



MARCH 2019

HAPPENINGS ON THE HILL by Glenn Luedke

BIOTECH LABELING RULES HAVE BEEN FINALIZED

The House and Senate Ag Committees took up the issue after bills were proposed by advocates and opponents of mandatory labeling rules. A proposal offered in the House incorporated national standards to govern biotech labeling that would be entirely voluntary to food processors and retailers. The Senate did not accept this. The National Biotech Food Disclosure Act was signed into law with the intention not to disrupt markets. Two years later, the USDA proposed rules that would implement legislation as a single set of national rules. The proposed rule adopted the phrase "bio-engineered" rather than the commonly used "genetically engineered" or "genetically modified". The new rules were signed into law the same day the President signed the new Farm Bill.

REQUEST FOR NEW RULES ON TREATED SEED

EPA is seeking public comment on a petition from the Center For Food Safety requesting EPA either issue rulemaking or issue a formal Agency interpretation for planted seeds treated with systemic insecticides. The petitioners take the position that EPA has improperly applied the treated article exemption in treated seed from additional registration and labeling requirements under FIFRA. If EPA sides with the petitioners, a substantial burden for growers and seed treaters will occur without benefit to the environment. Applying the treated article exemption to treated seed is a longstanding approach by EPA to prevent duplicative regulation.

FDA COMMISSIONER

A new FDA Commissioner will soon be named. Agriculture interests hope for smooth "dialogue and understanding" between USDA and FDA.

USDA BUDGET

The new Federal Budget presented indicates cuts in many ag programs, including sustainable research and education, food safety outreach, crop insurance and conservation technical assistance. Increases include a \$75 million dollar increase for the Agriculture and Food Research Initiative and an additional \$100 million to address aging research infrastructure. The 15% proposed overall cut reduces the Supplemental Nutrition Budget. Opponents of many of the cuts stated there is a clear disconnect between the White House list of priorities and the realities facing farmers, ranchers and rural communities. The House Ag Committee Chair predicts the planned cuts will go nowhere.

EPA

The President signed into law the "Pesticide Registration Improvement Extension Act of 2018". The rule has the broad support of ag producers, environmentalists and worker protection organizations along with numerous manufacturers. A key element of the law reauthorizes fee collection provisions and authorities available under FIFRA and addresses worker protection standards. In addition, the law outlines expedited review time frames and additional financial incentives for the development and submission of reduced risk pesticides.

Snapshot in Time Photo Contest

Families in Consulting/Research

Have your cameras ready between April 1st and April 7th to snap a picture of your family working together in a consulting or research business. Submit one photo to admin@naicc.org with a short caption and the general location where the picture was taken. Here is one example to get your creative thoughts flowing.



The boys keeping themselves busy while mom hand pollinates corn, Wisconsin

Photo must be submitted by end of day April 11th. Photographer must be a member of NAICC to participate. One photo per member. All submitted entries will become property of NAICC.

Are You Affected by the New Trial Separation Requirement? by Lisa Wheelock-Roney

It's that time of year again in the Midwest – trial bidding season! And with that, excitement for the upcoming growing season, but also some new challenges for Contract Research Organizations (CROs). Whether it is new compliance requirements, customizing/building new equipment or learning about a crop we're not too familiar with, contract research is never dull –even with feet of snow on the ground. One such challenge this year is a new separation requirement for residue field trials conducted under the same protocol (study). In

this article, I will specifically report on the changes in the distance separation option in protocols, not any other trial separation options, such as temporal.

Who remembers when trials under the same protocol just needed to be separated by county? For my company, the next county is less than five miles away, and it was easy to run two trials close together, and be considered independent of each other. Sometime since then and now, sponsor companies changed it to a minimum 20-mile separation, and we all became comfortable with that. This year, some bids are coming in with a minimum of a 25-mile separation. I've interviewed sponsors, a management company and CROs to see if I could get to the bottom of this change, and how it affects us.

First, we must consider where the minimum 20-mile trial separation requirement came from. One sponsor company stated the EPA, push back for trials under one study that were not found to be uniquely different. Yet another source may be data acceptance in Europe (OECD or EFSA), for the same reason. So, as a CRO, you may not find this exact mile requirement in any sort of regulation, it falls under the category of "industry standard", but nevertheless is a protocol requirement. So, where did the new minimum 25-mile trial separation come from? I've learned it was to provide an extra "cushion", to ensure trials were in fact making that 20-mile minimum to be considered independent and unique. I must emphasize the minimum 25-mile trial separation is as the crow flies, and not by GPS driving directions.

It may be normal for new requirements or changes every year, however this isn't a simple change. The reasoning behind this article is to be the voice of CROs that are affected the most by this. For those of us who primarily work with annual row crops, this requirement may be easy to follow; lease another half-acre five miles or more away. For stationary crops, such as tree crops, it's not that easy. Imagine having long standing relationships with growers who are more than 20 miles apart, but less than 25 miles – new relationships will need to be formed to comply with this requirement. For example, let's just say you have a tree crop that only blooms once during the season, and is native to only a small region. The only way to uniquely separate the trials is distance, as you don't have the opportunity to use temporal separation. You will not be able to conduct multiple trials for a study in this case. In the part of the world where Great Lakes Ag-Research Service, Inc. is located, the closest CRO is more than 25 miles away, making the problem of trial separation only an "in house" problem. Now picture if you have another CRO in your back yard. You are probably used to working with them on trial separation previously, but as stated before, you have relationships in place and have set "boundaries" with them. You'll have to reset those boundaries along with working with new growers in 2019. Again, remember it's a minimum of 25 miles as the crow flies.

If you haven't already, check those bids and make sure you haven't missed this new separation requirement. If you're not affected by this, you're lucky! But remember in the back of your head, who your friends are, and next year's bids are a whole different story.

Hot/Topics by Lisa Wheelock-Roney

If you have any hot topics that you would like to appear in the newsletter, please contact any member of the newsletter committee or myself (lwheelock@greatlakesag.com). What is important to one NAICC member is important to the organization!

Have a wonderful spring season!

NAICC

Your professional society representing the nation's crop production, research consultants and quality assurance professionals.

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