CropLife America & RISE Regulatory Conference

CONFERENCE AGENDA AS OF 4.7.20

Renaissance Arlington Capital View

Wednesday, July 8, 2020

12:00 pm — **Registration Opens**

1:00 – 4:00 pm — **Salon 1,2 - Interactive Workshop: Partnering to Promote Efficiency and Understanding in the Registration Process**

This space-limited workshop is open to all EPA staff and invited RISE and CLA members. Please contact Stephanie Binns (sbinns@pestfacts.org) if you are interested in participating or would like more information.

It takes a crowd to create a pesticide product, write its label, and submit a registration to EPA. It also takes a crowd to review and approve the product for sale in the United States. Challenges can arise at any stage in this process, causing delays and creating more work. This interactive workshop will focus on what both registrants and EPA do to get a product registered – and how we can work together to find solutions to issues in the submission and registration process. Attendees will be expected to participate actively in the conversation, seek mutual understanding, and contribute to finding solutions to common challenges.

5:00 – 7:00 pm — **Reception**

Sponsored by Arent Fox LLP and Valent

Thursday, July 9, 2020

7:00 am — **Registration Opens**

7:00 – 8:00 am — **Breakfast**

8:00 – 10:00 am — **General Session I, Salon 4 – Navigating Advancement in Science, Complex Regulation, and Consumer Perception!**

Kick off this year's Regulatory Conference with a panel from U.S. EPA's Office of Pesticide Programs discussing current and future agency priorities. EPA leaders will provide an overview of their division's priorities with opportunity for audience questions.

10:00 – 10:30 am — **Coffee Break**

Sponsored by ADAMA and Tessenderlo Kerley, Inc.

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10:30 am – 12:00 pm **Series I, Studio B - The Use of Environmental Epidemiology and Toxicology Data in Risk Assessment**

Environmental epidemiological study data can complement the use of data from toxicology studies in the risk assessment of crop-protection products. Given that most environmental epidemiology studies are observational in nature, the validity/reliability of data derived from such studies needs to be evaluated carefully, before being used in risk assessments. This session will discuss how epidemiological data can complement toxicological data in public health decision-making; how epidemiological study design can be improved to fit the risk assessment's data needs; and finally, how better communication between the epidemiologists, the toxicologists and the risk assessors can improve the public health decision-making process.

10:30 am – 12:00 pm **Series I, Studio C - Translating Science for Policy Makers**

This session will focus on how our industry can provide knowledge and resources our lawmakers on Capitol Hill and in state legislatures across the country can use. Participants will gain a better understanding of how proactive engagement on the Hill should work, hear perspectives from staffers supporting our congressional representatives, and learn more about the unique opportunities scientists have to support the preservation of our current science-based regulatory approach.

10:30 am – 12:00 pm **Series I, Studio D - Cracking the Egg: Challenges & Changes in Avian Testing and Risk Assessment**

Avian regulatory testing remains relatively unchanged for more than 20 years, yet how avian toxicity data is used to determine ecological risk is evolving. This session will examine a broad array of avian topics on exposure and effects characterization. What improvements could be made to avian regulatory testing and assessment? What additional benefit is there to altering the design or even the statistical approaches that determine the endpoint? What new models are available for risk assessment refinement or how can we improve the existing models?

10:30 am – 12:00 pm **Series I, Studio E - Skin Absorption in Occupational Dermal Exposure and Risk Assessments to Agrochemicals**

Currently in North America, occupation dermal risk assessment for agrochemicals require a 28-day dermal toxicity study or in vivo/triple pack dermal absorption studies in lieu of default absorption factor. These studies not only require animal testing but also the data generated has little relevance to humans because of the fundamental differences in the skin of rodents versus humans. Although OECD in vitro absorption test guidelines are available, they have not been fully implemented in the North American regulatory risk

assessment process. This session will provide an overview of the progress made so far and future expectations towards adoption in vitro dermal absorption studies as stand alone.

12:00 – 1:00 pm **Keynote Luncheon - Promoting Agricultural Trade: Opportunities and Challenges (Tentative)**
Sponsored by Corteva
Enjoy lunch while listening to the latest in pesticide registration.

1:15 – 2:45 pm **Series II, Salon 1,2,3 - EPA Labels Live!**
The EPA-stamped label underpins the life of a pesticide product from its development in the lab, to its registration with regulatory authorities, to its application by consumers and professionals and everything in between. Join us for our fifth annual EPA Labels Live! session designed for EPA and government agency staff (participation is open to all conference attendees). This year's session will focus on application techniques for unique pesticide use patterns, such as aquatic and structural uses. Participants will leave with a better understanding of how pesticide label language is designed to capture the intricacies of these less-common use patterns and ensure safe and effective applications.

1:15 – 2:45 pm **Series II, Studio B - Farm Bill Update**
The Farm Bill is the primary agricultural and food policy tool of the federal government. The comprehensive omnibus bill is renewed every five years and deals with both agriculture and all other affairs under the purview of the United States Department of Agriculture (USDA). The 2018 Farm Bill, enacted December 20, 2018, builds upon many of the crucial programs that serve America's agricultural producers. In this session, you will get an update from the 2018 Farm Bill on topics like pesticides usage survey, pollinator activities, biostimulants, and the methyl bromide emergency use provision.

1:15 – 2:45 pm **Series II, Studio C - Talking Science**
Got a grasp on the science behind pesticides? Now learn how to talk about it! This session will walk you through messages that resonate as well as provide tips and tricks to help you tell an effective story about today's agriculture.

1:15 – 2:45 pm **Series II, Studio D - Application of RISK21 Framework in Regulatory Based Decision Making: From Business Decisions to Prioritization to Risk Assessment**
A risk-based approach should be the basic operating principle for decision-making for chemical prioritization and evaluation. An exposure-driven assessment for chemicals proposes a paradigm shift in support of a harmonized risk assessment-based regulatory decision-making. A common framework of an

integrated approach that enhances efficiency and informs business and risk management decisions that is scientific, transparent, and efficient is available and easy to incorporate into any chemical decision process. This session will provide an overview of The Health and Environmental Sciences Institute (HESI) Risk Assessment in the 21st Century (RISK21; www.RISK21.org) project initiated to develop a scientific, transparent, and efficient approach to the evolving world of risk assessment.

2:45 – 3:00 pm **Coffee Break**

3:00 – 4:30 pm **Series III, Studio A - Translating Science to the Judges & Juries**
Learn about the legal issues surrounding ESA and FIFRA. Featuring a panel of legal representatives from Washington, D.C., offices and CLA counsel, this session will provide methods for bridging the gap between law and regulation, as well as a framework of the legal landscape and the litigation process.

3:00 – 4:30 pm **Series III, Studio B - Drone Application Technology and Regulatory Challenges**
As UAV technology for ag uses are further developed, what are the biggest challenges to facilitate adoption of drone application of pesticides? This session will serve as a glance into the current state of technology and how drones are utilized for these purposes in other countries.

3:00 – 4:30 pm **Series III, Studio C - Challenges in the State Registration Process for Adjuvants and Soil Amendments**
Some states require registration of adjuvant and soil amendment products, while EPA and most other states do not. The interaction with EPA regulation of inert ingredients can be confusing, but this session will address the current activities, challenges, and opportunities.

3:00 – 4:30 pm **Series III, Studio D - Progress in Endangered Species & Crop Protection Risk Assessment**
The last year brought new developments in the Endangered Species Act (ESA) and Federal Insecticide Fungicide and Rodenticide Act (FIFRA) space. These include pesticide risk assessment interface, proposed changes by EPA's Office of Pesticide Programs to the 2013 'interim approach', improvements in the risk assessment tool kit, and continuing efforts by the registrant community. Presentations in this session will provide an overview of some of these ongoing efforts to improve the risk assessment paradigm.

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3:00 – 4:30 pm **Series III, Studio E - International Trade Policy and the Pesticide Industry**
International trade policies can enable or hinder markets around the world for pesticides, as well as the crops they protect. Personnel from USTR, USDA-FAS and EPA-HED will review ongoing initiatives to reduce non-tariff trade barriers, and to identify opportunities for collaboration across U.S.-stakeholders.

5:00 – 7:00 pm **Reception**
Sponsored by Crowell & Moring and Latham and Watkins

Friday, July 10, 2020

7:00 am **Registration Opens**

7:00 – 8:00 am **Breakfast**
Sponsored by Syngenta

8:00 – 9:30 am **General Session II, Salon 4**
Our closing general session will highlight EPA's milestone achievements in 2019 and the road ahead. This panel will include CLA, RISE and industry leadership.

9:30 – 9:45 am **Coffee Break**
Sponsored by Exponent

9:45 – 11:00 am **Series IV, Salon 2 - Challenges & Best Practices in Resistance Management Pt. 1**
Pesticide resistance becomes a problem when the same chemicals are used over and over to control a particular pest. After a period, the pest may develop resistance to a chemical so that the chemical no longer effectively controls the pest at the same rate, and higher rates and more frequent applications become necessary until eventually the chemical provides little or no control. This two-part series will exhibit perspectives and recommendations from varied sources.

9:45 – 11:00 a.m. **Series IV, Salon 3 - Improving the Approval of Inert Ingredients at the Federal Level**
While inert ingredients are not "registered" by EPA they must go through a rigorous approval process. There are opportunities for both industry and EPA to improve the process by using self-certification to develop the petition, submitting the petition through the EPA Portal, and making the review process more efficient.

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9:45 – 11:00 a.m. **Series IV, Studio B - Application of NAMs in Human Health and Eco Risk Assessment**

A paradigm shift has been proposed to move away from the use of mammalian laboratory animals in favor of the application of in vitro assays and in silico models to inform human health risk assessment needs. This change has many challenges to develop and qualify these new approach methods (NAMs) for use in chemical evaluation and risk assessment. A lot of progress has been made in developing NAMs to replace the acute studies used in determining acute toxicity for human health. The establishment of NAMs to answer the many and varied questions surrounding intermediate and chronic assessments for human and ecological risk are in their early stages of consideration and development. This session will discuss the challenges and concerns around elimination and replacement of the repeat dose mammalian guideline studies used for pesticide registration and the considerations that need to be addressed around human health, ecological, and societal concerns as these test guidelines are replaced.

9:45 – 11:00 a.m. **Series IV, Studio D - Driving Positive Consumer Dialogue on Pesticides**

Combating pests is an ongoing part of the job when it comes to crop production. It's important that producers can make use of different tools, including pesticides, to protect our food supply from destructive weeds, insects, and diseases. However, with so much misinformation circulating about pesticides, consumers sometimes perceive them to be a safety concern rather than a tool that helps deliver a variety of safe, healthy and affordable food products. In this session, we invite speakers across different sectors to discuss their perspectives and knowledge regarding the general public's perception of pesticides, comment on how they think the industry is doing in communicating their necessity and science and provide recommendations on how to more effectively communicate to consumers.

9:45 – 11:00 a.m. **Series IV, Studio E - Public and Proprietary Exposure Data and it's Utilization in Consumer Safety Communication and Human Risk Assessment**

Around the world, governments monitor pesticide residues in food to enforce local food safety standards. In the U.S., the USDA systematically samples foods as consumed which provides information on "residues on the plate." The generation of this data provides the basis for higher tiered risk dietary assessment, including cumulative assessments. These data are also used regularly in public communications regarding consumer safety of agricultural products. Additionally, industry taskforces have developed a variety of data to address the operator and residential exposure. This session will provide examples of the use and value of this data.

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11:00 – 11:15 am **Coffee Break**
Sponsored by Intrinsik

11:15 am– 12:30 pm **Series V, Salon 2 - Challenges & Best Practices in Resistance Management Pt. 2**
Pesticide resistance becomes a problem when the same chemicals are used over and over to control a particular pest. After a period, the pest may develop resistance to a chemical so that the chemical no longer effectively controls the pest at the same rate, and higher rates and more frequent applications become necessary until eventually the chemical provides little or no control. This two-part series will exhibit perspectives and recommendations from varied sources.

11:15 am– 12:30 pm **Series V, Salon 3 - E-Commerce and Pesticides**
The internet has made purchasing products, including pesticides, quick and easy. While the online market is an important channel for manufacturers, it also poses unique challenges for registrants and enforcement agencies that want to ensure the products users buy are authentic and sold legally. This session will bring stakeholders together to discuss concerns about e-commerce and activities to stop and prevent illegal online pesticide sales.

11:15 am– 12:30 pm **Series V, Studio B - Opening the Black Box of Modeling: Introducing Population Modeling Guidance, Use, Interpretation, and Development for Ecological Risk Assessment**
The assimilation of population models into the Ecological Risk Assessment (ERA) process has been hindered by their range of complexity, uncertainty, resource investment, and data availability. Recent research efforts have begun to tackle these challenges by creating an integrated Modeling Framework and Decision Guide to aid the development of population models with respect to ERA objectives and data availability. In this session, we introduce Pop-GUIDE through several case studies, highlighting model development for risk assessments under FIFRA and ESA.

11:15 am– 12:30 pm **Series V, Studio D - Current MRL Challenges**
Maximum residue levels are the highest pesticide level legally tolerated on food and feed and may differ from region-to-region globally. Accordingly, they play a critical role in international agricultural trade. A lack of international harmonization of MRLs continues to challenge trade although there are continuous efforts to reverse this. In this session, government officials, legal experts, and farmers will share their perspectives on the current progress and obstacles for international MRL harmonization and the impact MRL policies have on trade.