b) (6) Cell phone  
[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Janet Collins <(b) (6)@croplifeamerica.org>  
**Sent:** Tuesday, August 28, 2018 10:55:43 AM  
**To:** Kunickis, Sheryl - OSEC  
**Cc:** Cindy Baker-Smith <(b) (6)@gowanco.com>  
**Subject:** RE: Call

Sheryl- do you have a couple of minutes to talk this afternoon?

Any time in particular?

Janet  
 (b) (6) (direct)



(b) (6) (mobile)

---

**From:** Cindy Smith <(b) (6)@gowanco.com>  
**Sent:** Tuesday, August 28, 2018 10:23 AM  
**To:** Janet Collins (b) (6)@croplifeamerica.org>  
**Subject:** Call  
**Importance:** High

Please see if you and I can talk to Sheryl together?

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**From:** [CropLife America & RISE](#)  
**To:** [Julius Fajardo](#)  
**Cc:** (b) (6) Julius Fajardo  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:51 PM

---

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If you no longer want to receive emails from Francesca Purcell please click this link: [Opt-Out](#)



**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Courtney DeMarco](#)  
**Cc:** [Stephanie Ann Binns](#); [Janet Collins](#)  
**Subject:** Re: RISE/CLA Comments on Proposed Changes to USDA NRCS's IPM Standard  
**Date:** Friday, September 21, 2018 2:58:16 PM

---

Thank you!

---

**From:** "Courtney DeMarco" <(b) (6) @croplifeamerica.org>  
**Date:** Friday, September 21, 2018 at 2:56:43 PM  
**To:** "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Cc:** "Stephanie Ann Binns" <(b) (6) @pestfacts.org>, "Janet Collins" <(b) (6) @croplifeamerica.org>  
**Subject:** RISE/CLA Comments on Proposed Changes to USDA NRCS's IPM Standard

Ms. Kunickis,

Please see attached comments from RISE and CLA regarding USDA NRCS's proposed changes to its National Handbook of Conservation Practices. We specifically provide comments on its proposed changes to its IPM standard.

Please do not hesitate to contact Stephanie Binns (b) (6) or Janet Collins (b) (6) if you have any questions.

Thank you,

Courtney DeMarco  
 Science and Regulatory Affairs  
 CropLife America  
 1156 15<sup>th</sup> Street, NW  
 Suite 400  
 Washington, DC 20005  
 (b) (6)

**From:** no-reply@regulations.gov <no-reply@regulations.gov>  
**Sent:** Friday, September 21, 2018 2:41 PM  
**To:** Janet Collins (b) (6) @croplifeamerica.org>  
**Subject:** Your Comment Submitted on Regulations.gov (ID: NRCS\_FRDOC\_0001-0255)



*Please do not reply to this message. This email is from a notification only address that cannot accept incoming email.*

**Your comment was submitted successfully!**

**Comment Tracking Number:** 1k2-95ju-gpyv

**Your comment may be viewable on Regulations.gov once the agency has reviewed it. This process is dependent on agency public submission policies/procedures and processing times. Use your tracking number to find out the status of your comment.**

**Agency:** Natural Resources Conservation Service (NRCS)

**Document Type:** Rulemaking

**Title:** Proposed Changes to National Handbook of Conservation Practices for Natural Resources Conservation Service

**Document ID:** NRCS\_FRDOC\_0001-0255

**Comment:**

Please see the attached comments from RISE and CropLife America.

**Uploaded File(s):**

- RISE\_CLA NRCS Conservation Practice Standards Comments FINAL.pdf

**This information will appear on Regulations.gov:**

First Name: Janet

Last Name: Collins

**This information will not appear on Regulations.gov:**

*All of the information will appear on Regulations.gov*

**For further information about the Regulations.gov commenting process, please visit <https://www.regulations.gov/faqs>.**

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** (b) [@croplifeamerica.org](#)  
**Cc:** [Janet Collins](#); [Mary Jo Tomalewski](#); [Courtney DeMarco](#)  
**Subject:** Re: CLA April Regulatory Conference  
**Date:** Thursday, March 29, 2018 12:31:06 PM

---

Yes. Crazy busy here. I see another message from Mary Jo and will respond on the dates she has provided.

Cheers!  
Sheryl

Sent from my iPad

On Mar 29, 2018, at 8:21 AM, Jay Vroom (b) (6) [@croplifeamerica.org](#)> wrote:

Hi Sheryl!

Could Janet and I find some  
Time To Come Over and brief you and your team about our April conference and  
get any additional suggestions for things we  
Might add —And talk about how we Could go about seeking lots of USDA  
participation?

AndWhile there we. Might check in on a few other issues?

Jay

Sent from my iPhone

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**From:** [Janet Collins](#)  
**To:** [Anandaraman, Neena - OSEC](#); [Jim Cranney](#); [Ray McAllister](#)  
**Cc:** [Courtney DeMarco](#); [Lowery, Kenneth - OSEC](#); [Washington, DC](#); [Fajardo, Julius - OCE](#); [Herndon, George-FASContact](#)  
**Bcc:** [Fajardo, Julius](#)  
**Subject:** RE: Codex TFAMR for Comments CoP2  
**Date:** Tuesday, August 7, 2018 1:37:19 PM

Understood.

Janet

(b) (6) (direct)  
 (b) (6) (mobile)

---

**From:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Sent:** Tuesday, August 7, 2018 12:46 PM  
**To:** Janet Collins <(b) (6)@croplifeamerica.org>; Jim Cranney <(b) (6)@ccqc.org>; Ray McAllister <(b) (6)@croplifeamerica.org>  
**Cc:** Courtney DeMarco <(b) (6)@croplifeamerica.org>; Lowery, Kenneth - OSEC, Washington, DC <[Ken.Lowery@osec.usda.gov](mailto:Ken.Lowery@osec.usda.gov)>; Fajardo, Julius - OCE <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>; Herndon, George-FASContact <[herndon.george@epa.gov](mailto:herndon.george@epa.gov)>  
**Subject:** RE: Codex TFAMR for Comments CoP2

Thanks Jim and Janet.

The documents are far from solid. They are still at the electronic working group stage and at Step 3 in the process which means everything is bracketed and up for debate at the next Task Force meeting in December.

This is a 3-4 year Task Force and we are just on the second meeting this December.

We will get another chance to comment as a Member State (rather than an Electronic Working Group Member) on what is drafted from what we comment on now around late September to late October.

The Electronic Working Group has to give people a draft of something to comment on and that's all you are seeing here.

Office: 202-260-8789

Cell: (b) (6)

---

**From:** Janet Collins <(b) (6)@croplifeamerica.org>  
**Sent:** Tuesday, August 7, 2018 11:30 AM  
**To:** Jim Cranney <(b) (6)@ccqc.org>; Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; (b) (6)@croplifeamerica.org  
**Cc:** Courtney DeMarco <(b) (6)@croplifeamerica.org>; Lowery, Kenneth - OSEC, Washington, DC <[Ken.Lowery@osec.usda.gov](mailto:Ken.Lowery@osec.usda.gov)>; Fajardo, Julius - OCE <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>; Herndon, George-FASContact <[herndon.george@epa.gov](mailto:herndon.george@epa.gov)>  
**Subject:** RE: Codex TFAMR for Comments CoP2

Thanks Jim- I was aware of the background but thought further push was an option; I will leave this to your direction at this point.

These documents are solid; but/and this exercise is going to take much longer to retrofit- perhaps that is ok as well.

Thanks again to all.

Janet

(b) (6) (direct)  
 (b) (6) (mobile)

---

**From:** Jim Cranney <(b) (6)@ccqc.org>  
**Sent:** Tuesday, August 7, 2018 11:21 AM  
**To:** Janet Collins <(b) (6)@croplifeamerica.org>; Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; Ray McAllister <(b) (6)@croplifeamerica.org>  
**Cc:** Courtney DeMarco <(b) (6)@croplifeamerica.org>; Lowery, Kenneth - OSEC, Washington, DC <[Ken.Lowery@osec.usda.gov](mailto:Ken.Lowery@osec.usda.gov)>; Fajardo, Julius - OCE <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>; Herndon, George-FASContact <[herndon.george@epa.gov](mailto:herndon.george@epa.gov)>  
**Subject:** RE: Codex TFAMR for Comments CoP2

Hello Janet,

The ARM Task Force is operating at the Codex Commission level, which is to say that it is the policy people acting over all of the Codex Committees. I provided two background documents that pretty much show that there is no practical possibility of pushing back on the inquiries about antimicrobials on crops or their inclusion in the Code of Practice document.

The first document is a call for information about antimicrobial use on crops from FAO and WHO at the 2017 Codex Committee meeting on pesticide residues. The London document provides information on the genesis of the task force and its objectives.

I think our best option is to continue to work with U.S. government agencies to formulate reasonable scientific positions that are consistent with our approach in the United States and to form a close working relationship with government officials, so more radical international forces won't unhinge our regulatory approach in the United States. As I mentioned in my previous comments, this would



also include a close working relationship on public communication.

Meanwhile, I think we should try to have as much influence as we can in the Codex process without calling too much attention to the horticultural sector.

Regards,  
Jim

James R. Cranney, Jr.  
California Citrus Quality Council  
853 Lincoln Way  
Auburn, CA 95603  
Office (530) 885-1894  
Mobil (b) (6)  
(b) (6) @CCQC.org

---

**From:** Janet Collins (b) (6) @croplifeamerica.org  
**Sent:** Tuesday, August 7, 2018 6:07 AM  
**To:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; Ray McAllister (b) (6) @croplifeamerica.org  
**Cc:** Courtney DeMarco (b) (6) @croplifeamerica.org; Lowery, Kenneth - OSEC, Washington, DC <Ken.Lowery@osec.usda.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Herndon.George-FASContact <herndon.george@epa.gov>; Jim Cranney (b) (6) @ccqc.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

My point is that they already are working on this, there is a less than one percent issue with crops—and while I understand they made the request, I don't believe the request was specific to crops (I will look at this again). This is a huge distraction and will take time to put together. That's why I am trying to find out how likely any pushback would have an impact.

Thanks.

Janet  
(b) (6) (direct)  
(b) (6) (mobile)

---

**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Sent:** Tuesday, August 7, 2018 8:48 AM  
**To:** Janet Collins (b) (6) @croplifeamerica.org; Ray McAllister (b) (6) @croplifeamerica.org  
**Cc:** Courtney DeMarco (b) (6) @croplifeamerica.org; Lowery, Kenneth - OSEC, Washington, DC <Ken.Lowery@osec.usda.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Herndon.George-FASContact <herndon.george@epa.gov>; Jim Cranney (b) (6) @ccqc.org  
**Subject:** Re: Codex TFAMR for Comments CoP2

Hi Janet, I'm not sure I understand the question. It's FAO and WHO that asked Codex, their food standards organization to take up the work and encouraged expansion to crops and the environment. FAO just held an expert meeting to provide scientific advice to this Codex Task Force I shared with this distribution a few weeks ago: <http://www.fao.org/antimicrobial-resistance/news-and-events/news/news-details/en/c/1144999/>

Happy to talk if you need more background.

---

**From:** "Janet Collins" (b) (6) @croplifeamerica.org  
**Date:** Tuesday, August 7, 2018 at 8:34:54 AM  
**To:** "Anandaraman, Neena - OSEC" <Neena.Anandaraman@osec.usda.gov>, (b) (6) @croplifeamerica.org (b) (6) @croplifeamerica.org  
**Cc:** "Courtney DeMarco" (b) (6) @croplifeamerica.org, "Lowery, Kenneth - OSEC, Washington, DC" <Ken.Lowery@osec.usda.gov>, "Fajardo, Julius - OCE" <Julius.Fajardo@OCE.USDA.GOV>, "Herndon.George-FASContact" <herndon.george@epa.gov>, "Jim Cranney" (b) (6) @ccqc.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

All- see this. It is an FAO/OIE/WHO program- can we get pushback from FAO on moving the CoP for crops forward?

The FAO/OIE/WHO initiatives, together with public and private organizations, shares responsibility for addressing and coordinating global activities addressing AMR at the animal-human-ecosystems interface. FAO is working closely with key partners such as the World Organisation for Animal Health (OIE), the World Food Organisation (WHO) and others in a global response to the threat of AMR.

Janet  
(b) (6) (direct)  
(b) (6) (mobile)

---

**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Sent:** Monday, August 6, 2018 8:25 AM



(b) (6) (cell)

(b) (6) @croplife.us

On Aug 4, 2018, at 7:29 PM, Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)> wrote:

Hi Janet,

I've only been able to work through your comments so far and haven't made it to Ray's or Jim's. While I understand that you all have concerns about mixing crop information into this document, unfortunately, that only seems to be the opinion of the US and we will be isolated. So completely removing references to crops is a failing option. The objectionable language you are seeing in this document is coming from the EU and others and we will not be successful in just asking it to be kept out. Everyone is pushing for it to be in so if you all could give us alternate appropriate language to put in a separate crop section, we could try to ask for a separate section applicable to crops and get the rest out, but we need help from our crop experts for that.

I'm attaching the draft Julius originally did that we edited with your comments. I'm also attaching my comments to your comments. I recognize the crop community has not been engaged on this issue as it has pushed forward in the other sectors and I'm happy to talk through any of the background on WHO Global Action Plans and National Action Plans if helpful, but I really need help from the crop experts in order to make appropriate US comments with appropriate proposed language and justification.

I need language from you all and I'm happy to talk if a conference call would be helpful. Even better, since I have my hands full in trying to address the animal side too, if you could work with Julius and the experts at EPA, I'm happy to take what you all come up with.

Office (b) (6)  
Cell: (b) (6)

---

**From:** Janet Collins [[mailto:\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]  
**Sent:** Friday, August 3, 2018 7:58 PM  
**To:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Cc:** (b) (6) @croplifeamerica.org; Courtney DeMarco (b) (6) @croplifeamerica.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

Neena- many apologies for the delay; we appreciate your permitting CLA to provide comments by today (Friday)- granted its after hours but they are complete for these documents with input from both me and Ray.

Other document review to come on time- Monday. Have a good weekend.

My best,

Janet  
(b) (6) (direct)  
(b) (6) (mobile)

---

**From:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>  
**Sent:** Monday, July 30, 2018 1:30 PM  
**To:** Lowery, Kenneth - FSIS <[Kenneth.Lowery@fsis.usda.gov](mailto:Kenneth.Lowery@fsis.usda.gov)>; Allison Phibbs (b) (6) @chickenusa.org; Anjulen ANDERSON (b) (6) @elanco.com; (b) (6) @chickenusa.org; Barbara Madden <(b) (6) @nwhort.org>; Bob Bruss (b) (6) @nufarm.com; Brian Ronholm <(b) (6) @arentfox.com>; Clint Nesbitt <(b) (6) @bio.org>; Courtney Knupp <(b) (6) @nppc.org>; Dan Botts (b) (6) @ffva.com; Daniella Taveau <(b) (6) @kslaw.com>; Danielle Larochelle <(b) (6) @nufarm.com>; Dave White <dwhite25@utk.edu>; Dick White (b) (6) @nmpf.org; Ed Ruckert (b) (6) @mwe.com; George Sundin <sundin@msu.edu>; Heidi Irrig (b) (6) @syngenta.com; (b) (6) @nmpf.org; Janet Collins (b) (6) @croplifeamerica.org; Jay Pscheidt <pscheidj@science.oregonstate.edu>; Jean Halloran (b) (6) @consumer.org; Jeff Watts (b) (6) @zoetis.com; Jim Adaskaveg <jim.adaskaveg@ucr.edu>; Jim Cranney (b) (6) @ccqc.org; Joel Newman <(b) (6) @afia.org>; (b) (6) @beef.org; Kerik Cox <kdc33@cornell.edu>; (b) (6) @dtbassociates.com; Laura MacCleery (b) (6) @cspinet.org (b) (6) @afia.org; Lisa Efferts - CSPI (b) (6) @cspinet.org; (b) (6) @turkeyfed.org; (b) (6) @nppc.org; Mallory L. Gage <(b) (6) @gmaonline.org>; Mano Basu (b) (6) @gmaonline.org; Margaret Malkoski <(b) (6) @nfi.org>; Maria Del Mar Jimenez-Gasco <jimenez-gasco@psu.edu>; Mark Trimmer (b) (6) @TrimmerConsulting.com; Michael HANSEN (b) (6) @consumer.org; Mike MCGOWAN <(b) (6) @zoetis.com>; Nick Gardner <(b) (6) @gmaonline.org>; Patricia McManus <psm@plantpath.wisc.edu>; Phyllis Marquitz <(b) (6) @effem.com>; Quan Zeng <Quan.zeng@ct.gov>; Rachel Cumberbatch <(b) (6) @ahi.org>; Randy Singer <rsinger@umn.edu>; Ray McAllister <(b) (6) @croplifeamerica.org>; Richard CARNEVALE <(b) (6) @ahi.org>; Rodney Akers (b) (6) @arysta.com; Sarah Sorscher (b) (6) @cspinet.org; Stephanie Slinski (b) (6) @citrusrdf.org; Steve Suppan <(b) (6) @iatp.org>; Steven ROACH (b) (6) @foodanimalconcerns.org; Taw Richardson <(b) (6) @agrosourcenet>; Thomas Shryock (b) (6) @arysta.com; Tim Wilson (b) (6) @arysta.com; Green, Alice - FSIS <[Alice.Green@fsis.usda.gov](mailto:Alice.Green@fsis.usda.gov)>; Andrew Chi Yuen Yeung <[Andrew.Yeung@fda.hhs.gov](mailto:Andrew.Yeung@fda.hhs.gov)>; Basu, Pat - FSIS <[Pat.Basu@fsis.usda.gov](mailto:Pat.Basu@fsis.usda.gov)>; Bennett, Patty - AMS <[Patty.Bennett@ams.usda.gov](mailto:Patty.Bennett@ams.usda.gov)>; McCluskey, Brian J - APHIS <[brian.j.mccluskey@aphis.usda.gov](mailto:brian.j.mccluskey@aphis.usda.gov)>; Canavan, Jeff - FSIS <[Jeff.Canavan@fsis.usda.gov](mailto:Jeff.Canavan@fsis.usda.gov)>; Caroline De Waal <[Caroline.DeWaal@fda.hhs.gov](mailto:Caroline.DeWaal@fda.hhs.gov)>; Jackson, Charlene <[Charlene.Jackson@ARS.USDA.GOV](mailto:Charlene.Jackson@ARS.USDA.GOV)>; Charles Pixley <[Charles.Pixley@fsis.usda.gov](mailto:Charles.Pixley@fsis.usda.gov)> <[Charles.Pixley@fsis.usda.gov](mailto:Charles.Pixley@fsis.usda.gov)>; Daniel Folmer

<Daniel.Folmer@cfsan.fda.gov>; McChesney, Daniel <daniel.mcchesney@fda.hhs.gov>; David A Dargatz <David.A.Dargatz@aphis.usda.gov>; David Edwards <David.Edwards@fda.hhs.gov>; David Ingram <David.Ingram@fda.hhs.gov>; David Miller <Miller.Davidj@epa.gov>; Dawn Sievert <dsievert@cdc.gov>; Evans, Don - FAS <Don.Evans@fas.usda.gov>; LaFond, Dorian - AMS <Dorian.LaFond@ams.usda.gov>; Felicia B. Billingslea <Felicia.Billingslea@fda.hhs.gov>; Herndon.George-FASContact <herndon.george@epa.gov>; Goldman, David - Commissioned Corps - FSIS <David.Goldman@fsis.usda.gov>; Gregory Noonan <Gregory.Noonan@fda.hhs.gov>; Heather Tate <Heather.tate@fda.hhs.gov>; Henry Kim <henry.kim@fda.hhs.gov>; Jean Whichard <zyr3@cdc.gov>; Jenny Scott <Jenny.Scott@fda.hhs.gov>; Hain, Joe - FAS <Joe.Hain@fas.usda.gov>; Clifford, John R - APHIS <John.Clifford@aphis.usda.gov>; Greifer, John K - APHIS <John.K.Greifer@aphis.usda.gov>; John Sheehan <John.Sheehan@fda.hhs.gov>; Frye, Jonathan <Jonathan.Frye@ars.usda.gov>; Julia Doherty@ustr.eop.gov; Julie Callahan <Julie\_E\_Callahan@ustr.eop.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Schwegel, Justin - FAS <Justin.Schwegel@fas.usda.gov>; Bjork, Kathe E - APHIS <Kathe.E.Bjork@aphis.usda.gov>; Granger, Larry M - APHIS <Larry.M.Granger@aphis.usda.gov>; Larry Kerr <Larry.Kerr@hhs.gov>; Lauren Robin <lauren.robin@fda.hhs.gov>; Lesley V. D'Anglada <D'Anglada.Lesley@epa.gov>; Leslie Yang <Leslie\_Yang@ustr.eop.gov>; Wanida Lewis-FASContact <LewisWF@state.gov>; Durso, Lisa <Lisa.Durso@ARS.USDA.GOV>; Lynn Filpi <Lynn.Filpi@hhs.gov>; McKinnell, Cathy - FAS <Cathy.McKinnell@fas.usda.gov>; Rosenblum, Micah - FAS <Micah.Rosenblum@fas.usda.gov>; Michael Choi <ChoiMI@state.gov>; David, Michael J - APHIS <Michael.J.David@aphis.usda.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; McCluskey, Patrick - AMS <Patrick.J.McCluskey@ams.usda.gov>; Paul S. Honigfort <Paul.Honigfort@fda.hhs.gov>; Paul South <Paul.South@fda.hhs.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; Robinson, Brandi <Brandi.Robinson@fda.hhs.gov>; Hammond, Rose <Rose.Hammond@ARS.USDA.GOV>; Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>; Stanley, Mary - FSIS <Mary.Stanley@fsis.usda.gov>; Steven Wilson <Steven.Wilson@noaa.gov>; Susan Jennings <Jennings.Susan@epa.gov>; Dutko, Terry - FSIS <Terry.Dutko@fsis.usda.gov>; Thompson, Christopher D - AMS <Christopher.D.Thompson@ams.usda.gov>; Norden, Timothy - AMS <Timothy.D.Norden@ams.usda.gov>; Vito Su <svu@state.gov>; William Jones <William.Jones@fda.hhs.gov>

**Subject:** FW: Codex TFAMR for Comments CoP2

Gentle reminder

Office: (b) (6)  
Cell: (b) (6)

**From:** Lowery, Kenneth - FSIS

**Sent:** Monday, July 16, 2018 8:09 AM

**To:** Allison Phibbs <(b) (6) @chickenusa.org>; Anjulen ANDERSON <(b) (6) @elanco.com>; (b) (6) @chickenusa.org; Barbara Madden <(b) (6) @nwhort.org>; Bob Bruss <(b) (6) @nufarm.com>; Brian Ronholm <(b) (6) @arentfox.com>; Clint Nesbitt <(b) (6) @bio.org>; Courtney Knupp <(b) (6) @nppc.org>; Dan Botts <(b) (6) @ffva.com>; Daniella Taveau <(b) (6) @kslaw.com>; Danielle Larochelle <(b) (6) @nufarm.com>; Dave White <dwhite25@utk.edu>; Dick White <(b) (6) @mwe.com>; Ed Ruckert <(b) (6) @mwe.com>; George Sundin <sundin@msu.edu>; Heidi Irrig <(b) (6) @syngenta.com>; (b) (6) @nmpf.org; Janet Collins <(b) (6) @croplifeamerica.org>; Jay Pscheidt <pscheidt@science.oregonstate.edu>; Jean Halloran <(b) (6) @consumer.org>; Jeff Watts <(b) (6) @zoetis.com>; Jim Adaskaveg <jim.adaskaveg@ucr.edu>; Jim Cranney <(b) (6) @ccac.org>; Joel Newman <(b) (6) @afia.org>; (b) (6) @beef.org; Kerik Cox <kdc33@cornell.edu>; (b) (6) @dtbassocates.com; Laura MacCleery <(b) (6) @cspinet.org>; (b) (6) @afia.org; Lisa Efferts - CSPI <(b) (6) @cspinet.org>; (b) (6) @turkeyfed.org; (b) (6) @nppc.org; Mallory L. Gage <(b) (6) @gmaonline.org>; Mano Basu <(b) (6) @gmaonline.org>; Margaret Malkoski <(b) (6) @nfi.org>; Maria Del Mar Jimenez-Gasco <jimenez-gasco@psu.edu>; Mark Trimmer <(b) (6) @TrimmerConsulting.com>; Michael HANSEN <(b) (6) @consumer.org>; Mike MCGOWAN <(b) (6) @zoetis.com>; Nick Gardner <(b) (6) @gmaonline.org>; Patricia McManus <psm@plantpath.wisc.edu>; Phyllis Marquitz <(b) (6) @effem.com>; Quan Zeng <Quan.zeng@ct.gov>; Rachel Cumberbatch <(b) (6) @ahi.org>; Randy Singer <rsinger@umn.edu>; (b) (6) @croplifeamerica.org; Richard CARNEVALE <(b) (6) @ahi.org>; Rodney Akers <(b) (6) @arysta.com>; Sarah Sorscher <(b) (6) @cspinet.org>; Stephanie Slinski <(b) (6) @citrusrdf.org>; Steve Suppan <(b) (6) @iatp.org>; Steven ROACH <(b) (6) @foodanimalconcerns.org>; Taw Richardson <(b) (6) @agrosourcenet.net>; Thomas Shryock <(b) (6) @arysta.com>; Tim Wilson <(b) (6) @arysta.com>; Green, Alice - FSIS <Alice.Green@fsis.usda.gov>; Andrew Chi Yuen Yeung <Andrew.Yeung@fda.hhs.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bennett, Patty - AMS <Patty.Bennett@ams.usda.gov>; McCluskey, Brian J - APHIS <brian.j.mccluskey@aphis.usda.gov>; Canavan, Jeff - FSIS <Jeff.Canavan@fsis.usda.gov>; Caroline De Waal <Caroline.DeWaal@fda.hhs.gov>; Jackson, Charlene <Charlene.Jackson@ARS.USDA.GOV>; Charles Pixley <Charles.Pixley@fsis.usda.gov>; Charles.Pixley@fsis.usda.gov; Daniel Folmer <Daniel.Folmer@cfsan.fda.gov>; McChesney, Daniel <daniel.mcchesney@fda.hhs.gov>; David A Dargatz <David.A.Dargatz@aphis.usda.gov>; David Edwards <David.Edwards@fda.hhs.gov>; David Ingram <David.Ingram@fda.hhs.gov>; David Miller <Miller.Davidj@epa.gov>; Dawn Sievert <dsievert@cdc.gov>; Evans, Don - FAS <Don.Evans@fas.usda.gov>; LaFond, Dorian - AMS <Dorian.LaFond@ams.usda.gov>; Felicia B. Billingslea <Felicia.Billingslea@fda.hhs.gov>; Herndon.George-FASContact <herndon.george@epa.gov>; Goldman, David - Commissioned Corps - FSIS <David.Goldman@fsis.usda.gov>; Gregory Noonan <Gregory.Noonan@fda.hhs.gov>; Heather Tate <Heather.tate@fda.hhs.gov>; Henry Kim <henry.kim@fda.hhs.gov>; Jean Whichard <zyr3@cdc.gov>; Jenny Scott <Jenny.Scott@fda.hhs.gov>; Hain, Joe - FAS <Joe.Hain@fas.usda.gov>; Clifford, John R - APHIS <John.Clifford@aphis.usda.gov>; Greifer, John K - APHIS <John.K.Greifer@aphis.usda.gov>; John Sheehan <John.Sheehan@fda.hhs.gov>; Frye, Jonathan <Jonathan.Frye@ars.usda.gov>; Julia Doherty@ustr.eop.gov; Julie Callahan <Julie\_E\_Callahan@ustr.eop.gov>; Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>; Schwegel, Justin - FAS <Justin.Schwegel@fas.usda.gov>; Bjork, Kathe E - APHIS <Kathe.E.Bjork@aphis.usda.gov>; Granger, Larry M - APHIS <Larry.M.Granger@aphis.usda.gov>; Larry Kerr <Larry.Kerr@hhs.gov>; Lauren Robin <lauren.robin@fda.hhs.gov>; Lesley V. D'Anglada <D'Anglada.Lesley@epa.gov>; Leslie Yang <Leslie\_Yang@ustr.eop.gov>; Wanida Lewis-FASContact <LewisWF@state.gov>; Durso, Lisa <Lisa.Durso@ARS.USDA.GOV>; Lynn Filpi <Lynn.Filpi@hhs.gov>; McKinnell, Cathy - FAS <Cathy.McKinnell@fas.usda.gov>; Rosenblum, Micah - FAS <Micah.Rosenblum@fas.usda.gov>; Michael Choi <ChoiMI@state.gov>; David, Michael J - APHIS <Michael.J.David@aphis.usda.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; McCluskey, Patrick - AMS <Patrick.J.McCluskey@ams.usda.gov>; Paul S. Honigfort <Paul.Honigfort@fda.hhs.gov>; Paul South <Paul.South@fda.hhs.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; Robinson, Brandi <Brandi.Robinson@fda.hhs.gov>; Hammond, Rose <Rose.Hammond@ARS.USDA.GOV>; Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>; Stanley, Mary - FSIS <Mary.Stanley@fsis.usda.gov>; Steven Wilson

<[Steven.Wilson@noaa.gov](mailto:Steven.Wilson@noaa.gov)>; Susan Jennings <[Jennings.Susan@epa.gov](mailto:Jennings.Susan@epa.gov)>; Dutko, Terry - FSIS <[Terry.Dutko@fsis.usda.gov](mailto:Terry.Dutko@fsis.usda.gov)>; Thompson, Christopher D - AMS <[Christopher.D.Thompson@ams.usda.gov](mailto:Christopher.D.Thompson@ams.usda.gov)>; Norden, Timothy - AMS <[Timothy.D.Norden@ams.usda.gov](mailto:Timothy.D.Norden@ams.usda.gov)>; Vito Su <[suv@state.gov](mailto:suv@state.gov)>; William Jones <[William.Jones@fda.hhs.gov](mailto:William.Jones@fda.hhs.gov)>  
**Cc:** Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; USA - Ron Miller <[Ron.Miller@fda.hhs.gov](mailto:Ron.Miller@fda.hhs.gov)>; 'Ruby.Singh@fda.hhs.gov' <[Ruby.Singh@fda.hhs.gov](mailto:Ruby.Singh@fda.hhs.gov)>; Kishore, Rita - FSIS <[Rita.Kishore@fsis.usda.gov](mailto:Rita.Kishore@fsis.usda.gov)>  
**Subject:** Codex TFAMR for Comments CoP2

Dear TFAMR Stakeholders,

Please see attached a new version of the revised text for the Code of Practice to Minimize and Contain Antimicrobial Resistance from the Electronic Working Group Chair and Co-chairs.

Please send comments by July 30, 2018 to [Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov) , [Ron.Miller@fda.hhs.gov](mailto:Ron.Miller@fda.hhs.gov) ; [Ruby.Singh@fda.hhs.gov](mailto:Ruby.Singh@fda.hhs.gov) ; [Kenneth.Lowery@fsis.usda.gov](mailto:Kenneth.Lowery@fsis.usda.gov) for consideration in drafting of U.S. Comments. When sending comments, please provide text for suggested revision and justification as much as possible. The Electronic Working Group Chair and Co-chairs will next review comments submitted to prepare a report including further revised text for submission to the Codex Secretariat. Our understanding is that the report will be circulated ahead of the next meeting of the TFAMR in December 2018 for further comment by Member States and Observers.

Neena Anandaraman, DVM, MPH, DACVPM  
Veterinary Science Policy Advisor  
Office of the Chief Scientist  
United States Department of Agriculture  
Office: (b) (6)  
Cell: (b) (6)

*Ken*

Kenneth Lowery  
International Issues Analyst  
U.S. Codex Office  
Office of the Under Secretary  
Trade and Foreign Agricultural Affairs  
Room 4861-S  
1400 Independence Avenue SW  
Washington DC 20250-3700  
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<Revised RCP61.EWG-COP2 July 2018\_na.docx>  
<CropBestPracticeGuidelines.docx>

**From:** [CropLife America & RISE](#)  
**To:** [Teung Chin](#)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:50 PM

---

SC18 Invite with Sponsors\_v2

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**From:** [CropLife America & RISE](#)  
**To:** [Julius Fajardo](#)  
**Cc:** (b) (6) Julius Fajardo  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Monday, March 19, 2018 6:55:09 AM

Header\_2.15.18



Dear Julius:

Your registration has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

Registration Information:		
Registration Items		
Julius Fajardo	CLA & RISE 2018 Regulatory Conference	
Sessions		
Julius Fajardo	Networking Breakfast	26-Apr-2018 7:00 AM
Julius Fajardo	General Session	26-Apr-2018 8:00 AM
Julius Fajardo	Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process	26-Apr-2018 10:30 AM
Julius Fajardo	Networking Lunch	26-Apr-2018 12:00 PM
Julius Fajardo	Series II - Trading Up: How Crop Protection Influences Agricultural Exports (and Vice Versa)	26-Apr-2018 1:15 PM
Julius Fajardo	Series III - Establishing Tolerances and MRLs: Down in the Weeds	26-Apr-2018 3:00 PM
Julius Fajardo	Series V - Other Ingredients and Their Roles in Crop Protection	27-Apr-2018 11:15 AM
Additional Information		
Julius Fajardo	When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee	

[Click here for the event agenda](#)

[Add to Calendar](#)

**Event Registration Confirmation number:** [DXNQH5CBNHV](#)

We look forward to seeing you in April!

CropLife America & RISE

[Share on Twitter](#)

[Book your group hotel for CropLife America & RISE Regulatory Conference](#) until April 6!

Footer\_2.15.18



**Content**

\*\*\*\*\*

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\*\*\*\*\*

If you no longer want to receive emails from Francesca Purcell please click the link below. [Opt-Out](#)



**From:** [Jay Vroom](#)  
**To:** [sheryl.kunickis@ars.usda.gov](mailto:sheryl.kunickis@ars.usda.gov)  
**Bcc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Time for a phone call?  
**Date:** Friday, February 23, 2018 5:59:06 PM

---

Left you a voicemail message RE chance to talk before your data meeting Monday?  
Jay

Sent from my iPhone

**From:** [Kellie Bray](#)  
**To:** [Kunickis, Sheryl - OSEC](#); [Jay Vroom](#)  
**Cc:** [Janet Collins](#); [Rachel Lattimore](#)  
**Subject:** RE: Call  
**Date:** Saturday, February 24, 2018 9:35:45 AM

---

Talk to you all soon -  
 Call in: 866-398-2885 Passcode (b) (6)

-----Original Message-----

From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
 Sent: Saturday, February 24, 2018 9:35 AM  
 To: Jay Vroom (b) (6) @croplifeamerica.org>  
 Cc: Kellie Bray (b) (6) @croplifeamerica.org>; Janet Collins (b) (6) @croplifeamerica.org>; Rachel Lattimore (b) (6) @croplifeamerica.org>  
 Subject: Re: Call

That works!

Sent from my iPhone

> On Feb 24, 2018, at 9:34 AM, Jay Vroom (b) (6) @croplifeamerica.org> wrote:

>

> That's a great plan Kellie, thanks!!

>

> Sent from my iPhone

>

>> On Feb 24, 2018, at 9:32 AM, Kellie Bray <(b) (6) @croplifeamerica.org> wrote:

>>

>> I'm available this morning - how about 10:30? I can send a call in number.

>>

>> -----Original Message-----

>> From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]

>> Sent: Saturday, February 24, 2018 9:05 AM

>> To: Jay Vroom (b) (6) @croplifeamerica.org>

>> Cc: Kellie Bray <(b) (6) @croplifeamerica.org>; Janet Collins (b) (6) @croplifeamerica.org>; Rachel Lattimore <(b) (6) @croplifeamerica.org>

>> Subject: Re: Call

>>

>> Anytime works! Just provide time and number!

>>

>> Sent from my iPhone

>>

>>> On Feb 24, 2018, at 8:52 AM, Jay Vroom (b) (6) @croplifeamerica.org> wrote:

>>>

>>> Sheryl,

>>>

>>> By copy of this to Rachel, Janet and Kellie I'm checking their availability yet today. Hoping one or all of them might be able to join you and I on the phone.

>>>

>>> ..I'm busy between 9 and 9:45am and 11:30 am to 1pm....

>>>

>>> Jay

>>>

>>> Jay Vroom

>>> President & CEO  
>>> CropLife America  
>>> Direct Dial: (b) (6)  
>>> Mobile: (b) (6)  
>>> Executive Assistant: Mary Jo Tomalewski (b) (6), (b) (6) @croplifeamerica.org

>>>  
>>>

>>> -----Original Message-----

>>> From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
>>> Sent: Friday, February 23, 2018 10:19 PM  
>>> To: Jay Vroom (b) (6) @croplifeamerica.org>  
>>> Subject: Re: Call

>>>

>>> Yes. Just let me know a time. Hope it was a lovely evening!

>>>

>>> Sent from my iPhone

>>>

>>>> On Feb 23, 2018, at 10:17 PM, Jay Vroom (b) (6) @croplifeamerica.org> wrote:

>>>>

>>>> Hi Sheryl,

>>>> Apologies— I've been in a dimmer meeting since 6 pm. Can I try to arrange a phone call with you tomorrow morning please?

>>>> Jay

>>>>

>>>> Sent from my iPhone

>>>>

>>>>> On Feb 23, 2018, at 6:25 PM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>>>>>

>>>>> Supper at 6:30. Anytime after 7 or let me know if Saturday or Sunday are better. Just home from Ag Outlook Forum.

>>>>>

>>>>> Sent from my iPhone

>>>>>

>>>>>

>>>>>

>>>>>

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**From:** [CropLife America & RISE](#)  
**To:** [Alexander Domesle](#)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Tuesday, April 10, 2018 11:46:17 AM

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Dear Alexander:

Your registrat on has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

Registration Information:		
Registration Items		
Alexander Domesle	CLA & RISE 2018 Regulatory Conference	
Sessions		
Alexander Domesle	Networking Breakfast	26-Apr-2018 7:00 AM
Alexander Domesle	General Session	26-Apr-2018 8:00 AM
Alexander Domesle	Series I - Application of Environmental Epidemiology in Risk Assessment and Decision-Making	26-Apr-2018 10:30 AM
Alexander Domesle	Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process	26-Apr-2018 10:30 AM
Alexander Domesle	Networking Lunch	26-Apr-2018 12:00 PM
Alexander Domesle	Series II - Charting a Path Forward for the Use of Population Modeling in Ecological Risk Assessment	26-Apr-2018 1:15 PM
Alexander Domesle	Series III - Novel Approaches for Assessing Inhalation Risk in Human Health Risk Assessments	26-Apr-2018 3:00 PM
Alexander Domesle	Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome	26-Apr-2018 3:00 PM
Alexander Domesle	Networking Reception	26-Apr-2018 4:45 PM
Alexander Domesle	Series IV - Tox Testing & Risk Assessment for Human Health: How Should We Approach Globalization?	27-Apr-2018 9:45 AM
Alexander Domesle	Series V - State of Toxicology Assessment in Human Health Risk Assessments	27-Apr-2018 11:15 AM
Additional Information		
Alexander Domesle	When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee	

[Click here for the event agenda](#)  
[Add to Calendar](#)  
**Event Registration Confirmation number:** [XFN8VMZ3397](#)

We look forward to seeing you in April!

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**Content**

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 \*\*\*\*\*

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---

**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Jay Vroom](#)  
**Subject:** Re: Accepted: Meeting with Sheryl Kunickis  
**Date:** Friday, April 13, 2018 7:32:34 AM

---

Jay- I can put together the overview from the Beck meeting if you want something in writing.

> On Apr 13, 2018, at 7:27 AM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>

> Excellent! See you and Janet soon!

>

> Sent from my iPhone

>

>> On Apr 13, 2018, at 7:21 AM, Jay Vroom <(b) (6)@croplifeamerica.org> wrote:

>>

>> I believe this is to be me and Janet--I will be there for sure! Thanks

>>

>> Jay Vroom

>> President & CEO

>> CropLife America

>> Direct Dial: (b) (6)

>> Mobile: (b) (6)

>> Executive Assistant: Mary Jo Tomalewski (b) (6), (b) (6)@croplifeamerica.org)

>>

>> -----Original Message-----

>> From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]

>> Sent: Friday, April 13, 2018 6:59 AM

>> To: Mary Jo Tomalewski (b) (6)@croplifeamerica.org>

>> Cc: Jay Vroom <(b) (6)@croplifeamerica.org>

>> Subject: Re: Accepted: Meeting with Sheryl Kunickis

>>

>> Hi Mary Jo,

>> I am confirming our meeting at USDA 9:30-10:30 am today. I accepted on April 2, but this does not show on my calendar. I will meet everyone shortly before 9:30 am at the 3rd wing visitor's entrance.

>> Cheers,

>> Sheryl

>>

>> Sent from my iPhone

>>

>>> On Apr 2, 2018, at 8:55 AM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>>>

>>>

>>> <meeting.ics>

>>>

>>>

>>>

>>>

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**From:** [Ray McAllister](#)  
**To:** [julius.fajardo@ars.usda.gov](mailto:julius.fajardo@ars.usda.gov); [Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)  
**Cc:** [Janet Collins](#)  
**Subject:** [CAUTION: Suspicious Link]Re: Combating Antibiotic Resistance in the U.S. - HHS has scheduled a public meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria for May 16, 2018 in Washington, DC to focus on antibiotic ste...  
**Date:** Friday, April 27, 2018 6:06:21 AM

---

**PROCEED WITH CAUTION:** This message triggered warnings of **potentially** malicious web content. Evaluate this email by considering whether you are expecting the message, along with inspection for suspicious links.

Questions: Spam.Abuse@wdc.usda.gov

Julius & Neena:

Do you folks have a role in this federal advisory committee? Is it coordinated with the US delegation to TFAMR?

Ray S. McAllister, PhD  
 Senior Director, Regulatory Policy  
 CropLife America

(b) (6) (office)  
 (b) (6) (cell)  
 (b) (6) @croplife.us

Begin forwarded message:

**From:** "Jimmy Liu" (b) (6) @fien.com>  
**Date:** April 26, 2018 at 3:22:42 PM EDT  
**To:** (b) (6) @fien.com>  
**Subject:** **Combating Antibiotic Resistance in the U.S. - HHS has scheduled a public meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria for May 16, 2018 in Washington, DC to focus on antibiotic stewardship for animal and plant ...**

**Combating Antibiotic Resistance in the U.S. - The U.S. Department of Health and Human Services (HHS) has scheduled a public meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria for May 16, 2018 in Washington, DC to "... focus on the topic of antibiotic stewardship for animal and plant health ..." - For those unable to attend in person, a live webcast will be available - The mission of the Advisory Council is to "... provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial**



**infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance ..."**

**Document Title:** The title of the April 26, 2018 HHS Federal Register Notice is "Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria"

**Organization:** The April 26, 2018 Federal Register Notice was signed on April 19, 2018 by Jomana F. Musmar who is the Acting Designated Federal Officer for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

**Source:** April 26, 2018 Department of Health and Human Services (HHS) Federal Register Notice

**Comments Due By:** May 9, 2018

**Applications Due By:** Pre-registration for attending the meeting in person is due by May 9, 2018

**Web site:** The April 26, 2018 HHS Federal Register Notice is posted at <http://www.gpo.gov/fdsys/pkg/FR-2018-04-26/html/2018-08803.htm>

\* Registration for the meeting is available at

<http://www.hhs.gov/ash/advisory-committees/paccarb/meetings/may-16-2018-registration-form-presidential-advisory-council-combating-antibiotic-resistant-bacteria-paccarb.html>

\* A Draft Agenda is posted at

<http://www.hhs.gov/sites/default/files/paccarb-public-meeting-may-16-2018-draft-v5-.pdf>

\* The webcast will be made available on the date and time of the meeting at <http://www.hhs.gov/live>

Additional information about the meeting is available at

<http://www.hhs.gov/ash/advisory-committees/paccarb/meetings/upcoming-meetings/may-16-2018-public-meeting/index.html>

Additional information about the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria is available at

<http://www.hhs.gov/ash/advisory-committees/paccarb/about-paccarb/index.html>

**Contact:** Questions may be directed to Jomana Musmar who is the Acting Designated Federal Officer for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria with the HHS Office of the Assistant Secretary for Health at 202 690 5566; e-mail: [CARB@HHS.gov](mailto:CARB@HHS.gov)

**Summary:** The following information is taken from the April 26, 2018 HHS Federal Register Notice:

**SUPPLEMENTARY INFORMATION:** Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and

evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic- Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.


#####

Go to the HHS Notice for additional information and details.

#####

This article (#43166) was distributed by e-mail on April 26, 2018 to those whose names are on the FIEN, LLC Subject Matter Distribution Lists for Agricultural Research; Dairy; Fisheries; Food Safety; Government Administrative Actions; Meat, Poultry and Eggs; Medical Issues; Risk Assessment and Communication; Veterinary Medicine

-end-

The above information was sent to you by Jimmy Liu of the Food Industry Environmental Network, LLC --- <http://www.fien.com> --- mobile: 240 476 5958 --- e-mail @fien.com

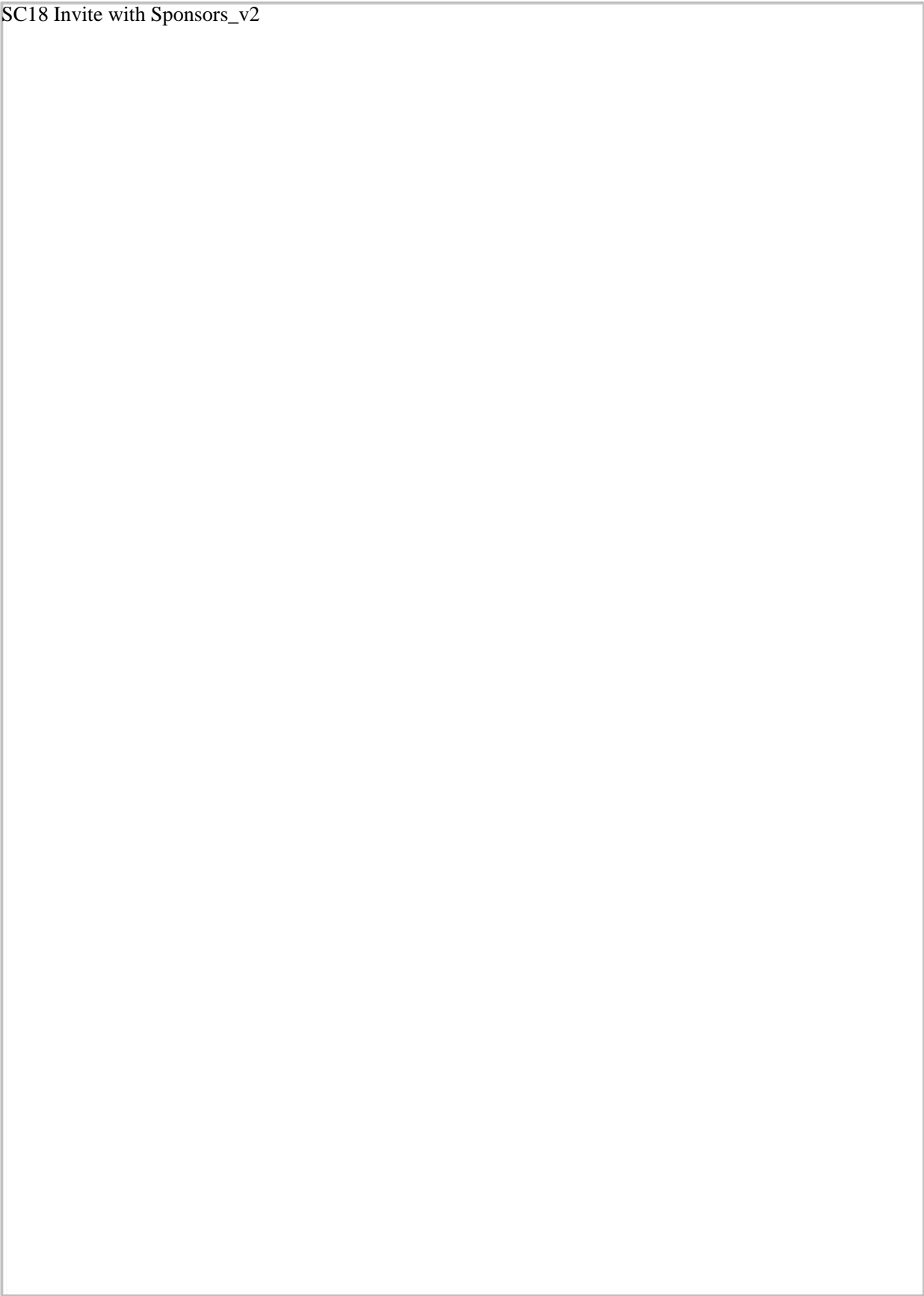
\* Messages prefaced with [SFM] are FIEN Shortened Messages which are distinguished from FIEN Traditional Messages as described at <http://www.fien.com/SFM.php>

\* The Searchable Index of Previously Distributed FIEN Messages is available at [http://www.fien.com/login/logins.php?RELOAD=/search\\_article.php](http://www.fien.com/login/logins.php?RELOAD=/search_article.php)

**From:** [CropLife America & RISE](#)  
**To:** [Sheryl Kunickis](#)  
**Subject:** You're Invited! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Friday, March 16, 2018 4:37:52 PM

---

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**From:** [Courtney DeMarco](#)  
**To:** [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Cc:** [Janet Collins](#)  
**Subject:** 2018 CLA & RISE Regulatory Conference - Speaker Invitation  
**Date:** Friday, March 16, 2018 2:16:44 PM  
**Importance:** High

---

March 16, 2018

Dear Sheryl Kunickis,

CropLife America and RISE are delighted to confirm your participation as a guest speaker at our 2018 Regulatory Conference, April 25-27, 2018. It will be held at the Renaissance Arlington Capital View Hotel, located at 2800 S Potomac Avenue, Arlington, Virginia, 22202. This year's Conference will highlight ongoing regulatory science and policy issues currently engaging our industry, including ESA and FIFRA risk assessments and risk management; inerts and mixtures; alternative methods for human health assessment; use of precision agriculture tools; and many other timely topics. We also have confirmed participation of speakers and EPA's Office of Pesticide Programs leadership across sessions that we think will provide valuable input and expertise.

We welcome your participation as a session speaker, you will address what you've learned about the consultation process to date and what they still need to develop going forward, during our session, What We've Learned, What We Need: The FIFRA/ESA Consultation Process on April 26, at 10:30 AM. The session goal is session goal, and the session will include other speakers with expertise in this area. Panel presentations will be followed by an audience Q&A session.

You are asked to forward your biography as soon as possible, and all presentation materials including PowerPoint presentations to Courtney DeMarco at [\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org), no later than April 16<sup>th</sup>. If you have any questions about the Conference, please don't hesitate to contact Courtney by email or by phone at [\(b\) \(6\)](tel:(b) (6)). We look forward to seeing you at our 2018 CLA/RISE Regulatory Conference!

Respectfully,

Janet E. Collins  
Hobbs  
Executive Vice President, Science and Regulatory Affairs

Aaron  
President

CropLife America

RISE

**From:** [CropLife America & RISE](#)  
**To:** [Clayton Myers](#)  
**Cc:** [sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)  
**Bcc:** [Clayton.Myers-ARS@MGD.USDA.GOV](mailto:Clayton.Myers-ARS@MGD.USDA.GOV)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 21, 2018 2:33:31 PM

Header\_2.15.18



Dear Clayton:

Your registration has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

Registration Information:		
Registration Items		
Clayton Myers	CLA & RISE 2018 Regulatory Conference	
Sessions		
Clayton Myers	Networking Breakfast	26-Apr-2018 7:00 AM
Clayton Myers	General Session	26-Apr-2018 8:00 AM
Clayton Myers	Series I - Application of Environmental Epidemiology in Risk Assessment and Decision-Making	26-Apr-2018 10:30 AM
Clayton Myers	Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process	26-Apr-2018 10:30 AM
Clayton Myers	Networking Lunch	26-Apr-2018 12:00 PM
Clayton Myers	Series II - Charting a Path Forward for the Use of Population Modeling in Ecological Risk Assessment	26-Apr-2018 1:15 PM
Clayton Myers	Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome	26-Apr-2018 3:00 PM
Clayton Myers	Networking Reception	26-Apr-2018 4:45 PM
Clayton Myers	Networking Breakfast	27-Apr-2018 7:00 AM
Clayton Myers	General Session	27-Apr-2018 8:00 AM
Clayton Myers	Series IV - Challenges and Recommendations for Generating and Utilizing Higher-Tier Data in Ecologic	27-Apr-2018 9:45 AM
Clayton Myers	Series IV - Pollinator Protection Priorities	27-Apr-2018 9:45 AM
Clayton Myers	Series V - Other Ingredients and Their Roles in Crop Protection	27-Apr-2018 11:15 AM
Additional Information		
Clayton Myers	When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee	

[Click here for the event agenda](#)

[Add to Calendar](#)

**Event Registration Confirmation number:** K3NEBH2ZGWL

We look forward to seeing you in April!

CropLife America & RISE

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[Content](#)

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\*\*\*\*\*

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Courtney DeMarco](#)  
**Cc:** [Echeverria, Marietta](#); [Cathy Tortorici - NOAA Federal](#); [Shultz, Gina](#); [Bernalyn McGaughey](#)  
**Subject:** Re: What We've Learned, What We Need: The FIFRA/ESA Consultation Process - session details  
**Date:** Tuesday, April 17, 2018 5:53:36 PM

---

Hi Courtney,  
I understand this session is cancelled.  
Sheryl

Sent from my iPhone

On Apr 17, 2018, at 5:42 PM, Courtney DeMarco (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)> wrote:

All,  
Just a couple of quick info sheet on your session at the 2018 CLA/RISE Regulatory Conference.

**Session title and timing:** *What We've Learned, What We Need: The FIFRA/ESA Consultation Process on Thursday, April 26th at **10:30 AM – 12:00 PM**.*

**Logistics:** Please be in the session room no later than 10:20 a.m. so we can be sure your presentation is loaded onto the computer.

**Follow up items:** If you have not done so already, please send me your CV or a paragraph to use for introductions by this Thursday. Also, please send your presentation to me by email and also bring on a flash drive.

Thanks very much and look forward to seeing you next week.

Courtney DeMarco  
Science and Regulatory Affairs  
CroLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005

(b) (6)

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delete the email immediately.

**From:** [Courtney DeMarco](#)  
**To:** [Ray McAllister](#); [Courtney DeMarco](#)  
**Bcc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Fwd: October 31st PPDC Meeting Agenda  
**Date:** Tuesday, October 23, 2018 10:51:32 AM  
**Attachments:** [PPDC Agenda - 10.31.18.Final.docx](#)

---

To: CLA Members, Allies, & Friends

FROM: Ray S. McAllister, Ph.D.  
Senior Director, Regulatory Policy  
CropLife America  
(b) (6) (office)  
(b) (6) (mobile)  
(b) [@croplife.us](#)

Attached is the agenda for the coming PPDC meeting. We will prepare the customary "annotated" version for distribution at our breakfast meeting on the 31st. We welcome your input for talking points on these agenda topics.

Begin forwarded message:

**From:** "Jewell, Shannon" <[jewell.shannon@epa.gov](mailto:jewell.shannon@epa.gov)>  
**Date:** October 19, 2018 at 4:12:26 PM CDT  
**To:** Undisclosed recipients;;  
**Subject: October 31st PPDC Meeting Agenda**

Dear PPDC Members:

Please see attached the agenda for the October 31<sup>st</sup> PPDC meeting. It will be posted online to the PPDC website as soon as the OPP Web Team is able to do so.

Hope everyone has a nice weekend,  
Shannon

**Shannon Jewell** · (b) (6) · [jewell.shannon@epa.gov](mailto:jewell.shannon@epa.gov)  
Pesticide Program Dialogue Committee, DFO  
PPDC website: <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc>  
EPA Office of Pesticide Programs, Immediate Office



## PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA

Conference Line: 1-866-299-3188; Conference Code: (b) (6)

Wednesday, October 31, 2018

**8:30-8:45**     **Welcome and Opening Remarks**

*Nancy Beck, PhD., Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention*

*Rick Keigwin, Director, Office of Pesticide Programs*

**8:45-9:00**     **Introductions by PPDC Members**

**9:00-9:30**     **1. Pesticide Registration Improvement Act (PRIA)**

*Session Chair: Steve Schaible, OPP PRIA Coordinator*

*Session Goal: To provide the PPDC with an update on EPA's progress in implementing the Pesticide Registration Improvement Act.*

9:00-9:15     EPA

9:15-9:30     PPDC Discussion

**9:30-10:30**    **2. Smart Label Project/e-CSF**

*Session Chair: Patricia Parrott, Associate Division Director, Field and External Affairs Division*

*Session Goal: To provide the PPDC with an overview the electronic pesticide label, the benefits to EPA and stakeholders, and next steps.*

9:30-10:00    EPA

10:00-10:30   PPDC Discussion

**10:30-10:45**   **Break**

**10:45-11:45**   **3. Emerging Application Technologies**

*Session Chair: Ed Messina, Acting Deputy Office Director*

*Session Goal: To inform the PPDC about how new unmanned aerial vehicle (UAV) technology is working in the field for pesticide applications and how this new technology may benefit the agricultural sector.*

10:45-11:15   Speaker Panel

11:15-11:45   PPDC Discussion

**11:45-1:15**     **Lunch**

**1:15-2:15**     **4. Benefits of Biological Products: Industry Perspective**

*Session Chairs: Keith Jones, Executive Director, Biological Products Industry Alliance & Nina Wilson, Gowan*

## PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING – p. 2

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA  
 Conference Line: 1-866-299-3188; Conference Code: (b) (6)

*Session Goal: To explain BPPD's focus on low risk products and biopesticides, how EPA encourages low risk products by having a different division and registration timelines and costs. To explain how pesticides, whether conventional or biological, are reviewed with rigor and held to the same safety standard.*

1:15-1:45 Nina Wilson & Keith Jones

1:45-2:15 PPDC Discussion

### 2:15-2:45 5. Integrated Mosquito Management Training

*Session Chair: Stan Cope*

*Session Goal: To provide awareness of on-line training and manual (in English and Spanish) focusing on Integrated Mosquito Management created by AMCA with funding by the Centers for Disease Control and Prevention.*

2:15-2:30 Stan Cope

2:30-2:45 PPDC Discussion

### 2:45-3:00 Break

### 3:00-3:45 6. Public Health Workgroup

*Session Chair: Wynne Miller, Acting Deputy Office Director*

*Session Goal: To report on the progress of the group's Emergency Preparedness Plan and solicit feedback.*

3:00-3:20 PHWG

3:20-3:45 PPDC Discussion

### 3:45-4:45 7. 21st Century Toxicology: OPP's Efforts on Non-Animal Alternative Testing for the Acute 6-Pack

*Session Chair: Anna Lowit, Senior Science Advisor, OPP*

*Session Goal: To update the PPDC on OPP's recent progress toward the reduction of animal use in testing, and the implementation of alternative methods.*

3:45-4:15 EPA

4:15-4:45 PPDC Discussion

### 4:45-5:00 Public Comment

### 5:00 Meeting Adjourns

**From:** [Mary Jo Tomalewski](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Jay Vroom](#); [Janet Collins](#); [Courtney DeMarco](#)  
**Subject:** Re: Accepted: Meeting with Sheryl Kunickis  
**Date:** Friday, April 13, 2018 8:00:36 AM

---

Confirmed! Thanks, Sheryl.

Sent from my iPhone~Please excuse any typos!

> On Apr 13, 2018, at 6:59 AM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>

> Hi Mary Jo,

> I am confirming our meeting at USDA 9:30-10:30 am today. I accepted on April 2, but this does not show on my calendar. I will meet everyone shortly before 9:30 am at the 3rd wing visitor's entrance.

> Cheers,

> Sheryl

>

> Sent from my iPhone

>

>> On Apr 2, 2018, at 8:55 AM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>>

>>

>> <meeting.ics>

>

>

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>

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**From:** [Sci Reg](#)  
**To:** [Scott Teed; Myers, Clayton - OCE](#)  
**Cc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: CropLife America & RISE Speaker Invitation - Please RSVP  
**Date:** Wednesday, February 13, 2019 3:20:17 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)

---

Clayton,

Thank you for your consideration and response.

Best,

Ashley Boles  
Temp  
Science and Regulatory Affairs  
CropLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005  
(b) (6)  
[Sciereg@croplifeamerica.org](mailto:Sciereg@croplifeamerica.org)

---

**From:** Scott Teed (b) (6) @intrinsic.com>  
**Sent:** Wednesday, February 13, 2019 11:06 AM  
**To:** Myers, Clayton - OCE <Clayton.Myers@OCE.USDA.GOV>; Sci Reg <SciReg@CropLifeAmerica.org>  
**Cc:** Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>  
**Subject:** RE: CropLife America & RISE Speaker Invitation - Please RSVP

Clayton,

Thank you for considering the presentation. I look forward to seeing you and Sheryl at CLA/RISE.

Cheers,

Scott

---

**From:** Myers, Clayton - OCE [<mailto:Clayton.Myers@OCE.USDA.GOV>]  
**Sent:** February-13-19 11:01 AM  
**To:** Sci Reg <[SciReg@CropLifeAmerica.org](mailto:SciReg@CropLifeAmerica.org)>  
**Cc:** Scott Teed (b) (6) @intrinsic.com>; Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>



**Subject:** RE: CropLife America & RISE Speaker Invitation - Please RSVP

Stephanie,

Thank you for the invite but I will need to decline.

USDA-OPMP will be attending the conference and will certainly be in the audience for this session. I hope that you can find some participants from EPA-OPP that are more directly a part of the usage data discussions.

Regards,  
Clayton

---

**From:** Sci Reg <[SciReg@CropLifeAmerica.org](mailto:SciReg@CropLifeAmerica.org)>  
**Sent:** Friday, February 8, 2019 11:48 AM  
**To:** Myers, Clayton - OCE <[Clayton.Myers@OCE.USDA.GOV](mailto:Clayton.Myers@OCE.USDA.GOV)>  
**Subject:** CropLife America & RISE Speaker Invitation - Please RSVP



Mr. Clayton Myers  
Ecologist  
Office of Pest Management Policy  
U.S. Department of Agriculture  
1400 Independence Avenue, SW  
Washington, DC 20250-0314

February 8, 2019

Dear Mr. Myers:

CropLife America and RISE are delighted to invite you to participate as a guest speaker during our 2019 Regulatory Conference taking place April 3-5. It will be held at the Renaissance Arlington Capital View Hotel, located at 2800 S Potomac Avenue, Arlington, Virginia. This year's Regulatory Conference will highlight a range of regulatory science and policy issues important to our members and will feature speakers from government, our industry, and others who work with and regulate pesticide products.

We welcome your participation as a speaker to discuss sources and availability of use/usage data and their relevance to agricultural practices in the United States for 15 minutes during our breakout session, "Expert Panel: Application of Use and Usage Data in an Endangered Species Risk Assessment," on April 4, 2019 at 1:15 pm. The session will include other speakers with expertise in

this area, and an audience Q&A session will follow panel presentations.

We kindly ask you to confirm your availability and interest in speaking during the conference at your earliest convenience. Once confirmed, we would also appreciate your professional biography for use in our conference program and for speaker introductions. If you plan to use a PowerPoint or other materials during your presentation, please send them to Ashley Boles at [scireg@croplifeamerica.org](mailto:scireg@croplifeamerica.org) no later than March 25 or bring them on flash drive before the start of the session.

We also encourage you to register for the conference via our conference website once you have confirmed you will speak; we will be sure to provide you with the link when our website is live. Please indicate your status as a "Federal Government Employee" when registering to ensure you receive your complimentary registration.

If you have any questions about the conference, please do not hesitate to contact Ashley by email or by phone at (b) (6) We look forward to seeing you at the conference!

Best regards,

A handwritten signature in black ink that reads "Stephanie Binns". The signature is written in a cursive style with a large initial 'S'.

Stephanie Binns  
Director of Regulatory Affairs, RISE  
2019 CLA/RISE Regulatory Conference Program Manager

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**From:** [Kellie Bray](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: Call received  
**Date:** Wednesday, March 14, 2018 11:09:44 AM

---

Thanks Sheryl, I hope you are having a good (and safe) trip!

We can connect on Monday when you return - thanks!  
Kellie

-----Original Message-----

From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
Sent: Wednesday, March 14, 2018 11:03 AM  
To: Kellie Bray <(b) @croplifeamerica.org>  
Subject: Call received

Hi Kelly,  
I am (b) (6) back Monday. How can I help?  
Sheryl

Sent from my iPhone

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**From:** [Kunickis, Sheryl - OSEC](#)  
**To:** [Kellie Bray](#)  
**Subject:** Re: Call received  
**Date:** Wednesday, March 21, 2018 9:18:00 AM

---

Ok. Lucky you to be at the AgriPulse event - great speakers!

Sent from my iPad

On Mar 21, 2018, at 9:17 AM, Kellie Bray <(b) (6)@croplifeamerica.org> wrote:

Hi Sheryl! I'm at the Agri-Pulse event this morning and then a conference call until 2 pm. Feel free to call me any time after that today on my cell phone – (b) (6).

Thanks,  
 Kellie

---

**From:** Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
**Sent:** Wednesday, March 21, 2018 8:53 AM  
**To:** Kellie Bray <(b) (6)@croplifeamerica.org>  
**Subject:** Re: Call received

Hi Kellie,  
 Still catching up! I hoped to see you at CLA yesterday, but.. Could we follow up today after 10:30 am? I have a call until that time. USDA staff are teleworking. Hope you are well!  
 Sheryl

Sent from my iPad

On Mar 14, 2018, at 11:09 AM, Kellie Bray <(b) (6)@croplifeamerica.org> wrote:

Thanks Sheryl, I hope you are having a good (and safe) trip!

We can connect on Monday when you return - thanks!  
 Kellie

-----Original Message-----

**From:** Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]  
**Sent:** Wednesday, March 14, 2018 11:03 AM  
**To:** Kellie Bray <(b) (6)@croplifeamerica.org>  
**Subject:** Call received

Hi Kelly,  
 I am (b) (6) back Monday. How can I help?  
 Sheryl

Sent from my iPhone

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**From:** [Ray McAllister](#)  
**To:** [Jim Cranney](#); [Dan Botts](#) (b) (6) @ffva.com); [Michael Aerts](#); [Phil Korson - Cherry Marketing Institute](#) (b) (6) @aol.com); [Mark Seetin](#); [Barbara Madden](#) (b) (6) @nwhort.org); [Bob McClain](#) (b) (6) @calpear.com)  
**Cc:** [Jim Adaskaveg](#) (jim.adaskaveg@ucr.edu); [George Sundin](#); [Fajardo, Julius](#); [Ed Ruckert](#) (b) (6) @mwe.com)  
**Subject:** RE: Follow-up  
**Date:** Monday, March 19, 2018 5:20:09 PM  
**Attachments:** [bmeps \(bactericides\\_jrc edits\) rsm.docx](#)

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I have added some edits and comments to Jim's file. I will also defer to the real experts.

My crop protection industry contacts have emphasized the need to keep the bactericide and fungicide issues separate in discussion of antimicrobial resistance. Regarding the potential for agricultural fungicide use to influence susceptibility of human fungal pathogens, there is a significant research program in progress at this time.

Ray S. McAllister, PhD  
 Senior Director Regulatory Policy  
 CroLife America  
 O: (b) (6) C: (b) (6)  
 (b) (6) @croplife.us

---

**From:** Jim Cranney (b) (6) @ccqc.org>  
**Sent:** Wednesday, March 14, 2018 8:50 PM  
**To:** Dan Botts (b) (6) @ffva.com) <(b) (6) @ffva.com>; Michael Aerts <(b) (6) @ffva.com>; Phil Korson - Cherry Marketing Institute (b) (6) (b) (6) >; Mark Seetin <(b) (6) @usapple.org>; Barbara Madden (b) (6) @nwhort.org) (b) (6) @nwhort.org>; Bob McClain (b) (6) @calpear.com) (b) (6) @calpear.com>  
**Cc:** Jim Adaskaveg (jim.adaskaveg@ucr.edu) <jim.adaskaveg@ucr.edu>; George Sundin <sundin@msu.edu>; Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>; Ray McAllister (b) (6) @croplifeamerica.org>; Ed Ruckert (b) (6) @mwe.com) (b) (6) @mwe.com>  
**Subject:** RE: Follow-up

Here are my comments on the document. I would defer to Adaskaveg and Sundin.

Regards,  
Jim

James R. Cranney, Jr.  
 California Citrus Quality Council  
 853 Lincoln Way  
 Auburn, CA 95603  
 Tel: (530) 885-1894  
 Mobile: (b) (6)  
 (b) (6) @CCQC.org

---

**From:** Jim Cranney  
**Sent:** Tuesday, March 13, 2018 1:54 PM

**To:** Dan Botts (b) (6) [REDACTED]@ffva.com (b) (6) [REDACTED]@ffva.com>; 'Michael Aerts' (b) (6) [REDACTED]@ffva.com>; Phil Korson - Cherry Marketing Institute (b) (6) [REDACTED]@aol.com>; 'Mark Seetin' (b) (6) [REDACTED]@usapple.org>; Barbara Madden (b) (6) [REDACTED]@nwhort.org (b) (6) [REDACTED]@nwhort.org>; Bob McClain (b) (6) [REDACTED]@calpear.com (b) (6) [REDACTED]@calpear.com>

**Cc:** Jim Adaskaveg (jim.adaskaveg@ucr.edu) <jim.adaskaveg@ucr.edu>; George Sundin <sundin@msu.edu>; Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>; Ray McAllister (b) (6) [REDACTED]@croplifeamerica.org <(b) (6) [REDACTED]@croplifeamerica.org>; Ed Ruckert (b) (6) [REDACTED]@mwe.com (b) (6) [REDACTED]@mwe.com>

**Subject:** FW: Follow-up

Hello Everyone,

You are probably aware that there is a Codex task force that is developing best management practices for the use of antibiotics in agricultural production. The primary focus is to prevent human resistance to antibiotics. Many members of the task force seem to be setting aside science as the primary driver in making policy decisions, so there have been proposals to limit or suspend the use of antibiotics in agricultural production.

The U.S. delegation to the task force feels that the best approach is to submit draft best management practices (BMP) that reflect current practices for horticultural uses. USDA's Julius Fajardo has developed a draft BMP document that captures label language and common practices for use of antibiotics in the United States. If this document is accepted by the task force it wouldn't require any changes to our current practices. The delegation plans to submit this document to preclude other proposals that would limit or suspend the use of antibiotics in horticulture.

Please review the document, and send your edits to Julius who is copied on this message.

Please let me know if you have any questions or need additional information.

Regards,  
Jim

James R. Cranney, Jr.  
California Citrus Quality Council  
853 Lincoln Way  
Auburn, CA 95603  
Tel: (530) 885-1894  
Mobile: (b) (6) [REDACTED]  
(b) (6) [REDACTED]@CCQC.org

---

**From:** Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>

**Sent:** Tuesday, March 13, 2018 12:04 PM

**To:** (b) (6) [REDACTED]@croplifeamerica.org; Jim Cranney <(b) (6) [REDACTED]@ccqc.org>

**Subject:** Follow-up

Just to follow-up on your comments about the attached document. Neena will be needing the revised language by early next week. Thanks and best regards.

Julius

\*\*\*\*\*

**Julius E. Fajardo, Ph.D.** | *Plant Pathologist* | *USDA-Office of Pest Management Policy* | 1400 Independence Ave SW, Rm 3861-South Bldg (MS 0314) | Washington, DC 20250 | Tel. 202-720-3186 | Fax 202-720-3191 | Cell (b) (6) | [julius.fajardo@ars.usda.gov](mailto:julius.fajardo@ars.usda.gov) | <http://www.ars.usda.gov/opmp>

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**Practices that Minimizes the Development of Antibiotic Resistance in Agricultural Crops**

- Technical experts from universities, government agencies, agriculture extension workers, distributors, and farmers can develop region-specific resistance management guidelines to inform labeling and use of specific antimicrobial agents.
- Only authorized antimicrobial agents labeled for specific use should be used. For example, key practices to implement could include:
  - Specifying a Grouping or Code on the label for the mode of action of the active ingredient, based on the region or country's technical committee recommendations
  - To reduce the likelihood that bacteria develop resistance, alternation of bactericides with a different modes of action
  - No more than two consecutive applications of the same antibiotic code or group
  - Implement resistance management strategies using involving the implementation of integrated pest management, consider use of crop varieties resistant to the pathogen of concern, use of disease forecasting models to determine application timing, and sanitation
  - Consultation with a local extension specialist or certified crop consultant, State agricultural advisor, or manufacturer when necessary.
- Label restrictions and precautions to minimize AMR could include:
  - Not applying Do not apply antimicrobial agents in orchards where the soil has been fertilized with animal waste or manure.
  - Prohibiting animal grazing in treated areas and public notification through posting restriction signs along the perimeter of the treatment area.
  - Restricting the conditions of use such as the number of times an antimicrobial agent can be used through label requirements that are determined by research.
  - Limit consumer exposure by requiring a pre-harvest interval (PHI) which specifies the timing of the last antibiotic application relative to the harvest of the treated crops, based on residue trials.

Antibiotic	Crop	PHI
Streptomycin	Apples	50 days
	Pears	30 days
Kasugamycin	Apples / Pears	90 days
Oxytetracycline	Apples / Pears	60 days
	Peaches / Nectarines	21 days

- Limit consumer exposure to AMR by the establishment of permissible antibiotic residues and legal tolerances or maximum residue levels (MRL) for bactericides on raw agricultural commodities and processed products.

**Commented [JRC1]:** What does this mean?

**Commented [RM2R1]:** I believe it refers to a mode of action group, active ingredients should be alternated (rotated) from different groups to delay development of resistance to any one chemistry group. Such groups should be developed on an international/worldwide basis, rather than regional or national basis. It is significant for herbicides, fungicides, and insecticides. With the very limited number of bactericides used in agriculture, I don't know how relevant it is.

**Commented [RM3]:** I don't understand the relevance of such a restriction – but I'm not an expert.

**Commented [JRC4]:** I don't think it's necessary to include this table. Let each country determine PHIs based on their own research.

**Commented [RM5]:** This is not a label statement, and should be omitted. Compliance with label instructions assures that residues will be within MRLs already established.

- Research regarding alternatives to antibiotics that reduce the selection of antibiotic-resistant strains as well as the decrease the need for the number of treatments should be encouraged. Examples of alternatives that are currently being tested for efficacy under laboratory and field conditions include:
  - biological control (e.g. *Pseudomonas fluorescens* strain A506)
  - antimicrobial peptides
  - induced systemic resistance (e.g. acibenzolar-s-methyl)
  - durable host plant resistance
  - targeting bacterial biofilms (e.g. 2-aminoimidazole)
  - effector proteins
  - targeting quorum sensing
  - nanoparticles
  - innovations in delivery systems (e.g. endotherapy and thermotherapy)
  
- Access to University-based agriculture extension specialists and disease forecasting models can help optimize the timing of applications to target disease control and minimize the number of applications. Examples include:
  - Cougarblight, Maryblyt, ~~and Billing's system~~ ~~are few examples of disease predictive models for fire blight in pome fruit that~~ evaluate weather factors to predict if conditions are favorable for the disease and if antibiotics should be sprayed (<http://ipm.ucanr.edu/DISEASE/DATABASE/fireblight.html>). ~~These models can then be used to communicate with growers about the best time to make effective applications.~~
  - Maryblyt predicts specific infection events and symptom development for the different phases of fire blight epidemics in apples and pears. Maryblyt is used by growers and in research, extension and teaching programs in 32 U.S. states and in at least 36 countries.

**Commented [JRC6]:** I don't know that this should be included in a BMP document. It's understood that everyone would or should look for alternative to bactericides. These chemicals are more of a last resort, so research should be conducted to find alternatives, but this is not the place to mention it.

Specific examples of how regional guidelines and models can be used include:

- ~~The~~ Cooperative Extension ~~Leaders at~~ Cornell University developed guidelines for apple production regions in New York where streptomycin resistance has never been detected. In addition, the guidelines cover ~~antibiotic~~ ~~bactericide~~ management for high risk regions where streptomycin resistance has been detected and confirmed. Below is an excerpt of the guidelines:
  - ~~If~~ streptomycin resistance has been confirmed:
    - a. When the first blossom infection is forecast, apply kasugamycin at 64 fl oz. /acre in 100 gallons of water. Do not spray alternate row middles. Do not apply after petal fall. Consider including the penetrating surfactant Regulaid (1 pt/100 gal of spray solution) to enhance the effectiveness of kasugamycin.

- b. At the 2nd high risk period, apply a tank mix of streptomycin at 24 oz./acre in combination with either oxytetracycline at 32 oz./acre, or a bloom time rate of a registered copper product.
    - At the 3rd or 4th high risk periods, repeat steps 'a' and 'b', respectively.
  - If streptomycin resistance has not been confirmed, but is present in the region:
    - a. When the first blossom infection is forecast, apply a tank mix of streptomycin at 24 oz./acre in combination with either oxytetracycline at 32 oz./acre, or a bloom time rate of a registered copper product.
    - b. At the 2nd high risk period, apply kasugamycin at 64 fl oz./acre in 100 gallons. Consider including the penetrating surfactant Regulaid (1 pt/100 gal of spray solution) to enhance the effectiveness of kasugamycin.
    - At the 3rd or 4th high risk period, repeat steps 'a' or 'b' depending on concerns about the effectiveness of streptomycin.
  - Prohexadione-Calcium (Apogee) sprays should be applied at 6-12 oz/100 gal (3-6 oz/100 gal for tree <5 years) at 1-3 inches shoot growth. A second treatment should be made 14-21 days later. Apogee will not be effective if applied after you see fire blight symptoms.

**Commented [JRC7]:** In my opinion, this section should be deleted. This is a generic document meant to be used to develop global policy. This language doesn't belong in the document.

#### Surveillance and Monitoring of Antibiotic Resistance in Agricultural Crops

- ~~Competent~~Regulatory authorities and stakeholders should ~~determine~~identify research gaps and ~~determine whether there is a need~~to monitor ~~ing~~ for antibiotic resistance in plants
- Region-specific monitoring of AMR from specific antimicrobial agent use in the region should be conducted to address data gaps. For example, isolation and identification of total bacterial populations isolated from flower, leaf and soil samples from apple orchards applied with antimicrobial agents can be monitored.
- Multi-year, region-specific monitoring of AMR can help assess the extent and distribution of AMR to help determine effectiveness of the antimicrobial agent in the region.
- Genetic analysis of isolates to understand the origins and diversity of AMR in bacteria can be explored for utility in bacterial disease management, bacterial strain tracking and limiting the AMR spread in a region.

**Commented [JRC8]:** Plant host resistance is an efficacy issue. What is the relevance to human resistance.

**Commented [JRC9]:** What does this have to do with human resistance?

**Commented [JRC10]:** Will growers not know if bactericide applications are working or not? Do we want national or regional authorities telling growers when and when not to use a product? Regulators will be glad to participate here. We don't want them to. Ineffective products won't be used. Attentive researchers will know it.

**Commented [JRC11]:** Not sure about this. What's the human resistance impact?

**From:** [CropLife America](#)  
**To:** [Sheryl Kunickis](#)  
**Subject:** Invitation to the CropLife America 2018 Holiday Open House  
**Date:** Friday, November 16, 2018 4:20:29 PM

[View in browser](#)

CLA-HOH-Invite-2



Dear Sheryl,

You are invited to join us to celebrate the season! We hope to see you on Tuesday, December 11, 2018.

Please respond by clicking [Yes](#) or [No](#). We look forward to your response!

Sincerely,  
CropLife America  
(b) (6) @croplifeamerica.org

[Unsubscribe](#) | [Opt Out](#)

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**From:** [Ray McAllister](#)  
**To:** [LaPointe, Loren - FAS](#); [Schneller, Keith D. EOP/USTR](#); [Sheryl Kunickis](#); [courtney.knupp@fas.usda.gov](mailto:courtney.knupp@fas.usda.gov)  
**Cc:** [Janet Collins](#)  
**Subject:** FW: Importance of the GLP Audit and Inspection Program  
**Date:** Wednesday, November 21, 2018 12:15:52 PM  
**Attachments:** [RE China LOI.msg.msg](#)  
[Importance of the GLP Audit and Inspection Program...continued.msg.msg](#)

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Loren, Keith, Courtney, Sheryl:

At Loren's request, I am forwarding this letter, sent to Susan Bodine in July by CLA and NAICC, regarding a number of GLP issues. Ms. Bodine is the Assistant Administrator for the Office of Enforcement and Compliance Assurance (OECA), where the GLP Audit and Inspection program is now housed in EPA. Separately IR-4 sent an unsolicited letter to Susan Bodine (attached here) in support of our letter.

I thought we had mentioned the China situation specifically to Ms. Bodine, but the letter predates renewal of the US-China general Agreement on Cooperation in Science and Technology (in September), which opens the way for renewing the EPA-ICAMA Letter of Intent (LOI) on GLP. Most of the details are included in my November 2 email to Keith and Loren (also attached here). Let me know what else I can provide.

I also reached out recently to Jennifer Clever of FAS, who served recently as an ag attaché in Beijing and has worked directly on the GLP issues there. She is now in Spain, but may still have valuable perspective on the issues.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CroLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) (6)@croplife.us

---

**From:** Ray McAllister  
**Sent:** Thursday, July 19, 2018 9:49 AM  
**To:** 'Bodine.susan@Epa.gov' <Bodine.susan@Epa.gov>  
**Cc:** 'Starfield.lawrence@Epa.gov' <Starfield.lawrence@Epa.gov>; 'Morris.jeff@Epa.gov' <Morris.jeff@Epa.gov>; 'Wise.louise@Epa.gov' <Wise.louise@Epa.gov>; 'Beck.nancy@Epa.gov' <Beck.nancy@Epa.gov>; 'keigwin.richard@epa.gov' <keigwin.richard@epa.gov>; 'Messina.edward@Epa.gov' <Messina.edward@Epa.gov>; 'letendre.daisy@epa.gov' <letendre.daisy@epa.gov>; 'Sharpe, Kristinn' <Sharpe.Kristinn@epa.gov>; Janet Collins (b) (6) @croplifeamerica.org>; Jay Vroom (b) (6) @croplifeamerica.org>; Allison Jones (b) (6) @naicc.org (b) (6) @naicc.org>  
**Subject:** Importance of the GLP Audit and Inspection Program

Ms. Bodine:

On behalf of Crop Life America (CLA) and the National Association of Independent Crop Consultants (NAICC), we want to follow up the CLA visit with you on May 10 with more detail on the importance of the Good Laboratory Practice (GLP) Audit and Inspection program to the crop protection industry. We would welcome the opportunity to continue this conversation. I am taking the liberty of copying other EPA leaders with a stake in this program.

- We are concerned about a loss of vision within the management at the Environmental Protection Agency (EPA) regarding what the GLP program should do and be and accomplish.
- The GLP inspection and audit program is being starved of resources and personnel. In 1994, when the program was under the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), there were 19 inspectors, 6 support staff, and a contractor supporting the GLP program. Currently in the Office of Enforcement and Compliance Assurance (OECA) there are 4 inspectors and no support staff.
- A reasonable frequency of audit and inspection of the individual labs and facilities is necessary to assure EPA of the quality and integrity of the data supporting pesticide product registrations, as required by law, regulation, and international agreement.
- There are some 1400 laboratories, facilities, and field sites in the US participating in GLP research on pesticides. With current staffing of the audit and inspection program, keeping up with that number of facilities seems like an impossible task.
- By comparison, the burden of other GLP audit and inspection programs is more balanced, for example: US-FDA (300 labs, 75 inspectors); Canada (40 labs, 23 inspectors); UK (100 labs, 8 inspectors); Germany (160 labs, 53 inspectors). Many of these inspectors in other programs are part time.
- If inspections are not conducted with sufficient frequency, registrants may feel obligated to take their research to foreign contract research organizations (CROs), leading to loss of business for US laboratories.
- The US is obligated as a member of the Organization for Economic Cooperation and Development (OECD) to comply with requirements of formal OECD Decisions regarding GLP and audits and inspections. This has a direct bearing on the ability of US industry to operate internationally. Among other things, these requirements cover:
  - The nature and frequency of audits and inspections;
  - Providing statements of such audits and inspections to foreign governments in a timely manner.
- Historically, US has had a preeminent role in the development and management of the GLP and Mutual Acceptance of Data (MAD) programs under OECD. In recent years, EPA participation in the OECD GLP Committee and other international forums has been curtailed, resulting in loss of leadership, where the US should be in the forefront. The US should maintain active engagement in moulding and shaping the future direction of MAD.
- Because the EPA does not issue compliance certificates to GLP facilities, the inspection closure letters from EPA are vital in the registration submission process to many other countries, to assure studies have been conducted in a GLP-compliant facility. Lack of the closure letter creates a significant barrier to acceptance of US studies by other countries.
- Registrants experience delays in registrations when they have to obtain a closure letter from the laboratory to send to the monitoring authority in the foreign government. The current practice is to obtain the closure letter in advance to include with the study report in the

- registration application, and not wait for the monitoring authority to make a request.
- New CROs have a hard time breaking into the business, because of lack of inspections and lack of the ability to be inspected.
  - The industry – both registrants and CROs – have a great deal of confidence in and respect for Francis Liem who has led the audit and inspection effort for many years. The Agency must maintain this level of experience and expertise.
  - Interaction of audit and inspection staff with industry has been curtailed. We depend on frequent interaction with them in meetings and conferences to keep up to date on the latest developments in GLP.
  - The prospect of additional funding authorized by the Pesticide Registration Improvement Act (PRIA) to bolster the GLP program is heartening. It is the clear intent of PRIA legislation that this additional funding supplement, and not replace, current funding from appropriations. It is essential that the new funds set aside for this purpose be spent exclusively on the GLP program.
  - In 2016 there was serious consideration of moving the audit and inspection program to the Office of Chemical Safety and Pollution Prevention (OCSPP). We felt then and still feel now that this would be a very positive step for the program.
    - The GLP program began in OPPTS (now known as OCSPP), and was located there until the mid 1990s.
    - The principle purpose of EPA's GLP program is to support the registration decisions made by the Office of Pesticide Programs (OPP) within OCSPP.
    - With such an organizational change, the GLP program could be more responsive to the audit and inspection needs of OPP for specific studies and facilities.
    - Administration of funds from product maintenance fees under PRIA for the GLP program would be simpler and more straightforward in OCSPP, which administers all other PRIA funds.
    - The GLP program does not audit or inspect research performed by OPP, so the organizational connection would not represent a conflict of interest.
    - OCSPP can maintain the appropriate organizational structure to assure independence of the GLP program.
  - A robust GLP program in full compliance with the OECD MAD requirements demonstrates to all stakeholders the integrity of industry-supported and generated data that underpin pesticide registrations in the US and around the world. The EPA has a significant responsibility to vigorously defend its Pesticide Programs, and the GLP program should contribute in that regard.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CroLife America

(b) (6) (office)

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(b) [@croplife.us](mailto:ray@croplife.us)

Allison Jones



Executive Vice President  
National Alliance of Independent Crop Consultants (NAICC)

(b) (6)

(b) (6) [@NAICC.org](mailto: [REDACTED]@NAICC.org)

[www.NAICC.org](http://www.NAICC.org)

CC:

Larry Starfield, Principal Deputy Assistant Administrator, OECA  
Jeff Morris, Director, OPPT; chief US Head of Delegation to OECD on Chemicals  
Nancy Beck, Acting Assistant Administrator, OSCPP  
Louise Wise, Deputy Assistant Administrator, OSCPP  
Rick Keigwin, Director, OPP  
Ed Messina, Acting Deputy Director, OPP  
Daisy Letendre, Smart Sectors Program  
Kristinn Sharp, Smart Sectors Program

**From:** [Ray McAllister](#)  
**To:** [Schneller, Keith D. EOP/USTR](#); [LaPointe, Loren - FAS](#)  
**Cc:** [Janet Collins](#)  
**Subject:** RE: China LOI

---

Keith:

I talked to Loren LaPointe this afternoon (copied here) and understand you will meet with her on Monday. If there is any way I can help by coming over in person, please let me know, and I'll see if I can break free.

A few basics that you may already be familiar with:

- US EPA (and other pesticide regulatory authorities around the world) require that studies submitted by industry in support of pesticide product registrations be conducted according to Good Laboratory Practice Standards (GLP), in order to ensure quality and integrity of the data.
- OECD carries on an active GLP program to establish international standards, including a program for Mutual Acceptance of Data (MAD) among OECD member countries.
- Non-OECD countries (Including, China, Brazil, Argentina, etc.) can qualify for the GLP MAD program as provisional or full adherents, through a qualification process.
- China is now implementing a new pesticide regulation that requires that all studies supporting Chinese registrations be conducted in China.
- China has been reluctant to pursue participation in the OECD MAD program.
- China is willing to accept data from other countries, so long as there are bilateral MAD agreements on a country-by-country basis.
- US EPA has a long-standing cooperative effort with China's ICAMA (Letter of Intent) on capacity development for GLP, which is renewed on a periodic basis, but expired in 2017. The goal of the LOI is such a bilateral MAD agreement.
- The LOI operates under and depends on an umbrella US-China agreement on Cooperation in Science and Technology, dating from 1979, also periodically renewed.
- That umbrella agreement expired in 2016, and has been limping along since on extensions of a few months at a time. But in September (6 weeks ago) it was renewed for 5 years.
- We are concerned now that EPA/OECA may not renew the LOI and will not resume the effort with ICAMA.

There are additional concerns about the GLP audit and inspection program that we might discuss in person.

Ray S. McAllister, Ph.D.  
Senior Director, Regulatory Policy  
CroLife America  
(b) (6) (office)  
(b) (6) (mobile)  
(b) @croplife.us

---

**From:** Schneller, Keith D. EOP/USTR <Keith.D.Schneller@ustr.eop.gov>  
**Sent:** Friday, November 2, 2018 10:20 AM

**To:** Callahan, Julie E. EOP/USTR <Julie\_E\_Callahan@ustr.eop.gov>; Ray McAllister  
(b) (6) @croplifeamerica.org>  
**Cc:** Janet Collins (b) (6) @croplifeamerica.org>  
**Subject:** RE: China LOI

Hello Ray! I ran USDA's Agricultural Trade Offices in Guangzhou, Taipei, and Shanghai from 2003-2014 and took early retirement from USDA in 2015. Now I'm back in the USG and happy to be working with like-minded people at USTR.

I plan on visiting with some former colleagues at USDA/FAS on Monday and hope to get a little more information about the EPA/ICAMA situation you mentioned in your earlier messages to Julie. There's no reason for China to replicate pesticide tests in the future that have already been conducted by US authorities...

I look forward to meeting you in the coming weeks/months.

Best Regards,

Keith Schneller  
Agricultural Affairs  
Office of the U.S. Trade Representative  
O: (b) (6)  
C: [REDACTED]  
E: [keith.d.schneller@ustr.eop.gov](mailto:keith.d.schneller@ustr.eop.gov)

**From:** [Jerry Baron](#)  
**To:** [Bodine.susan@Epa.gov](mailto:Bodine.susan@Epa.gov)  
**Cc:** [keiqwin.richard@epa.gov](mailto:keiqwin.richard@epa.gov); [Messina.edward@Epa.gov](mailto:Messina.edward@Epa.gov); [Ray McAllister](#); [Jay Vroom](#); [Allison Jones](#); [Tammy White Barkalow](#); [Daniel Kunkel](#); [Sheryl Kunickis \(Sheryl.Kunickis@ARS.USDA.GOV\)](mailto:Sheryl.Kunickis@ARS.USDA.GOV)  
**Subject:** Importance of the GLP Audit and Inspection Program...continued  
**Date:** Friday, July 20, 2018 9:47:08 AM

---

Ms. Susan Bodine  
Assistant Administrator, Office of Enforcement and Compliance Assistance  
U.S. Environmental Protection Agency  
Ariel Rios Building, 2201A  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Dear Ms. Bodine:

The IR-4 Project is a federally funded national research program whose mission is to facilitate the registration of conventional chemical pesticides and biopesticides for specialty crops (fruits, vegetables, herbs, nuts, etc.) and minor uses on major crops. We partner with the State Land-Grant Universities, USDA-Agriculture Research Service, and the crop protection industry to develop EPA required data to support the registration of crop protection products on crops that are often deemed “orphans” by industry. IR-4 is required to develop data following the same regulations and guidelines as private industry. Our ability to be successful in our mission is contingent on many elements, one of them is having competent Good Laboratory Practice (GLP) program.

Regular periodic GLP inspections of the regulated community by the EPA Office of Enforcement and Compliance Assurance (OECA) are an essential requirement for us to fulfill our mission domestically. The EPA inspections are becoming more critical as U.S. Specialty Crop farmers attempt to increase exports to take advantage of lucrative international markets. IR-4 is also involved numerous global projects with other publically funded data develop organizations. The data we generate domestically and in cooperative international projects must meet US GLP requirements but must also satisfy the requirements of the Organization for Economic Co-operation and Development (OECD) Mutual Acceptance of Data Decision (MADD) when that data is used to support export tolerances for our US growers.

The IR-4 Project supports the efforts of various members of the GLP regulated community to express the importance of the GLP monitoring program, the historical decline in its ability to fulfill its mission to properly monitor studies required by trading partners. We understand that there is some consideration of the movement of the FIFRA GLP monitoring to the Office of Chemical Safety and Pollution Prevention (OCSPP). We believe this move would be a positive step in light of some potential changes in fee for service funding and the logic of having this program in an area of the EPA that is already handling the administration of these funds.

We support the efforts of Croplife America and National Association of Independent Crop Consultants to elevate the GLP monitoring program to a position where it can fulfill its mission of providing adequate oversight of the US EPA’s GLP program. A robust GLP program in full compliance with the OECD MAD requirements demonstrates to all stakeholders the integrity of generated data that underpin pesticide registrations in the US and around the world. The EPA has a significant responsibility to vigorously defend its Pesticide

Programs, and the GLP program should contribute in that regard.

Thank you for your consideration. If you have any questions or if I can be of assistance please feel free to reach out to me.

Sincerely yours,

**Jerry J. Baron, Ph.D**

**Executive Director**

**IR-4 Project**

**500 College Road East, Suite 201**

**Princeton, NJ 08540**

**[jbaron@njaes.rutgers.edu](mailto:jbaron@njaes.rutgers.edu)**

**Office: (b) (6) extension (b) (6)**

**Cell: (b) (6)**

**IR-4 Project Website: [www.ir4.rutgers.edu](http://www.ir4.rutgers.edu)**

**From:** [Epstein, David](#)  
**To:** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Janet Collins](#); (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Subject:** RE: FAO - News Article: FAO launches guide to tackle Fall Armyworm in Africa head-on  
**Date:** Friday, March 16, 2018 2:17:59 PM

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Ray,

My apologies for the delayed response. I am aware of the fall armyworm issues in Africa, but not directly involved in the FAO project. I do not know Dr. Meagher, but found his contact information on the web, below. Not being familiar with the project, I hesitate to speak further about it. If you do speak with him, I'd be interested in what he has to say.

Telephone: (b) (6)  
 E-mail: [Rob.Meagher@ars.usda.gov](mailto:Rob.Meagher@ars.usda.gov)  
<http://www.ars.usda.gov/saa/cmave/ibbru/rmeagher>

Dave

---

**From:** Ray McAllister [mailto:(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]  
**Sent:** Tuesday, March 13, 2018 12:09 PM  
**To:** Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>; Epstein, David <[David.Epstein@ARS.USDA.GOV](mailto:David.Epstein@ARS.USDA.GOV)>  
**Cc:** Janet Collins (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Subject:** FAO - News Article: FAO launches guide to tackle Fall Armyworm in Africa head-on

Sheryl & David:

Have you folks followed the FAO work on fall armyworm in Africa? In mid-February, FAO released "Integrated management of the Fall Armyworm on maize: A guide for Farmer Field Schools in Africa" (132 pp., see link below). I haven't had a chance to review it, but I understand that the approaches it espouses would deny to African farmers the modern effective tools that are used in the US to keep the pest in check.

The Acknowledgements claim input from, among others, "... entomologists and other researchers from the Americas with sound experience on FAW management." Among the 50+ people listed in the acknowledgements, the only US contributor is "Robert Meagher (USDA-Agriculture Research Service, Gainesville, Florida)." Do you have contact information for Dr. Meagher? I'd be interested in his impression of the guide.

<http://www.fao.org/news/story/en/item/1100355/icode/>

Ray S. McAllister, PhD  
 Senior Director, Regulatory Policy

CropLife America

(b) (6) [redacted] (office)

(b) (6) [redacted] (cell)

(b) (6) [redacted] [@croplife.us](mailto:[redacted]@croplife.us)

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**From:** [Sarah Macedo](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: Video for Jay  
**Date:** Monday, July 30, 2018 4:16:19 PM

---

Thank you, Sheryl!

---

**From:** Kunickis, Sheryl - OCE <Sheryl.Kunickis@OCE.USDA.GOV> **On Behalf Of** Kunickis, Sheryl - OSEC  
**Sent:** Monday, July 30, 2018 1:04 PM  
**To:** Sarah Macedo (b) (6) @croplifeamerica.org>  
**Subject:** Fw: Video for Jay

Hi Sarah,

Hope this isn't too late - see attached video. Please edit and do any touch ups needed. I cannot use DropBox on a govt computer.

Cheers,

Sheryl

Sheryl H. Kunickis, Ph.D., Director

U.S. Department of Agriculture - Office of Pest Management Policy

South Building, Room 3871; 1400 Independence Ave., SW;

Washington, D.C. 20250-0314

(b) (6) Desk phone - (b) (6) Cell phone

[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

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[Available until Aug 29, 2018](#)

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0 bytes



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**From:** [Janet Collins](#)  
**To:** [Francesca Purcell](#); [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Domesle, Alexander - OCE](#); [Fajardo, Julius - OCE](#); [Chou, Fan-Li - OCE](#); [Myers, Clayton - OCE](#); [Chin, Teung - OCE](#); [Schroeder, Jill - OCE](#); [Hill2, Elizabeth - OCE](#)  
**Subject:** Re: CLA Holiday Reception  
**Date:** Friday, November 30, 2018 7:36:36 AM

---

Thanks Francesca

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**From:** Francesca Purcell (b) (6) @croplifeamerica.org>  
**Sent:** Friday, November 30, 2018 6:53 AM  
**To:** Kunickis, Sheryl - OSEC  
**Cc:** Janet Collins; Domesle, Alexander - OCE; Fajardo, Julius - OCE; Chou, Fan-Li - OCE; Myers, Clayton - OCE; Chin, Teung - OCE; Schroeder, Jill - OCE; Hill2, Elizabeth - OCE  
**Subject:** Re: CLA Holiday Reception

Yes absolutely.

Sent from my iPhone

On Nov 29, 2018, at 3:17 PM, Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

Yes, and apologies. Their email addresses are below. David Epstein has already received an invitation.

Fan-Li.Chou@OCE.USDA.GOV  
Julius.Fajardo@OCE.USDA.GOV  
Alexander.Domesle@OCE.USDA.GOV  
Clayton.Myers@OCE.USDA.GOV  
Teung.Chin@OCE.USDA.GOV  
Jill.Schroeder@OCE.USDA.GOV  
Elizabeth.Hill2@OCE.USDA.GOV

Again, thanks!  
Sheryl

Sheryl H. Kunickis, Ph.D., Director  
U.S. Department of Agriculture - Office of Pest Management Policy  
South Building, Room 3871; 1400 Independence Ave., SW;  
Washington, D.C. 20250-0314

(b) (6) Desk phone (b) (6) Cell phone

[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Janet Collins (b) (6) <[janet.collins@croplifeamerica.org](mailto:janet.collins@croplifeamerica.org)>  
**Sent:** Thursday, November 29, 2018 2:34:23 PM  
**To:** Kunickis, Sheryl - OSEC  
**Cc:** Francesca Purcell; Domesle, Alexander - OCE; Fajardo, Julius - OCE; Chou, Fan-Li - OCE; Myers, Clayton - OCE; Chin, Teung - OCE; Schroeder, Jill - OCE; Hill2, Elizabeth - OCE  
**Subject:** Re: CLA Holiday Reception

Can you please send the email contacts - then we can get this sent out easily.

Thank you

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**From:** Kunickis, Sheryl - OSEC <[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)>  
**Sent:** Thursday, November 29, 2018 1:52 PM  
**To:** Janet Collins  
**Cc:** Francesca Purcell; Domesle, Alexander - OCE; Fajardo, Julius - OCE; Chou, Fan-Li - OCE; Myers, Clayton - OCE; Chin, Teung - OCE; Schroeder, Jill - OCE; Hill2, Elizabeth - OCE  
**Subject:** CLA Holiday Reception

Hi Janet,

It was nice to see you on Tuesday evening. As requested, I am sending the names of OPMP staff (and cc'ing them) on this message.

- Alex Domesle
- Fan-Li Chou
- Clayton Myers
- Elizabeth Hill
- Teung Chin
- Jill Schroeder
- Julius Fajardo

I believe the rest of our team have been contacted or may have RSVP's using my invitation since I could not add guests on my registration.

Cheers,  
Sheryl

Sheryl H. Kunickis, Ph.D., Director  
U.S. Department of Agriculture - Office of Pest Management Policy  
South Building, Room 3871; 1400 Independence Ave., SW;  
Washington, D.C. 20250-0314

(b) (6) Desk phone - (b) (6) Cell phone

[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

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**From:** [Ray McAllister](#)  
**To:** (b) (6) [@us.nufarm.com](#); (b) (6) [@agrosource.net](#)  
**Cc:** [Neena.Anandaraman@osec.usda.gov](#); [Janet Collins](#); [julius.fajardo@ars.usda.gov](#); [Rodney AKERS](#)  
**Bcc:** [julius.fajardo@oce.usda.gov](#)  
**Subject:** URGENT - Fwd: FAO/WHO paper  
**Date:** Sunday, December 9, 2018 7:02:19 PM  
**Attachments:** [image001.png](#)

---

Danielle & Taw:

Please read through this email thread and let me know if you are aware of anything more that is publicly available on oxytetracycline and streptomycin. Also let us know if any relevant research is still in progress. Please reply to all.

Ray McAllister  
CropLife America

Begin forwarded message:

**From:** "Fajardo, Julius - OCE" <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>  
**Date:** December 9, 2018 at 6:17:02 PM EST  
**To:** "Anandaraman, Neena - OSEC" <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>, "'Janet Collins'" (b) (6) [@croplifeamerica.org](#), (b) (6) [@croplifeamerica.org](#), (b) (6) [@croplifeamerica.org](#)  
**Cc:** Jim Cranney (b) (6) [@ccqc.org](#), "Jim Adaskaveg, Ph.D." <[jim.adaskaveg@ucr.edu](mailto:jim.adaskaveg@ucr.edu)>, "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Subject:** RE: FAO/WHO paper

So far the monitoring data available to the public is in EPA's docket titled "Review of Antibiotic Resistance Profile of 40 Isolates from CDC's Repository of Bacterial Isolates for Resistance to Streptomycin or Oxytetracycline".

<https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0820-0017>

In addition, oxytet and strep will undergo an EPA registration review this FY2019 to assess the ecological and human health risk assessments including their benefits on crop protection.

---

**From:** Anandaraman, Neena - OSEC  
**Sent:** Sunday, December 9, 2018 6:06 PM  
**To:** Fajardo, Julius - OCE <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>; 'Janet Collins' (b) (6) [@croplifeamerica.org](#); (b) (6) [@croplifeamerica.org](#)  
**Cc:** Jim Cranney (b) (6) [@ccqc.org](#); Jim Adaskaveg, Ph.D. <[jim.adaskaveg@ucr.edu](mailto:jim.adaskaveg@ucr.edu)>; Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>  
**Subject:** RE: FAO/WHO paper

That is helpful. If there is such information for the other two drugs, that would be helpful as well. Thanks!

---

**From:** Fajardo, Julius - OCE

**Sent:** Sunday, December 9, 2018 6:02 PM

**To:** 'Janet Collins' (b) (6) <[redacted]@croplifeamerica.org>; Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; (b) (6) <[redacted]@croplifeamerica.org>

**Cc:** Jim Cranney (b) (6) <[redacted]@ccgc.org>; Jim Adaskaveg, Ph.D. <jim.adaskaveg@ucr.edu>; Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>

**Subject:** RE: FAO/WHO paper

Neena, below is the link of the study on kasugamycin (Arysta's product) available to the public at EPA's docket –

Potential for cross resistance to clinically important aminoglycosides:

<https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0519-0016>

---

**From:** Janet Collins (b) (6) <[redacted]@croplifeamerica.org>

**Sent:** Sunday, December 9, 2018 5:32 PM

**To:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; (b) (6) <[redacted]@croplifeamerica.org>

**Cc:** Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Jim Cranney (b) (6) <[redacted]@ccgc.org>; Jim Adaskaveg, Ph.D. <jim.adaskaveg@ucr.edu>

**Subject:** Re: FAO/WHO paper

Ray- can you answer this? I do not know.

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**From:** Anandaraman, Neena - OSEC <neena.anandaraman@osec.usda.gov>

**Sent:** Sunday, December 9, 2018 3:24 PM

**To:** Ray McAllister; Janet Collins

**Cc:** Fajardo, Julius - OCE; Jim Cranney; Jim Adaskaveg, Ph.D.

**Subject:** RE: FAO/WHO paper

Hi Ray and Janet,

Apologies, I may have already asked, and you may have already sent this, but is the research Rodney refers to that Arysta has regarding AMR something that's published, or that we could share publicly, or at least with the participants at TFAMR (which would basically be public)?

Thanks,

Neena

---

**From:** Ray McAllister (b) (6) <[redacted]@croplifeamerica.org>

**Sent:** Thursday, December 6, 2018 12:59 PM

**To:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Lowery, Kenneth - OSEC, Washington, DC <Ken.Lowery@osec.usda.gov>

**Cc:** Akers, Rodney (b) (6) @arysta.com>; Janet Collins (b) (6) @croplifeamerica.org>  
**Subject:** RE: FAO/WHO paper

Don, Neena, Ken, & Julius:

Rodney Akers of Arysta sends the following candid comments on the FAO/WHO paper.

Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CroLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) @croplife.us

---

**From:** Akers, Rodney (b) (6) @arysta.com>  
**Sent:** Thursday, December 6, 2018 10:31 AM  
**To:** Ray McAllister <(b) (6) @croplifeamerica.org>; (b) (6) @us.nufarm.com; Wilson, Tim <(b) (6) @arysta.com>; (b) (6) @syngenta.com  
**Cc:** Janet Collins (b) (6) @croplifeamerica.org>; (b) (6) @ccqc.org  
**Subject:** RE: FAO/WHO paper

Ray,

I generally didn't have a problem with the areas highlighted but I was on the offense because the general statements about bactericides in AG crop production in the beginning of the report. When it comes to resistant bacteria, I believe the use of bactericides in AG crop production should be the last thing we discuss. Based on the resistance monitoring Arysta has conducted through George Sundin, I do not see an issue. I do have a few comments:

Summary: "There is clear scientific evidence that foods of plant origin may serve as a vehicle of foodborne exposure to antimicrobial-resistant bacteria. Fruits, vegetables and other foods of plant origin can become contaminated with antimicrobial-resistant bacteria and antimicrobial resistance genes (ARGs) anywhere along the food chain, from primary production to consumption." **This statement scared the "H" out of me. Leave off the end of the statement "from primary production to consumption". Thinking of how we are trying to defend our use of bactericides, this statement is wide open to interpretation and can be used politically instead of scientifically.**

Page 3 "There is convincing evidence that agricultural AMU is driving the emergence of antimicrobial-resistant fungi that are increasingly transmitted from the environment to humans" **Reference? Bold statement like this should have a reference or two. Otherwise it is an editorial comment that should be left out.**

Page 3 “Several antimicrobials are approved for use to specifically treat bacterial plant diseases in at least 20 countries. In countries where regulations and oversight of AMU are strong, the use of antimicrobials and their residues on foods of plant origin is minimal. However, in other countries, the quantity and types of antimicrobials being used for agronomic application are undocumented – a problem compounded by challenges of access to quality-assured antimicrobials, including a growing industry of fraudulent and substandard products. The consequences of AMU in plant production resulting in occupational exposure, food, and environmental contamination need to be assessed in order to develop science-based recommendations for mitigating the negative public health impacts of AMR.” **This paragraph comes before the paragraph that discussing contamination with human and animal waste. Nothing we have found in our research leads us to believe that our bactericides used in crop production are creating resistance that is transferred to humans yet this implies that we have a serious problem. I would think paragraphs discussing animal and human waste are more important and should be discussed well before we launch into how our bactericides used in crop product MIGHT cause resistance to bacteria that MIGHT be transferred to humans.**

Page 4 **To my knowledge, in the US and Canada, there has not been any resistance to the use of Kasugamycin documented. Again a broad statement.**

Best regards,  
Rodney  
Rodney Akers, PhD  
Sr. Regulatory Affairs Manager



Tel: (b) (6) Cell: (b) (6)  
15401 Weston Parkway, Suite 150 Cary, NC 27513

---

**From:** Ray McAllister (b) (6) <(b) (6)@croplifeamerica.org>  
**Sent:** Wednesday, December 5, 2018 11:48 PM  
**To:** (b) (6) <(b) (6)@us.nufarm.com>; Akers, Rodney <(b) (6)@arysta.com>; Wilson, Tim <(b) (6)@arysta.com>; (b) (6) <(b) (6)@syngenta.com>  
**Cc:** Janet Collins <(b) (6)@croplifeamerica.org>; (b) (6) <(b) (6)@ccqc.org>  
**Subject:** Fwd: FAO/WHO paper

Danielle, Rodney, Tim, & Heidi:

I saw that you folks had separately received this report from Ken Lowery. Neena Anandaraman also sent it to a smaller group involved in plant agriculture. Could you let me know first thing Thursday morning if you can respond by Friday mid-day at the latest to Neena’s request below? The TFAMR meeting starts Monday in Korea, and we need to be able to support the US delegation.



Ray S. McAllister, PhD  
 Senior Director, Regulatory Policy  
 CropLife America

(b) (6) (office)

(b) (6) (cell)

(b) (6) [@croplife.us](mailto:ray@croplife.us)

Begin forwarded message:

**From:** "Anandaraman, Neena - OSEC" <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>

**Date:** December 5, 2018 at 7:59:25 PM EST

**To:** Janet Collins (b) (6) [@croplifeamerica.org](mailto:(b)(6)@croplifeamerica.org), (b) (6) [@croplifeamerica.org](mailto:(b)(6)@croplifeamerica.org)

(b) (6) [@croplifeamerica.org](mailto:(b)(6)@croplifeamerica.org), "Jim Cranney" (b) (6) [@ccqc.org](mailto:(b)(6)@ccqc.org), "Jim Adaskaveg, Ph.D." <[jim.adaskaveg@ucr.edu](mailto:jim.adaskaveg@ucr.edu)>

**Cc:** "Prater, Donald" <[Donald.Prater@fda.hhs.gov](mailto:Donald.Prater@fda.hhs.gov)>, "Lowery, Kenneth - OSEC, Washington, DC" <[Ken.Lowery@osec.usda.gov](mailto:Ken.Lowery@osec.usda.gov)>

**Subject:** **FAO/WHO paper**

Hello Janet, Ray, Jim and Jim,

The FAO/WHO's expert meeting report is out. While we are still reviewing its content, we thought it would be helpful if you all could take a look and consider whether there is language here that would be consistent with our practices that we could potentially borrow from or modify, if needed during the meeting. I've highlighted some text for consideration (conclusions on page X1, bullets on pages 4 and 5), but there may be other language that is useful. Also, please take a look at page 20 and the use collection information, if any of it looks consistent with our situation.

Thanks,  
 Neena

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**From:** [Courtney DeMarco](#)  
**To:** [Ray McAllister](#); [Courtney DeMarco](#)  
**Bcc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** FW: PPDC Meeting Materials  
**Date:** Tuesday, October 30, 2018 5:07:29 PM  
**Attachments:** [Session 3.10.31.2018.PPDC.Trossbach UAV Presentation.pdf](#) Available online: [Epa.gov](#)  
[Session 3.10.31.2018.Reabe UAV Presentation.pdf](#)  
[Session 4.10.31.2018.PPDC.BPIA Bio Products.pdf](#) Available online: [Epa.gov](#)  
[Session 5.10.31.2018.PPDC Cope Mosquito Presentation.pdf](#) Available online: [Epa.gov](#)  
[Biotechnology Session Agenda.pdf](#)

TO: CLA Friends and Members (bbc'd)

FROM: Ray S. McAllister, Ph.D.  
 Senior Director, Regulatory Policy  
 CroLife America  
 (b) (6) (office)  
 (b) (6) (mobile)  
 (b) [@croplife.us](#)

FYI. Note: the agenda for the Thursday workshop (Biotechnology Session Agenda) is included.

**From:** Jewell, Shannon <[jewell.shannon@epa.gov](mailto:jewell.shannon@epa.gov)>  
**Sent:** Tuesday, October 30, 2018 12:43 PM  
**To:** (b) (6) [@pestfacts.org](#); (b) (6) [@migrantclinician.org](#); (b) [@zypate.com](#); (b) [@afschem.com](#);  
 Andrew Thostenson <[andrew.thostenson@ndsu.edu](mailto:andrew.thostenson@ndsu.edu)>; (b) (6) [@msfb.org](#); Charlotte Sanson  
 (b) (6) [@adama.com](#)>; [charlotte.liang@fda.hhs.gov](mailto:charlotte.liang@fda.hhs.gov); (b) (6) [@dairylandaviation.com](#);  
[Daniel.Kunkel@rutgers.edu](mailto:Daniel.Kunkel@rutgers.edu); (b) (6) [@hotmail.com](#); (b) (6) [@aradc.org](#); (b) (6) [@gmail.com](#);  
[egjevre@cdatribe-nsn.gov](mailto:egjevre@cdatribe-nsn.gov); (b) (6) [@mail.mil](#); Shultz, Gina <[gina\\_shultz@fws.gov](mailto:gina_shultz@fws.gov)>;  
 Gorman, John <[Gorman.John@epa.gov](mailto:Gorman.John@epa.gov)>; (b) (6) [@farmworkerjustice.org](#);  
 (b) (6) [@pestworld.org](#); (b) (6) [@americanchemistry.com](#); (b) (6) [@biologicaldiversity.org](#);  
 (b) (6) [@outlook.com](#); Liza Fleeson <[Liza.Fleeson@vdacs.virginia.gov](mailto:Liza.Fleeson@vdacs.virginia.gov)>;  
 (b) (6) [@gowanco.com](#); Bishop, Patricia (b) (6) [@hsi.org](#)>; [Richard.gragg@famu.edu](mailto:Richard.gragg@famu.edu);  
 (b) (6) [@TheHCPA.org](#); (b) (6) [@gmail.com](#); [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov);  
 (b) (6) [@cpda.com](#); (b) (6) [@pesticide.org](#); (b) (6) [@hit.net](#); (b) (6) [@croplifeamerica.org](#);  
[wda7@cdc.gov](mailto:wda7@cdc.gov)  
**Subject:** PPDC Meeting Materials

PPDC Members –

1. Attached are additional PPDC presentation materials for our meeting tomorrow. All materials will be printed and in your folders for you, and will also be posted to the PPDC website when possible.
2. A reminder re: entering OPP's office building: bring an acceptable form of photo identification, such as a driver's license. You will be asked to sign in and go through a metal detector at the front door, and then asked to sign-in at the PPDC registration desk just outside the conference room, so please give yourself enough time so we can begin at 8:30 am.

3. A press/media reminder: If you are asked for an interview by a reporter, you are welcome to answer any questions, or decline, that's up to you. Your only limitation is that you may not speak on behalf of the PPDC.
4. There are many issues that people are very passionate about (which is not unusual for a PPDC meeting). The PPDC has always had very respectful conversations and I don't see that changing. I look forward to a productive meeting!
5. Finally, the agenda for the Biotechnology Seminar, to occur this Thursday, November 1, is also attached.

I wish you safe travels. If anyone has any issues and you need to contact me, please call my cell phone – (b) (6) Thank you!

Regards,

**Shannon Jewell** · (b) (6) · [jewell.shannon@epa.gov](mailto:jewell.shannon@epa.gov)

Pesticide Program Dialogue Committee, DFO

PPDC website: <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc>

EPA Office of Pesticide Programs, Immediate Office

# **Aerial Application Using Unmanned Aircraft – A flight plan for success!!**

Brad Fritz  
USDA-ARS  
Aerial Application Technology  
Research Unit  
College Station, TX

Damon Reabe  
National Agricultural Aviation Association

# What is an Aerial Application?

- The FAA defines it as
  - ...the operation of an aircraft for the purpose of (1) dispensing any [pesticide, plant regulator, defoliant or desiccant], (2) dispensing any other substance intended for plant nourishment, soil treatment, propagation of plant life, or pest control, or (3) engaging in dispensing activities directly affecting agriculture, horticulture, or forest preservation, but not including the dispensing of live insects.

- So when an unmanned Aircraft performs a pesticide application is it an aerial application?

**–ABSOLUTELY**

# What we know

Our agriculture UAV crop dusters are a cost effective method to precision spray any liquid product on smaller acreage operations, up to whatever acreage you desire

Individual spot spraying via hovering, or mass acreage cover up to any size you require, are all within our capability.

Our agriculture UAV crop dusters are a cost effective method to precision spray any liquid product on smaller acreage operations, up to whatever acreage you desire.

We offer 'FOR SALE', UAV cop duster spraying helicopters and multi-rotor UAV drones for all your crop spraying needs.

Our capabilities cover any liquid product application, on any terrain type, whatever crop you are growing, you can reduce drastically your current fertilizer/pesticide application costs and labor time you are currently using.

Individual spot spraying via hovering, or mass acreage cover up to any size you require, are all within our capability.

Our unmanned aircraft systems (UAS) are highly efficient, low cost, environment friendly agriculture UAV crop duster sprayers that save pesticide, water and labor.





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## THE DRONE THAT CAN DO MORE

We created the most advanced technology for crop protection to be used at the industrial scale for almost all crop production farms. Kray Protection drone demonstrates outstanding performance of crop dusting while lowering farmers' expenses. It prevents yield losses that are inevitable when using other crop protection methods.

# What we know

“A User’s Guide for AgDRIFT 2.0.07: A Tiered Approach for the Assessment of Spray Drift of Pesticides” states – “... and fraction of driftable material (defined here as the fraction of volume containing drops less than or equal to 141  $\mu\text{m}$ )”

SPECIFICATIONS

- Operation speed up to 70 mph
- Take-off weight 77 lbs (35 kg)
- Chemical tank payload 33 lbm (15 kg)
- Application rate 0.6-4.5 lbm/ac (0.7-5 kg/Ha)
- Application strip width 16.4 ft (5 m)

[Get datasheet](#)



**UAV CROP SPRAYING AGRICULTURAL EQUIPMENT**



- Spray droplet diameter: 60 – 180  $\mu\text{m}$
- Optimal flying speed: 1 – 10 m/s
- Spraying swath: 3 – 5 m (even atomization)
- Pesticide/Liquid load: 10 – 20 kg
- Optimal spraying height: 1 – 5 m
- Control: Automatic scheduled or remotely controlled
- Discharge: 6-spray nozzle
- Outflow rate: 0.5 – 2.4 L/min (adjustable)

- **Smaller droplets = More pesticide drift**

# What we know

- More people at application site versus manned aircraft applications



- FAA requires a visual observer in addition to the pilot. Both are at the application site.

# What we know

Application rates of .13 GPA to 1.3 GPA. Far below minimum application rates required for non ULV aerial applications

Optimum spraying heights exceed any altitudes listed in current crop protection labels

## SPECIFICATIONS

- Operation speed up to 70 mph
- Take-off weight 77 lbs (35 kg)
- Chemical tank payload 33 lbm (15 kg)
- Application rate 0.6-4.5 lbm/ac (0.7-5 kg/Ha)
- Application strip width 16.4 ft (5 m)

[Get datasheet](#)



## UAV CROP SPRAYING AGRICULTURAL EQUIPMENT

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- Pesticide/Liquid load: 10 – 20 kg
- Optimal spraying height: 1 – 5 m
- Control: Automatic scheduled or remotely controlled
- Discharge: 6-spray nozzle
- Outflow rate: 0.5 – 2.4 L/min (adjustable)

# What we **DON'T** know

- Pesticide drift characteristics of UAV platforms
- Efficacy of droplet size
- What size is appropriate for AEZ
- Environmental and worker health impacts of additional fills due to small payload and presumably increased concentration of finished mix
- Environmental impact of distributing mixing and loading sites from containment systems at airports to uncontained systems in field

# So how do we ensure safety?

2019-DA-01329-F

- First we can't make decisions based on assumptions
  - Pesticide spray drift must first be researched prior to allowing UAS pesticide application
    - A task force of the same magnitude of the Spray Drift Task Force needs to be assembled to conduct field research needed for all UAS platforms (Multi rotary wing, single rotary wing, fixed wing, mixed wing etc.) at speeds, altitudes and nozzle configurations aircraft will be operated in field
    - Results will need to become part of AgDrift Model
    - EPA can then perform spray drift risk assessments for registering and re-registering pesticides using current worst case scenario assumptions currently used in risk assessments

# Ensuring safety cont'd

- Efficacy studies will need to be conducted to ensure droplet size classifications (DSC) used by UAS will be effective
- EPA will need to establish AEZ size and compliance methods
- Pesticide risk assessments will need to account for worker exposure from additional fills, increased concentration of finished mix and additional workers present at time of application (Pilot and observers)
- Additional human and ecological risk assessments will need to be performed to determine impact of Non-Point mixing and loading sites

# Ensuring safety cont'd

- American National Standards Institute (ANSI) echoes these concerns in a recent UAS standards document. They cited the need for standards in pesticide application using UAS with emphasis on:
  - Communication
  - Treatment Efficacy
  - Operational Safety
  - Environmental Protection
  - Equipment Reliability
  - Airspace integration



# Are exemptions needed?

- Possibly
  - Used as replacement of backpack and other hand operated application tools
  - Acreage completely inaccessible to manned aircraft provided treatment area is small
  - Small total treated acres by individual UAS or “Swarms”

# Summary

- UAS pesticide applications are aerial applications
- Current aerial label language applies and is likely not being complied with
- Current WPS rules apply and requires more in depth assessment due to more people on site
- Further research and testing will likely result in UAS specific label language
- An exemption process should be looked at for extremely small treatment areas

# Emerging Technologies Presentation Agenda

November 1, 2018

*Through a series of sessions with discussion, EPA will provide an overview of emerging technologies as they relate to pesticides and provide opportunities for participants to share their thoughts on what these technologies might mean to them.*

Remote access available at (b) (6)

Conference Line: 1-866-299-3188; Conference Code: (b) (6)

*All presenters are affiliated with the Biopesticides and Pollution Prevention Division in EPA's Office of Pesticide Programs*

**Welcome** – Robert McNally, Director

**Moderator** – Mike Mendelsohn, Chief, Emerging Technologies Branch

**9:00 AM**    **Session I - Biotechnology-Based and Emerging Technology Pesticides**

**10:00 AM**   **Session II - EPA's Role within the U.S. Government**

**10:30 AM**   **Break**

**10:45 AM**   **Session III - EPA's Oversight of Emerging Technology Pesticides**

**11:30 AM**   **Session IV – Future Products**

**Noon**       **Wrap-up and Adjourn**

**From:** [Rachel Lattimore](#)  
**To:** [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Subject:** CLA/ABA Event May 8  
**Date:** Wednesday, May 2, 2018 5:35:19 PM  
**Attachments:** [ABA CLA 2018 Event Agenda.pdf](#)

---

Sheryl,

It was a pleasure to see you earlier today. Here's a copy of the event agenda I mentioned then. The event is open to the public and free of charge. It may be of interest to you or your staff.

Best regards,

Rachel

Rachel G. Lattimore  
Senior Vice President, General Counsel, Secretary  
CroLife America  
1156 15<sup>th</sup> Street, NW  
Suite 400  
Washington, DC 20005

(b) (6) – direct  
(b) (6) – main

(b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
[www.croplifeamerica.org](http://www.croplifeamerica.org)

**ABA Section of Environment, Energy and Resources and CropLife America Annual Event**  
**New Developments in Pesticide Law and Policy**

Step toe & Johnson LLP  
1330 Connecticut Ave NW  
Washington, DC 20036

May 8, 2018  
11:00 am -5:00 pm (ET)

**11:00 am-11:15 am**

**Coffee and Networking**

**11:15 am-11:30 am**

**Welcome and Introductory Remarks**

Rachel Lattimore, CropLife America  
Larry Culleen, Arnold & Porter Kaye Scholer LLP  
Keith Matthews, Wiley Rein LLP

**11:30 am – 12:30 pm**

**FIFRA Enforcement & Compliance**

Panelists:

Jon Jacobs, Jacobs Law Firm  
Greg Sullivan, Director, Waste and Chemical Enforcement Division,  
EPA Office of Enforcement and Compliance Assurance  
Nena Shaw, Senior Advisor, EPA Smart Sectors Program

Moderator:

Lisa Campbell, Bergeson & Campbell, P.C.

**12:30 pm – 1:45 pm**

**Lunch**

12:45 pm- 1:30 pm

Keynote Speaker

**1:45 pm – 2:45 pm**

**Endangered Species Protection- New Opportunities and Approaches**

Panelists:

Jake Li, Defenders of Wildlife  
Steve Richardson, Wiley Rein LLP  
Third Speaker to be Confirmed

Moderator:

Stacey VanBelleghem, Latham & Watkins LLP

**2:45 pm- 3:00 pm**

**Break**

**3:00 pm – 4:00 pm**

**Europe’s Hazard- Based Criteria for Crop Protection Products:  
Potential Impacts for Trade**

Panelists:

Mayur Patel, Associate General Counsel, United States Trade  
Representative [Invited]  
Craig Thorn, DTB Associates  
Lorenzo Terzi, Minister Counselor Health and Food Safety,  
Delegation of the European Union to the United States of America

Moderator:

Sara Beth Watson, Steptoe & Johnson LLP

**4:00 pm- 5:00 pm**

**Increased Transparency Initiatives in Europe and Potential  
Impacts**

Panelists:

Darren Abrahams, Steptoe & Johnson LLP  
Kris Kring, Bayer CropScience  
Kathy Szmuszkovicz, Beveridge & Diamond, P.C.

Moderator:

Karen Carr, Arent Fox LLP

**From:** [Kellie Bray](#)  
**To:** [Epstein, David - OCE](#)  
**Cc:** [Myers, Clayton - OCE](#)  
**Bcc:** [Epstein, David](#); [Myers, Clayton - ARS](#)  
**Subject:** RE: Invitation to speak to CropLife America Pollinator Work Group  
**Date:** Thursday, September 13, 2018 9:16:39 AM

---

Thanks! Talk to you soon.

---

**From:** Epstein, David - OCE <David.Epstein@OCE.USDA.GOV>  
**Sent:** Thursday, September 13, 2018 9:16 AM  
**To:** Kellie Bray (b) (6) @croplifeamerica.org>  
**Cc:** Myers, Clayton - OCE <Clayton.Myers@OCE.USDA.GOV>  
**Subject:** RE: Invitation to speak to CropLife America Pollinator Work Group

Thanks, Kellie, got it.

---

**From:** Kellie Bray (b) (6) @croplifeamerica.org>  
**Sent:** Thursday, September 13, 2018 9:12 AM  
**To:** Epstein, David - OCE <David.Epstein@OCE.USDA.GOV>  
**Cc:** Myers, Clayton - OCE <Clayton.Myers@OCE.USDA.GOV>  
**Subject:** RE: Invitation to speak to CropLife America Pollinator Work Group

Dave,

I don't know why this didn't go through on Monday (see below) so thank you for following up! Yes, the 1 pm to 2 pm time slot works just fine. Most of our group has had to stay home due to hurricane concerns so we are all on the phone today.

The call in number is 866-398-2885 and the passcode is (b) (6)

Thank you!

---

**From:** Kellie Bray  
**Sent:** Monday, September 10, 2018 8:41 AM  
**To:** Epstein, David - OCE <David.Epstein@OCE.USDA.GOV>  
**Cc:** Myers, Clayton - OCE <Clayton.Myers@OCE.USDA.GOV>  
**Subject:** Re: Invitation to speak to CropLife America Pollinator Work Group

David, that works for us - thank you! I'll send you call in information when I get to my computer. I'm currently in sessions at NASDA.

Talk to you soon!  
Kellie

Sent from my iPhone

On Sep 10, 2018, at 7:53 AM, Epstein, David - OCE <[David.Epstein@OCE.USDA.GOV](mailto:David.Epstein@OCE.USDA.GOV)> wrote:

Hi Kellie,

Clayton and I are both scheduled to be meeting with the Mint Industry Research Council's Scientific Affairs Committee at the Melrose Georgetown Hotel on Thursday from 11am-noon. We then have a scheduled meeting with EPA-OPP at 3pm in Crystal City. How about we call in at 1pm. We'd have to be on the road by 2pm to get to Crystal City, but can schedule 1-hr with the CLA Pollinator WG. Let me know if that works.

David

---

**From:** Kellie Bray <(b) [REDACTED]@croplifeamerica.org>

**Sent:** Sunday, September 9, 2018 2:04 PM

**To:** Myers, Clayton - OCE <[Clayton.Myers@OCE.USDA.GOV](mailto:Clayton.Myers@OCE.USDA.GOV)>; Epstein, David - OCE <[David.Epstein@OCE.USDA.GOV](mailto:David.Epstein@OCE.USDA.GOV)>

**Subject:** Invitation to speak to CroLife America Pollinator Work Group

Hello David and Clayton,

The CroLife America Pollinator Work Group will be meeting this coming Thursday, September 13 and is interested in hearing from you about USDA efforts regarding non-Apis bees and stewardship efforts.

Would you be available to speak to the group (either in person or by phone) from 11 am to noon? If that time does not work, we will be meeting from 9 am to 3 pm that day and would be happy to have you join at another time that works for you both.

Please let me know if you are able to join us on Thursday. We look forward to the conversation.

Best,  
Kellie

Kellie Bray  
Senior Director, Government Affairs  
CroLife America  
1156 15<sup>th</sup> St., NW  
Suite 400  
Washington, DC 20005  
(b) (6) (office)  
(b) (6) (cell phone)



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<image001.jpg>

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**From:** [Mary Jo Tomalewski](#)  
**To:** [Jay Vroom](#); [Janet Collins](#); [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Cc:** [Courtney DeMarco](#)  
**Subject:** Meeting with Sheryl Kunickis

---

**From:** [Janet Collins](#)  
**To:** [Anandaraman\\_Neena - OSEC](#)  
**Cc:** [Jim Cranney](#); [Ray McAllister](#); [Courtney DeMarco](#); [Lowery\\_Kenneth - OSEC\\_Washington\\_DC](#); [Fajardo\\_Julius - OCE](#); [Herndon.George-FASContact](#)  
**Bcc:** [Fajardo\\_Julius](#)  
**Subject:** Re: Codex TFAMR for Comments CoP2  
**Date:** Wednesday, August 8, 2018 5:57:43 AM

No concerns at all that we are working at cross purposes- we completely support you i the role you are taking.

I apologize if my words suggested otherwise.

Thanks

Sent from my iPhone

On Aug 7, 2018, at 12:46 PM, Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)> wrote:

Thanks Jim and Janet.

The documents are far from solid. They are still at the electronic working group stage and at Step 3 in the process which means everything is bracketed and up for debate at the next Task Force meeting in December.

This is a 3-4 year Task Force and we are just on the second meeting this December.

We will get another chance to comment as a Member State (rather than an Electronic Working Group Member) on what is drafted from what we comment on now around late September to late October.

The Electronic Working Group has to give people a draft of something to comment on and that's all you are seeing here.

Office: (b) (6)  
 Cell: (b) (6)

---

**From:** Janet Collins [[mailto:\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)]  
**Sent:** Tuesday, August 7, 2018 11:30 AM  
**To:** Jim Cranney [(b) (6)@ccqc.org]; Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; (b) (6)@croplifeamerica.org  
**Cc:** Courtney DeMarco <(b) (6)@croplifeamerica.org>; Lowery, Kenneth - OSEC, Washington, DC <[Ken.Lowery@osec.usda.gov](mailto:Ken.Lowery@osec.usda.gov)>; Fajardo, Julius - OCE <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>; Herndon.George-FASContact <[herndon\\_george@epa.gov](mailto:herndon_george@epa.gov)>  
**Subject:** RE: Codex TFAMR for Comments CoP2

Thanks Jim- I was aware of the background but thought further push was an option; I will leave this to your direction at this point.

These documents are solid; but/and this exercise is going to take much longer to retrofit- perhaps that is ok as well.

Thanks again to all.

Janet  
 (b) (6) (direct)  
 (b) (6) (mobile)

---

**From:** Jim Cranney [(b) (6)@ccqc.org]  
**Sent:** Tuesday, August 7, 2018 11:21 AM  
**To:** Janet Collins [(b) (6)@croplifeamerica.org]; Anandaraman, Neena - OSEC <[Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov)>; Ray McAllister [(b) (6)@croplifeamerica.org]  
**Cc:** Courtney DeMarco [(b) (6)@croplifeamerica.org]; Lowery, Kenneth - OSEC, Washington, DC <[Ken.Lowery@osec.usda.gov](mailto:Ken.Lowery@osec.usda.gov)>; Fajardo, Julius - OCE <[Julius.Fajardo@OCE.USDA.GOV](mailto:Julius.Fajardo@OCE.USDA.GOV)>; Herndon.George-FASContact <[herndon\\_george@epa.gov](mailto:herndon_george@epa.gov)>  
**Subject:** RE: Codex TFAMR for Comments CoP2

Hello Janet,

The ARM Task Force is operating at the Codex Commission level, which is to say that it is the policy people acting over all of the Codex Committees. I provided two background documents that pretty much show that there is no practical possibility of pushing back on the inquiries about antimicrobials on crops or their inclusion in the Code of Practice document.

The first document is a call for information about antimicrobial use on crops from FAO and WHO at the 2017 Codex Committee meeting on pesticide residues. The London document provides information on the genesis of the task force and its objectives.

I think our best option is to continue to work with U.S. government agencies to formulate reasonable scientific positions that are consistent with our approach in the United States and to form a close working relationship with government officials, so more radical international forces won't unhinge our regulatory approach in the United States. As I mentioned in my previous comments, this would also include a close working relationship on public communication.

Meanwhile, I think we should try to have as much influence as we can in the Codex process without calling too much attention to the horticultural sector.

Regards,  
 Jim

James R. Cranney, Jr.  
 California Citrus Quality Council  
 853 Lincoln Way  
 Auburn, CA 95603  
 Office (530) 885-1894  
 Mobil (b) (6)  
 (b) (6)@CCQC.org

---

**From:** Janet Collins (b) (6)@croplifeamerica.org  
**Sent:** Tuesday, August 7, 2018 6:07 AM  
**To:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; Ray McAllister (b) (6)@croplifeamerica.org  
**Cc:** Courtney DeMarco <(b) (6)@croplifeamerica.org>; Lowery, Kenneth - OSEC, Washington, DC <Ken.Lowery@osec.usda.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Herndon.George-FASContact <herndon.george@epa.gov>; Jim Cranney (b) (6)@ccqc.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

My point is that they already are working on this, there is a less than one percent issue with crops—and while I understand they made the request, I don't believe the request was specific to crops (I will look at this again). This is a huge distraction and will take time to put together. That's why I am trying to find out how likely any pushback would have an impact.

Thanks.

Janet  
 (b) (6) (direct)  
 (b) (6) (mobile)

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**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Sent:** Tuesday, August 7, 2018 8:48 AM  
**To:** Janet Collins (b) (6)@croplifeamerica.org; Ray McAllister (b) (6)@croplifeamerica.org  
**Cc:** Courtney DeMarco (b) (6)@croplifeamerica.org; Lowery, Kenneth - OSEC, Washington, DC <Ken.Lowery@osec.usda.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Herndon.George-FASContact <herndon.george@epa.gov>; Jim Cranney (b) (6)@ccqc.org  
**Subject:** Re: Codex TFAMR for Comments CoP2

Hi Janet, I'm not sure I understand the question. It's FAO and WHO that asked Codex, their food standards organization to take up the work and encouraged expansion to crops and the environment. FAO just held an expert meeting to provide scientific advice to this Codex Task Force I shared with this distribution a few weeks ago: <http://www.fao.org/antimicrobial-resistance/news-and-events/news/news-details/en/c/1144999/>

Happy to talk if you need more background.

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**From:** "Janet Collins" (b) (6)@croplifeamerica.org  
**Date:** Tuesday, August 7, 2018 at 8:34:54 AM  
**To:** "Anandaraman, Neena - OSEC" <Neena.Anandaraman@osec.usda.gov>; (b) (6)@croplifeamerica.org  
 (b) (6)@croplifeamerica.org  
**Cc:** "Courtney DeMarco" (b) (6)@croplifeamerica.org; "Lowery, Kenneth - OSEC, Washington, DC" <Ken.Lowery@osec.usda.gov>; "Fajardo, Julius - OCE" <Julius.Fajardo@OCE.USDA.GOV>; "Herndon.George-FASContact" <herndon.george@epa.gov>; "Jim Cranney" (b) (6)@ccqc.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

All- see this. It is an FAO/OIE/WHO program- can we get pushback from FAO on moving the CoP for crops forward?

The FAO/OIE/WHO initiatives, together with public and private organizations, shares responsibility for addressing and coordinating global activities addressing AMR at the animal-human-ecosystems interface. FAO is working closely with key partners such as the World Organisation for Animal Health (OIE), the World Food Organisation (WHO) and others in a global response to the threat of AMR

Janet  
 (b) (6) (direct)  
 (b) (6) (mobile)

---

**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Sent:** Monday, August 6, 2018 8:25 AM  
**To:** Janet Collins (b) (6)@croplifeamerica.org; Ray McAllister (b) (6)@croplifeamerica.org  
**Cc:** Courtney DeMarco <(b) (6)@croplifeamerica.org>; Lowery, Kenneth - OSEC, Washington, DC <Ken.Lowery@osec.usda.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Herndon.George-FASContact <herndon.george@epa.gov>; Jim Cranney (b) (6)@ccqc.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

The aren't complete. There are a number of items that we have flagged that we have to work out with other US agencies on a position this



isolated. So completely removing references to crops is a failing option. The objectionable language you are seeing in this document is coming from the EU and others and we will not be successful in just asking it to be kept out. Everyone is pushing for it to be in so if you all could give us alternate appropriate language to put in a separate crop section, we could try to ask for a separate section applicable to crops and get the rest out, but we need help from our crop experts for that.

I'm attaching the draft Julius originally did that we edited with your comments. I'm also attaching my comments to your comments. I recognize the crop community has not been engaged on this issue as it has pushed forward in the other sectors and I'm happy to talk through any of the background on WHO Global Action Plans and National Action Plans if helpful, but I really need help from the crop experts in order to make appropriate US comments with appropriate proposed language and justification.

I need language from you all and I'm happy to talk if a conference call would be helpful. Even better, since I have my hands full in trying to address the animal side too, if you could work with Julius and the experts at EPA, I'm happy to take what you all come up with.

Office: (b) (6)  
Cell: (b) (6)

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**From:** Janet Collins [mailto:(b) (6)@croplifeamerica.org]  
**Sent:** Friday, August 3, 2018 7:58 PM  
**To:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Cc:** (b) (6)@croplifeamerica.org; Courtney DeMarco (b) (6)@croplifeamerica.org  
**Subject:** RE: Codex TFAMR for Comments CoP2

Neena- many apologies for the delay; we appreciate your permitting CLA to provide comments by today (Friday)- granted its after hours but they are complete for these documents with input from both me and Ray.

Other document review to come on time- Monday. Have a good weekend.

My best,

Janet  
(b) (6) (direct)  
(b) (6) (mobile)

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**From:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>  
**Sent:** Monday, July 30, 2018 1:30 PM  
**To:** Lowery, Kenneth - FSIS <Kenneth.Lowery@fsis.usda.gov>; Allison Phibbs (b) (6)@chickenua.org; Anjulen ANDERSON (b) (6)@elanco.com; (b) (6)@chickenua.org; Barbara Madden (b) (6)@nwhort.org; Bob Bruss (b) (6)@nufarm.com; Brian Ronholm (b) (6)@arentfox.com; Clint Nesbitt (b) (6)@bio.org; Courtney Knupp (b) (6)@nppc.org; Dan Botts (b) (6)@ffva.com; Daniella Taveau (b) (6)@kslaw.com; Danielle Larochelle (b) (6)@nufarm.com; Dave White <dwhite25@utk.edu>; Dick White (b) (6)@nfi.org; Ed Ruckert (b) (6)@mwe.com; George Sundin <sundin@msu.edu>; Heidi Irrig (b) (6)@syngenta.com; (b) (6)@nmpf.org; Janet Collins (b) (6)@croplifeamerica.org; Jay Pscheidt <pscheidj@science.oregonstate.edu>; Jean Halloran (b) (6)@consumer.org; Jeff Watts (b) (6)@zoetis.com; Jim Adaskaveg <jim\_adaskaveg@ucr.edu>; Jim Cranney (b) (6)@ccqc.org; Joel Newman <(b) (6)@afia.org>; (b) (6)@beef.org; Kerik Cox <kdc33@cornell.edu>; (b) (6)@dtbassociates.com; Laura MacCleery (b) (6)@cspinet.org; (b) (6)@afia.org; Lisa Efferts - CSPI (b) (6)@cspinet.org; (b) (6)@turkeyfed.org; (b) (6)@nppc.org; Mallory L. Gage (b) (6)@psu.edu; Mano Basu (b) (6)@gmaonline.org; Margaret Malkoski (b) (6)@nfi.org; Maria Del Mar Jimenez-Gasco <Jimenez-gasco@psu.edu>; Mark Trimmer (b) (6)@TrimmerConsulting.com; Michael HANSEN (b) (6)@consumer.org; Mike MCGOWAN (b) (6)@zoetis.com; Nick Gardner (b) (6)@gmaonline.org; Patricia McManus <psm@plantpath.wisc.edu>; Phyllis Marquitz (b) (6)@effem.com; Quan Zeng <Quan.zeng@ct.gov>; Rachel Cumberbatch (b) (6)@ahi.org; Randy Singer <rsinger@umn.edu>; Ray McAllister (b) (6)@croplifeamerica.org; Richard CARNEVALE (b) (6)@ahi.org; Rodney Akers (b) (6)@arysta.com; Sarah Sorscher (b) (6)@cspinet.org; Stephanie Slinski (b) (6)@citrusrdf.org; Steve Suppan (b) (6)@jatp.org; Steven ROACH <(b) (6)@foodanimalconcerns.org>; Taw Richardson (b) (6)@agrosources.net; Thomas Shryock (b) (6)@arysta.com; Tim Wilson <(b) (6)@arysta.com>; Green, Alice - FSIS <Alice.Green@fsis.usda.gov>; Andrew Chi Yuen Yeung <Andrew.Yeung@fda.hhs.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bennett, Patty - AMS <Patty.Bennett@ams.usda.gov>; McCluskey, Brian J - APHIS <brian.j.mccluskey@aphis.usda.gov>; Canavan, Jeff - FSIS <Jeff.Canavan@fsis.usda.gov>; Caroline De Waal <Caroline.DeWaal@fda.hhs.gov>; Jackson, Charlene <Charlene.Jackson@ARS.USDA.GOV>; Charles Pixley <Charles.Pixley@fsis.usda.gov>; Charles Pixley <Charles.Pixley@fsis.usda.gov>; Daniel Folmer <Daniel.Folmer@cfsan.fda.gov>; McChesney, Daniel <daniel.mcchesney@fda.hhs.gov>; David A Dargatz <David.A.Dargatz@aphis.usda.gov>; David Edwards <David.Edwards@fda.hhs.gov>; David Ingram <David.Ingram@fda.hhs.gov>; David Miller <Miller.Davidj@epa.gov>; Dawn Sievert <dsievert@cdc.gov>; Evans, Don - FAS <Don.Evans@fas.usda.gov>; LaFond, Dorian - AMS <Dorian.LaFond@ams.usda.gov>; Felicia B. Billingslea <Felicia.Billingslea@fda.hhs.gov>; Herndon, George - FASContact <herndon.george@epa.gov>; Goldman, David - Commissioned Corps - FSIS <David.Goldman@fsis.usda.gov>; Gregory Noonan <Gregory.Noonan@fda.hhs.gov>; Heather Tate <Heather.tate@fda.hhs.gov>; Henry Kim <henry.kim@fda.hhs.gov>; Jean Whichard <zvr3@cdc.gov>; Jenny Scott <Jenny.Scott@fda.hhs.gov>; Hain, Joe - FAS <Joe.Hain@fas.usda.gov>; Clifford, John R - APHIS <John.Clifford@aphis.usda.gov>; Greifer, John K - APHIS <John.K.Greifer@aphis.usda.gov>; John Sheehan <John.Sheehan@fda.hhs.gov>; Frye, Jonathan <Jonathan.Frye@ars.usda.gov>; Julia Doherty@ustr.eop.gov; Julie Callahan <Julie.E.Callahan@ustr.eop.gov>; Fajardo, Julius - OCE <Julius.Fajardo@OCE.USDA.GOV>; Schwegel, Justin - FAS <Justin.Schwegel@fas.usda.gov>; Bjork, Kathe E - APHIS <Kathe.E.Bjork@aphis.usda.gov>; Granger, Larry M - APHIS <Larry.M.Granger@aphis.usda.gov>; Larry Kerr <Larry.Kerr@hhs.gov>; Lauren Robin <lauren.robin@fda.hhs.gov>; Lesley V. D'Anglada

<DAniglada.Lesley@epa.gov>; Leslie Yang <Leslie\_Yang@ustr.eop.gov>; Wanida Lewis-FASContact <LewisWE@state.gov>; Durso, Lisa <Lisa.Durso@ARS.USDA.GOV>; Lynn Filpi <Lynn.Filpi@hhs.gov>; McKinnell, Cathy - FAS <Cathy.McKinnell@fas.usda.gov>; Rosenblum, Micah - FAS <Micah.Rosenblum@fas.usda.gov>; Michael Choi <ChoiMI@state.gov>; David, Michael J - APHIS <Michael.J.David@aphis.usda.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; McCluskey, Patrick - AMS <Patrick.J.McCluskey@ams.usda.gov>; Paul S. Honigfort <Paul.Honigfort@fda.hhs.gov>; Paul South <Paul.South@fda.hhs.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; Robinson, Brandi <Brandi.Robinson@fda.hhs.gov>; Hammond, Rose <Rose.Hammond@ARS.USDA.GOV>; Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>; Stanley, Mary - FSIS <Mary.Stanley@fsis.usda.gov>; Steven Wilson <Steven.Wilson@noaa.gov>; Susan Jennings <Jennings.Susan@epa.gov>; Dutko, Terry - FSIS <Terry.Dutko@fsis.usda.gov>; Thompson, Christopher D - AMS <Christopher.D.Thompson@ams.usda.gov>; Norden, Timothy - AMS <Timothy.D.Norden@ams.usda.gov>; Vito Su <suv@state.gov>; William Jones <William.Jones@fda.hhs.gov>

**Subject:** FW: Codex TFAMR for Comments CoP2

Gentle reminder

Office: (b) (6)  
Cell: (b) (6)

**From:** Lowery, Kenneth - FSIS

**Sent:** Monday, July 16, 2018 8:09 AM

**To:** Allison Phibbs <(b) (6)@chickenusa.org>; Anjulen ANDERSON <(b) (6)@elanco.com>; (b) (6)@chickenusa.org; Barbara Madden <(b) (6)@nwhort.org>; Bob Bruss <(b) (6)@nufarm.com>; Brian Ronholm <(b) (6)@arentfox.com>; Clint Nesbitt <(b) (6)@bio.org>; Courtney Knupp <(b) (6)@nppc.org>; Dan Botts <(b) (6)@ffva.com>; Daniella Taveau <(b) (6)@kslaw.com>; Danielle Larochelle <(b) (6)@nufarm.com>; Dave White <dwhite25@utk.edu>; Dick White <(b) (6)@nufarm.com>; Ed Ruckert <(b) (6)@mwe.com>; George Sundin <(b) (6)@msu.edu>; Heidi Irrig <(b) (6)@syngenta.com>; (b) (6)@nmpf.org; Janet Collins <(b) (6)@croplifeamerica.org>; Jay Pscheidt <pscheidt@science.oregonstate.edu>; Jean Halloran <(b) (6)@consumer.org>; Jeff Watts <(b) (6)@zoetis.com>; Jim Adaskaveg <jim.adaskaveg@ucr.edu>; Jim Cranney <(b) (6)@cccac.org>; Joel Newman <(b) (6)@afia.org>; (b) (6)@beef.org; Kerik Cox <kdc33@cornell.edu>; (b) (6)@dtbassociates.com; Laura MacCleery <(b) (6)@cspinet.org>; lwilkinson@afia.org; Lisa Efferts - CSPI <(b) (6)@cspinet.org>; (b) (6)@turkeyfed.org; (b) (6)@nppc.org; Mallory L. Gage <(b) (6)@psu.edu>; Mano Basu <(b) (6)@gmaonline.org>; Margaret Malkoski <(b) (6)@nfi.org>; Maria Del Mar Jimenez-Gasco <jimenez-gasco@psu.edu>; Mark Trimmer <(b) (6)@trimmerconsulting.com>; Michael HANSEN <(b) (6)@consumer.org>; Mike MCGOWAN <(b) (6)@zoetis.com>; Nick Gardner <(b) (6)@gmaonline.org>; Patricia McManus <psm@plantpath.wisc.edu>; Phyllis Marquitz <(b) (6)@effem.com>; Quan Zeng <Quan.zeng@ct.gov>; Rachel Cumberbatch <(b) (6)@ahi.org>; Randy Singer <rsinger@umn.edu>; (b) (6)@croplifeamerica.org; Richard CARNEVALE <(b) (6)@ahi.org>; Rodney Akers <(b) (6)@arysta.com>; Sarah Sorscher <(b) (6)@cspinet.org>; Stephanie Slinski <(b) (6)@citrusrdf.org>; Steve Suppan <(b) (6)@iatp.org>; Steven ROACH <(b) (6)@foodanimalconcerns.org>; Taw Richardson <(b) (6)@agrosourcenet>; Thomas Shryock <(b) (6)@arysta.com>; Tim Wilson <(b) (6)@arysta.com>; Green, Alice - FSIS <Alice.Green@fsis.usda.gov>; Andrew Chi Yuen Yeung <Andrew.Yeung@fda.hhs.gov>; Basu, Pat - FSIS <Pat.Basu@fsis.usda.gov>; Bennett, Patty - AMS <Patty.Bennett@ams.usda.gov>; McCluskey, Brian J - APHIS <brian.j.mccluskey@aphis.usda.gov>; Canavan, Jeff - FSIS <Jeff.Canavan@fsis.usda.gov>; Caroline De Waal <Caroline.DeWaal@fda.hhs.gov>; Jackson, Charlene <Charlene.Jackson@ARS.USDA.GOV>; Charles Pixley <Charles.Pixley@fsis.usda.gov>; Charles.Pixley@fsis.usda.gov>; Daniel Folmer <Daniel.Folmer@fzan.fda.gov>; McChesney, Daniel <daniel.mcchesney@fda.hhs.gov>; David A Dargatz <David.A.Dargatz@aphis.usda.gov>; David Edwards <David.Edwards@fda.hhs.gov>; David Ingram <David.Ingram@fda.hhs.gov>; David Miller <Miller.Davidj@epa.gov>; Dawn Sievert <dsievert@cdc.gov>; Evans, Don - FAS <Don.Evans@fas.usda.gov>; LaFond, Dorian - AMS <Dorian.LaFond@ams.usda.gov>; Felicia B. Billingslea <Felicia.Billingslea@fda.hhs.gov>; Herndon.George-FASContact <herndon.george@epa.gov>; Goldman, David - Commissioned Corps - FSIS <David.Goldman@fsis.usda.gov>; Gregory Noonan <Gregory.Noonan@fda.hhs.gov>; Heather Tate <Heather.tate@fda.hhs.gov>; Henry Kim <henry.kim@fda.hhs.gov>; Jean Whichard <zvr3@cdc.gov>; Jenny Scott <Jenny.Scott@fda.hhs.gov>; Hain, Joe - FAS <Joe.Hain@fas.usda.gov>; Clifford, John R - APHIS <John.Clifford@aphis.usda.gov>; Greifer, John K - APHIS <John.K.Greifer@aphis.usda.gov>; John Sheehan <John.Sheehan@fda.hhs.gov>; Frye, Jonathan <Jonathan.Frye@ars.usda.gov>; Julia Doherty@ustr.eop.gov; Julie Callahan <Julie.E.Callahan@ustr.eop.gov>; Fajardo, Julius <Julius.Fajardo@ARS.USDA.GOV>; Schwegel, Justin - FAS <Justin.Schwegel@fas.usda.gov>; Bjork, Kathe E - APHIS <Kathe.E.Bjork@aphis.usda.gov>; Granger, Larry M - APHIS <Larry.M.Granger@aphis.usda.gov>; Larry Kerr <Larry.Kerr@hhs.gov>; Lauren Robin <lauren.robin@fda.hhs.gov>; Lesley V. D'Aniglada <DAniglada.Lesley@epa.gov>; Leslie Yang <Leslie\_Yang@ustr.eop.gov>; Wanida Lewis-FASContact <LewisWE@state.gov>; Durso, Lisa <Lisa.Durso@ARS.USDA.GOV>; Lynn Filpi <Lynn.Filpi@hhs.gov>; McKinnell, Cathy - FAS <Cathy.McKinnell@fas.usda.gov>; Rosenblum, Micah - FAS <Micah.Rosenblum@fas.usda.gov>; Michael Choi <ChoiMI@state.gov>; David, Michael J - APHIS <Michael.J.David@aphis.usda.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; McCluskey, Patrick - AMS <Patrick.J.McCluskey@ams.usda.gov>; Paul S. Honigfort <Paul.Honigfort@fda.hhs.gov>; Paul South <Paul.South@fda.hhs.gov>; Moreau, Robert <Robert.Moreau@ARS.USDA.GOV>; Robinson, Brandi <Brandi.Robinson@fda.hhs.gov>; Hammond, Rose <Rose.Hammond@ARS.USDA.GOV>; Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>; Stanley, Mary - FSIS <Mary.Stanley@fsis.usda.gov>; Steven Wilson <Steven.Wilson@noaa.gov>; Susan Jennings <Jennings.Susan@epa.gov>; Dutko, Terry - FSIS <Terry.Dutko@fsis.usda.gov>; Thompson, Christopher D - AMS <Christopher.D.Thompson@ams.usda.gov>; Norden, Timothy - AMS <Timothy.D.Norden@ams.usda.gov>; Vito Su <suv@state.gov>; William Jones <William.Jones@fda.hhs.gov>

**Cc:** Anandaraman, Neena - OSEC <Neena.Anandaraman@osec.usda.gov>; USA - Ron Miller <Ron.Miller@fda.hhs.gov>; 'Ruby.Singh@fda.hhs.gov' <Ruby.Singh@fda.hhs.gov>; Kishore, Rita - FSIS <Rita.Kishore@fsis.usda.gov>

**Subject:** Codex TFAMR for Comments CoP2

Dear TFAMR Stakeholders,

Please see attached a new version of the revised text for the Code of Practice to Minimize and Contain Antimicrobial Resistance from the Electronic Working Group Chair and Co-chairs.

Please send comments by July 30, 2018 to [Neena.Anandaraman@osec.usda.gov](mailto:Neena.Anandaraman@osec.usda.gov) , [Ron.Miller@fda.hhs.gov](mailto:Ron.Miller@fda.hhs.gov) ; [Ruby.Singh@fda.hhs.gov](mailto:Ruby.Singh@fda.hhs.gov) ; [Kenneth.Lowery@fsis.usda.gov](mailto:Kenneth.Lowery@fsis.usda.gov) for consideration in drafting of U.S. Comments. When sending comments, please provide text for suggested revision and justification as much as possible. The Electronic Working Group Chair and Co-chairs will next review comments submitted to prepare a report including further revised text for submission to the Codex Secretariat. Our understanding is that the report will be circulated ahead of the next meeting of the TFAMR in December 2018 for further comment by Member States and Observers.

Neena Anandaraman, DVM, MPH, DACVPM  
Veterinary Science Policy Advisor  
Office of the Chief Scientist  
United States Department of Agriculture  
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*Ken*

Kenneth Lowery  
International Issues Analyst  
U.S. Codex Office  
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<Revised RCP61.EWG-COP2 July 2018\_na.docx>  
<CropBestPracticeGuidelines.docx>





**From:** [Courtney DeMarco](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Cc:** [Stephanie Ann Binns](#); [Janet Collins](#)  
**Subject:** RISE/CLA Comments on Proposed Changes to USDA NRCS's IPM Standard  
**Date:** Friday, September 21, 2018 2:56:39 PM  
**Attachments:** [RISE CLA NRCS Conservation Practice Standards Comments FINAL.pdf](#)

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Ms. Kunickis,

Please see attached comments from RISE and CLA regarding USDA NRCS's proposed changes to its National Handbook of Conservation Practices. We specifically provide comments on its proposed changes to its IPM standard.

Please do not hesitate to contact Stephanie Binns (b) (6) ) or Janet Collins (b) (6) if have any questions.

Thank you,

Courtney DeMarco  
 Science and Regulatory Affairs  
 CroPLife America  
 1156 15<sup>th</sup> Street, NW  
 Suite 400  
 Washington, DC 20005  
 (b) (6)

**From:** no-reply@regulations.gov <no-reply@regulations.gov>  
**Sent:** Friday, September 21, 2018 2:41 PM  
**To:** Janet Collins (b) (6) @croplifeamerica.org>  
**Subject:** Your Comment Submitted on Regulations.gov (ID: NRCS\_FRDOC\_0001-0255)



*Please do not reply to this message. This email is from a notification only address that cannot accept incoming email.*

**Your comment was submitted successfully!**

**Comment Tracking Number:** 1k2-95ju-gpyv

**Your comment may be viewable on Regulations.gov once the agency has reviewed it. This process is dependent on agency public submission policies/procedures and processing times. Use your tracking number to find out the status of your comment.**

**Agency:** Natural Resources Conservation Service (NRCS)

**Document Type:** Rulemaking

**Title:** Proposed Changes to National Handbook of Conservation Practices for Natural Resources Conservation Service

**Document ID:** NRCS\_FRDOC\_0001-0255

**Comment:**

Please see the attached comments from RISE and CropLife America.

**Uploaded File(s):**

- RISE\_CLA NRCS Conservation Practice Standards Comments FINAL.pdf

**This information will appear on Regulations.gov:**

First Name: Janet

Last Name: Collins

**This information will not appear on Regulations.gov:**

*All of the information will appear on Regulations.gov*

**For further information about the Regulations.gov commenting process, please visit <https://www.regulations.gov/faqs>.**



September 21, 2018

Mr. Bill Reck  
 National Environmental Engineer  
 Conservation Engineering Division  
 U.S. Department of Agriculture  
 Natural Resources Conservation Service  
 1400 Independence Avenue, SW  
 South Building, Room 6136  
 Washington, DC 20250

*Submitted via regulations.gov.*

Re: Proposed Changes to National Handbook of Conservation Practices for Natural Resources Conservation Service; Docket ID No. NRCS\_FRDOC\_0001-0255; 83 Fed. Reg. 42864 (August 24, 2018).

Dear Mr. Reck:

Thank you for the opportunity to provide comments to the United States Department of Agriculture's Natural Resource Conservation Service (NRCS) on proposed changes to its Conservation Practice Standards published August 24, 2018. We appreciate NRCS's work to continually update its standards to ensure they take the most recent, proven science into account.

We specifically offer comments on the proposed changes to the Integrated Pest Management (IPM) standard, which outlines NRCS's IPM practices "[o]n all land where pests are managed and crop-specific IPM systems have been developed by a land grant university (LGU) or other qualified crop consultants."<sup>1</sup> While the application of these standards may be limited, other federal programs look to NRCS policies for guidance on their own implementation of IPM practices, and it is important that the standard reflect scientifically sound pest management practices.

While the goals outlined in the proposed IPM standards are important, we believe the definition should directly reflect the federal definition of IPM set out in the 1996 Food Quality Protection Act (PL 104-170) and the Food, Conservation, and Energy Act of 2008 (PL 110-234). Congress defines IPM as "a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks."

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<sup>1</sup> United States Department of Agriculture, Natural Resources Conservation Service, Proposed Full Text for Practice Standard Code 595, Integrated Pest Management, May 2018 at 1.

An effective IPM strategy will use a variety of methods to control pests, and any method may be used at any point in the process, as long as it will effectively minimize risks. In some situations, using a chemical method is the best way to do this while controlling pests. Accordingly, the purpose of IPM is not to reduce or eliminate the use of pesticides. Rather, IPM allows pesticide applicators to make their own, case-by-case decisions to meet pest management needs in a way that minimizes economic, health and environmental risks.

Given that the updates to the IPM standards as a whole recognize the role pesticides play in an IPM program, we believe the definition and purpose sections should be updated to reflect the federal definition of IPM, which advocates for the use of different pest management tools when appropriate. This will ensure applicators can both reduce risks and effectively control pests.

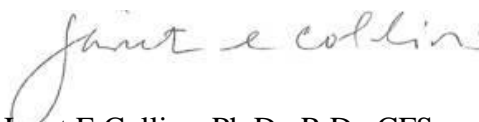
Thank you for reviewing our comments, and please contact us with any questions.

Sincerely,



Aaron Hobbs  
President  
RISE, Responsible Industry for a Sound  
Environment  
1156 15th Street, NW  
Suite 400  
Washington, DC 20005

(b) (6)



Janet E Collins, Ph.D., R.D., CFS  
Executive Vice President, Science and  
Regulatory Affairs  
CropLife America  
1156 15th Street, NW  
Suite 400  
Washington, DC 20005

(b) (6)

cc: Sheryl Kunickis, USDA Agricultural Research Service, Office of Pest Management Policy

---

RISE is a national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

Established in 1933, CropLife America represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: Do you have a few minutes to talk this afternoon?  
**Date:** Tuesday, August 21, 2018 4:02:43 PM

---

Can you give me 30 minutes or so to call you?

Janet

(b) (6) (direct)  
(b) (6) (mobile)

---

**From:** Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>  
**Sent:** Tuesday, August 21, 2018 4:02 PM  
**To:** Janet Collins (b) (6) @croplifeamerica.org>  
**Subject:** Re: Do you have a few minutes to talk this afternoon?

Yes. I will call right now.

Sheryl H. Kunickis, Ph.D., Director

U.S. Department of Agriculture - Office of Pest Management Policy

South Building, Room 3871; 1400 Independence Ave., SW;

Washington, D.C. 20250-0314

(202 720-5375 Desk phone - (b) (6) Cell phone

[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Janet Collins (b) (6) @croplifeamerica.org>  
**Sent:** Tuesday, August 21, 2018 4:00:54 PM  
**To:** Kunickis, Sheryl - OSEC  
**Subject:** Do you have a few minutes to talk this afternoon?

Quick question.

Thanks.

Janet

(b) (6) (direct)  
(b) (6) (mobile)

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**From:** [Janet Collins](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** RE: Do you have a few minutes to talk this afternoon?  
**Date:** Tuesday, August 21, 2018 4:04:37 PM

---

Can you call now?

Janet

(b) (6) (direct)  
(b) (6) (mobile)

---

**From:** Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov>  
**Sent:** Tuesday, August 21, 2018 4:02 PM  
**To:** Janet Collins (b) (6) @croplifeamerica.org>  
**Subject:** Re: Do you have a few minutes to talk this afternoon?

Yes. I will call right now.

Sheryl H. Kunickis, Ph.D., Director

U.S. Department of Agriculture - Office of Pest Management Policy

South Building, Room 3871; 1400 Independence Ave., SW;

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(202 720-5375 Desk phone - (b) (6) Cell phone

[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)

---

**From:** Janet Collins (b) (6) @croplifeamerica.org>  
**Sent:** Tuesday, August 21, 2018 4:00:54 PM  
**To:** Kunickis, Sheryl - OSEC  
**Subject:** Do you have a few minutes to talk this afternoon?

Quick question.

Thanks.

Janet

(b) (6) (direct)  
(b) (6) (mobile)



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**From:** [Jay Vroom](#)  
**To:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Re: Bee Health and USDA!  
**Date:** Tuesday, October 16, 2018 7:53:26 PM

---

Thanks Sheryl—

A great coincidence!

Jay

Sent from my iPhone

On Oct 16, 2018, at 5:34 PM, Kunickis, Sheryl - OSEC <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)> wrote:

Good Evening!

Very timely message! Our office via Dr. David Epstein was in touch with Stephanie re: Fieldwatch last week about hosting a meeting at USDA as there is interest. Glad to help move this forward per your direction. Let me know how we can assist.

Cheers,  
Sheryl

---

**From:** "Jay Vroom" <(b) (6)@croplifeamerica.org>  
**Date:** Tuesday, October 16, 2018 at 5:39:43 PM  
**To:** "Boswell, Kristi - OSEC, Washington, DC" <[Kristi.Boswell@osec.usda.gov](mailto:Kristi.Boswell@osec.usda.gov)>  
**Cc:** "Bachmann, Peter - OCR, Washington, DC" <[Peter.Bachmann@osec.usda.gov](mailto:Peter.Bachmann@osec.usda.gov)>, "Ruthann Anderson" <(b) (6)@capca.com>, "Stephanie Regagnon" <(b) (6)@fieldwatch.com>, "Kunickis, Sheryl - OSEC" <[Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)>, (b) (6)@croplifeamerica.org", (b) (6)@croplifeamerica.org", "Jeff Case" <(b) (6)@croplifeamerica.org>, "Janet Collins" <(b) (6)@croplifeamerica.org>, "Kellie Bray" <(b) (6)@croplifeamerica.org>  
**Subject:** Re: Bee Health and USDA!

Thanks Kristi,

I'm sure Sheryl will have some ideas. Also there's no particular rush so take some time and then we can figure out how to best connect all the parties — maybe with a conference call supported by some PPT slides.

Jay

Sent from my iPhone

On Oct 16, 2018, at 3:36 PM, Boswell, Kristi - OSEC, Washington, DC

<[Kristi.Boswell@osec.usda.gov](mailto:Kristi.Boswell@osec.usda.gov)> wrote:

Jay,

Great to meet you. Let me do some tracking and figure out who the right agency folks are to loop in. I'll be in touch!

Thanks,  
Kristi Boswell

Get [Outlook for iOS](#)

---

**From:** Bachmann, Peter - OCR, Washington, DC  
**Sent:** Tuesday, October 16, 2018 12:56:46 PM  
**To:** (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC;  
 (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray;  
 Boswell, Kristi - OSEC, Washington, DC  
**Subject:** Re: Bee Health and USDA!

No worries, Jay. My colleague, Kristi Boswell, is the Secretary's Senior Advisor with the Research/Pesticide Portfolio. She should be able to assist!

Peter

---

**From:** Jay Vroom (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org)>  
**Sent:** Tuesday, October 16, 2018 12:51:39 PM  
**To:** Bachmann, Peter - OCR, Washington, DC  
**Cc:** Ruthann Anderson; Stephanie Regagnon; Kunickis, Sheryl - OSEC;  
 (b) (6) [@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org); Jeff Case; Janet Collins; Kellie Bray  
**Subject:** Bee Health and USDA!

Hi Peter,

I just spoke at the annual meeting of the California Association of Pest Control Advisors (CAPCA) — their CEO Ruthann Anderson is copied here, as is Fieldwatch CEO Stephanie Regagnon.

CAPCA and Fieldwatch are teaming up to implement what I think may be the most comprehensive bee tracking and transparency program I've seen yet— and in the state with the highest pollination services demand. They want it operational for 2019.

I'm not sure you are the right political lead person at USDA to connect with but I know you'll get us connected in all the right places at USDA ! In addition to those (like Dr Kunickis) who track pesticide issues at the intersection with bee health I think those who oversee bee loss info

including emergency livestock loss payments to beekeepers all need to know about this new initiative in California!

Let me know how else I can help connect the dots?

I'll Also Share his with EPA!

Jay

Sent from my iPhone

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**From:** [Mary Jo Tomalewski](#)  
**To:** [Jay Vroom](#); [Janet Collins](#); [Sheryl.Kunickis@osec.usda.gov](mailto:Sheryl.Kunickis@osec.usda.gov)  
**Cc:** [Courtney DeMarco](#)  
**Subject:** Meeting with Sheryl Kunickis

---

**From:** [CropLife America & RISE](#)  
**To:** [David Epstein](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Tuesday, April 3, 2018 1:57:59 PM

Header\_2.15.18



Dear David:

Your registrat on has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
 2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
 \$0.00  
 \$0.00

Registration Information:		
Registration Items		
David Epstein	CLA & RISE 2018 Regulatory Conference	
Sessions		
David Epstein	Networking Breakfast	26-Apr-2018 7:00 AM
David Epstein	General Session	26-Apr-2018 8:00 AM
David Epstein	Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process	26-Apr-2018 10:30 AM
David Epstein	Networking Lunch	26-Apr-2018 12:00 PM
David Epstein	Series II - Emerging UAS Technology for Precision Ag	26-Apr-2018 1:15 PM
David Epstein	Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome	26-Apr-2018 3:00 PM
Additional Information		
David Epstein	When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee	

[Click here for the event agenda](#)

[Add to Calendar](#)

[Event Registration Confirmation number: KWN6BFLD3LW](#)

We look forward to seeing you in April!

CropLife America & RISE

[Share on Twitter](#)

[Book your group hotel for CropLife America & RISE Regulatory Conference](#) until April 6!

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**Content**

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\*\*\*\*\*

If you no longer want to receive emails from Francesca Purcell please click the link below. [Opt-Out](#)



**From:** [CropLife America & RISE](#)  
**To:** [Rosalind James](#)  
**Cc:** [dianne.fowler@ars.usda.gov](mailto:dianne.fowler@ars.usda.gov)  
**Subject:** Last week for Early Bird Rates! CropLife America & RISE 2018 Regulatory Conference  
**Date:** Tuesday, April 3, 2018 1:47:29 PM

---

Sponsor Invite



**[View Event Fees](#)**

Early Bird rates still available for THIS WEEK ONLY - book today!

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[View Event Agenda](#)

Ready to RSVP? Respond by clicking one of the buttons below!



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**From:** [CropLife America](#)  
**To:** [Sheryl Kunickis](#)  
**Subject:** Invitation to the CropLife America Board & Allies Dinner  
**Date:** Tuesday, February 12, 2019 3:07:35 PM

---



## You're Invited!

CropLife America cordially invites you to join our board of directors for cocktails and dinner.

Tuesday, March 5, 2019

6:30 pm - 9:30 pm

The Ritz-Carlton Pentagon City

Salon I-II Ballroom

1250 South Hayes Street, Arlington, Virginia, 22202

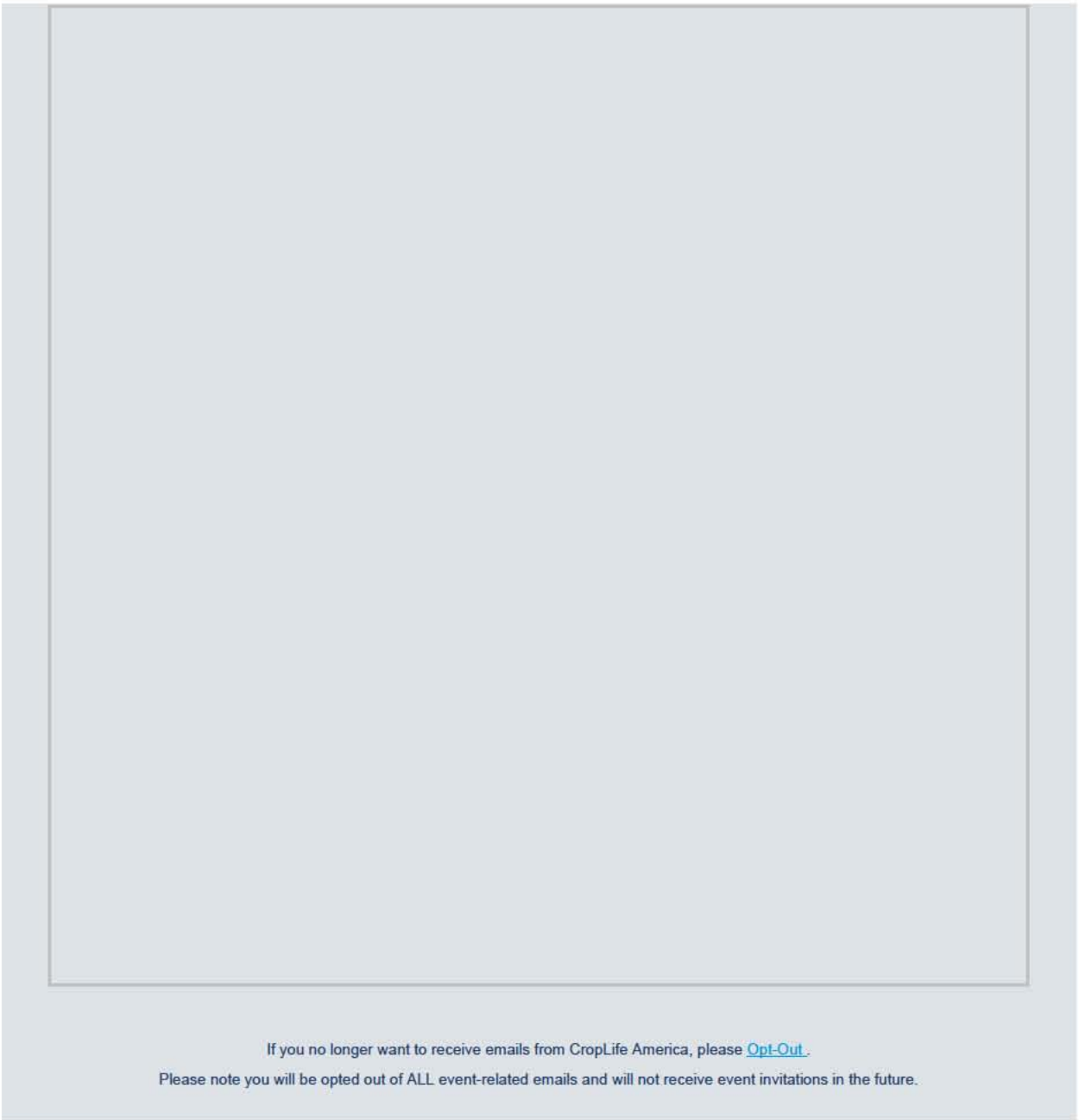
**Ready to RSVP?** Please respond by clicking [Yes](#) or [No](#).

We look forward to your response!

Sincerely,

CropLife America

Need to email our event planner? Get in touch with Francesca at [\(b\) \(6\)@croplifeamerica.org](mailto:(b) (6)@croplifeamerica.org).



If you no longer want to receive emails from CropLife America, please [Opt-Out](#).  
Please note you will be opted out of ALL event-related emails and will not receive event invitations in the future.

---

**From:** [CropLife America & RISE](#)  
**To:** [Jill Schroeder](#)  
**Subject:** Registration Confirmed - CropLife America & RISE 2018 Regulatory Conference  
**Date:** Wednesday, March 21, 2018 9:36:26 AM

Header\_2.15.18



Dear Jill:

Your registration has been confirmed for the CropLife America & RISE 2018 Regulatory Conference. Please save this email for future reference.

**EVENT DETAILS:**

**WHEN:** Wednesday, April 25, 2018 3:30 PM - Friday, April 27, 2018 12:30 PM, Eastern Time

**WHERE:** Renaissance Arlington Capital View Hotel  
2800 South Potomac Avenue, Arlington, Virginia 22202, USA

**DRESS CODE:** Business Casual

\$0.00  
\$0.00  
\$0.00

Registration Information:		
Registration Items		
Jill Schroeder	CLA & RISE 2018 Regulatory Conference	
Sessions		
Jill Schroeder	General Session	26-Apr-2018 8:00 AM
Jill Schroeder	Series I - What We've Learned, What We Need: The FIFRA/ESA Consultation Process	26-Apr-2018 10:30 AM
Jill Schroeder	Series II - Emerging UAS Technology for Precision Ag	26-Apr-2018 1:15 PM
Jill Schroeder	Series III - When Endangered Species Mitigation and Risk Management Meet: Perspectives on Outcome	26-Apr-2018 3:00 PM
Jill Schroeder	General Session	27-Apr-2018 8:00 AM
Jill Schroeder	Series IV - Challenges and Recommendations for Generating and Utilizing Higher-Tier Data in Ecologic	27-Apr-2018 9:45 AM
Jill Schroeder	Series V - Other Ingredients and Their Roles in Crop Protection	27-Apr-2018 11:15 AM
Additional Information		
Jill Schroeder	When I attend the Regulatory Conference event, I'm attending as a: Federal Government employee	

[Click here for the event agenda](#)

[Add to Calendar](#)

[Event Registration Confirmation number: MDNJ8JZZR7L](#)

We look forward to seeing you in April!

CropLife America & RISE

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[Book your group hotel for CropLife America & RISE Regulatory Conference](#) until April 6!

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[Content](#)

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\*\*\*\*\*

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**From:** [Sarah Macedo](#)  
**To:** [sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)  
**Subject:** RE: Jay Vroom Video Project - TOP SECRET and Revised Upload Link  
**Date:** Friday, June 22, 2018 11:04:30 AM  
**Attachments:** [image001.png](#)

---

Good Morning,

This is a friendly reminder of the project outlined below for Jay Vroom's upcoming retirement.

**Please note the due date for uploading your video to [Dropbox](#) is July 2.**

Please do not hesitate to let me know of any questions!

Best,  
Sarah

---

**From:** Sarah Macedo  
**Sent:** Friday, May 25, 2018 12:08 PM  
**To:** 'sheryl.kunickis@osec.usda.gov' <[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)>  
**Subject:** RE: Jay Vroom Video Project - TOP SECRET and Revised Upload Link

Good Afternoon,

I wanted to send a friendly reminder of the project outlined below before the holiday weekend and pass along a **revised link** to upload your short video message:

(b) (6)

Please do not hesitate to let me know if you have any questions!

Best,  
Sarah

---

**From:** Sarah Macedo  
**Sent:** Thursday, May 17, 2018 2:05 PM  
**To:** 'sheryl.kunickis@osec.usda.gov' <[sheryl.kunickis@osec.usda.gov](mailto:sheryl.kunickis@osec.usda.gov)>  
**Subject:** Jay Vroom Video Project - TOP SECRET

Good Afternoon,

After 30 years leading CropLife America, President and CEO Jay Vroom is retiring and we would like you to be a part of this significant milestone! We are reaching out to those who have worked with Jay over the years to help us create a short video to air during our 2018 Annual Meeting.

We encourage you to send us a 10 – 20 second video message for Jay – it may contain your well wishes, a brief story, congratulations – just be sure to make it your own! Please upload your video to

the following DropBox link **by July 2:**

(b) (6). After your video is uploaded to DropBox, our video editors will make your contribution look great! Rest assured, if you don't understand the technical stuff, just give me a call and I'm happy to walk you through it.

Finally, your discretion is of utmost importance! **We would love to keep this a surprise as much as we possibly can - please do not let anyone know.**

Do not hesitate to let me know of any questions and thank you for helping us celebrate Jay's life and career!

Best,  
Sarah

**Sarah Macedo**

Manager, New Media Content  
CropLife America  
1156 15th Street N.W., Suite 400  
Washington, D.C. 20005  
Office: (b) (6)

Show that you #GiveaCrop by tagging your social media posts and check out our campaign at [www.GiveaCrop.org](http://www.GiveaCrop.org)!



**From:** [Janet Collins](#)  
**To:** [Jay Vroom](#)  
**Cc:** [Kunickis, Sheryl - OSEC](#)  
**Subject:** Re: Accepted: Meeting with Sheryl Kunickis  
**Date:** Friday, April 13, 2018 7:22:01 AM

---

I will plan to join Jay.

> On Apr 13, 2018, at 7:20 AM, Jay Vroom (b) (6) @croplifeamerica.org> wrote:

>

> I believe this is to be me and Janet--I will be there for sure! Thanks

>

> Jay Vroom

> President & CEO

> CropLife America

> Direct Dial: (b) (6)

> Mobile: (b) (6)

> Executive Assistant: Mary Jo Tomalewski (b) (6) @croplifeamerica.org)

>

> -----Original Message-----

> From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]

> Sent: Friday, April 13, 2018 6:59 AM

> To: Mary Jo Tomalewski <(b) (6) @croplifeamerica.org>

> Cc: Jay Vroom (b) (6) @croplifeamerica.org>

> Subject: Re: Accepted: Meeting with Sheryl Kunickis

>

> Hi Mary Jo,

> I am confirming our meeting at USDA 9:30-10:30 am today. I accepted on April 2, but this does not show on my calendar. I will meet everyone shortly before 9:30 am at the 3rd wing visitor's entrance.

> Cheers,

> Sheryl

>

> Sent from my iPhone

>

>> On Apr 2, 2018, at 8:55 AM, Kunickis, Sheryl - OSEC <Sheryl.Kunickis@osec.usda.gov> wrote:

>>

>>

>> <meeting.ics>

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