Message

From: Ray McAllister [RMcAllister@croplifeamerica.org]
Sent: 10/11/2018 4:38:45 AM
To: Beck, Nancy [Beck.Nancy@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]
CC: janet collins [jcollins@croplifeamerica.org]; Chris Novak [novak@croplifeamerica.org]; Bolen, Derrick [bolen.derrick@epa.gov]; Herndon, George [Herndon.George@epa.gov]
Subject: GLP Concerns & Certificates of Origin
Attachments: Importance of the GLP Audit and Inspection Program

Dr. Beck and Mr. Baptist:

Thank you for taking the time to meet with us last week regarding the Good Laboratory Audit and Inspection program, as well as Certificates of Origin for export of pesticides from the United States. CropLife America urgently requests EPA to:

1. Continue issuing letters summarizing the GLP compliance history of US laboratories, in order to support pesticide registrations in other countries.
2. Resume issuing Certificates of Origin for pesticides manufactured in the United States and exported to other countries, in order to support (a) US export business and (b) the anti-counterfeiting efforts of our trading-partner countries.

The day before we met, Chris Novak of CLA had a few brief moments to raise these two issues on behalf of CropLife America in the Smart Sector meeting with Acting Administrator Wheeler on October 2. In advance of that meeting, we shared the concise description (highlighted below) of our concerns with Daisy Letendre of EPA's Smart Sectors program. Also attached is a more complete description of our GLP concerns, shared with Susan Bodine of OECA and members of her staff in July. These contacts, in and of themselves, are not sufficient to resolve our concerns, and we welcome your direction on next steps to explore the details and make progress.

The following paragraph is excerpted from a message received just yesterday, illustrating the problem with GLP compliance letters, one example of multiple such inquiries we have received. The "decision" mentioned here has not benefited from any consultation with industry stakeholders or consideration of the effects on international business.

> "… [we] recently requested Frances Liem to write a letter to the product registration regulators at a foreign country, and listing all [GLP] inspections conducted by the EPA at [our lab]. Frances has always been very responsive in getting us these letters; however, for this request she informed us that her *superiors have decided* that she (or maybe EPA in general) cannot prepare these letters any longer. From an international registration point, these letters have been required by some countries in order to get the product(s) registered. As you might guess, this new policy could definitely impact product registration. … we would like to request that you and Crop Life America follow up with the EPA."

Ray S. McAllister, Ph.D.
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From: Ray McAllister
Sent: Wednesday, September 26, 2018 4:26 PM
To: 'Letendre, Daisy' <letendre.daisy@epa.gov>
Cc: 'Shaw, Nena' <Shaw.Nena@epa.gov>; Chris Novak <Novak@croplifeamerica.org>; Janet Collins <jcollins@croplifeamerica.org>; Mary Jo Tomalewski <mjtomalewski@croplifeamerica.org>; 'Sharpe, Kristinn'

<Sharpe.Kristinn@epa.gov>
Subject: RE: REMINDER TO RSVP: Smart Sectors Event w/ Administrator Wheeler

Daisy:

Under the "Business portion" of the Smart Sectors event, CropLife America would like to volunteer the following issue for discussion with Mr. Wheeler. We hope to see the EPA be more proactive in supporting international markets for US products in small but very effective ways. Instead we are hearing that international activities are being "deprioritized." We'd love to discuss this in more detail with your staff. For example:

1. Our industry exports crop protection products to countries around the world. Many of those countries require a certificate of origin from EPA to confirm that the product indeed comes from the US. This helps those countries fight traffic in counterfeit, substandard, potentially dangerous products from unregulated sources. EPA discontinued issuing such certificates, and there is no good substitute. Exports have become much more problematic.
2. Also, research conducted in the US supports the registration of crop protection products in countries around the world. Those countries rely on statements from EPA that the studies are indeed conducted according to internationally recognized Good Laboratory Practices. EPA has told some of our member companies that they intend to discontinue such statements. This could seriously disrupt regulatory support for US crop protection products in those countries.

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From: Letendre, Daisy
Sent: Tuesday, September 18, 2018 2:41 PM
To: Letendre, Daisy <letendre.daisy@epa.gov>
Cc: Jackson, Ryan <jackson.ryan@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Smart Sectors Event w/ Administrator Wheeler

Smart Sector Partners –

On behalf of the U.S. Environmental Protection Agency's (EPA) Acting Administrator Andrew Wheeler, we would like to invite the principal of your organization – or his/her designee – to attend our second annual EPA Smart Sectors roundtable. This event marks one year of Smart Sectors' work, and Acting Administrator Wheeler would like to share with you successes from the last year, engage in meaningful dialogue about agency priorities, and discuss environmental improvements across manufacturing sectors.

WHO: EPA Acting Administrator Andrew Wheeler and EPA's Smart Sectors Program Partners
Attendees may bring an additional representative.
WHAT: A roundtable meeting highlighting Smart Sectors Program successes and open discussion
WHEN: Tuesday, October 2, 2018 at 11:00AM
WHERE: U.S. EPA Headquarters – Rachel Carson Green Room
RSVP BY: September 27, 2018 to Letendre.Daisy@epa.gov

SCHEDULE
10:30 – 11:00AM
Coffee and Conversation

Open Press
11:00AM
Remarks from Acting Administrator Wheeler

Closed Press
11:20AM – Business Portion of Meeting*

12:00PM – Meeting Wraps

We will be following up with many of you individually in order to inform the business portion of the meeting.

Daisy C. Letendre
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