

October 6, 2010

Ms. Cynthia Smith
Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20585

Dear Ms. Smith:

Thank you for taking the time to meet with BIO members on September 8. The information that you and Mike Gregoire provided was very informative.

As we mentioned to you and Mike at that meeting, BIO's member companies are very concerned about their ability to comply with APHIS's August 4, 2010, requirements for submitting planting reports for field trials conducted under notification. In particular, the time provided for submitting an accurate planting report is insufficient, especially during peak planting times, and the 35 days between BRS's announcement and policy implementation does not allow enough time to make the necessary changes to computer systems.

At the September 8 meeting, as well as in prior and subsequent conversations with BRS staff, BIO requested a delay in the September 10 implementation of the August 4 revisions to the *BRS User's Guide for Notification*. Our member companies need an opportunity to work with BRS to develop a reporting schedule that would consistently provide USDA with planting information that is both timely and accurate. Unfortunately, our request for a delay was not granted. As a result, the current notification schedule likely means companies will need to choose between timeliness and accuracy for some reports, leading to compliance infractions and increasing the workload of BRS staff. In this letter, we propose an alternative that will ensure reports submitted throughout the year are timely and accurate.

To provide some background, in a November 9, 2009, memorandum, BRS announced a significant shift in its policy: monthly planting reports for field tests conducted under notification, which BIO members had been submitting voluntarily, would be mandatory as of January 31, 2010. The memorandum also outlined compliance infractions and enforcement activities for late, missing and inaccurate reports. Our members concluded that, given the amount of time provided by the new reporting requirements, compliance infractions would likely occur. They also knew that November 9 – January 31 did not provide sufficient time for making



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the changes in their computer systems necessitated by the new policy.¹ These potential compliance problems led BIO to ask for a delay in policy implementation and an in-person meeting with Tom Sim, and other appropriate staff.

BRS graciously accommodated our request for a delay, and staff members met with our Compliance Task Force on April 22, 2010, so that the companies could explain their primary concerns:

- The new requirement to submit reports 28 days after the planting start date does not provide enough time to ensure accuracy.
- The clarity provided by a set reporting date, rather than a rolling date, is more compatible with the software that companies use for collecting and organizing field trial data and scheduling report submissions.
- Companies need 6-12 months notice if any policy change necessitates a change in their computer systems, because they rely on sophisticated, company-specific computer software to collect, maintain, collate, handle and analyze the data submitted to BRS.

BIO and its members greatly appreciate BRS's past willingness to work with us, listen to our concerns, and attempt to respond to our requests. However, the August 4 draft of the *User's Guide* exacerbated two of the three problems companies described at the April 22 meeting and in a subsequent proposal submitted to BRS on behalf of our member companies (Attachment).

- According to the current *User's Guide*, information for a planting initiated March 30 must be provided in an April 15 planting report: providing only 15 days for submission, which is significantly fewer than the 28 days companies previously said was insufficient. Because initiation of planting is the trigger for determining a report's due date, a planting begun on March 30, stopped due to weather, and ended on April 14 must be submitted on April 15. The unrealistic deadline may well mean the planting reports are timely, but inaccurate. There are many variables to consider when determining a realistic deadline, including the time needed for field staff to submit the planting dates. Most companies provide 7-14 days just for the planting dates to be entered into their internal databases. This alone consumes a significant portion of the 15 days between a late month planting and the 15th of the month deadline.
- The 83 days between the November 9 announcement and implementation on January 31, which companies explained was not enough time to make requisite changes in data reporting software, was decreased to 35 days (August 4 – September 10). Because of the ongoing dialogue with BRS to identify an appropriate resolution, companies did not begin instituting computer changes in November.

¹ This is unrelated to the operation of the BRS ePermits system; it relates solely to a company's capacity to provide accurate information in a format that is more useful to BRS than data that are not collated and verified.

We recognize that this policy change was triggered by a recommendation in an audit report from USDA's Office of Inspector General: "Revise regulations to require all permit and notification holders to submit planting notices, 4-week/28-day reports..." The auditors may not have understood that a 28-day reporting requirement is workable for the number of field trials done under permits, but not for the thousands done under notification, when compliance managers and field site supervisors are attempting to balance many competing priorities while ensuring compliance with BRS's performance standards. They also may not appreciate the role weather plays in determining what companies can do and when they can do it, and the difficulty of complying with rigid timeframes when biological organisms are involved.

BIO and its members want to work with APHIS to develop a reporting system that is responsive to the auditor's recommendation. To be effective, that system must take into account not only the realities of agriculture and the regulated community, but also the constraints under which BRS is operating. After reviewing the notes from our meetings and conversations with BRS staff, discussing the information BRS staff provided in the August 19 Q&A session, and analyzing the details of the August 4 revision to the *User's Guide*, BIO proposes an alternative for the timing of submission of the planting reports that we believe should be acceptable to BRS.

According to the current version of the *User's Guide*, plantings that occur from April 1-April 30 must be reported by May 15. Therefore, according to BRS, the maximum amount of time that can elapse between planting initiation and reporting is 45 days. BRS staff mentioned this 45-day limit a number of times in the Q&A session. Therefore, we propose the following language in place of the requirement to report plantings on the 15th of the month: "A planting report must be submitted within 45 days of the planting start date."

Each company will decide how best to comply with this requirement. The scenario that companies spent most time discussing is one in which a company submits planting reports twice monthly, on the 15th and 30th. Not only will this reporting scheme be workable and compatible with our members' computer systems, it should also lessen the likelihood of a flood of reports arriving at BRS at the same time.

Our member companies recognize 45 days is the *maximum* allowable time and will make every effort to provide planting reports in advance of 45 days. The option of submitting some reports on the 30th of the month that follows planting initiation solves the problem of insufficient time during the peak season for reporting plantings that begin the last week of a month, as well as those that start at the end of one month but are not completed until the following month.

In addition to suggesting a change regarding the 15th of the month reporting requirement, our member companies also request the following changes to the current *User's Guide*.

- Replace the rigid requirement of providing the GPS coordinate of the field site's northwest corner with a requirement for a GPS coordinate within 100 feet of the field test site. Companies have already programmed their systems to provide GPS coordinates previously requested by BRS. Our companies know of no instance in which the existing

system made it difficult for an inspector to locate a field test. The flexibility in the language proposed above also accounts for the variability in GPS measurements between GPS devices and the number of satellites available at any one time.

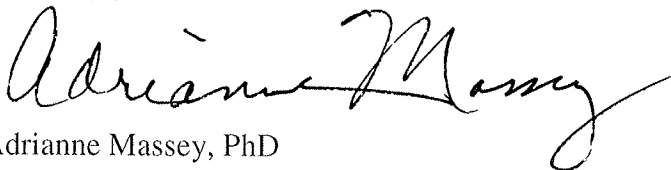
- The requirement to have all material removed from the field by the expiration date does not take into account the lack of predictability inherent in working with biological organisms under natural conditions. We ask that BRS change the current guidance to allow collection of field tests results and associated regulatory data if these extend beyond the expiration date of the acknowledged notification.
- In the future, please announce the details of a policy change at least six months before implementation if the change requires significant reprogramming of computer systems. It will remain very helpful if BRS is able to consult with BIO members before the implementation of any policy changes so that both parties may fully understand the implications to the agency and the regulated community.

The original intent of the notification process was to streamline the approval process for crops that pose negligible, if any, plant pest, human or animal health, or environmental risks. Mandating additional reporting requirements for crops grown under notification negates the reason APHIS developed the notification process. In addition, regulatory requirements that present an excessive administrative burden for companies and BRS staff, while offering no concomitant increase in safety, may satisfy the auditor's request but, we believe, do more harm than good.

As you know, BIO and its members have always supported a rigorous, science-based regulatory program that includes an adequate risk assessment for all field trials, inspections and emergency management capabilities. Our companies are rightfully proud of their long history of consistent compliance with APHIS requirements. We do not want to see our compliance history tainted by an inability to meet unrealistic deadlines, especially when missing the deadline will very likely have no adverse impact on the environment, human health or agriculture.

Thank you for your consideration, and we welcome the opportunity to discuss these concerns further, if needed.

Sincerely yours,



Adrienne Massey, PhD
Managing Director, Science and Regulatory Affairs

Attachment

cc: Michael Gregoire
Tom Sim

BIO Compliance Task Force Response to BRS Planting Notifications Proposal

Background

BIO appreciates the openness at the April 22 briefing on BRS's proposed changes to planting notifications. As promised, we have been working to provide constructive comments that will address the shared goal of a timely, accurate planting notification system.

As we mentioned in the April 22 meeting, requiring submission of planting notifications within 28 days after initiation of planting may not be feasible and would reduce the ability of regulated entities to provide BRS with substantive and accurate information.

As part of BIO's analysis seeking to create a reporting framework that meets both BRS needs and the realities of the regulated community, we noticed some inconsistencies in the BRS proposed reporting framework, specifically around "due dates". The information provided during the April 22nd meeting would suggest that planting information is required within 28 days after initiation of planting (i.e., information provided 29 days after planting would be considered late). However, information provided in the Agency's November 9, 2009 Memorandum entitled "Clarification Regarding Notification Planting Reports" suggests the information can be provided later than 28 days after the initiation of planting without any penalties ("(p)lanting information must be provided in a written report no later than the end of the month following the month in which the planting has occurred.")

BIO Proposal

In an effort to meet the intention of the proposed 28-day planting report, but maintaining the flexibility outlined in the November 9, 2009 Memorandum, BIO members propose submitting monthly planting reports (submitted at the end of each month) that include available planting information for the month in which the report is submitted and any planting information not reported the previous month. The following example outlines the framework for a monthly planting notification:

If Planting begins on May 17:

- May Planting Report (submitted no later than May 31) would include:
 - All plantings that were initiated and completed in May that may feasibly and accurately be included in the May report.
 - All plantings that were initiated and completed from April 1 through April 30 that were not included in the April Planting Report.

- If May 17 planting cannot feasibly be included in May Report, the information will be provided in June Planting Report (submitted no later than June 30) and considered by the agency to be on time.

The monthly planting report would provide BRS with information for plantings initiated that month, but, consistent with the November 2009 BRS Memo, does not penalize biotechnology notification holders if some planting information is provided in the next month's planting report. We believe this would allow for BRS to collect timely information but still ensure the integrity of information submitted to the agency.