Message

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Sent: 7/19/2018 5:36:55 PM
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Subject: Follow up to our meeting this past Tuesday
Attachments: ATT00001.txt; Triazine Network Scientist Comments Oct 2016- EPA-HQ-OPP-2013-0266-1035.pdf

Charlotte and Nancy -

Gary is traveling but he and I wanted to reach out post our meeting on Tuesday.

Thank you very much for the opportunity to visit with both of you and your other staff earlier this week. The Triazine Network seeks a fair, science-based outcome to the registration review for Triazines. We hope this meeting helped bring you up to date on the network and the current status of the issue.

As was requested in the meeting, we have attached our comments to the docket on the issue we raised about the aquatic community Level of Concern (LOC). Our comments and the scientific study we commissioned on the issue we believe clearly shows the current proposed LOC is way out of line from what the science says.

If the agency had followed the recommendations from several of its own previous SAP's, clearly EPA's own data would reach a similar conclusion to those from our scientist in the comments .

Please know this is an important issue to the entire Network and the farmers across the US who we represent. We value our relationship with EPA and will continue to stay engaged on this issue moving forward.

If you have any further questions, please let us know. Again, thank you for the opportunity to meet and discuss this extremely important issue.

Sincerely,

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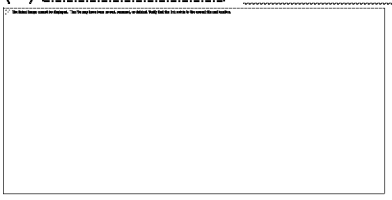

TITLE

Review of EPA's Preliminary Ecological Risk Assessment for Atrazine

TEST GUIDELINE

N/A

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COMPLETION DATE

10/04/2016

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REVIEW OF EPA'S ECOLOGICAL RISK ASSESSMENT FOR ATRAZINE

FINAL REPORT

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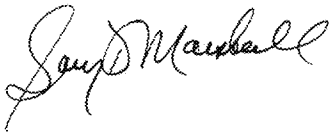

Gary Marshall
Chair
Triazine Network

October 4, 2016

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This report is a Review of EPA's Ecological Risk Assessment for Atrazine and is consistent with the requirements of FIFRA. As such, it is not required to comply with 40CFR Part 160.

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EXECUTIVE SUMMARY

Atrazine is a selective triazine herbicide used for pre-emergent control of many broadleaf and grass weeds in corn, sorghum, sugarcane, and other row and field crops. The United States Environmental Protection Agency (EPA) recently released a draft ecological risk assessment (ERA) for atrazine as part of the registration review process. The draft ERA was overly conservative and contained numerous scientific deficiencies. At the request of the Triazine Network, we reviewed and critiqued the methods and assumptions used in the ERA.

The main issues pertained to data quality and selection, errors, hyper-conservative assumptions, inadequate consideration of the best available science, and the procedures used to calculate the level of concern (LOC) for aquatic plants. In several instances, EPA (2016a) ignored the advice and recommendations provided by five separate Scientific Advisory Panels (SAP). The main issues of the report are summarized below:

- The interpretation of the monitoring data contained a number of shortcomings. Most importantly, a very large dataset currently exists that targeted the most vulnerable watersheds and high use areas. This dataset, the Atrazine Ecological Monitoring Program (AEMP), is a targeted monitoring program required by EPA with daily or near-daily samples and minimal uncertainty of missing peaks. However, EPA (2016a) opted to include a far broader range of available datasets, despite low sampling frequencies, errors, and other issues (e.g., high detection limits). In their interpretation of the data, EPA (2016a) did not account for errors in reporting, duplicate entries, infilling errors for periods when samples were not available, and use of non-detect samples with levels of detection much higher than their proposed LOC.
- EPA (2016a) also used highly conservative modeling to estimate aquatic exposure concentrations. Modeled exposure concentrations were as much as 260-fold higher than corresponding monitoring data.
- Despite the advice and recommendations of SAPs (2009, 2012) and other independent data reviews (Giddings, 2012; Moore et al., 2015, 2016), EPA (2016a) used low quality endpoints that were not scientifically defensible. EPA (2016a) established an LOC for aquatic plants of 3.4 µg/L despite evidence showing no significant effects at concentrations less than 30 µg/L when acceptable studies only are considered. Therefore, EPA's LOC is an order of magnitude lower than the lowest reliable effects concentrations and is overly conservative.
- The effects metrics selected by EPA (2016a) often did not represent the best available data. For example, EPA (2016a) used a flawed (as noted in its own data evaluation record; Bryan et al., 2014) Japanese medaka chronic exposure study (Papoulias et al., 2014) to generate chronic effects metrics for both freshwater and marine fish. This study had a number of limitations including no true negative control, high female to male ratio, low fecundity, and high control mortality. As a result, an updated medaka study was submitted by Syngenta that followed standard testing guidelines and had improved methods (Schneider et al., 2015). This study was available at the time the ERA was being drafted and was more appropriate for use. In addition, a marine fish study was available for atrazine (Cafarella, 2005 [MRID 46648203]). No scientific justification was provided for using a freshwater fish study to interpret risks to marine fish, particularly given the availability of a high-quality marine study.

- To estimate risks to aquatic-phase amphibians, EPA (2016a) ignored previous conclusions of no effects and instead relied on a large dataset primarily comprised of very low quality data where effects were often not observed. Conclusions drawn from that dataset are highly uncertain and likely inaccurate.
- The screening-level wildlife assessment relied on highly conservative assumptions, including wildlife obtaining 100% of their diet from treated fields, wildlife having homogeneous diets several of which are implausible (e.g., 20 g birds foraging only on short grass or broadleaf foliage), outdated food ingestion rate calculations, default body weights that were not representative of the study animals, and a default foliar degradation half-life that was two times higher than the longest half-life observed in the field for atrazine.
- The refined avian assessment also had a number of shortcomings and, further, was not extended to mammals, despite findings of potential risk in the screening-level assessment. For birds, the dermal exposure calculations relied on data for other far more toxic pesticide classes and likely greatly over-estimated the contribution of dermal exposure. EPA (2016a) also opted for worst-case values in determining fraction of time spent on fields and fraction of pesticide retained, rather than using best available data for atrazine.

The above and other issues led to overestimates of acute and chronic risks of atrazine to aquatic and terrestrial biota. In this report, we have made a number of recommendations that would improve EPA's ecological risk assessment for atrazine.

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1.0 INTRODUCTION

Atrazine is a selective triazine herbicide. It was first registered by the United States Department of Agriculture (USDA) in 1958 (SAP, 2012) and is currently used extensively in the United States for pre-emergent control of many broadleaf and grass weeds in corn, sorghum, sugarcane, and other row and field crops, including Christmas tree plantations and conifer forests. Atrazine is applied to over 90% of corn crops in the US and 65% of sorghum and sugarcane crops (EPA, 2016a).

The Environmental Protection Agency (EPA, 2016a) recently released a Preliminary Ecological Risk Assessment for Atrazine. EPA focused their assessment on the parent compound, as degradates have equal or lesser toxicity to terrestrial and aquatic receptors (EPA, 2016a). EPA's standard toolbox of conservative models was used, including the Surface Water Concentration Calculator (SWCC) for aquatic exposure analysis, T-REX, TIM, MCnest, and AEMP monitoring data.

EPA concluded that risks to aquatic and flowering plant communities in heavy use areas are likely and chronic risks to fish, aquatic-phase amphibians and aquatic invertebrates are also likely in high use areas. Risks to birds and mammals are primarily related to chronic exposure.

The Triazine Network retained Intrinsik Environmental Sciences (US), Inc. (Intrinsik) to review and evaluate the preliminary atrazine ERA. The Triazine Network is concerned with a number of effects metrics relied on by EPA (2016a), exposure methods used, and procedures used to calculate the level of concern for aquatic plants. In addition, EPA (2016a) ignored much of the advice and recommendations provided by five separate Scientific Advisory Panels (SAP). The SAPs were comprised of members picked by EPA and were developed to provide expert guidance to EPA on atrazine issues.

Five meetings of SAP members have evaluated the available data for atrazine and offered recommendations and provided direction to EPA to improve future assessments (SAP, 2003, 2007, 2009, 2011, 2012). The SAPs focused on data quality and use of best available methods for estimating risk. Discussion points included the evaluation process for identifying high quality data, the potential for gonadal effects on larval amphibians from atrazine exposure, developing benchmark water quality criteria that are protective of aquatic plants, and initiation of a water monitoring program. The SAPs have identified a number of concerns with EPA's methods for developing a community-level level of concern (LOC) for aquatic plants. The SAPs highlighted incorrect scoring of effects data, use of low quality, unacceptable studies, and poor methods for derivation of the LOC. The SAPs also offered recommendations for improvements to future LOC estimations. However, EPA (2016a) failed to acknowledge most of the recommendations and used poor data and methods to calculate an LOC. A detailed evaluation of the current LOC proposed by EPA (2016a) is presented in this report.

The Triazine Network has also taken issue with the data and methods used in the preliminary ERA (EPA, 2016a) to generate risk conclusions for aquatic and terrestrial receptors. For example, EPA (2016a) used outdated effects metrics for fish and terrestrial plants, when new studies have been performed using current products and improved methods. Similar patterns were noted in the derivation of avian and mammalian effects metrics, and the reliance on invalid study data for aquatic-phase amphibians.

The purpose of this report is to highlight the areas where improvements are needed in the ERA for atrazine.

2.0 AQUATIC RECEPTORS

2.1 Monitoring Data

Since 2004, EPA has overseen the conduct of an extensive monitoring program known as the Atrazine Ecological Monitoring Program (AEMP) in corn and sorghum growing areas and, for a time, in sugarcane growing areas. The program has targeted the most vulnerable watersheds in areas of high atrazine use with daily or near daily sampling of atrazine concentrations. There have also been a large number of monitoring studies conducted for atrazine outside of the AEMP. Many non-AEMP monitoring datasets had low sampling frequencies that prevented an understanding of daily variation in atrazine concentrations. To deal with this deficiency, data infilling was used by EPA (2016a) to create daily chemographs. Incorrect infilling, however, created many errors, particularly in those datasets that had the minimum required sample size of 4 but had less than 12 samples per year and in datasets with no samples for large portions of the year prior to initial sampling. Concerns identified in the interpretation of the monitoring data are reviewed below:

- In each monitoring dataset, EPA projected the first sampling date back to January 1. In cases where the first sampling date also represented the peak concentration (i.e., maximum concentration observed over an entire year), it was assumed that the peak concentration was achieved for the entire time period between January 1 and the first sampling date. When more than 60 days spanned the infilling period, the extrapolation resulted in a 60-day average concentration equal to the peak daily concentration. However, daily monitoring data (e.g., as in the AEMP) indicate that atrazine concentrations rapidly decrease after an initial peak corresponding to the application date(s). Therefore, a 60-day average concentration would and should be much less than the peak concentration observed.
- When only one data point was available for a 60-day period, EPA (2016a) used this single data point to calculate a maximum 60-day average. Again, this resulted in a 60-day average concentration that equaled the peak concentration. This error occurred in 53% of datasets with four to 11 samples per year.
- Extensive data quality errors were identified in the monitoring database used in the ERA.
    - EPA (2016a) incorporated 9,899 duplicates in 42,941 site years of data. Therefore, 23% of the data points used by EPA in their analyses represented duplicate samples. Duplicate occurrences were not removed by EPA prior to their analyses.
    - Duplicate samples have identical latitude and longitude coordinates, and sample time and date stamps. Thus, removal of the duplicate samples should have been an easy exercise.
- EPA (2016a) retained data samples that had levels of detection (LOD) many-fold higher than the level of concern (LOC) that would be protective of aquatic plants as estimated by EPA (2016a).
    - For samples below the level of detection (LOD), EPA (2016a) assigned a concentration of half the LOD to those samples. In one monitoring dataset, the LOD was 100 μg/L (ppb). Samples with concentrations below this LOD were automatically reported as 50 μg/L in the ERA, well above EPA's LOC of 3.4 μg/L. As a result, EPA (2016a) assumed that locations with concentrations reported as

50 µg/L were at risk from atrazine exposure even though atrazine was not detected at these locations.
    - Atrazine monitoring programs routinely have levels of detection of <0.1 µg/L. Clearly, datasets with levels of detection that are 4 or more orders of magnitude higher than routine levels of detection should have been excluded from EPA's analysis of available monitoring data. Such datasets are of unacceptable scientific quality.
- Errors in reporting analytical units.
    - Samples with known unit reporting errors were found in EPA's draft ecological risk assessment for atrazine. For example, samples originally reported as ng/L were erroneously cited in EPA's assessment with the same numeric value but in units of µg/L.

EPA should have relied solely on the AEMP in its analysis of available monitoring data. The AEMP is a targeted monitoring program required by EPA in their 2003 interim registration document for atrazine. The program was designed to sample the most vulnerable agricultural headwater drainage basins in the Midwestern and southern United States with the highest atrazine use. The 70 selected watersheds represent the top 20th percentile for vulnerability to runoff as predicted by EPA's watershed regressions model for pesticides (WARP). The AEMP database contains samples from daily or near-daily sampling efforts between 2004 and 2015. The program has determined worst-case exposure with minimal uncertainty of missing peak concentrations because of the daily frequency of sampling over multiple years.

2.2 Aquatic Exposure Modeling

Despite the availability of the comprehensive AEMP dataset for atrazine (i.e., 288 site-years of daily or nearly daily data from 70 most vulnerable watersheds between 2004 and 2015), EPA (2016a) used their Surface Water Concentration Calculator (SWCC) model to predict atrazine concentrations for a variety of regions and use patterns. According to EPA (2016a), the SWCC model scenarios are intended to be conservative and represent the 90th percentile most vulnerable sites for first-order streams and static water bodies adjacent to atrazine use areas.

However, the SWCC significantly over-predicted the 1-in-10-year peak daily and 60-day average concentrations from all available monitoring data by as much as 260-fold. In considering the most vulnerable watershed sampled in the AEMP, the SWCC over-predicted 1-in-10-year peak daily and 60-day average concentrations by 12-fold.

EPA's SWCC and other screening-level models should not be used to make regulatory decisions. Adequate, targeted monitoring data exist that can be used to support atrazine use. To evaluate specific use patterns, EPA should consider using more refined watershed models such as the Soil Water Assessment Tool (SWAT).

EPA's standard screening-level models are not designed to identify the specific geographical locations where atrazine might truly pose a risk to aquatic organisms, a seemingly more useful approach for decision making. Refined watershed level modeling is a superior approach for such assessments because it provides exposure predictions at a fine geographical resolution with the ability to simultaneously simulate varying site-specific weather, soil, environmental, and cropping conditions within a watershed. Watershed modeling also simulates variation in pesticide application timing, and proximity of treated fields to surface water bodies and riparian

areas. Moreover, watershed level modeling simulates flowing and non-flowing water bodies as well as site-specific hydrologic conditions, water body depths and water body geometries. Examples of available watershed models that could have been used in the atrazine risk assessment include the SWAT, the Agricultural Policy EXtension (APEX) model, the Hydrologic Simulation Program-Fortran (HSPF) model and the Pesticide Root Zone Model – RIVerine Water Quality (PRZM-RIVWQ) model. All of these models, particularly the SWAT model, have undergone validation testing and have been shown to perform well.

Details on the aquatic exposure modeling effort are further discussed in a response document prepared by Waterborne on behalf of Syngenta that was submitted to the docket in October, 2016.

2.3 Derivation of a Level of Concern

As an herbicide, plants are expected to be more sensitive to atrazine than other receptor groups. Therefore, to ensure that atrazine concentrations in watersheds will not cause ecologically-significant effects to aquatic plant communities, EPA (2016a) developed a community-level level of concern (LOC). The LOC was compared to monitoring data to determine which watersheds have atrazine concentrations that could cause adverse effects to aquatic plants. Although the LOC was designed to be protective of aquatic plants communities, it's conservative nature was expected to also make it protective of other receptor communities (e.g., fish, invertebrates), which are less sensitive to atrazine exposure.

In the last several years, EPA has made multiple attempts to define a level of concern for community-level effects of atrazine to aquatic plants. Except for the most recent LOC of 3.4 μg/L in the draft EPA (2016a) assessment, the proposed LOCs have been thoroughly reviewed by EPA's own Scientific Advisory Panels (SAP, 2007, 2009, 2012). Notably, none of EPA's proposed LOCs have been formally accepted or endorsed. In fact, the latest SAP (2012) review strongly recommended increasing the proposed LOC of 4-7 μg/L (EPA, 2007) because many of the mesocosm studies purportedly showing effects at low concentrations were either of unacceptable quality or did not actually cause effects of ecological significance. In its draft assessment, however, EPA (2016a) ignored the advice of the SAP (2012) and the recommendations of other reviewers (e.g., Giddings, 2012; Moore et al., 2015, 2016) by continuing to use poor quality mesocosm study results to derive the lowest LOC that has been proposed to date. In the sections that follow, we comment on two major aspects of EPA's development of an LOC for atrazine, i.e., data selection and method of derivation.

2.3.1 Data Selection

The evaluation of available cosm studies and scoring of results are critical to the calculation of the level of concern (SAP, 2012). EPA (2016a) performed a preliminary screen to reject studies that evaluated mixtures or multi-active ingredients, studies that did not report exposure concentrations, studies that did not evaluate an aquatic plant community, and studies not presented in English. Studies meeting the preliminary criteria were further evaluated and rated as invalid if they did not contain basic elements, including use of controls and at least two replicates per treatment group (EPA, 2016a).

The SAP (2012) recommended evaluating cosm studies using a standard set of scoring criteria. The SAP (2009, 2012) also recommended that EPA re-evaluate and re-score all cosm studies

where effects were observed at concentrations less than 30 µg/L because of weaknesses in study design and data interpretation (see also Giddings, 2012). The SAP (2012) identified a number of studies that were incorrectly scored by EPA as having effects when in fact, no effects were observed during the studies or the studies were clearly of poor quality. Further, the SAP (2012) requested that the LOC be recalculated once the studies were re-scored.

In particular, the SAP (2012) recommended that 11 studies be re-evaluated. Those studies were re-evaluated by EPA (2016a), Giddings (2012) and Moore et al. (2015, 2016). Additional studies published since the SAP (2012) report were also evaluated. The results of the various evaluations are summarized below.

Lampert et al., 1989 [MRID 47543511]

Lampert et al. (1989) performed enclosure experiments with a natural plankton community. The communities were housed in plastic bags suspended in Lake Schohsee in northern West Germany. Bags were 1 meter by 2.70 meters in size and contained 1.70 m^3 of water. Bags were filled with lake water screened with 100 µm mesh then inoculated with zooplankton collected with a plankton net. Two bags per concentration were treated with atrazine dissolved in ethanol at concentrations of 0.1, 1, 10, and 100 µg/L and two bags were left untreated. The experiment lasted "no longer than three weeks". More than 90% of applied atrazine was measured 18 days post-application at concentrations of 1 µg/L and higher, but atrazine was not detected after 10 days in the 0.1 µg/L treatment. Similar results were found for all treatments. However, the study authors proposed an effect concentration of 1 µg/L and a NOEC of 0.1 µg/L.

EPA (2008) developed a Data Evaluation Record (DER) for Lampert et al. (1989). The DER highlighted the incomplete study design and lack of description of protocols. The DER critiqued the two replicate study design and lack of statistical analysis. Further, the DER notes that the bag enclosures may have inhibited mixing and recolonization, thus limiting their applicability to the natural environment. The DER concluded that the experiment did "not provide a realistic simulation of environmental conditions". The DER concluded that the study had extremely limited utility and should only be applied within the weight of evidence when conducting a risk assessment (EPA, 2008).

The SAP (2009, 2012) recommended excluding this study because the solvent used to deliver the atrazine likely caused a shift from an algal-dominant community to a bacteria-dominant community. Specifically, the use of high concentrations of ethanol increased bacterial growth and respiration in the enclosures, which led to decreased primary productivity. Further, ethanol was added to treatment enclosures, but not to controls, which prevented comparison of treatment-related effects.

Giddings (2012) also rejected the Lampert et al. (1989) study because of the solvent issue. Effects were first observed seven days after treatment, which is not consistent with atrazine's mode of action, where effects to productivity occur quickly. In addition, the study design did not include solvent controls to rule out solvent-related effects. Giddings (2012) went on to quote Brock et al. (2000), where it was stated that the Lampert et al. (1989) study is a prime example of "sometimes enormous effects" of ethanol on dissolved oxygen concentrations and other cosm properties.

Moore et al. (2015, 2016) rejected the study because of the solvent issue, no recovery period was included, and the low dissolved oxygen concentrations likely contributed to the observed

delayed effects. Additionally, the description of the study methodology was sparse, statistics were not reported, there was limited control and treatment replication, values of most physical-chemical properties (e.g., water temperature, air temperature, water pH, and conductivity) were not reported, and the study was not conducted following any international guidelines. No clear treatment-related effects were observed during the study.

Despite the extensive support for excluding the study, EPA (2016a) retained this study, asserting that the applied ethanol would have adequately vaporized and biodegraded, and thus was not responsible for observed effects on primary productivity. EPA (2016a) reclassified the endpoint as "effect", and actually lowered the effect level to 0.1 µg/L. However, given the reasoning above and the very poor study quality, this study should be rejected from use. Further, no treatment-related effects were observed at any test concentration (0.1 to 100 µg/L), and no effect level should have been designated.

deNoyelles et al., 1982

deNoyelles et al. (1982) treated experimental ponds with 20 or 500 µg/L of atrazine (CO-OP liquid, 41% a.i.). Two ponds per treatment concentration and two control ponds were maintained for 136 days. Ponds were 0.045 ha (0.11 acres) in size and filled with water and plankton from a nearby well, 50 bluegill sunfish (predator), 20 channel catfish (benthic omnivore), and seven gizzard shad (filtering omnivore). The authors reported that phytoplankton growth was depressed in all treatment ponds, followed by changes in species composition.

EPA (2009a) evaluated deNoyelles et al. (1982) for study quality, design and relevance of conclusions. EPA (2009a) was critical of the lack of statistical analyses reported by the study authors for some data comparisons. EPA (2009a) also criticized the limited replication (n = 2) and limited number of test concentrations (n = 2), "unclear presentation of results", and lack of pre-test analytical analyses of test solutions to confirm no presence of residual atrazine. Additionally, aquatic communities were not evaluated to confirm similarities among ponds. EPA (2009a) determined that data from deNoyelles et al. (1982) should be applied qualitatively only.

The SAP (2012) was critical of the effects level estimated by deNoyelles et al. (1982). Although minor effects on biomass and ^{14}C uptake in phytoplankton were observed at 20 µg/L, the confidence intervals overlapped with control levels. Additionally, survival of gizzard shad was not measured and differential survival among treatments may have caused the observed effects on biomass. Thus, the SAP (2012) concluded that the treatment level of 20 µg/L should be categorized as "no effect".

Giddings (2012) re-evaluated the raw data presented by deNoyelles et al. (1982) and Kettle (1987). Giddings (2012) found that only one of two control cosms demonstrated an algal bloom and phytoplankton biomass in one control pond was lower than the 20 µg/L treatment ponds. Re-analysis of the data found no significant difference between control and 20 µg/L treatment ponds. Therefore, 20 µg/L should not be designated as the effect level.

Moore et al. (2015, 2016) rejected the study because there was no recovery phase (70% of original concentration detected at Day 136), study methodology was not adequately described, a concentration-response relationship could not be determined because there were only two treatment concentrations, there was inconsistent shad and carp survival between controls, replication was limited (n = 2), no statistically significant responses were detected shortly after exposure began, and the study did not follow any internationally-recognized guidelines.

EPA (2016a) re-classified this endpoint at 20 µg/L as an "effect". Therefore, EPA (2016a) incorrectly scored this unacceptable study as having an effect at 20 µg/L and used the endpoint in their calculation of an LOC.

deNoyelles et al., 1989

deNoyelles et al. (1989) simulated exposure of pond communities to atrazine. Ponds were 0.04 ha in size and located at the University of Kansas Nelson Environmental Study Area near Lawrence, KS. Ponds were filled with well water and left undisturbed for one year to establish benthic plant and animal communities. Prior to test initiation, ponds were refilled with well water and stocked with gizzard shad (n = 10), channel catfish (n = 20) and bluegill sunfish (n = 50). After the first year, grass carp were also added (n = 4). Atrazine (reagent grade, 97% a.i. and CO-OP Liquid Atrazine, 41% a.i.) was applied once annually to the surface water of the ponds at concentrations of 20, 100, 200, and 500 µg a.i./L and ponds were observed for 805 days. Six and 12 months after each application, the concentration of atrazine had decreased to 70 and 25% of applied, respectively.

The authors reported that phytoplankton production and biomass were reduced compared to controls for all treatment levels, but recovered by three weeks. Zooplankton, a predatory planktonic insect (*Chaoborus*), channel catfish, and filter-feeding fish (gizzard shad) did not experience indirect effects to survival from a reduction in phytoplankton biomass. However, submerged and emergent macrophytes experienced significant declines in biomass and did not recover. Tadpoles, benthic insect grazers, grass carp, and bluegill sunfish experienced indirect effects as a result of the decline in macrophyte biomass. The authors assigned an effect concentration of 20 µg a.i./L.

The SAP (2009, 2012) was critical of the high stocking density of grass carp (30 fish/ha) and hypothesized that the high density of fish led to observed reductions in aquatic plant biomass. In fact, the SAP (2009, 2012) stated that the effect concentration of 20 µg/L was not treatment-related, but a result of carp grazing and should be re-categorized as "no effect". Additionally, no grass carp were present in one control replicate, which likely led to increased macrophyte biomass in that control replicate.

Criticisms by Giddings (2012) of the deNoyelles et al. (1982) study were also applicable to the deNoyelles et al. (1989) because one study was the extension of the other. High variability among replicates, particularly among control cosms, was of greatest concern. Giddings (2012) evaluated all study data and proposed "no effect" at 20 µg/L because the results were largely inconclusive.

Moore et al. (2015, 2016) rejected this study because there was no recovery phase (70% of original concentration after 6 months), sampling was only performed once during the first treatment year (or other sampling results were not reported), treatments occurred annually, there was no clear concentration-response relationship, timing of measured effects on macrophytes was not reported, and many study condition parameters were not reported.

EPA (2016a) combined the data from deNoyelles et al. (1982) and deNoyelles et al. (1989) to generate one effects endpoint (20 µg/L) for use in calculation of their LOC. However, given the high loading rate of grass carp, inconsistencies of results among control ponds, and study ratings of unacceptable, neither study produced a confident effect concentration and should not have been considered in the derivation of the LOC.

Carney and deNoyelles, 1986

This study was referred to in the main body of EPA's (2016a) draft risk assessment, but was referenced as Carney (1983) in the attachment EPA posted in the atrazine docket. The posted attachment, however, appears to be a document submitted in 2011, prior to the updates suggested by the SAP (2012). Carney (1983) is a master's thesis performed in the same laboratory (University of Kansas) as Carney and deNoyelles (1986). It is unclear how EPA (2016a) used the data from Carney and deNoyelles (1986) and/or Carney (1983) in the calculation of their LOC.

Carney (1983) investigated the effects of atrazine and grass carp on a freshwater macrophyte community. Atrazine (CO-OP liquid; 41% a.i.) was applied annually for two years to static ponds at concentrations of 20, 100, 200, and 500 µg/L. Measured concentrations were 69 to 104% of nominal at the second year of the study. In the first year of the study, there was no clear concentration-response relationship for macrophyte density, but some evidence for effects to community structure at 100 and 200 µg/L. In the second year of the study, there was an apparent concentration-response relationship for macrophyte density. The author reported that atrazine had significant effects on species composition within the macrophyte community, ultimately leading to a domination of Charophytes in the 100 µg/L pond. The author also observed declines in periphyton and emergent macrophyte biomass.

The SAP (2012) criticized the Carney and deNoyelles (1986) study because of the high stocking density of grass carp (20 carp/acre) and notable loss of fish in the control pond. According to the SAP (2012), common testing guidance recommends a stocking density of 2 fish per acre for grass carp to reduce effects from grazing carp. This is an order of magnitude fewer fish than stocked by Carney and deNoyelles (1986) and resulted in complete denudation of macrophytes from one control pond.

Giddings (2012) criticized the addition of grass carp in year two. In the first year of the study, no significant differences were found between control and 20 µg/L ponds. However, after addition of grass carp, differences were observed. In protected areas of the ponds, where no grass carp were permitted, no differences in macrophyte biomass were observed between the control and 20 µg/L treatment in any study year. Therefore, Giddings (2012) concluded that the effects concentration of 20 µg/L should be reclassified as "no effect".

Moore et al. (2015, 2016) rated the Carney (1983) study as not relevant because a recovery phase was not included (69-104% original concentration in second year of study). The study was also scored as unacceptable or supplemental because it only included two replicates, two to four exposure concentrations were evaluated, the study was not performed according to a recognized international guideline, sampling only occurred once in the first year and/or application dates were not provided, no concentration-response was observed during the first year, and there was potential for other stressors in the treated ponds.

Although it is unclear how EPA (2016a) used the Carney and deNoyelles (1986) and Carney (1983) data, we believe that EPA (2016a) maintained an effects concentration of 20 µg/L. However, the effects reported by the study authors at 20 µg/L are likely the result of compounding factors induced by the high stocking density of grass carp in the second year of the study and the lack of consistency among controls. Therefore, the effects concentration of 20 µg/L should be re-categorized as "no effect" or, better yet, completely excluded from the evaluation.

Dewey, 1986

In this study, atrazine was applied to 0.045 ha ponds at the University of Kansas Nelson Environmental Study Area at concentrations of 20, 100, and 500 µg/L. Ponds were stocked with bluegill, gizzard shad, channel catfish, and grass carp, as well as a natural aquatic plant and insect community present in the storage reservoir. Structure of the aquatic insect community was measured using partially submerged funnel emergence traps. The author noted a decrease in macrophyte production with increasing atrazine concentration, and an herbicide resistance of *Chara* sp. up to 100 µg/L. However, no statistical analyses of macrophyte biomass were reported. An effect level of 20 µg/L was estimated based on a significant reduction in emerging insects, insect abundance, and benthic insect species richness, none of which apply to aquatic plants.

The SAP (2012) rejected Dewey (1986) because the presence of high stocking densities of grass carp, gizzard shad, channel catfish, and bluegill likely contributed additional stress to the cosm system. No data on survival of fish were reported to confirm lack of compounding stress on aquatic plant community.

Giddings (2012) noted that the focus of the study was on insect emergence and bluegill reproduction endpoints, not effects on primary producers. Therefore, the study should not be used to calculate an LOC for an aquatic plant community.

Moore et al. (2015, 2016) rejected this study because statistically-significant direct effects on primary productivity were not reported. Further, the study was not conducted according to an internationally recognized guideline, survival of primary producers and fish in controls were not reported, there was high variability among controls, there were only two replicates, many study parameters were not measured and/or reported, and a clear concentration-response relationship for aquatic plants was not demonstrated.

Although it is unclear how EPA (2016a) used the data from Dewey (1986) in their calculation of an LOC, it appears that EPA (2016a) used an effects concentration of 20 µg/L. This effects concentration is inappropriate for use in determining an LOC for an aquatic plant community because it did not evaluate primary productivity, rather it evaluated the effects of atrazine on benthic invertebrates. This study should be rejected from use.

Kettle et al., 1987

Kettle et al. (1987) applied atrazine (CO-OP liquid, 40.8% a.i.) at concentrations of 20 or 500 µg/L to 0.045 ha ponds at the Nelson Environmental Study Area, Lawrence, KS. The ponds were stocked with 50 bluegill, 20 channel catfish, and seven gizzard shad obtained from local ponds and reservoirs. Approximately 70% of nominal concentrations were detected after 136 days. There were no significant differences in mortality of fish among treatments, and analysis of stomach contents of bluegill revealed significantly fewer prey items per stomach compared to bluegill in control ponds. Additionally, the number of retrieved bluegill young per pond was significantly reduced in treated ponds compared to control ponds. Visual observations revealed 60 and 90% declines in macrophyte biomass two months after application in the 20 and 500 µg/L ponds, respectively. No statistical analyses were performed on macrophyte biomass or primary productivity. The authors explicitly stated that the results from the plankton exposures were presented in deNoyelles et al. (1982) (discussed above), and the Kettle et al. (1987) study only presented results for macrophytes and bluegill populations. Moreover, Kettle et al. (1987)

propose an effect concentration for fish of 20 µg/L, but no effect concentration for aquatic plants.

The SAP (2009, 2012) criticized the high stocking densities of fish and the focus on fish survival, rather than effects on primary producers. The SAP (2012) also referenced deNoyelles et al. (1989), a related study that had zero grass carp survival in controls. It is apparent that the studies performed at the Nelson Environmental Study Area were performed in conjunction with one another and had the same flaws. Therefore, low grass carp survival in controls compared to treatment ponds would have positively impacted the availability of plant biomass in controls and negatively affected any comparisons made to control ponds.

Giddings (2012) rejected this study based on a lack of detail on study methods and lack of results for macrophytes. Giddings (2012) compared the Kettle et al. (1987) results to other studies performed at the Nelson Environmental Study Area and found inconsistencies in the results, with no effects at 20 µg/L reported by Carney (1983) and deNoyelles et al. (1982). Further, Carney (1983) and deNoyelles et al. (1982) referred to the macrophyte communities as "sparse" at the start of testing.

Finally, the study was rated not relevant by Moore et al. (2015, 2016) because it focused on fish instead of aquatic plants, there was no quantitative analysis of macrophyte abundance or species richness, and there was no recovery period (70% of original concentration detected at the end of the post-exposure period). The study was rated as unacceptable because it lacked information on study methods, community composition in controls was different from treatment cosms at test start, and the study did not demonstrate a concentration-response relationship for aquatic plants.

It is unclear how EPA (2016a) used data from Kettle et al. (1987) in the calculation of their LOC. However, based solely on the lack of quantitative analysis for primary producers, the data are inappropriate for use in determining a community-level LOC for aquatic plants. The study also lacks a number of crucial study details, and high stocking densities of fish coupled with inconsistencies in community composition among ponds at the start of the test make this study unacceptable for use in risk assessment.

Detenbeck et al., 1996

Detenbeck et al. (1996) treated wetland mesocosms with increasing concentrations of atrazine to simulate Midwestern surface waters during spring runoff. Experimental streams were located at the Monticello Ecological Research Station in Monticello, MN, and supplied with water from the Mississippi River. Flow-through wetland cosms were 230 m in length and contained four pools and four riffles. Stream flow was 76 L/min. Organic debris was allowed to accumulate over the gravel substrate and streams were populated through planting and natural succession. Two wetlands served as treatment cosms and two were controls. Commercial atrazine (AAtrex Nine-O; 85% a.i.) was dissolved in water and applied as a stepped exposure regime with four increasing concentrations; 15, 25, 50, and 75 µg/L. Stepped applications were made every two weeks (four weeks between 50 and 75 µg/L treatments). Periphyton biomass and production, macrophyte cover and growth rates, and growth and development of vertebrates were monitored throughout the study. Atrazine in control wetlands averaged 0.69 µg/L and likely originated from residues present in the Mississippi River. Atrazine concentrations in the outflow of treated wetlands were 78 to 96% of nominal. Resistance of atrazine by periphyton was observed in the 50 and 75 µg/L treatments. Gross productivity was significant reduced at 15

µg/L, and the depth of detritus was two times higher in control wetlands than treated wetlands. A significant reduction in respiration was observed in the 25 µg/L treatment, while a significant increase was observed in the 75 µg/L treatment. High variability in macrophyte biomass was found within treatments, but no significant effects were observed.

EPA (2009b) evaluated Detenbeck et al. (1996) and criticized the high levels of atrazine detected in control cosms (0.69 µg/L), the limited number of replicates (2 control and 2 treatments), and the high variability in results among treatments. These variables confound the ability to compare potential treatment-related effects to observations made in control cosms. In addition, the study used a very unconventional study design where exposure concentrations were increased in the same treatment cosms to simulate different concentration exposures over time. Therefore, it is unclear if measured concentrations represented peaks or averages. EPA (2009b) rated this study as qualitative and cautioned against use in risk assessments.

The SAP (2012) recommended excluding this study from consideration because the high accumulation of sediment and detritus would have put additional stress on the system and increased respiration rates. Although the authors stated that gross primary productivity (GPP) was impacted at 15 µg/L, the SAP (2012) questioned the validity of the results because no data were presented and GPP returned to control levels at higher concentrations. The SAP (2012) recommended that this study be excluded from consideration.

Giddings (2012) rejected this study because the exposure regime prevented a clear interpretation of concentration-response relationships. In fact, effects observed at low concentrations were not observed at higher concentrations, and treatment-related effects on periphyton and macrophytes were few. For example, effects on chlorophyll and dry weight were not observed, gross productivity was only reduced at 15 µg/L, and respiration was only reduced at 25 µg/L.

Moore et al. (2015, 2016) rejected this study primarily because of the unconventional study design. The two weeks between each stepped exposure were likely insufficient for full recovery of periphyton and macrophytes. Further, atrazine was detected in the control cosm (0.69 µg/L likely the result of agricultural runoff), control results were not reported, only two replicate cosms were employed, and measurements of residual atrazine in pore water and sediment due to stepped exposure were not reported.

EPA (2016a) used four effects endpoints from this study; 15 µg/L for gross productivity, 25 µg/L for respiration and net primary productivity, 50 µg/L for net primary productivity, and 79 µg/L (unclear if this is a nominal or measured concentration) for net primary productivity. However, there is a lack of evidence for a concentration-response relationship and critical failures in the design of the study and reporting of methods prevent confidence in the results. Further, this study has been highly criticized by EPA's own evaluation process (EPA, 2009b), a SAP (2012), Giddings (2012), and Moore et al. (2015, 2016). Therefore, this study should not be considered for use in the calculation of an LOC.

Kosinski, 1984; Kosinski and Merkle, 1984

Kosinski (1984) evaluated the effects of atrazine on species composition and standing crop of periphyton in artificial streams on the roof of a Texas A&M University campus building. The study was primarily designed to test resistance of the periphyton community. Recirculating artificial streams were treated with 0.1, 1, or 10 mg a.i./kg atrazine (Aatrex 80 WP; 100, 1000

and 10,000 µg a.i./L). Twice weekly, 15% of the stream volume was replaced with source water, including algae and nutrients. Half the test streams received an addition of 0.01 mg a.i./kg (10 µg a.i./L) atrazine at each water change to maintain chronic exposure concentrations and observe the potential for resistance. Colonization slides were maintained to measure changes in periphyton. Variability in biomass was high among and within streams. The authors reported significant reductions in primary productivity at 10 and 100 µg a.i./L.

The SAP (2009, 2012) rejected the effect endpoint of 10 µg a.i./L (0.01 mg a.i./kg) used by EPA (2003) and EPA (2016a) because no significant effects were found and there were insufficient data to assign effects at that level. The SAP (2009) highlighted the fact that the results were not supported by the tremendous amount of data available for atrazine. Instead, the SAP (2012) proposed an effect level of 100 µg a.i./L (0.1 mg a.i./kg). Kosinski and Merkle (1984) stated "there was little evidence that exposure to 0.01 mg a.i./kg herbicide during colonization modified the response of the algae to any of the herbicides".

Giddings (2012) also evaluated the data presented by Kosinski (1984) and Kosinski and Merkle (1984), finding that the results during the chronic exposure to 10 µg a.i./L were not consistent and significant effects never occurred on consecutive sampling days. Therefore, the effects at 10 µg/L were slight and transient, and Giddings (2012) proposed an effects score of "0", meaning no effect.

Moore et al. (2015, 2016) rated this study as relevant and supplemental. They also re-evaluated the study data and found a LOEC of 1000 µg a.i./L. Effects at 10 µg a.i./L were transient and only occurred at one sampling time, whereas no significant effects were observed at 100 µg a.i./L. Only at 1000 and 10,000 µg a.i./L were significant effects observed during consecutive sampling effects.

EPA (2016a) selected an effects concentration of 10 µg a.i./L for calculation of their LOC, but based on re-evaluation of the data by others (SAP, 2012; Giddings, 2012; Moore et al., 2015; 2016), a higher effects level is more appropriate.

Seguin et al., 2001

This study evaluated the sensitivity of phytoplankton to atrazine. Large outdoor tanks (3.4 m diameter, 1.2 m depth) capable of holding 5000 L of water were erected at the Ecole Nationale Superieure d'Agronomie de Rennes, France. Approximately 5 cm of natural sediment from a local pond was added to each cosm, along with a mixture of tap and pond water (containing phytoplankton and zooplankton) to a depth of 70 cm. Aquatic macrophytes (*Glyceria maxima*) were planted in two concentric circles in each tank. Atrazine dissolved in acetonitrile was added to three tanks per treatment concentration at rates of 0, 2, and 30 µg/L. There were no statistical differences in gross phytoplankton biomass among treatment and control tanks. Significant decreases in dominant taxonomic groups were only observed for Chlorophyceae. At 2 µg/L, biomass was significantly reduced at Day 17, but returned to control levels by the next sampling time (Day 23). In the 30 µg/L treatment, significant decreases in Chlorophyceae were observed on days 17 and 23, followed by a return to control levels.

EPA (2009c) reviewed Seguin et al. (2001), finding that the limited data provided made study evaluation and determination of relevance of reported results extremely difficult. The reviewer determined that any effects observed at 2 µg/L were transient and not likely treatment-related. The review further critiqued the lack of information on cosm construction, including analytical

measurements of cosm water to confirm that the cosms were not contaminated with atrazine before test start. Successional dynamics and only a three-week cosm colonization period may have confounded the results. The review also highlighted the lack of details provided for the Bray-Curtis dissimilarity index, as the equation and version used, as well as the level of taxa assessed can significantly affect the statistical analyses. EPA (2009c) recommended only using data from Seguin et al. (2001) within a qualitative weight-of-evidence assessment.

The SAP (2012) critiqued the use of acetonitrile as a solvent for ecotoxicological dosing. Seguin et al. (2001) did not report the concentrations used and this solvent is rarely used. Therefore, the effects of acetonitrile on phytoplankton biomass are unknown.

Giddings (2012) also reviewed this study and highlighted the transient nature of the negative effects observed on chlorophytes at 2 µg/L. After a thorough evaluation of the presented data, Giddings (2012) found that possible effects reported at 2 µg/L were slight and transient, and assigned a binary effects score of 0. Giddings (2012) recommended an effects level of 30 µg/L.

Moore et al. (2015, 2016) rated this study as not relevant because concentrations were not measured (or reported) to confirm atrazine levels over time. Data quality was rated as unacceptable or supplemental because a non-standard solvent was used and the quantity was not reported, control results were not reported, concentrations were not measured, limited test concentrations were evaluated, minimal study conditions were reported, and only minimal evidence for a concentration-response relationship was demonstrated. Moore et al. (2015, 2016) found significant effects at only 30 µg/L.

EPA (2016a) used an effects concentration of 2 µg/L in their calculation of an LOC. However, given the low quality of study and evidence of transient, inconsistent effects at 2 µg/L, 30 µg/L is a much more appropriate effects concentration for use in the calculation of an LOC and this value is supported by all reviewers (SAP, 2012; Giddings, 2012; Moore et al., 2015; 2016).

Seguin et al., 2002

Seguin et al. (2002) investigated the effects of atrazine on chlorophyll α production of freshwater phytoplankton communities. Four large, outdoor, circular tanks located at Institut National de la Recherche Agronomique, Rennes, France served as cosms for the study. Tanks were filled with 7 cm of natural sediment and 70 cm of pond water containing phytoplankton. Tanks were stocked with zooplankton collected with nets from local ponds and aquatic macrophytes (*Glyceria maxima*). Tanks were left to colonize over a period of three weeks before addition of atrazine. Two tanks received 30 µg/L atrazine and two tanks were left untreated. Chlorophyll α and dry weight were higher in control tanks than treated tanks nine days after application.

EPA (2009d) reviewed Seguin et al. (2002), finding several limitations in the study. Most notably, background concentrations were not measured in sediment or water prior to test start to confirm that controls were not contaminated. All criticisms were similar to those presented by EPA (2009c) regarding Seguin et al. (2001). Overall, EPA (2009d) recommended that data from Seguin et al. (2002) only be used qualitatively as part of a weight-of-evidence regarding potential effects to aquatic plants.

The SAP (2012) criticized the lack of recovery period included in Seguin et al. (2002). Following a review of the literature, the SAP (2012) concluded that recovery was expected following the 30% reduction in algal biomass observed over 21 days by Seguin et al. (2002). Therefore, SAP

(2012) were concerned about the use of the Seguin et al. (2002) study, but supported the effects concentration of 30 µg/L observed in the study.

Giddings (2012) evaluated Seguin et al. (2002), finding that the lack of study details limited the quality of the study and prevented an in-depth data quality assessment.

Moore et al. (2015, 2016) rated this study as not relevant because atrazine concentrations were not measured and a recovery period could not be established. The study was also rated as unacceptable because limited replication (n = 2) and test concentrations (n =1) were evaluated, minimal study conditions were reported, control results were not reported, and the study did not follow internationally-recognized guidelines.

Although this study is of low quality, effects to biomass, productivity and community structure of phytoplankton were apparent in the 30 µg/L treatment, as noted by EPA (2016a), Moore et al. (2015, 2016) and the SAP (2012). Therefore, inclusion of this endpoint by EPA (2016a) has high uncertainty, but is reasonable.

Baxter et al. (2011)

This study evaluated the effects of atrazine on primary productivity in outdoor microcosms located at the University of Guelph Turfgrass Institute Microcosm Facility, Guelph, ON. Sediment was added to 44% of the surface area of the cosm floors to a depth of 7 cm. Spring water from an adjacent irrigation pond was added to a depth of 1 m. Atrazine (96% a.i.) dissolved in acetone (<0.001% final cosm concentration) was applied to cosms at rates of 1, 10, 30, and 100 µg/L and cosms were observed for 73 days. Shoots of macrophytes, *Myriophyllum spicatum* and *Elodea canadensis,* were planted in pots in the cosms, as well as periphyton substrates. Observations were made on biomass of macrophyte, phytoplankton and periphyton populations. The authors reported no consistent concentration-response relationship, except for a reduction in macrophyte biomass at 100 µg/L.

Giddings (2012) reviewed Baxter et al. (2011) and found no consistent and significant effects on macrophytes, periphyton and phytoplankton over 73 days at concentrations of 1, 10 and 30 µg/L. At 100 µg/L, a significant decrease in wet and dry weight of macrophytes was observed, but effects to periphyton or phytoplankton were not observed.

EPA (2016a) used three effects concentrations from this study; 10, 30 and 100 µg/L. However, significant effects were transient and did not follow a true concentration-response relationship. Shoot weight was reduced 46, 19, and 78% in the 10, 30 and 100 µg/L treatments (Baxter et al., 2011). These results do not follow any trend, but instead show that there is high variation in response. Additionally, no statistically-significant differences were detected between shoot weights of treatment and control plants, except in the 100 µg/L treatment (Baxter et al., 2011). Therefore, an effect level of 100 µg/L is appropriate for macrophytes and >100 µg/L is appropriate for periphyton and phytoplankton.

Pannard et al., 2009

Pannard et al. (2009) evaluated the effects of atrazine on a controlled freshwater wetland phytoplankton community. Cosms were stocked with plankton collected from a freshwater wetland in Brittany, France and maintained under semi-continuous culture in the lab. At the start of the study, the phytoplankton community consisted of eight species and was dominated by *Oocystis* sp. and *Selenastrum bibraianum*. Before application of atrazine, the phytoplankton

community was "starved" by making the community phosphorus-deficient. On Day 0, atrazine was applied once weekly to cosms at rates of 0.1, 1, and 10 µg/L, along with 52.6 µg/L phosphorus. Cosms consisted of 500 mL Erlenmeyer bottles containing 240 mL water with phytoplankton community. Discontinuous fresh input of culture was made once weekly. The cosms were observed for seven weeks after the initial application to evaluate potential changes in photosynthetic activity, biomass and community structure. The authors noted significant effects on primary production and community structure in all treatments. However, there were no differences in chlorophyll α (biomass estimator) among treated and control cosms. Notably, the Simpson's index of diversity was significantly higher in treatments than controls.

This study was not evaluated by the SAP (2012), Giddings (2012) or Moore et al. (2015, 2016). However, the study was evaluated here following the guidance outlined in Moore et al. (2015, 2016). See Appendix A for the full study evaluation. The study was rated as not relevant because it did not include a recovery period and was rated unacceptable for data quality because the composition of species in controls decreased 40 to 92% over the course of the study, limited results were presented for sampling times and endpoints, limited study criteria were reported, and test concentrations were not measured. Additionally, the depletion of phosphorus at test start then addition of phosphorus throughout the study muddled possible treatment-related effects. This study focused more on the effects of phosphorus supply on biological productivity and less on the effects of atrazine. As a result, phosphorus availability was an additional stressor.

It is unclear how EPA (2016a) used the data from Pannard et al. (2009) in their ERA for atrazine, but EPA (2016a) did state that significant effects were observed at all test concentrations and a significant shift in community composition was observed at and above 1.0 µg/L. However, the large decrease in control cell density between test start and test end and the lack of effect on phytoplankton biomass from atrazine exposure, shows the presence of an additional stressor on the study system and poor study design. Thus, an effects concentration of 1.0 µg/L is not supported and should not be used in the derivation of an LOC. The study is critically flawed and should have been rejected by EPA (2016a).

King et al., 2014

King et al. (2014) simulated atrazine chemographs in streams of agriculture catchments receiving pulsed inputs. The system included riffles, pools and glides, and water was drawn from the North Bosque River then filtered through a wetland before reaching the study tank. Colonization of benthos taken from the North Bosque River was allowed for 30 days prior to test start. Twelve pots of *Ceratophyllum demersumi* were secured into the ponds and wild caught minnows were added to the glides. Nominal concentrations were selected to achieve 60-day mean concentrations of 10, 20, and 30 µg a.i./L. Streams were dosed with daily pulses of 50, 100, and 150 µg a.i./L for four days, followed by seven days of no dosing. The 11-day cycle of dosing was repeated three times, followed by a recovery period of 26 days. Mean 60-day measured concentrations were 0.07 10.7, 20.9, and 31.0 µg a.i./L atrazine for the control, 10, 20, and 30 µg a.i./L treatments, respectively. The authors concluded that no significant effects on structural endpoints were observed at concentrations up to 30 µg/L and only transient functional effects were observed at 30 µg/L. Full recovery was observed by day 60.

The study was evaluated by EPA (2016b), who determined that the statistical approaches used by King et al. (2014) were not appropriate for evaluating significant changes in community

structure. EPA (2016b) also asserted that statistically and biologically significant effects were observed without subsequent recovery. EPA (2016b) determined an effects concentration of 10 µg a.i./L based on biologically significant decreases in metaphyton production, periphyton biomass, and dissolved oxygen. EPA (2016b) also determined that King et al. (2014) had limited use in the calculation of an LOC because of the mitigating effects of high nitrogen and phosphorus levels present in the study.

EPA (2016a) misinterpreted this study. Although EPA (2016a) asserted that nutrient levels were too high, they were not. The study was specifically designed to represent 2nd and 3rd order Midwestern streams in corn-growing areas and nutrient levels were consistent with those locations. Further, the study design was based on recommendations of the SAP (2012) and is state-of-the-art, including the statistical analyses conducted by King et al. (2014). The results indicate only transient effects at the highest test concentration and thus all test concentrations from this study should have been scored by EPA (2016a) as a zero in deriving the LOC.

Data Conclusions

EPA (2016a) stated:

> "those freshwater and estuarine/marine monitoring sites with a 60-day running average at or above 3.4 µg/L have atrazine concentrations that are above the CELOC, and that ecologically significant changes in aquatic plant community structure, function, and/or productivity would be expected."

This conclusion is untrue. The results of Giddings (2012), two SAPs (2009, 2012) and Moore et al. (2015, 2016) demonstrate that no statistically significant effects occurred at atrazine concentrations less than 30 µg/L. Moore et al. (2015) also evaluated new cosm studies published since the SAP (2012) review (Baxter et al., 2013; Choung et al., 2013; Halstead et al., 2014; Knauer and Hommen, 2012; Murdock and Wetzel, 2012). In these studies, no effects were observed at concentrations less than 30 µg/L. Therefore, EPA's 60-day LOC of 3.4 µg/L is almost an order of magnitude lower than the lowest reliable effects concentrations observed in mesocosm studies, and is overly conservative.

EPA (2016a) did not account for recovery. However, the mode of action of atrazine is reversible upon removal of atrazine exposure at the target site of both terrestrial and aquatic plants (Brain et al., 2012a,b; Brockway et al., 1984; Hughes et al., 1988; Jensen et al., 1977; Jones et al., 1986; Juttner et al., 1995; Klaine et al., 1996; Mohammad et al., 2008, 2010; Moorhead and Kosinski, 1986; Shimabukuro et al., 1970; Stay et al., 1985, 1989; Vallotton et al., 2008). Monitoring data from the AEMP have shown that the median duration of concentration peaks greater than 15 µg/L is 2 days (Brain, 2012). Atrazine is likely to enter natural systems as pulses during runoff events. Independent of degradation, water dynamics, flow and dilution would disperse the atrazine away from the point of input and decrease the concentration quite rapidly, particularly in larger flowing waterbodies. Decreasing concentration levels would immediately allow for recovery of aquatic communities (Brain, 2012). The recovery potential of plant communities is further reviewed by Brain (2012), where the influences of exposure magnitude and duration are shown to have limited impact on recovery. Brain (2012) concluded that, "relative to worst-case environmentally measured durations and concentrations, aquatic plants would be expected to fully recover from episodic atrazine exposures."

2.3.2 *Method of Derivation*

EPA (2016a) used the Plant Assemblage Toxicity Index (PATI) method to derive an LOC for aquatic plants. The PATI uses singles species toxicity studies to derive an index against which cosm data and monitoring chemographs are compared. PATI inputs are at the population level of biological organization and the method makes binary predictions (e.g., effect or no effect) regarding community-level effects. The PATI method is very sensitive to changes in inputs (e.g., scoring of cosm studies).

The first step of the PATI method is to develop an effects index based on single species toxicity data and a species sensitivity distribution (SSD). However, for chemicals with highly variable exposure profiles (e.g., atrazine), SSDs have several major shortcomings:

- The inputs (i.e., EC50s) to an SSD are generally from one to four-day toxicity tests with constant exposure concentrations. If an LOC was derived from an SSD percentile (e.g., 5th percentile), what is the appropriate exposure duration for judging risk? Is it the peak exposure concentration? In this case, the assumption would be that high peaks of short duration pose more risk than short peaks that last much longer. Such an assumption has no scientific basis, as risk is a function of both magnitude and duration of exposure. Calculating an average exposure duration (e.g., 4 days to approximately match durations of toxicity studies) can also be problematic for situations in which atrazine exposures are considerably longer. Thus, an SSD-based LOC likely has limitations for determining whether a particular atrazine chemograph is or is not an issue for aquatic plant communities.
- Even if exposure durations in the field were comparable to those used in toxicity tests, SSDs have other limitations for determining community-level impacts for a particular environmental concentration. The HC5, for example, is the concentration that will cause a 50% impact (e.g., reduced growth rate) for the 5th percentile species on the SSD. However, more sensitive species would experience greater than 50% impact and slightly more tolerant species would also experience some impact though less than 50% impact.

There are two major assumptions in the PATI calculations: (1) the sensitivity distribution is representative of the range of plant sensitivities in waterbodies near where atrazine is used, and (2) all species are weighted equally. In reality, natural aquatic plant communities have species that are more and less dominant than others.

Next, a cumulative PATI distribution is constructed, taking into account exposure duration. However, the cumulative PATI assumes: (1) there is no residual toxicity from previous days and toxicity is only a function of the current day's exposure; (2) over time there is no replacement of sensitive individuals by more tolerant individuals within a species and no replacement of sensitive species by more tolerant species; and (3) a specific reduction in growth over one day is equivalent to half that reduction persisting over two days or a quarter of that reduction persisting over four days.

Finally, the cumulative PATI is calibrated with results from cosm studies. This process involves a number of assumptions, including: (1) environmental conditions affecting exposure, sensitivity and/or recovery of aquatic plant communities are unimportant; (2) the disparity in exposure magnitudes and durations across available cosm studies can be accounted for by normalizing to

units of cumulative PATI (% effect-days); and (3) the magnitudes of effects observed in the cosm studies are unimportant to derivation of the LOC_{PATI}. Therefore, the PATI process is very sensitive to the assumed assessment period and the determination of effect versus no effect for cosm studies.

The SAP (2012) expressed concerns over the reliance on the PATI method by EPA (2003, 2012) to develop the LOC, as well as the scheme used by EPA to score cosm data. Most importantly, the SAP (2012) panel disagreed with the selection process used to determine the cosm dataset employed to calculate the LOC, as the PATI method is highly sensitive to which cosm studies are included in calculations. The SAP (2012) expressed minimal confidence in the LOC of 4 to 7 µg/L calculated by EPA (2003) in their IRED.

Weaknesses of the PATI method that were highlighted by the SAPs (2009, 2012) included the following:

- The method does not account for environmental conditions in the receiving environment including several that could significantly affect exposure to atrazine, atrazine toxicity and post exposure recovery rates (e.g., nutrient levels, total suspended solids).
- The cumulative PATI does not correspond to the fractional change in aquatic plant community biomass over time. This point is readily apparent when one considers the $PATI_{60\,d}$ LOCs calculated for various cosm datasets. All of the values are greater than 100% effect-days which would imply complete elimination of primary producers over the course of a 60-day exposure. This was obviously not the case in the vast majority of cosm treatments even in treatments with $PATI_{60\,d}$ values well in excess of 1000% effect-days. There are several reasons to explain the discrepancy between cumulative PATI and fractional change in aquatic plant community biomass over time. First, the PATI method assumes that sensitivities of populations and the plant community do not change over time. However, the most sensitive individuals and populations are likely replaced by more tolerant individuals and populations during a long-term atrazine exposure. Thus, overall community growth rate on a daily basis is less affected as time goes by even if atrazine concentrations are constant. Second, the PATI method assumes that there is a linear relationship between index values and community growth rate. This is likely not the case for plant communities that are not in the exponential growth phase. High PATI values may have little impact on plant communities at or near carrying capacity because effects due to atrazine may be offset by release from self-shading and nutrient depletion (Schafer et al., 1994). Third, plants may adapt to atrazine exposure over time by, for example, increasing chlorophyll content to compensate for reduced photosynthesis (see discussion in EPA, 2012a). Such adaptations are likely important at low to modest exposure concentrations. Thus, the assumption that long exposures at low concentrations (e.g., daily PATI = 5% effect-days for 20 days) are of equal concern to short exposures at high concentrations (e.g., daily PATI = 100% effect-days for 1 day) is very tenuous.
- There is no means of evaluating model performance with respect to estimates of toxic effects. Because the PATI is a relative index of effect (see preceding bullet), there is no way to directly test or evaluate model performance using community cosm or field test data not used in the calibration step. The risk of making a wrong decision in regulatory decision making depends on the reliability of the model predictions. Therefore, there is a

strong need to establish the validity of the PATI method, but unfortunately no way to do so.

- The use of test results from tolerant species weakens the reliability of the cumulative PATI score in stage 2. As a result, the SAP (2012) recommended testing of a broader range of primary producer species. However, we do not agree that inclusion of some tolerant species is a weakness of the PATI methodology. First, primary producers in water bodies close to atrazine use areas are likely "tolerant" of various stresses stemming from being present in agro-ecosystems including frequent exposure to pesticides. It is a generally accepted notion among ecologists that systems with a history of disturbance are more likely to recover quickly from a disturbance, particularly those that mimic historical disturbance events (Denslow, 1985; Rapport et al., 1985). Thus, inclusion of atrazine-tolerant species in the cumulative PATI score is appropriate. Second, and more importantly, the sensitivity analyses conducted by EPA (2012a) demonstrated that the taxonomic composition of the dataset used to estimate the cumulative PATI in stage 2 has little impact on estimates of atrazine risk for different chemographs. The stage 3 calibration to cosm results is far more important than the stage 2 calculation of the cumulative PATI.
- The method does not adequately account for interactions between and within aquatic plant species. This point is true for calculation of daily or cumulative PATI scores. That said, calibration of the PATI scores to the results of cosm studies implicitly accounts for interactions between and within aquatic plant species.
- The PATI methodology is highly sensitive to the cosm data selected. Therefore, mis-scoring of effects or no effects and/or inclusion of poor quality data could have large implications on the estimated LOC.
- Use of binary decisions for each cosm treatment (no effect, effect) results in a large loss of information regarding magnitude and duration of responses across a range of community-level endpoints.
- The EPA (2012a, 2016a) definition of "recovery" in cosm studies (i.e., recovery to pre-exposure conditions for populations) is unrealistic because aquatic plant communities are dynamic and change throughout the growing season. As noted by Landis et al. (1996, 1998) and others (e.g., Chapin et al., 1996), recovery is not a fundamental property of ecosystems although they may have characteristic patterns and boundaries that are set by the prevailing environmental conditions. Thus, expecting populations in cosm studies to recover to pre-exposure conditions is misguided. Rather, change to the general structure and function observed in control communities during the post exposure period is a more realistic indication of "recovery".

As outlined above, the PATI method has a number of uncertainties and weaknesses. Instead of relying on a single method, Moore et al. (2015, 2016) described a weight-of-evidence approach for deriving an LOC protective of aquatic plant communities for atrazine. The weight-of-evidence approach included four methods (PATI, Comprehensive Aquatic Systems Model for atrazine [CASM], EPA's water quality criteria method, and direct interpretation of cosm studies) to independently calculate LOCs and then used a weighted calculation to estimate a community-level LOC. The PATI method was described above. The CASM is a bioenergetics-based aquatic

food web model that was previously used by EPA (2003, 2007). CASM simulates daily changes in biomass production of aquatic primary producer and consumer communities, as well as changes in water quality parameters over a model year (Bartell et al., 2009). The Water Quality Criteria (WQC) method is a standardized approach used by EPA (1985) to establish aquatic benchmarks. The LOC is estimated from a species or genus sensitivity distribution. For atrazine, Moore et al. (2015, 2016) calculated a genus sensitivity distribution using specific growth rate of aquatic plants. Finally, Moore et al. (2015, 2016) calculated an LOC directly from the results of cosm studies. All data points were first classified using the Brock et al. (2000) 5-point system then plotted by exposure concentration and duration to estimate 30- and 60-day LOCs.

The LOCs calculated with the four methods ranged from 19.6 to 26 µg/L and the weighted LOC was 23.6 µg/L. This LOC is consistent with the results of all acceptable cosm studies, which indicate that negative effects are not likely at concentrations less than 30 µg/L. The LOC calculated by Giddings (2012) and Moore et al. (2015, 2016) using the PATI method was 25 µg/L, which is almost an order or magnitude higher than the LOC calculated by EPA (2016a). Therefore, it is clear that correct interpretation and scoring of cosm results strongly influences the calculation of an LOC. By using invalid data and mis-scoring key effects endpoints, EPA (2016a) generated an extremely conservative LOC. We recommend that EPA re-evaluate the data used and employ a weight of evidence approach to estimate a more scientifically defensible LOC for aquatic plants.

2.4 Fish

2.4.1 Freshwater Fish

EPA (2016a) selected a chronic exposure study using Japanese medaka (*Oryzias latipes*) (Papoulias et al., 2014) as the basis of their chronic effects metrics for both freshwater and estuarine/marine fish. Papoulias et al. (2014) exposed breeding groups of one male and four females to atrazine in a static renewal system for up to 38 days. Nominal test concentrations were 0.5, 5.0, and 50 µg/L. The authors found reduced egg production at all treatment levels.

The study (Papoulias et al., 2014) was flawed, as EPA noted in its own DER (Bryan et al., 2014). The study did not follow a standard guideline, had high intra-treatment variability, particularly in the solvent control treatment, and did not demonstrate a clear concentration-response relationship (Bryan et al., 2014). EPA further highlighted other limitations of the study, including lack of a true negative control treatment, a high female to male ratio (4:1 versus 1:1), no results reported for time zero sampling, low fecundity in the control treatment (9.7 eggs/female/day), and high mortality in the solvent control. The study authors found significant effects to egg production and reproduction at all treatment levels (NOEC < 0.5 µg/L), but EPA (2016a; Bryan et al., 2014) re-evaluated the study data and determined a NOEC of 5 µg/L and a LOEC of 50 µg/L. In fact, all differences in egg production were within the variability in the dataset, high variability was noted throughout the test, and only weak statistical evidence of an atrazine effect was observed at 50 µg/L (Bryan et al., 2014).

Because of the many flaws in the Papoulias et al. (2014) study, Syngenta sponsored a GLP study on Japanese medaka that followed standard testing protocols (GLP; OCSPP Guideline 890.1350; OECD 229) to provide a higher quality study for future use in risk assessments (Schneider et al., 2015 [MRID 49694001]).

Schneider et al. (2015) exposed Japanese medaka to atrazine under flow-through conditions for 21 days. Nominal exposure concentrations were 0, 0.49, 4.9, and 49 µg a.i./L, which corresponded to mean measured concentrations of <0.125, 0.59, 5.4, and 53 µg a.i./L, respectively. Schneider et al. (2015) found no significant effects on fecundity or fertility at any treatment level. Control fecundity was 40.9 eggs/female/day/replicate, compared to 9.7 eggs/female/day in Papoulias et al. (2014). Mean control fertility in Papoulias et al. (2014) was 62%, while mean control fertility in Schneider et al. (2015) was 91.7%. Only the Schneider et al. (2015) study meets the OECD guidelines, which require ≥80% fertility.

Although medaka is not a recommended species in the OCSPP guideline, it is a recommended species for OECD 229 and the purpose of the study was to replicate the original non-guideline study performed by Papoulias et al. (2014). Schneider et al. (2015) made several improvements to the study design used by Papoulias et al. (2014), including use of a flow-through exposure system, achieving much higher fecundity in controls, no reliance on solvent, and alignment with recommended guidelines. Therefore, Schneider et al. (2015) offers significantly higher data quality than the Papoulias et al. (2014) study relied upon by EPA (2016a) in their ERA for atrazine. Schneider et al. (2015) were not able to reproduce the results of Papoulias et al. (2014). In fact, the higher quality study found no treatment-related effects at the test concentrations previously used by Papoulias et al. (2014), further decreasing the value of the effects metric used in the ERA.

EPA also evaluated Schneider et al. (2015) in a DER (Marton et al., 2015). The reviewers determined that the study was scientifically sound and the methods used were generally consistent with OCSPP guideline 890.1350. Marton et al. (2015) agreed with the study authors that no significant treatment-related effects were observed at any test concentration. Therefore, we recommend that EPA re-consider the effects metric used in their ERA and rely on high quality data, instead of merely using the lowest NOEC available.

2.4.2 Estuarine/Marine Fish

EPA (2016a) used the Japanese medaka study listed above (Papoulias et al., 2014) as a surrogate effects metric for chronic effects to estuarine/marine fish. EPA (2016) provided no support or reasoning for their choice and provided no evidence indicating that freshwater and estuarine/marine fish have similar sensitivities to atrazine. Further, EPA (2016) ignored a chronic marine fish study that is available for sheepshead minnow (Cafarella, 2005 [MRID 46648203]).

Under GLP conditions, Cafarella (2005) exposed fertilized sheepshead minnow eggs from 26-hours post-fertilization to 28 days after hatch to concentrations of atrazine (FL-881692; 97.1% purity) ranging from 200 to 3200 µg a.i./L. Mean measured concentrations were 150, 300, 570, 1100, and 2200 µg a.i./L. Larval length and wet weight were the most sensitive endpoints, resulting in a NOEC of 1100 µg a.i./L and LOEC of 2200 µg a.i./L.

EPA previously scored the Cafarella (2005) study as supplemental because it did not fulfill guideline requirements (Volz, 2006 [MRID 46952604]). The flaws highlighted by EPA included: the study only maintained two replicate aquaria, did not assess time-to-hatch, and the study duration was 28 days post-hatch instead of the recommended 32 days. Syngenta subsequently amended the reported and provided support for re-scoring of the study (Volz, 2006). The issues are addressed below:

- Description of test substance: Provided to EPA in amended report.
- Replication: Current OPPTS Guidelines (850.1400) recommend at least two replicates, with 60 eggs total. Cafarella (2005) had 40 eggs per replicate, and thus 80 eggs per treatment. The guideline requirements were met.
- Duration: OPPTS Guideline 850.1400 clearly states that the study should last 28 days post-hatch for sheepshead minnow. This duration was used in the original study (Cafarella, 2005).
- Reporting of dilution water analysis: Provided to EPA in amended report.
- pH range: According to OPPTS Guideline 850.1400, a pH range of >7.5 to <8.5 is appropriate for marine testing. This is consistent with the pH range of 7.8 to 8.2 measured by Cafarella (2005).
- Time-to-hatch: Although treatment effects on time-to-hatch were not directly evaluated to avoid injuring newly hatch fry, percent hatch was determined on Day 5. On Day 5, percent hatch among treatments and controls was not significantly different, indicating that atrazine did not affect hatch.

Based on data provided in the amended report and consistencies between the original study methods and OPPTS guideline 850.1400, this study is appropriate for use in a risk assessment and should have been used by EPA in their atrazine assessment for estuarine and marine fish. Further, the NOEC for sheepshead minnow (1100 µg a.i./L; Cafarella, 2005) is 220 times higher than the NOEC (5 µg/L; Papoulias et al., 2014) used by EPA (2016a) and at least 22 times higher than the NOEC (>53 µg/L) determined by Schneider et al. (2015). For the reasons described above, EPA (2016a) had no scientific justification for relying on a poorly conducted freshwater fish study as the basis for the chronic effects metric for estuarine and marine fish, particularly given the availability of a well-conducted chronic study on sheepshead minnow.

2.5 Aquatic-phase Amphibians

In 2004, EPA initiated a data call-in (DCI) request for studies related to gonadal development of aquatic-phase amphibians. Following submission of a registrant-sponsored study on *Xenopus laevis* (Kloas et al., 2009), EPA (2012a) discounted all other data, which were deemed low quality, and focused all risk assessments on the high quality DCI study. Ultimately, based on the DCI study, EPA (2012a) determined that effects to aquatic-phase amphibians and reptiles from exposure to atrazine are unlikely.

Although the SAP (2012) deemed the study robust and agreed that this was the only study of high quality that should be used quantitatively, it had a number of concerns with reliance on only this study because the study employed a flow-through exposure regime that is unlike the natural environment of frogs and unlikely to include exposure to potential atrazine degradates and transformation products, and use of an insensitive strain of *Xenopus* that may not be indicative of the risks posed to other amphibians. Previous SAPs (2003, 2007) agreed that atrazine likely had limited potential for negative effects to aquatic-phase amphibians. However, the most recent SAP (2012) suggested that EPA reconsider the results of some of the previously eliminated studies in a weight-of-evidence assessment because results for one species (*Xenopus laevis*) from the only high quality study may not be protective of all species. Therefore, in their draft ERA, EPA (2016a) shifted its approach and instead included all available toxicity data for aquatic-phase amphibians in a weight-of-evidence assessment.

EPA (2007) listed several requirements for studies to be of acceptable quality. Studies were rated as invalid if they included any of the following:

1. Nominal atrazine concentrations not reported;
2. Insufficient replication (n = 2 or lower);
3. No use of control treatments and solvent controls if solvent used to dissolve test chemical;
4. Test chemical contamination of controls;
5. >30% control mortality;
6. >0.05% solvent concentration;
7. Sufficient data and statistical analyses not reported;
8. Presence of other stressors in controls and/or treatments; and
9. Confounding effects in controls (e.g., high incidence of intersex or skewed sex ratio).

Studies that were considered valid were further evaluated to determine their level of quality. Acceptable (or quantitative) studies also contained the following elements:

1. If a solvent was used, included both negative and solvent control groups;
2. No significant differences between negative and solvent control groups;
3. <0.01% solvent concentration and no use of DMSO as a solvent;
4. No use of plastic test vessels or vessel that have the potential to leach;
5. Use of a technical product;
6. Use of recommended loading rate (e.g., <1 tadpole/L/day); and
7. Use of laboratory-reared organisms.

EPA (2007) evaluated 75 open literature studies. Possible contamination of controls was not determined in 59% of studies and at least 40% of studies had loading rates higher than recommended (>1 tadpole/L/day). Among other uncertainties, water quality parameters were often not thoroughly reported and test organisms were often wild-caught with no indication of past exposure. All studies classified as invalid or valid (qualitative) with a low level of confidence were excluded, so as not to mask the ability to discern effects based on study quality. This left 10 studies for consideration in determining risk of atrazine to aquatic-phase amphibians. Following a thorough review of all data, EPA (2007) concluded that the available data were not sufficient to make inferences on risk to aquatic-phase amphibians.

EPA (2016a) incorporated 55 studies into their weight-of-evidence analysis. Only studies rated as invalid (see above) were excluded from the analysis. This left one quantitative and 54 qualitative studies, spanning a range of data qualities. However, EPA (2016a) noted that studies often did not report and/or measure atrazine concentrations, used wild-caught organisms, and did not adequately report or maintain physical and chemical test characteristics.

The mortality data used by EPA (2016a) in their weight-of-evidence analysis were constructed from one quantitative study, two studies rated qualitative with high data quality, four studies rated qualitative with medium data quality, and 18 studies rated qualitative with low data quality. An additional 10 qualitative studies were included, but did not include data quality rankings. Therefore, of the 25 studies with data quality rankings, 18 (72%) were of low quality. Additionally, of the 44 data points used in their mortality data array, 32 (72%) represented studies that had no effects at the test concentrations evaluated, and spanned the range of concentrations included in the array.

A similar story occurred in the amphibian development data array, which included one quantitative study, two studies rated qualitative with high data quality, two studies rated qualitative with medium data quality, and 12 studies rated qualitative with low data quality. An additional six qualitative studies were included, but did not include data quality rankings. Therefore, of the 17 studies with data quality rankings, 12 (71%) were of low quality, and 28 of 41 (68%) data points were endpoints with no effects (i.e., unbounded). Similarly, for growth and reproductive, 13 of 17 (76%) and 10 or 12 (83%) of studies with data quality rankings, respectively, were of low quality. For growth, 29 of 51 (57%) data points were unbounded, and for reproduction, 18 of 31 (58%) data points were unbounded.

Despite having the highest percentage of unbounded effects data (72%), mortality data were weighted by EPA (2016a) as having the highest degree of confidence of all lines of evidence (mortality, growth, development, reproduction). Additionally, more than 70% of ranked data points for all lines of evidence were of low quality. That is very concerning as data quality is essential for accurate interpretation of risk. In fact, by their own admission, EPA (2016a) overlooked study quality in favor of evaluating the entire range of data. EPA (2016a) also pointed out that many studies with the lowest data points were of dubious quality and results could not be replicated in other studies with the same species. Therefore, reliance on a large dataset primarily comprised of very low quality data and in many cases, studies where no effects were observed, is overly conservative and careless when used to predict risks to amphibians. Conclusions drawn from the data presented by EPA (2016a) are highly uncertain and likely inaccurate.

Finally, EPA (2016a) compared their weight-of-evidence predictions for aquatic-phase amphibians to their LOC for aquatic plants. The LOC was reviewed in detail above. Despite using an LOC that is an order of magnitude lower than effect concentrations observed in cosm studies and nearly an order of magnitude lower than the LOC predicted by others (Moore et al., 2015, 2016; Giddings, 2012), EPA (2016a) believes that their LOC (3.4 µg/L) is protective of potential direct and indirect effects to aquatic-phase amphibians. Therefore, use of higher quality test data and fewer no effects concentrations would likely be further protective of amphibians.

This position is further supported by Hanson et al. (2016), who updated the quantitative weight-of-evidence assessment and determined that atrazine does not pose a significant risk of adverse effects to amphibians. Hanson et al. (2016) reviewed available data and scored studies by relevance and quality. Ten study characteristics were scored on a scale of zero to four. For example, a study with a score of four in each category would be considered to show "strong evidence of adverse effects", while a score of one would show "weak evidence of no adverse effects". Mean scores for each category and endpoint were determined to estimate the average response. No endpoint resulted in mean score representing evidence of adverse effects.

3.0 TERRESTRIAL RECEPTORS

3.1 Terrestrial Plants

For terrestrial plants, EPA (2016a) chose effects endpoints from Chetram (1989a,b). Both the seedling emergence and vegetative vigor studies were performed according to GLP and evaluated the effects of atrazine on ten crops: soybean, lettuce, carrot, tomato, cucumber, cabbage, oat, ryegrass, corn, and onion. In the seedling emergence study (Chetram, 1989a), atrazine (FL-850612; 97.7% purity) was applied to bare soil at rates of 0.0025 to 4.0 lb a.i./A. The most sensitive metric was plant dry weight, with NOECs for oat and carrot of 0.0025 lb a.i./A (Chetram, 1989a). For the vegetative vigor study (Chetram, 1989b), atrazine (FL-850612) was applied to the foliage of seedlings in the 1-3 true leaf stage at rates of 0.0025 to 4.0 lb a.i./A. Plant dry weight was again the most sensitive metric, resulting in a NOEC of 0.0025 lb a.i./A for cabbage (Chetram, 1989b). The Chetram (1989a,b) studies are outdated (see discussion below) and did not evaluate recovery. A recovery phase is an important study design component for herbicides such as atrazine that have a reversible mode of action following cessation of exposure. In fact, European Food Safety Authority (EFSA, 2012) guidance recommends that the potential for ecological recovery be integrated into a risk assessment. For non-target terrestrial plants, EFSA evaluates recovery at the population level for germination (seedling emergence), biomass, and vegetative vigor.

Recently, new seedling emergence (Martin, 2015a [MRID 49639102]) and vegetative vigor (Martin, 2015b [MRID 49639101]) studies were performed using a current product (Atrazine SC; 43.0% a.i.). The new studies followed GLP, OCSPP Guideline 850.4100 and OECD 208. The Martin (2015a,b) studies applied a typical end-use product, which is required for OCSPP 850.4100 guidelines. Conversely, the Chetram (1989a,b) studies applied technical atrazine which is not what terrestrial plants would be exposed to from spray drift in the field. Terrestrial plants are exposed to end-use products, as exposure is the result of spray drift to non-target areas during and shortly after application.

The Martin (2015a,b) studies included a recovery phase to determine the long-term effects of atrazine application on terrestrial plants. In the seedling emergence study, Martin (2015a) applied Atrazine SC to bare ground and observed plants for 28 days after 50% emergence in controls. After 14 days, the most sensitive monocot was oat, with a NOEC of 0.021 lb a.i./A and an EC25 of 0.0456 lb a.i./A based on dry weight. The most sensitive dicot was cabbage, with a NOEC of 0.097 lb a.i./A and an EC25 of 0.0299 lb a.i./A based on dry weight. After 28 days, the most sensitive monocot was onion, with a NOEC of 0.025 lb a.i./A and an EC25 of 0.0341 lb a.i./A based on dry weight, and the most sensitive dicot was cabbage, with a NOEC of 0.0099 lb a.i./A and an EC25 of 0.0177 lb a.i./A based on dry weight. Recovery was analyzed for the growth rate endpoint. Martin (2015a) observed recovery in cabbage shoot length growth rate and in tomato shoot length and dry weight growth rates. Other species either exhibited no recovery or recovery was non-significant.

In the vegetative vigor study, Martin (2015b) applied Atrazine SC to crops. Observations were made at 21 and 42 days after application to determine effects and the potential for recovery. After 21 days, the most sensitive monocot was onion, with a NOEC of <0.044 lb a.i./A and an EC25 of 0.0379 lb a.i./A based on dry weight. The most sensitive dicot was cucumber, with a NOEC of <0.0099 lb a.i./A and an EC25 of 0.0145 lb a.i./A based on dry weight. After 42 days,

the most sensitive monocot was onion, with a NOEC of 0.092 lb a.i./A and an EC25 of 0.0996 lb a.i./A based on dry weight. The most sensitive dicot was soybean, with a NOEC of <0.0044 lb a.i./A and an EC25 of 0.00397 lb a.i./A based on dry weight. Recovery of vegetative vigor was analyzed using growth rate. Recovery was observed for all species, except for corn (no concentration-response relationship at up to six times registered application rate; 2.0 lb a.i./A) and shoot dry weight for oat.

When evaluating the effects of an herbicide on the terrestrial environment, the potential for recovery must be considered. Agro-ecosystems in dynamic environments are likely to recover from disturbances (e.g., pesticide applications), especially disturbances that mimic historical events (e.g., previous pesticide applications; Denslow, 1985; Rapport et al., 1985; Moore, 1998).

Recent studies with terrestrial plants suggest that tested species generally recover following single and repeated exposures to atrazine at environmentally relevant concentrations. Dalton and Boutin (2010) applied atrazine to microcosms and single species to determine the potential for effects and recovery. Nine terrestrial and seven wetland plant species (1 monocot and 15 dicots) found in Eastern Ontario and Western Quebec were evaluated. The study compared EC25s for percent of control biomass in different experimental systems (short- and long-term greenhouse and outdoor microcosm environments). Short-term experiments were 28 days and long-term experiments spanned 60 and 70 days for terrestrial and wetland microcosms, respectively. AAtrex® 480 (Syngenta Crop Protection; 470.4 g a.i./L) was applied at doses selected to achieve 20 to 80% effect in target species.

Some recovery was observed in the long-term microcosms, and EC25s for total microcosm biomass were higher in longer-term microcosms than in the 28-day greenhouse microcosms. Overall, EC25s were within an order of magnitude of one another, with total microcosm biomass EC25s ranging from approximately 0.09 to 0.45 lb a.i./A. These values are within the range of single-species growth EC25s reported in the Tier II atrazine studies (Chetram, 1989a,b; Martin, 2015a,b).

There is no scientific justification for EPA (2016a) excluding two high quality terrestrial plant studies that follow standard guidelines and use a current product (i.e., Martin et al., 2015a,b). In addition, it is critical that recovery be considered for herbicides such as atrazine. Herbicides are developed to eradicate unwanted plants. Therefore, it is understandable that spray drift and runoff to non-target areas could cause negative effects to non-target plants. However, if recovery is possible, it could mitigate the initial effects of atrazine and show that non-target plants are able to tolerate higher concentrations than initially assumed using shorter toxicity tests.

3.2 Wildlife

Included below is a brief summary of the key issues identified in the bird and mammal risk assessments performed by EPA (2016a). Details are further discussed in a response document submitted to the docket by Syngenta (Olson et al., 2016).

3.2.1 Exposure Assessment

EPA (2016a) used T-REX version 1.5.2 in their screening-level assessment to estimate risks to birds and mammals potentially exposed to atrazine. However, T-REX uses a number of highly conservative assumptions to estimate risk, including the following:

- One residue unit dose is used for all arthropods, despite varying residues based on location and behavior of the arthropods. For example, flying insects are likely to have much lower residues than crop-dwelling insects. Therefore, residues ingested by birds that consume only flying insects may be several fold lower than residues ingested by birds that consume soil surface or crop-dwelling arthropods. For realistic dietary exposure estimates, residues should be quantified for different invertebrate groups using available pesticide data.
- The model assumes that wildlife obtain 100% of their daily diet from treated locations immediately after application, while in reality most species forage on and off the field and will vacate the area during application, only returning after the disturbance has ceased.
- The model does not allow for analysis of mixed diets and instead considers homogeneous diets, several of which are implausible (e.g., 20 g bird consuming only foliage; Sullivan and Wisk, 2012).
- Food ingestion rate is estimated in T-REX with allometric equations derived from Nagy (1987). However, more up-to-date equations are currently available (e.g., Nagy et al., 1999). Further, the calculations should be based on field metabolic rates, gross energies of dietary items, and assimilation efficiencies of the dietary items consumed.

In its assessment, EPA (2016a) used a default 35-day foliar dissipation half-life, despite acknowledging appropriate residue studies for atrazine. These residue studies reported a maximum observed half-life of 17 days. EPA (2012b) guidance directs risk assessors to estimate a 90% upper confidence limit on a mean half-life when there are three or more half-lives available. EPA (2016a) failed to follow their own guidance, citing degradates of atrazine as the primary reason. However, no data were presented by EPA (2016a) that support a longer half-life for atrazine or that describe the nature of residues on foliage. Further, a field study investigating atrazine residues on grain sorghum supports foliar dissipation half-lives between four and five days for "equivalently toxic" residues (Selman, 1995).

3.2.2 Effects Assessment

3.2.2.1 Birds

EPA (2016a) selected an acute LD50 of 783 mg a.i./kg bw and a slope of 2.263 to estimate acute risks to birds. Although the original study reported an oral LD50 of 940 mg a.i./kg bw with a corresponding slope of 2.263 (Fink, 1976 [MRID 00024721]), the LD50 used by EPA (2016a) was recalculated from raw data provided in the original study. EPA (2016a) re-analyzed the raw data using probit analysis, resulting in an LD50 of 783 mg a.i./kg bw and a probit slope of 3.836. However, when generating effects metrics for the ERA, EPA (2016a) paired the recalculated LD50 with the probit slope reported in the original study. This is incorrect. The correct LD50 and slope should be 783 mg a.i./kg bw and 3.836, respectively.

To estimate chronic risks to birds, EPA (2016a) selected a NOEC of <75 mg a.i./kg diet for hatchling weight and LOEC of 225 mg a.i./kg diet for egg production and food consumption

(Pedersen and DuCharme, 1992 [MRID 42547101]). A number of issues have been identified with the use of these endpoints, and include the following:

- When analyzing the raw data, the dead female in the 225 mg a.i./kg diet group should have been excluded from analyses for reproduction, so as not to skew the results.
- Data for egg production were analyzed using the William's Multiple Comparison Test, which is only acceptable for continuous data (Piegorsch and Bailer, 1997). It would have been more appropriate to use the Dunnett's test (Zar, 2010). Use of the Dunnett's test would have resulted in a NOEC of 225 mg a.i./kg diet and LOEC of 625 mg a.i./kg diet. When calculated with the appropriate statistical analyses, the endpoints are at least three-fold higher.
- The NOEC selected by EPA (2016a) for hatchling weight is likely the result of inherent variability in hatchling weights and not ecologically significant. In fact, the original study authors (Pedersen and DuCharme, 1992 [MRID 42547101]) noted that the lower hatchling weight values observed on day 1 were likely attributable to normal biological variation not atrazine exposure. Statistical analyses showed large variations among birds within treatments, including within controls. Therefore, the statistical significance identified by EPA (2016a) is likely trivial from an ecological standpoint and a more appropriate endpoint showing clear a concentration-response relationship should be selected.
- Estimates of food consumption were calculated incorrectly by EPA (2016a). Food consumption depends on a number of factors, particularly body weight. Therefore, food consumption is generally normalized to body weight. However, not only did EPA (2016a) fail to normalize the data, but they also included data points for dead birds and capped the food limit at 4600 g per cage per week for reasons unstated. This led to inaccurate food consumption calculations and artificial censoring of the data. If the raw data are recalculated to normalize for body weight and exclude dead individuals, the NOEL is ≥675 mg a.i./kg diet.

3.2.2.2 Mammals

EPA (2016a) selected a chronic NOEL of 3.7 mg a.i./kg bw/d to estimate long-term effects to mammals. EPA (2016a) stated that their endpoint was calculated from a NOEC of 50 mg a.i./kg diet reported by Mainiero et al. (1987 [MRID 40431303]). However, the selection of the chronic NOEL was not discussed anywhere in the assessment and we could not replicate the calculations, despite access to raw data. Therefore, the accuracy of the NOEL is unknown.

3.2.3 Risk Characterization

While characterizing risk to birds and mammals, EPA (2016a) used default body weights for test species. The default body weights for birds and mammals are 178 g (northern bobwhite) and 350 g (rat), respectively. However, the actual body weights of animals tested in the corresponding toxicity studies were considerably lower. The northern bobwhite chicks used by Fink (1976 [MRID 00024721]) weighed 33 to 35 g, while the rats used by Sachsse and Bathe (1975 [MRID 00024706]) weighed 160 to 180 g. In risk calculations, EPA (2016a) scaled all effects metrics to body weight. For example, the adjusted LD50 for birds was 516 mg a.i./kg bw. However, if the mean body weight corresponding to the study animals is used, the adjusted

LD50 is 564 mg a.i./kg bw. Discrepancies in adjusted LD50 calculations could have significant impacts on risk calculations.

No other lines of evidence were discussed by EPA (2016a) to validate their conclusions. Some additional information should have included:

- The lack of incident reports for birds or mammals associated with atrazine exposure despite many decades of widespread use.
- Potential avoidance, as is often observed with other pesticides at high doses.
- Comparison of acute oral gavage and acute dietary risk estimates and the reasons why the former are overly conservative (i.e., oral gavage is a worst-case exposure for birds and does not represent how exposure occurs in the field).
- The implications of their assessment being based on sprayed vegetation rather than sprayed soil, which is the predominant timing of application for atrazine in corn.

3.2.4 Refined Risk Assessment

The refined risk assessment for birds was conducted using the TIM and MCnest models. However, there are numerous issues. Many of the input values chosen by EPA (2016a) did not follow their guidance or were not appropriately determined from studies and the models incorporated a number of overly conservative assumptions that are inappropriate for a refined assessment. Some of the issues are described below and further reviewed by Olson et al. (2016):

The Assumptions in the ERA were Not Supported by Best Available Data

- EPA used a dermal effects ratio for birds that relied on data for organophosphates and carbamates, the applicability of which to atrazine are unknown. As a result of the effects ratio, 80% of the predicted exposure was contributed by dermal contact. However, birds have feathers that will intercept and significantly decrease exposure, most birds will leave a treated area during application, and atrazine becomes rainfast within one to two hours. Therefore, contact exposure is likely to be much lower.
- A dermal effects ratio for atrazine and related chemicals (i.e., triazines) is much more applicable. For example, an effects ratio produced from data for triazine compounds reduces the estimated mortality of vesper sparrows by two thirds.
- EPA did not incorporate the vast amount of field data showing the fraction of time birds spend on treated fields. Fitting distributions to the available data, rather than using worst case scenarios, is a more applicable approach for estimating the potential for exposure.
- EPA assumed a default foliar half-life of 35 days, despite a number of field studies demonstrating a half-life of 17 days or less for atrazine. Use of the default half-life was not supported and did not follow EPA's own guidance.

The ERA Contained Significant Errors that Impacted Risk Estimates

- To estimate acute risks to birds, EPA used an LD50 and slope that were calculated using different methods. When the LD50 was paired with the appropriate slope, mortality estimates were reduced by almost 50%.
- To estimate chronic risks to birds, EPA made several errors in the selection and use of statistical analyzes. When the correct statistics are used, the NOEC increases from <75

mg a.i./kg-diet to 225 mg a.i./kg-diet. This has a significant impact on chronic risk estimates.

The ERA was Hyper-Conservative

- EPA selected an arbitrary hourly fraction of pesticide retained rather than calculating one from available data. The calculated value is lower, which decreases the potential for toxicity over long-term or multiple exposures.
- Instead of using average exposure values over the duration required to elicit reproductive effects in birds, EPA used one-day peak exposure values. This greatly increased the exposure estimates.
- EPA assumed complete nest failure when exposure exceeded the no observed effect concentration (NOEC), despite studies showing only a 24% reduction in clutch size at the LOEC and modeling showing no impacts on reproductive success when the clutch size is lowered by 22%.

The ERA for Mammals was Inadequate

- Despite identifying potential risk concerns for mammals, EPA did not consider any exposure refinements for mammals and no other lines of evidence were discussed.

The issues summarized above led to significant overestimates of acute and chronic risks for birds and mammals potentially exposed to atrazine. Using the vesper sparrow as an example, EPA's conservative assumptions predicted 21.8% mortality in treated corn fields. However, this is not supported by 50 years of incident data or field studies. When best available data are applied, negligible risks are predicted for birds and mammals as described in Olson et al. (2016).

4.0 CONCLUSIONS

The draft risk assessment recently released by EPA (2016a) was overly conservative, relied on poor quality data, and had a number of errors. A number of issues were highlighted in this report and include the following:

- Monitoring data were often misinterpreted and included erroneous values. We suggest that EPA work together with registrants for future assessments to ensure that data are correctly selected and interpreted.
- Aquatic and terrestrial exposure modeling relied on highly conservative assumptions that may not be representative of atrazine use areas.
- The best available effects data were not employed for fish, terrestrial plants, aquatic-phase amphibians, wildlife, and aquatic plants.
- Refined risk analyses were not performed for mammals, despite indications of potential risks in the screening-level assessment.
- Numerous issues were identified in EPA's refined avian assessment. When best available data are used as inputs to the exposure model, avian risks are negligible.
- Calculation of a level of concern for aquatic plants relied on poor quality data that have previously been rejected by multiple sources (SAP, 2009; 2012; Giddings, 2012; Moore et al., 2015; 2016).

Atrazine has an incredibly rich database of information with regard to exposure and effects to aquatic and terrestrial organisms. Numerous Scientific Advisory Panels have also given thoughtful recommendations and advice to the EPA that, if accepted, would have led to a far less conservatively biased and more scientifically defensible assessment. At almost every turn in the atrazine assessment, EPA ignored this advice and the availability of much high quality scientific information in favor of making decisions that significantly overestimated ecological risk.

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Appendix A
Study Evaluations

Study Evaluation for Panard et al. (2009) Study

Study Reference: Pannard, A., B.L. Rouzic and F. Binet. 2009. Response of phytoplankton community to low-dose atrazine exposure combined with phosphorus fluctuations. Archives of Environmental Contamination and Toxicology 57:50-59.

Classification for Relevance: Not relevant

Classification for Data Quality: Unacceptable

Abstract: The effects of atrazine on a controlled phytoplankton community derived from a natural freshwater wetland exposed to low doses of this photosynthesis-inhibiting herbicide were examined. The community was exposed for 7 weeks to doses of 0.1, 1, and 10 µg/L atrazine, combined with changes in nutrient concentration, and the photosynthetic activity, biomass, and community structure were noted during the experiment. Responses of the phytoplankton community were examined in terms of photosynthetic activity, biomass, and community structure. Significant effects of atrazine on the phytoplankton assemblage, in terms of primary production and community structure, were highlighted, even at doses as low as 1 and 0.1 µg/L, when associated with phosphorus fluctuations. The most abundant Chlorophyceae decreased in concentration with increasing atrazine dose, whereas cyanobacteria were more tolerant to atrazine, particularly with increased nutrient supply. The subinhibitory doses of atrazine used in the present study confirmed the higher sensitivity of long-term exposure of multispecies assemblages under resource competition. Our study supports the emerging hypothesis that the increasing prevalence of cyanobacterial blooms in European aquatic systems may result from a combination of unbalanced nutrient enrichment and selective pressures from multiple toxicants.

Table 1. Evaluation of data relevance[a]		
Question	***Yes or No***	***Comments***
Was the study relevant to communities of aquatic plants?	Yes	Phytoplankton community derived from a natural freshwater wetland; macrozooplankton filtered out; cultured semi-continuously until the start of the test; eight species, dominated by two Chlorophyceae at test stat.
Was atrazine the only active ingredient to which test organisms were exposed?	Yes	Commercial pure atrazine (Atrazine Pestanal, Riedel-de-Haen)
Were the test endpoints direct measures of community-level effects for aquatic plants (e.g., primary productivity, community structure, species richness, relative abundances of different guilds)?	Yes	Short-term – rate of ^{14}C incorporation Long-term - Photosynthetic activity, biomass and community structure
Was the exposure route in the study relevant to what is expected in the environment?	Yes	Water exposure
Was a recovery phase included?	No	Atrazine renewed weekly
CLASSIFICATION FOR RELEVANCE[b]		**NOT RELEVANT**

a. Only endpoints related to atrazine effects to aquatic plants were evaluated and presented in Tables 1, 2 and 3
b. Study is relevant if all answers are "yes", otherwise the study is not relevant

Table 2	Evaluation of data quality		
Assessment Factor	***Questions***	***Score***	***Comments***
Objectivity	Was the study conducted according to a recognized international standard (e.g., EFSA, OPPTS, OECD, SANCO)? If not, was a complete description of the test system and methods given, and were the methods used considered acceptable practices?	0/3	Study was not conducted according to a recognized international standard or laboratory guidance. Study score 0 for one Clarity and Transparency criterion
Clarity and Transparency	Were the identification, purity and source of test substance given and comparable to the current technical material?	1/3	**ID:** Commercial pure (Atrazine Pestanal) **Source:** Riedel-de-Haen **Batch #:** Not reported. **Purity/proportion a.i.:** Not reported. **Carrier solvent:** None
	Were appropriate controls included, reported and results adequate? Was a carrier solvent used? If a solvent was used, were positive and negative controls included? Did positive and negative controls have similar results?	1/3	Negative controls used, with results reported for species composition. No positive control used in the study and water quality parameters not reported. 40.0 to 92.4% decrease in species composition (one species increased) in controls over the course of the experiment
	Were statistical procedures reported and appropriate?[a]	2/3	**Short-term (48 hours)** **Method:** Non-parametric two-factor Friedman analysis for rate of carbon dioxide incorporation **# test concentrations:** 4 **# replicates:** 5 **Long-term (7 weeks)** **Method:** Non-parametric two-factor Friedman analysis for rate of carbon dioxide incorporation and evolution of biomass; chi-square analysis used to test homogeneity of community structures at different times and doses; single-factor (dose) or two-factor (time and dose) ANOVA used to evaluate species densities; Kruskall-Wallis analysis used to evaluate effects on Simpson's index of diversity **# test concentrations:** 3 **# replicates:** 4
	Were test concentrations provided and measured?	2/3	**Short-term (48 hours)** **Application method:** Applied

Table 2	Evaluation of data quality		
Assessment Factor	***Questions***	***Score***	***Comments***
			once to water **Nominal concentrations:** 0, 0.05, 0.5, 5.0, and 50 µg/L **Measured concentrations:** Not measured. **<u>Long-term (7 weeks)</u>** **Application method:** Discontinuous fresh input weekly and weekly renewal of atrazine concentrations **Nominal concentrations:** 0, 0.1, 1.0, and 10 µg/L **Measured concentrations:** Not measured.
	Was sampling sufficient for characterizing test system and responses?	2/3	**Sampling times:** **<u>Short-term</u>** **Rate of ^{14}C incorporation:** Measured after 1, 16, 22, 40, and 46 hours **<u>Long-term</u>** **Phytoplankton biomass:** Measured weekly by chlorophyll a concentration **Biological activity:** Measured weekly by carbon dioxide incorporation **Taxonomic incorporation:** Measured at test start then at 1, 4, and 7 weeks
	Was a concentration-response relationship clearly demonstrated?	0/3	Concentration-response observed for some species, but not others; usually no significant differences among treatments; large difference in community composition in controls between start and end of test is highly suspect. No results provided for individual concentrations, times, and endpoints.
	Were observed effects consistent with atrazine mode of action (i.e., effects apparent during or directly after treatment period)?	1/3	No negative effects observed for first few weeks of test and no significant effects observed for biomass
	Were appropriate test conditions (e.g., pH, conductivity, temperature, dissolved oxygen, water hardness, mesocosm size, etc.) reported and within	1/3	**Study location:** Natural phytoplankton community collected from freshwater wetland in Brittany, Pleine-

Table 2	Evaluation of data quality		
Assessment Factor	***Questions***	***Score***	***Comments***
	acceptable ranges?		Fougeres, France **General weather conditions:** Not reported. **pH:** Not reported. **Conductivity:** Not reported. **Air temperature:** 20°C **Water temperature:** Not reported. **Dissolved oxygen:** Not reported. **Water hardness:** Not reported. **Mesocosm size:** 240 mL water in 500 mL bottles
Integrity	Was the study conducted under GLP?	0/1	No GLP compliance statement
TOTAL SCORE OF STUDY		10/28	
CLASSIFICATION (ACCEPTABLE, SUPPLEMENTAL, UNACCEPTABLE) FOR DATA QUALITY[b]		**UNACCEPTABLE**	

[a] The appropriate statistical approach will depend on the type of data being analyzed (e.g. binomial, ordinal or continuous responses), and whether or not parametric or non-parametric approaches should be applied. For ECx estimation, appropriate statistical methods include probit, logit, Gompertz, Weibull, Gumbell and Burr, and appropriate Generalized Linear Models for parametric tests. Some non-parametric tests for ECx estimation included the Spearman-Karber and Trimmed Spearman-Karber methods. Graphical interpolation is not an acceptable method for calculating ECx values. For calculation of NOELs or LOELs, Dunnett's test is often used to compare treatment groups to controls when data are normally distributed and have homogeneity of variance. T-tests with Bonferroni correction can also be used when the number of replicates is not the same for all concentrations. When assumptions are not met, data can be transformed, or a non-parametric test such as Steel's Many-one Rank Test or Wilcoxon's Rank Sum Test may be used. For binomial data such as mortality, the Fisher's exact test should be used to establish the NOEL or LOEL.

[b] Acceptable studies have scores of 22-28, supplemental studies have scores of 12-21, and unacceptable studies have scores of 0-11.

Table 3. Study Results

Receptor Group (e.g., algae, periphyton, macrophytes)	*Exposure Duration (d)*	*Recovery Period (d)*	*Treatment Concentration (µg ai/L)*	*Effect Class*[a]	*Notes on Observed Responses*	*Study Classification (Table 2)*
Phytoplankton	7 weekly applications	0	0.1	1	Chlorophyll a increased progressively. No significant difference compared to controls. Large difference in community composition in controls between start and end of test.	Unacceptable
Phytoplankton	7 weekly applications	0	1.0	1	Chlorophyll a increased progressively. No significant difference compared to controls. Large difference in community composition in controls between start and end of test.	Unacceptable
Phytoplankton	7 weekly applications	0	10	1	Chlorophyll a increased progressively. No significant difference compared to controls. Large difference in community composition in controls between start and end of test.	Unacceptable

[a] Effect Class 1: No statistically significant effects from treatment or observed differences from controls show no clear causal relationship
Effect Class 2: Slight and transient effects (i.e., short-term, restricted to one or a few sensitive endpoints and/or sampling periods)
Effect Class 3A: Pronounced effects with recovery in <8 weeks of first application or period of effects <8 weeks; temporary effects on several species or endpoints; effects observed at some subsequent samples
Effect Class 3B: Pronounced effects with recovery in <8 weeks after last application; with repeated treatments, total duration of effects >8 weeks is possible; effects observed at some subsequent samples
Effect Class 4: Pronounced effects but study too short to demonstrate recovery within 8 weeks of last application
Effect Class 5A: Pronounced effects for >8 weeks and no recovery within 8 weeks of last application; full recovery by end of test
Effect Class 5B: Pronounced effects for >8 weeks and no recovery within 8 weeks of last application; no full recovery by end of test

Other Comments and Notes:

N/A

Message

From: Bostick, Thomas [TBostick@dna.com]
Sent: 7/9/2018 12:48:19 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Keigwin, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=151baabb6a2246a3a312f12a706c0a05-Richard P Keigwin Jr]; McNally, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efa5514317e34b9895687d73730fdde9-Robert McNally]; Mendelsohn, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=720b16e1b31742738a728d8d2814beef-Mendelsohn, Mike]; Shurdut, Brad [BShurdut@dna.com]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]
Subject: RE: Follow up
Attachments: ATT00001.txt; Oxitec Response_OX513A Mosquito EUP.PDF; Appendix 1_ Allergenonline letter.pdf

Flag: Flag for follow up

Dear Nancy, one follow up to my earlier email this morning. This second PDF attached (Appendix 1) provides the rationale for removal of the octacoral/ akane sequence from the Allergenonline database which you requested.

Let me know if you have any questions.

Best,
Tom

From: Bostick, Thomas
Sent: Monday, July 9, 2018 8:18 AM
To: 'Beck, Nancy'
Cc: 'Keigwin.Richard@epa.gov'; 'McNally.Robert@epa.gov'; 'Mendelsohn.Mike@epa.gov'; Shurdut, Brad
Subject: Follow up

Dear Nancy, trust that you have had a relaxing time away from DC.

Thank you again for taking the time for my call. As a follow up to our call, and in preparation for a call on 13 July (if we can align calendars), please see attached response.

Safe travels!

Best regards,
Tom

Thomas P Bostick, PhD, PE, NAE

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Appendix 1

University of Nebraska Lincoln

FOOD ALLERGY RESEARCH AND RESOURCE PROGRAM
Department of Food Science & Technology

23 March, 2018

Subject: Re-review of the potential allergenicity of the Green Fluorescent Protein family Alkane that was entered into AllergenOnline.org database in January, 2018.

Dear AllegenOnline.org user:

Thank you for asking about the validity of the Akane sequences that we entered into AllergenOnline.org in January, 2018, version 18 of our database. There are four closely related sequences that are from 89% to 99% identical, all entered in the GenBank public database as "Novel Allergenic Proteins" from the Octocoral species *Scleronephthya gracillima*, by authors of the publication (Kato et al., 2017, Luminescence 32(6):1009-1016).

Our original review of the publication by Kato was based on the process we described in 2016 for the generation and curation of our AllergenOnline.org database. However, this is one of the instances when the panel of experts was a bit divided in the original review. I reviewed our archival notes on version 18 and found that no one called this a clear "allergen", and there was grading by some that the protein was not even "putative" within our definition. Therefore I asked the rest of the panel (7 other experts) to join me in a re-review of the Kato et al., 2017 paper and our decision. I have described the details of the information in the Kato publication here, and the final decision that the group came to following the re-review, on 19 March, 2018.

Review points:

1. Only one publication can be found in PubMed of allergy to the source organism, *Scheronephthya sp*. That is the one by Kato et al., 2017.
2. Kato et al., described conjunctival, dermal and asthma disease symptoms in some fishermen and workers who process mollusks and in lobster fishermen. They also described testing guinea pigs with extracts of a related red octocoral organism.
3. Kato et al., experimental details.
    a. Serum donors included a panel of an unlisted number of patients who are lobster fishermen from the Pacific coast of Miyazaki, with the range of symptoms (conjunctivitis, dermatitis or asthma), and they pooled their sera. They also had a pool of "healthy controls".
    b. Kato et al., collected octocoral samples of *S. gracillima* and extracted proteins in 10 mM sodium phosphate buffer, then concentrated proteins by precipitation with ammonium sulfate, then dialyzed to remove ammonium sulfate.

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Richard E. Goodman, PhD, rgoodman2@unl.edu Office phone (402) 472-0452; Cell (402) 417-5549

c. Kato et al., performed partial purification of the fluorescent protein(s) using gel filtration and ion exchange chromatography, following the protein with UV absorbance detection.
d. Kato et al., separated the semi-pure mixtures by SDS-PAGE and transferred proteins to PVDF membranes for immunoblots with pooled patient and control sera. The western blots were blocked with non-fat dry milk, and after serum samples were incubated and washed, they used polyclonal goat anti-human IgE coupled with horse radish peroxidase (HRP). The HRP was detected with chemiluminescence (ECL Plus), with exposure of X-ray films. There was faint binding to a 27 kDa band, not to control serum pool by 1D immunoblots. There was stronger detectable band to a 22 kDa band by control and patient pools (figure 2).
e. Paragraph 2.6 in Kato et al., seems out of place. They describe selection of IgE from patient pool by immunoblotting onto a crude extract, then using that captured sera as primary antibody. It is not clear if that was used in the first 1D immunoblot, or only in the 2D immunoblot.
f. Section 2.8 describes trypsin-digestion of the proteins, 22 kDa, 27 kDa and 45 kDa. They only describe two peptides (one has an ambiguity "I" vs"L" as part of the 27 kDa protein (Table 1), the other, 10 aa peptide is shown in Table 1 and is in Table 2 as peptides from the 8 spots in the 2D gel (Figure 6) which shows immunoblots of the pooled "allergic" sera, and the pooled "control" sera. Interestingly the 10 AA peptide was seen in all 8 spots from 27 kDa and the 22 kDa spot. No peptides are identified from the 45 kDa spot.
g. Section 2.9 describes cDNA cloning by RACE, starting from the Poly A selected RNA. Unfortunately there is no description of the starting sequence for RACE.
h. Figure 5 shows 1D immunoblots of "raw" 22, 27 and 45 kDa proteins with immunoblots without absorption ((b) and with absorption (c), P-1, not P-2, of sera bound or not to raw extract. Kato et al., attribute the apparent lack of binding to 27 kDa protein in (c) as indicating that the only allergenic protein if from 27 kDa protein.
i. Figure 6 (b) shows very light spots 4, 6 and 7 at 27 kDa with patient sera, but a very intense two spots at 22 kDa that they dismiss. Clearly from stained gel (a), the two spots are most abundant. However, the spots 6 and 7 in stained gel are fairly abundant based on staining. Yet immunoblots show only faint "ghost" spots (b) and lighter in (c) with control sera on spot 7.
j. The results describe interesting fluorescence behavior of the proteins showing emissions for green and red proteins when stimulated with UV.
k. Kato et al., have not demonstrated clear IgE binding to proteins that they claim to have cloned. They also show only light apparent binding in a 2D immunoblot to spots 4 and 6. They have not shown sequences that correspond to all of the blots, not have they demonstrated any differences that would explain why spots 4 and 6 should be "allergens", except apparent light immunoblot patterns.

SUMMARY. In our first review of the data of the "Akane" proteins presented by Kato et al., 2017, some of the panel thought there was sufficient evidence to suggest that the protein(s) described by Kato et al., 2017, could be considered "putative allergens" and included in our version 18 database. However, as we have gone through a second round of review and looked at their publication a second time in great detail, the complete panel of eight allergen experts (listed below), have concluded that there is not sufficient evidence to call the protein(s) even putative allergens. The authors (Kato et al) have speculated on dimers of the protein that have not been demonstrated for this protein, and they have speculated that their results demonstrate allergenicity. However, the requirements of our classification scheme presented in Goodman et al., 2016 has not been sufficiently demonstrated to approve the four cDNA sequences listed as Accession numbers BAW321535.1, BAW32536.1, BAW32537.1 and BAW32538.1, as "putative" allergens. Certainly they lack proof of biological activity of "allergens" that would require not only specific IgE binding, but also biological activity of allergenicity (basophil activity, skin prick test reactivity or other in vivo challenge positive reactivity).

As a panel, we have unanimously agreed to remove these four sequences from the AllergenOnline.org database since the only data of "possible" allergenicity is that presented by the Kato et al., 2017 publication.

REVIEW PANEL:

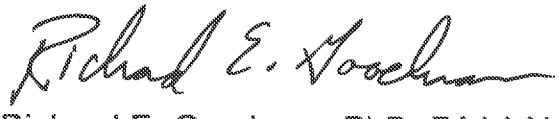
1. Joe Baumert, Ph.D.,
   University of Nebraska, Lincoln, NE, USA
2. Barbara Bohle, Ph.D.,
   Medical University of Vienna, Vienna, Austria
3. Motohiro Ebisawa, M.D.,
   National Sagamihara Hospital, Sagamihara, Japan
4. Fatima Ferreira, Ph.D.,
   University of Salzburg, Salzburg, Austria
5. Richard E. Goodman, Ph.D.,
   University of Nebraska, Lincoln, NE, USA
6. Joerg Kleine-Tebbe, MD, FAAAAI., (member since 2016)
   Allergie- & Asthma-Zentrum Berlin Westend, OPD Hanf, Ackermann & Kleine-Tebbe, Berlin, Germany
7. Steve L. Taylor, Ph.D.,
   University of Nebraska, Lincoln, NE, USA
8. Ronald van Ree, Ph.D.,
   Academic Medical Center, Amsterdam, The Netherlands

References:

Kato Y, Jimbo M, Sakakibara Y, Onizuka R, Takahashi T, Matsuhashi S, Mita H, Amada K, Imahara Y, Tanabe K, Toda A, Kamiya H. 2017. Characterization of a novel allergenic protein from the octocoral Scheronephthya gracillima (Kuekenthal) that corresponds to a new GFP-like family named Akane. Luminescence. 32(6):1009-1016.

Goodman RE, Ebisawa M, Ferreira F, Sampson HA, van Ree R, Vieths S, Baumert JL, Bohle B, Lalithambika S, Wise J, Taylor SL. 2016. AllergenOnline: A peer-reviewed, curated allergen Database to assess novel food proteins for potential cross-reactivity. Mol Nutr Food Res 60(5):1183-1198.

Sincerely,



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Nancy Beck, Ph.D.
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Mail Code 7101M
Washington, D.C 20460

Re: Information Provided in Support of OX513A EUP and Section 3 Registration Applications

Dear Nancy,

Thank you for taking the time to speak with me and my colleague, Brad Shurdut, on Friday, June 29, regarding Oxitec's applications submitted under Section 5 and Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the OX513A mosquito. Oxitec has worked diligently with the Biopesticides and Pollution Prevention Division (BPPD) of the Office of Pesticide Programs (OPP) to address and satisfy all requirements under Section 5 of FIFRA for an Experimental Use Permit (EUP) to release the OX513A mosquito in the Florida Keys and Harris County, Texas, and for registration of the OX513A mosquito under Section 3 of FIFRA.

I would like to assure you that Oxitec has gone to great lengths to address all data requirements that BPPD has informed us are applicable to the OX513A mosquito, and that we are willing to expeditiously provide any additional data and information that may be required of us to support final approval of both the Section 5 EUP, and the Section 3 pesticide registration.

As you are aware, under the Pesticide Registration Improvement Act (PRIA) amendments to FIFRA, there are essentially 3 separate review periods relevant to experimental use permits and pesticide registrations. During the first review period – the 21-day content screen – EPA determines whether an application has all the components required for a particular type of application. The 21-day content screen is entirely non-substantive; it merely is a check to see if all the pieces of an application are present, all documents are properly signed and dated, etc. The second review period is a preliminary technical review. The purpose of this review period is for EPA to assess whether the applicant has submitted sufficient data and information for EPA to begin the substantive review of the application. Congress added the preliminary technical review period in the 2012 PRIA amendments to ensure that applications contained sufficient data and information for EPA to begin the substantive review of applications. The preliminary technical review was not intended by Congress to be a substantive review to assess whether a particular application completely satisfies the requirements for approval. If EPA determines that an application is substantively deficient, EPA notifies the applicant and identifies the deficiencies. The applicant then has 10 business days to satisfy the identified deficiencies. If the applicant submits sufficient data for EPA to begin the substantive review, the third review period begins. In the final substantive review of the application, the EPA is to assess whether the applicant presents sufficient data and information to satisfy the FIFRA standard of no unreasonable adverse effects.

The PRIA deadline for a decision on Oxitec's OX513A EUP application is July 25th. On March 22, 2018, BPPD informed Oxitec that it had determined that the OX513A Section 5 EUP application had specific deficiencies, and that it was necessary for Oxitec to address the identified deficiencies within 10 business days, i.e., by April 9, 2018. Oxitec met with BPPD, in person and via telephone, on March 28, to discuss the deficiencies identified by EPA and to ensure that Oxitec scientists were absolutely clear on the data and information that was required to satisfy these deficiencies. During

that meeting, BPPD staff and Oxitec scientists and management engaged in what Oxitec considered to be useful and informative discussion of the identified deficiencies. At the conclusion of the meeting, Oxitec had what it believed to be a clear understanding of the data and information that BPPD required to begin the substantive review of the OX513A EUP application. Oxitec resolved to make every effort to provide all information identified by BPPD as being required for initiation of the substantive review of the EUP application. Moreover, Oxitec has met weekly with EPA over this time and routinely inquired about any potential issues that still needed to be addressed.

Oxitec believes that it has submitted data and information that completely address all of the additional information requested by EPA. As part of this letter, we have provided a data matrix (Table 1) that was derived from the confidential appendix that BPPD included to the March 22 letter. This table provides the data deficiencies concerning allergenicity, assay uncertainties, human exposure to DsRed2 and tTAV proteins and the manufacturing process, and information submitted to address these deficiencies.

I'd like to also provide additional background on why Oxitec believes that the data and information submitted were completely responsive to BPPD's requests for additional data. The formal response to the March 22 letter is filed in OPP's central data repository as MRID 50560401, and it is accompanied by a number of subdocuments that each have their own separate MRID designations.

To begin with, I'd like to address the issue of the homology of the DsRed2 protein to a newly discovered protein that was claimed to be an allergen in a report by Japanese researchers. I note at the outset that it is not the DsRed2 protein that was listed as a putative occupational allergen. Rather, the Japanese researchers claimed that a Green Fluorescent Protein (GFP)-like protein had allergenic properties. This raised an issue with respect to DsRed2 because DsRed2 is a GFP, and the purported GFP-like protein has some sequence homology to DsRed2. The GFP-like protein, 'Akane' was originally listed on the AllergenOnline database in Feb 2018 and later withdrawn from the database on 23 March 2018, with a complete scientific rationale and explanation for the removal, written by all eight members of the AllergenOnline peer review panel. The panel's explanation for the removal of the GFP-like protein from the database is available on the AllergenOnline website: http://www.allergenonline.org/versionhistory.shtml (see also the linked pdf on that page).

In the deficiency letter dated 22 March 2018, BPPD requested that Oxitec address the listing of the Akane protein in the database and the 58% homology of DsRed2 to Akane. In MRID 50560401 (Appendix 1, p36-40, 9 April 2018), we provided the detailed scientific rationale for the removal of the Akane GFP-like protein from the AllergenOnline database on 23 March 2018, and for convenience, we have also provided a copy of this appendix (see pages 16-20). The scientific rationale that Oxitec included in MRID 50560401 provided a detailed scientific response by a panel of 8 independent allergen experts to the paper that claimed that the Akane protein was an occupational allergen. The response concluded that there was insufficient evidence to classify the Akane protein even as a putative allergen.

Subsequently, in a deficiency letter issued on 4 June 2018 in response to our Section 3 application, BPPD requested further "new data or expanded scientific rationales" for the removal of Akane from the AllergenOnline database. In a call with BPPD on 12 June 2018, BPPD indicated that the main data request was for an explanation regarding why the database initially included the protein as a putative allergen, but then later removed it, based on the same data (i.e., the paper published by the Japanese researchers). Oxitec responded to the 4 June Section 3 application deficiency letter on 19 June (MRID 50608001). In this response, Oxitec highlighted the procedures by which the AllergenOnline review panel reached their initial decision to include the Akane protein on the

database, and then the reasons for their removal (MRID 50608001, p19-20 19 June 2018). Oxitec also requested that the chair of the AllergenOnline review panel, Prof Richard Goodman (University of Nebraska, Lincoln), provide in confidence to the BPPD reviewers, the minutes and emails relating to these decisions. However, it must be emphasized here that the main point is not whether the AllergenOnline review panel looked at any new data as part of the re-evaluation. Rather, what is important is how the existing data were assessed, and the sound bases and conclusions that the review panel relied upon in determining that the Akane protein should not be classified as an allergen.

It is also important to note that the chair of the peer review panel for a competing allergen database, COMPARE, was a signatory to the AllergenOnline database scientific rationale for the removal of Akane from the AllergenOnline database in March 2018. With the formal removal of the GFP-like protein from the Allergen Online database, and the ongoing re-evaluation of the COMPARE database listing, Oxitec believes that it is indisputable that the unconfirmed assertion by one group of researchers, that the GFP-like protein is an allergen, has no relevance to DsRed2. Moreover, we also noted in our response that homology screening is but one aspect considered as part of a weight of evidence assessment for allergenicity. DsRed2 also has a long history of safe use as a fluorescent marker used in pharmaceutical research, and is digested rapidly when challenged in vitro with simulated gastric fluids and with proteases involved in environmental degradation.

I'd also like to address the issue of protein quantitation in the OX513A mosquito, which is one of the pieces of data required to estimate likely human exposure to DsRed2 and tTAV proteins. This was one of the areas we discussed with BPPD scientists during a call on 28 March 2018. Based on the additional explanation provided by BPPD scientists, we thought we had a good understanding of the information requested and subsequently addressed the apparent data deficiencies highlighted by the reviewers.

In Oxitec's response (MRID 50560401, p17, 9 April 2018) to the EUP deficiency letter, BPPD scientists acknowledged the challenges of 'proving the negative' when OX513A did not express DsRed2 and tTAV at detectable levels. To help overcome this challenge, BPPD suggested providing reference journal articles that demonstrated that the antibodies used by Oxitec to quantify DsRed2 and tTAV proteins worked in a variety of eukaryotic species expressing DsRed2 and tTAV. Oxitec provided relevant peer-reviewed articles that demonstrate that the antibodies have been used to ascertain the presence of DsRed2 and tTAV in numerous eukaryote species including insects, which were requested by BPPD as part of the justification of the validity of these antibodies for the assays being conducted.

The BPPD reviewers had also raised a valid concern that the protein extraction methods used to extract DsRed2 and tTAV proteins from OX513A mosquitoes might not efficiently extract cytosolic proteins, and in response to this Oxitec repeated the experiments with new extraction methods to address this concern. In these repeated experiments we also provided positive controls in the form of purified DsRed2 and tTAV protein (from *E. coli*) mixed into wild-type *Aedes aegypti* cytosolic lysates (MRID 50560407, p7 and p11-40) which demonstrated that the antibodies were able to detect the proteins in the context of *Aedes aegypti* lysates (and that the proteins were stable in lysates, where protein degradation might be expected to occur). It appeared to us, from the discussion on 28 March 2018, that these two additional sets of data, together with the statistically robust assay limits of detection, would have been sufficient to address the concerns raised by BPPD.

In a call with BPPD on 12 June 2018, when we discussed the deficiency letter issued on 4 June 2018 in response to our application under Section 3 of FIFRA, at least one BPPD reviewer indicated that

they had not realised that positive controls including mosquito lysates had been provided, which seemed to indicate that they might not have reviewed the data fully. BPPD scientists seemed to indicate on that call that these positive controls would probably have been sufficient to address the apparent deficiency that was highlighted again on 4 June 2018.

However, as these concerns regarding positive controls were raised again in the Section 3 deficiency letter (4 June 2018), which prompted the call with BPPD on 12 June 2018, Oxitec carried out another set of additional experiments, provided in MRID 50608003 and MRID 50608001 on 19 June 2018, as outlined in points (c) and (d) below. These further controls corroborated and validated the data provided on 9 April 2018:

MRID 50608001, MRID 50608003 (19 June 2018):

a) Oxitec screened some of its other transgenic insect research strains (in a variety of insects, including mosquitoes and fruit flies), and found that a research strain of *Aedes aegypti* expressed tTAV and DsRed2 proteins at high levels, that were detectable using the same assay conditions as previously used for OX513A. Oxitec then used this research strain to demonstrate that all antibodies were able to detect DsRed2 and tTAV proteins endogenously expressed in *Aedes aegypti*, and hence the qWestern blot assays worked as expected (MRID 50608003, p11-25).

b) These positive controls should have addressed any potential remaining concerns from the BPPD reviewers concerning the validity of the exposure data for OX513A mosquito adults, mosquito larvae or female mosquito saliva.

c) Oxitec was also able to improve assay sensitivity by using slightly different gel matrices for these analyses, resulting in slightly lower LoDs, but with results corroborating those reported on 9 April 2018. The final set of exposure data were:

- **tTAV protein** cannot be detected in larval OX513A mosquitoes above the assay Limit of Detection (LoD) of 1.56 ng, and is detected in adult OX513A mosquitoes at *de minimis* amounts i.e., up to 1.34 ng/mosquito (assay LoD is 0.39 ng per adult mosquito) (MRID 50608003, p25).
- **DsRed2 protein** cannot be detected in larval or adult OX513A mosquitoes above the assay LoD of 25 and 15 ng per mosquito, respectively (MRID 50608003, p24).
- **tTAV and DsRed2 proteins** are not detectable in OX513A female saliva (from 5 female mosquitoes) above the assay LoD of 0.8 ng and 2.5-5.0 ng, respectively (MRID 50326404).

d) The BPPD review team also suggested on the call on 12 June 2018 that Oxitec attempt to quantify DsRed2 and tTAV by analysing pooled OX513A mosquito samples. Oxitec attempted to respond to this suggestion by carrying out the additional experiments suggested (MRID 50608001 p27-33), but the results demonstrated that this analytical method was not appropriate to address the experimental question.

In summary, the protein exposure data provided by Oxitec, both on April 9, 2018 and supplemented on June 19, 2018 with additional corroborating data, should be sufficient for BPPD to conduct an in-depth risk assessment for OX513A. In addition, **since human exposure to the OX513A proteins is only possible via a biting female's saliva, and there is no secretory signal that allows for the secretion of protein to the mosquito's saliva, human exposure is implausible. This is corroborated by the lack of detectable protein in our analysis of saliva samples.**

You also mentioned on our call that BPPD was seeking further information on quality control, containment measures, etc. as part of information on the manufacturing process. Some requests for further information were made in the 22 March 2018 EUP deficiency letter, and we discussed these

on a call with BPPD on 28 March 2018, indicating that we would provide summaries of all manufacturing SOPs to address the deficiency identified on 22 March 2018. No specific requests for information about quality control or containment measures were made in the EUP deficiency letter dated 22 March 2018. The SOP summaries were provided in MRID 50560402 (Confidential attachment, p16-20). BPPD made further specific requests for information regarding quality control and containment measures, but only in the Section 3 deficiency letter (4 June 2018). These were provided in full in MRID 50608001 (p14-18, a summary), and MRID 50608002 on 19 June 2018, and included the following:

a) 21 complete manufacturing and shipping SOPs (MRID 50608002, Attachments 2 and 5) which also included details of containment measures.
b) Images of mechanical sorting devices for separating larvae from pupae, and male from female pupae (MRID 50608002, Attachments 3 and 4).
c) Quality Control measures and required standards, for
    - fitness of lab-reared colonies
    - mating competitiveness
    - number of flying males
    - penetrance of OX513A trait
    - detection of resistance to self-limiting trait, and measures to mitigate
    - detection of establishment in the environment, and measures to mitigate

In summary, the manufacturing and quality control data provided by Oxitec, both on April 9, 2018 and supplemented on June 19, 2018 with additional details requested on 4 June 2018, should be sufficient for BPPD to conduct an in-depth assessment of our OX513A applications under FIFRA.

Nancy, I recognize that this is a rather voluminous response to our discussion last week. However, the team and I feel that it is important to ensure that you are fully aware of all of the data and information that Oxitec has provided to be responsive to the data requests by BPPD. Oxitec has diligently and promptly undertaken its very best efforts to address and satisfy every data request that it has received from BPPD. Moreover, as noted above, Oxitec has sought specific guidance from BPPD to ensure that there was complete understanding of what data and information were required, and that there was a mutual understanding of what data and information would satisfy those requests. Our team also conscientiously followed up with your staff weekly in the event there were questions or clarifications needed.

As we have discussed on numerous occasions, the OX513A mosquito has been demonstrated in numerous release scenarios worldwide to be a safe and effective way to significantly reduce populations of *Aedes aegypti*. Moreover, as Oxitec has demonstrated in numerous submissions for both the EUP and Section 3 applications, the active and inert proteins in OX513A, tTAV and DsRed2 have been utilized for many years by countless researchers in numerous different organisms with no concern that either of these proteins presents any risk of harm to any species, except in the context of transcriptional squelching that the tTAV protein is intended to cause. The potential for tTAV and DsRed2 proteins to pose risk to humans is only possible via a biting female's saliva. Based on the absence of detectable tTAV and DsRed2 proteins in OX513A female saliva ((MRID: 50326404), exposure to these proteins will be negligible. Furthermore, both tTAV and DsRed2 lack the secretory signals required for secretion of proteins from salivary glands into saliva (MRID: 50560401). **Hence exposure is not only *de mimimis* based on our assessment of salivary proteins, but also biologically implausible.**

Oxitec very much appreciates your time in addressing the issue of the OX513A FIFRA applications, and I look forward to speaking with you on Friday, July 13.

Best regards,

Thomas P. Bostick
Lt. Gen. (Ret.), PhD, PE, NAE
Chief Operating Officer
M: 240.660.1519 | tbostick@intrexon.com
intrexon
better DNA
www.dna.com

cc: Rick Keigwin, Director, Office of Pesticide Programs
Bob McNally, Director, Biopesticides and Pollution Prevention Division
Mike Mendelsohn, Chief, Emerging Technologies Branch

Table 1: EPA's 90-Day Preliminary Technical Screening results, and Oxitec's Response				
	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
Allergenicity				
A search of the AllergenOnline database (Version 18A, February 01, 2018) found DsRed2 to have significant homology to a putative allergen (GFP-like protein; Kato et al., 2017). Thus, allergenicity of the modified DsRed2 cannot be excluded and human exposure to the protein must be addressed.	50560401 Appendix 1	36-40	The most recent version of AllergenOnline, Version 18b, 23 March 2018, no longer lists the GFP-like Akane proteins as allergens. Justification for this version update was provided and is summarised below. The Akane protein was removed because the initial paper identifying it as allergen failed to demonstrate IgE binding to the GFP-like protein. Conclusions were speculative based on very faint IgE blots that identified protein binding in both control and 'allergic' serum samples, and proteomic data identifying the sequence of the apparent allergen was ambiguous and showed poor protein coverage. Further detailed reasons for the removal of the Akane proteins from AllergenOnline (authored by the AllergenOnline review panel) are attached as an **Appendix 1** to this letter. **Note: Subsequently, in a deficiency letter issued on 4 June 2018 in response to our Section 3 application, BPPD requested further information regarding the removal of Akane from the AllergenOnline Oxitec responded to these requests on 19 June 2018, as outlined in Table 2 (below).**	• We have provided sufficient information for EPA to begin the substantive review of our applications. • Furthermore, we have provided data to show human exposure to the OX513A proteins via a biting female's saliva is not only biologically implausible for DsRed2, but also not detectable (see below).
Assay uncertainties: Quantitative Detection of DsRed2 and tTAV protein in OX513A female saliva				
Potential human exposure via female mosquito bites to tTAV and DsRed2 proteins	50560401	17	**1. BPPD requested we demonstrate that endogenously produced DsRed2 and tTAV can be recognised by VP16 and DsRed2 antibodies and indicated that the use *of E.coli***	• We have provided sufficient information for EPA to begin the substantive review of our applications.

Table 1: EPA's 90-Day Preliminary Technical Screening results, and Oxitec's Response				
	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
cannot be ruled out due to uncertainties in assay methodologies. Use of *E. coli* produced DsRed2 and tTAV proteins as positive controls are not sufficient to ensure the validity of the assays, particularly in light of a lack detection of mosquito/endogenously produced DsRed2 and tTAV proteins in whole mosquito larvae and adult assays.			**produced DsRed2 and tTAV proteins as positive controls were not sufficient, particularly in light of lack of detection in whole mosquito and adults assay.** **On a call with BPPD on 28 March 2018 , BPPD acknowledged the difficulties in 'proving a negative' if OX513A really did not express these proteins at a high enough level to be detected. To help address this question, Oxitec was requested to provide reference journal articles that demonstrated that the antibodies used worked in a variety of eukaryotic species expressing DsRed2 and tTAV as part of the justification of the validity of these antibodies for the assays conducted.** Oxitec provided relevant articles demonstrating that the antibodies worked in eukaryotes, including insects. Oxitec also provided *E. coli*-expressed proteins as positive controls, but 'spiked' these controls into wild-type mosquito lysates or wild-type mosquito saliva. Both the saliva protein detection study and the mosquito protein quantitation study were thus able to detect DsRed2 and tTAV proteins in the relevant analytes above the assay limits of detection. Hence, the antibodies used for protein detection were able to detect the relevant recombinant positive control samples. Further, the antibodies used have been validated in a wide variety of species. We also defined statistically robust limits of detection for each assay. Therefore, we did not expect that there would be	• We provided new data and information that supports the validity of the assay method and corroborates the assay results of negligible proteins

Table 1: EPA's 90-Day Preliminary Technical Screening results, and Oxitec's Response				
	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
			any difficulties in using these antibodies to detect these proteins expressed in mosquitoes, if they were present in quantities above the inherent limits of detection of the assays used, which they were not. Furthermore, we provided data that shows both tTAV and DsRed2 lack the secretory signals required for secretion of proteins from salivary glands into saliva (MRID: 50560401, 50608009) which further corroborated our analytical results and our contention that exposure via the dermal route is highly implausible.	
	50560401	18-20	**2. BPPD requested that we provide data on total protein extracted from saliva and how this relates to the protein amount expected to be secreted during normal blood feeding. BPPD remarked that the positive control Aegyptin is expected to be present in high concentrations in female saliva and the immunoblot may therefore not be sensitive enough to detect endogenously produced DsRed2 and tTAV.** We provided evidence to show that a) saliva collected from five female mosquitoes is comparable to the total amount of saliva present in an adult female's salivary glands, b) an Aedes adult female mosquito has approximately 3 µg of total salivary protein, and about half this amount is lost during the blood meal, c) mosquitoes reingest saliva while feeding, and about 25% of the salivary apyrase activity is recovered in the mosquito gut after a blood meal. In short, mosquitoes lose ~1.5 µg of salivary protein during the blood	• We have provided sufficient information for EPA to begin the substantive review of our applications • We provided new data and information that supports the validity of the assay method and corroborates the assay results of negligible proteins

Table 1: EPA's 90-Day Preliminary Technical Screening results, and Oxitec's Response				
	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
			meal, ~0.75 µg is reingested, and ~0.75 µg stays in the host. In the saliva Western blot study, we thus used induced saliva from 5 mosquitoes as the unit of detection. This corresponds to about one pair of mosquito salivary glands, and about 4 times the amount injected into a host during probing and feeding of the mosquito. The limits of detection for the recombinant proteins (TAV ~ 0.8 ng and DsRed2 ~ 2.5-5 ng) are in line with the lowest amounts of salivary proteins injected by a mosquito. Regarding the sensitivity of the Western blot assay: aegyptin is indeed present in high concentrations in mosquito saliva, which is why it was chosen as a control for efficient saliva extraction. However, blots were first probed for tTAV or DsRed2 and imaged, prior to stripping the blots and reprobing for aegyptin, which should rule out any concerns around aegyptin detection/overexposure affecting the sensitivity of the detection method chosen.	
Assay uncertainties: Quantitative Detection of DsRed2 and tTAV protein in whole body extracts of OX513A adults				
Mosquito-produced proteins could not be detected in whole mosquito body extracts, furthering uncertainties of the methodologies employed in the test of saliva. Validation controls for the whole mosquito larvae and	50560401	22	**1. BPPD requested we provide empirical data or information to show how the current protein extraction method utilized for adult mosquitoes will yield cytosolic proteins:** Oxitec acknowledged the concerns raised by EPA, and, following helpful discussions on 28 March 2018, conducted a new quantitative protein analysis on OX513A adults and larvae using a different extraction method that captures	• We have provided sufficient information for EPA to begin the substantive review of our applications. • We provided new data and information that supports the validity of the assay method and corroborates the assay results of negligible proteins.

Table 1: EPA's 90-Day Preliminary Technical Screening results, and Oxitec's Response				
	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
adults assays were poor and the assays displayed unexplained uncertainties. For example, DsRed2 can be detected in OX513A larvae by making use of its ability to fluoresce at certain wavelengths. These DsRed2 containing larvae can be seen under a microscope with the human eye. However, the assay data supplied by Oxitec shows that DsRed2 protein in fluorescing red larvae cannot be detected, rendering the whole mosquito larvae and adult protein assays questionable.			cytosolic proteins from mosquito adults and larvae. To confirm this, we also demonstrated using an additional Western blot control that we could detect the cytoplasmic protein Hsp70. Full details of the extraction methods used for adults and larvae, and the full analysis of tTAV and DsRed2 protein levels in these samples was submitted as MRID 50560407.	
	50560407	7, 11-40	**2. BPPD expressed assay uncertainties concerning the absence of positive controls and the two primary antibodies not being able to recognize endogenously produced proteins [** Following discussions with BPPD on 28 March 2018, Oxitec provided data to show that positive controls showing that *E. coli*-expressed DsRed2 and tTAV could be detected in wild-type *Aedes aegypti* cytosolic lysates (see discussion above for more details). **Note: In a call with BPPD on 12 June 2018, at least one of the BPPD reviewers indicated that they had not realised that positive controls including lysates had been provided. Hence BPPD scientists seemed to indicate on that call that these positive controls would probably have been sufficient to address the apparent deficiency. However, Oxitec responded further by providing additional controls as detailed in Table 2.**	
	50560401	22	**3. BPPD pointed out that DsRed2 can be detected in OX513A larvae by making use of its ability to fluoresce at certain wavelengths whilst the qWestern assay data supplied by Oxitec shows that DsRed2 protein in**	

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	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
			fluorescing red larvae cannot be detected, and hence illustrated a concern with the assays: Oxitec provided sufficient data to explain this: DsRed2 protein is visible in larvae under a suitable fluorescence microscope but its distribution is limited to a number of small foci in a punctate pattern rather than being present in detectable quantities in every cell in the mosquito larva. Microscopy is inherently a much more sensitive detection technique than protein detection by Western blot. This explained the apparent discrepancy between the fluorescence microscopic detection of DsRed2, and the inability to detect DsRed2 by Western blot in crude larval extracts above the assay LoD of 50 ng.	
	50560401	23	**4. BPPD requested that we explain why LOD of the DsRed2 and tTAV proteins are less sensitive as in the saliva protein study (MRID 503264-04), and why two different primary antibodies were used for the detection of tTAV in the saliva and whole-body assays:** The repeated Western blot study (MRID 50560407) used the same antibodies as in the saliva protein study. The new LoDs for tTAV (1.6 ng in adults and 3 ng in larvae) and DsRed2 (50 ng) are consistently higher than the LoDs used in the saliva protein study (0.8 ng and 5.0 ng, respectively). Because of much higher protein background in the whole-mosquito lysates, the antibodies had to be used at lower concentrations than in the saliva study, which is most likely the reason for the reduced sensitivity relative to the saliva	

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	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
			protein study.	
Human Exposure to DsRed2 and tTAV proteins				
Potential human exposure to tTAV and DsRed2 proteins via saliva from female mosquito bites cannot be ruled out due to uncertainties in assay methodologies.	50560401	19-20	As we have provided new data and information that supports the validity of the assay method, the assay results of undetectable tTAV and DsRed2 proteins in OX513A female saliva (from 5 female mosquitoes) remain valid. LoD for DsRed2 in saliva is 2.5-5.0 ng LoD for tTAV in saliva is 0.8 ng Furthermore, both tTAV and DsRed2 lack the secretory signals required for secretion of proteins from salivary glands into saliva (MRID: 50560401, 50608009). This data supports the assay results.	• We have provided sufficient information for EPA to begin the substantive review of our applications. • We provided new data and information that supports the validity of the assay and corroborates the assay results of undetectable proteins. • We provided data to show that both tTAV and DsRed2 lack the secretory signals required for secretion of proteins from salivary glands into. This data supports the assay results. Furthermore, this data also shows that human exposure to the OX513A proteins via a biting female's saliva is biologically implausible for DsRed2.
Manufacturing process				
Update your information to ensure that all standard manufacturing processes in all UK and US facilities are described.	50560402	Confidential Attachment	Updated information to address the deficiencies noted by EPA can be found in in the revised product characterization report MRID 50560402. A brief summary is also provided below.	• We have provided sufficient information for EPA to begin the substantive review of our applications **Further QC questions were received when EPA**

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	Oxitec's response			
EPA's 90-Day Preliminary Technical Screening Results, 22 Mar 2018	**MRID number**	**Page numbers**	**Summary of response**	**Data conclusions**
Discrepancies between the rearing protocols, and MRID 503264-04 were noted. It appears that individual standard operating procedures (#00002-00011) depicted in the flow chart exist. Please specifically clarify the reason for the pupae sex sorting in step 00007. Also, provide other pertinent information, such as shipping conditions between the UK and the US. This information appears to have been previously submitted to FDA (MRID 504435-13).		15-20 2-3 13-14 15	Oxitec provided a summary description of each manufacturing SOP applicable to both UK and US facilities. There are 21 manufacturing SOPs in total. Discrepancy has been resolved. As mentioned in MRID 50560402, the reason for pupae sex sorting is for egg production, sex sorting is used to set up adult cages with controlled male:female ratios. As mentioned in MRID 50560402, OX513A Aedes aegypti eggs are packaged in triple containment and shipped with temperature-monitoring.	**sent the Section 3 deficiency letter on 4 June 2018 and these have been addressed in our response sent 19 June 2018, and, for convenience, are also summarised in Table 2.**

Table 2: 90-day Preliminary Technical Screening Results June 4, 2018 (Section 3), and Oxitec's Response			
Additional data provided (June 19, 2018)	**MRID number**	**Page numbers**	**Data conclusions**
Minutes/Emails from AllergenOnline documenting removal of Akane GFP-like protein from database	N/A	N/A	Minutes/emails were provided directly to BPPD by Prof Richard Goodman explaining the AllergenOnline process for inclusion and later removal of Akane from AllergenOnline.
Additional Western blots using Oxitec *Aedes aegypti* research strain expressing higher levels of DsRed2 and tTAV proteins	50608003	11-25	Antibodies used in 50326404 and 50560407 (9 April 2018) were re-validated and shown to be capable of detecting endogenously expressed DsRed2 and tTAV in an additional Oxitec *Aedes aegypti* research strain expressing DsRed2 and tTAV at higher levels than OX513A, and corroborating/validating the exposure data provided previously, showing no detectable DsRed2 in OX513A mosquitoes or in OX513A saliva, and tTAV only detectable in adult OX513A at 1.34 ng per mosquito, and undetectable in larvae or saliva. Oxitec was able to improve assay sensitivity by using slightly different gel matrices for these analysis, resulting in slightly lower LoDs, but with results corroborating those reported on 9 April 2018.
Additional Western blots using lysates from multiple mosquitoes (response to BPPD request in technical call on 12 June 2018)	50608001	27-33	Oxitec carried out these additional Western blots as suggested by BPPD scientists, and demonstrated that these methods had significant shortcomings which meant they were not appropriate to detect accurately the quantity of DsRed2 present in OX513A mosquitoes.
Complete manufacturing and shipping SOPS	50608002	Confidential Attachments 2 and 5	These supplement the summary of SOPs by providing full SOPs, as requested on 4 June 2018.
Images of Mechanical Sorting Devices for separating larvae from pupae and male from female pupae	50608002	Confidential Attachments 3 and 4	These diagrams show details of the mechanical sorting devices, as requested on 4 June 2018.
Quality control measures	50608002	25-29, and Confidential Attachments	Quality Control measures and required standards, including - fitness of lab-reared colonies - mating competitiveness - number of flying males - penetrance of OX513A trait - detection of resistance to self-limiting trait, and measures to mitigate - detection of establishment in the environment, and measures to mitigate

Message

From: Keller, Kaitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7A6B15ADFD745C6ADA1C121DEC27AC4-KELLER, KAI]
Sent: 7/5/2018 2:16:18 PM
To: Tim Lust [tim@sorghumgrowers.com]
CC: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Debra Lloyd [debral@sorghumgrowers.com]; Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]
Subject: RE: Meeting Request

Tim,

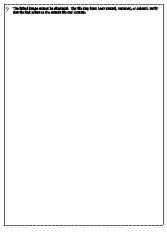
I've scheduled this meeting for 7/17 at 9-9:30. Please use the William Jefferson Clinton East Building entrance (1201 Constitution Ave NW) and call (202) 564-2910 when you arrive. Please also plan to allow additional time to get through security on this day. Let me know if anything changes or if you have questions prior to your meeting.

Thanks,
Kaitlin

Kaitlin Keller, Special Assistant
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
(202) 564-7098

From: Tim Lust [mailto:tim@sorghumgrowers.com]
Sent: Wednesday, July 04, 2018 6:11 PM
To: Keller, Kaitlin <keller.kaitlin@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Debra Lloyd <debral@sorghumgrowers.com>; Bolen, Derrick <bolen.derrick@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>
Subject: Re: Meeting Request

Please schedule us for 9:00-9:30 am. I expect to have Gary Marshall from Missouri Corn and Greg Krissek with Kansas Corn join us. Regards, Tim



Tim Lust
Chief Executive Officer
Ex. 6 office
cell
sorghumgrowers.com
Sorghum: The Smart Choice.

On Tue, Jul 3, 2018 at 3:56 PM, Keller, Kaitlin <keller.kaitlin@epa.gov> wrote:

> Tim,

I can assist with scheduling. Would 7/17 at 9-9:30 am or 4:30-5pm work for you?

Thanks,

Kaitlin

Kaitlin Keller, Special Assistant

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

(202) 564-7098

From: Beck, Nancy
Sent: Monday, July 02, 2018 9:38 AM
To: Tim Lust <tim@sorghumgrowers.com>
Cc: Debra Lloyd <debral@sorghumgrowers.com>; Bolen, Derrick <bolen.derrick@epa.gov>; Keller, Kaitlin <keller.kaitlin@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>
Subject: Re: Meeting Request

Tim,

I'm looping in some folks to assist w the schedule.

Regards,

Nancy

****

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

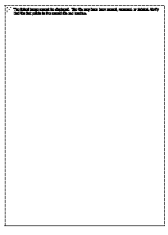
P: 202-564-1273

M: Ex. 6

beck.nancy@epa.gov

On Jul 2, 2018, at 9:29 AM, Tim Lust <tim@sorghumgrowers.com> wrote:

> On behalf of the Triazine Network executive committee I would like to request a meeting with you to discuss the reregistration status of the Triazines. I could not find a direct contact for your scheduler so please let me know if I need to work directly with a scheduler. I would like to request the meeting for July 17th but have some flexibility the day before or the day after. Thank you. Tim



Tim Lust
Chief Executive Officer
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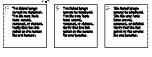
cell
sorghumgrowers.com
Sorghum: The Smart Choice.



Message

From: Bostick, Thomas [TBostick@dna.com]
Sent: 7/3/2018 2:52:23 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; Shurdut, Brad [BShurdut@dna.com]; Huff, Karen [KHuff@dna.com]
Subject: RE: EUP

Dear Nancy, thank you for taking time for our call last Friday. I can only imagine how busy you are, so your time was much appreciated and most helpful in clarifying some of the concerns.

As we discussed, we're confident that we have thoroughly addressed the issues that you raised. We'll ensure that we highlight our efforts to address these concerns and specifically where we addressed them in our next submission. We will include you on our response to EPA.

We look forward to our next follow up discussion on July 13th.

Happy 4th of July! Thank you for your service at EPA.

Best,
Tom

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Friday, June 22, 2018 1:32 PM
To: Bostick, Thomas
Cc: Bolen, Derrick
Subject: RE: EUP

Hi Tom,
I'm looping in Derrick to see what the art of possible is. I think next Friday may likely be best, but he will surely find the best time.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6
beck.nancy@epa.gov

From: Bostick, Thomas [mailto:TBostick@dna.com]
Sent: Friday, June 22, 2018 10:40 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: EUP

Nancy, would it be possible to have a call to discuss our EUP sometime next week?

If so, it can be one-on-one, or if possible, I would include Brad Shurdut, our regulatory lead.

Have a nice Friday and weekend.

Best,
Tom

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6
beck.nancy@epa.gov

From: Bostick, Thomas [mailto:TBostick@dna.com]
Sent: Saturday, June 2, 2018 11:13 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: EUP

Dear Nancy, greetings and trust that you and the EPA team are well.

I appreciate the ongoing efforts by EPA to process our EUP and Section 3 requests. Given all of the comments on the EUP, I wanted to be sure that you saw the attached letter from Health Secretary Pedro Mello from Piracicaba, Brazil. Following submission to the EUP docket, Secretary Pedro Mello provided my team with this courtesy copy that I'd also like to share with you. As noted in Secretary Mello's letter, we have successfully and safely deployed our OX513A mosquitoes in Piracicaba over the last few years.

Thank you again!

Best,
Tom

Thomas P Bostick, PhD, PE, NAE

Chief Operating Officer
intrexon
20374 Senaca Meadows Pkwy | Germantown, MD 20876
M: Ex. 6 O: XXX-XXX-XXXX | tbostick@dna.com

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Message

From: Card, Lorine - Virtual US [Lorine.Card@mosaicco.com]
Sent: 7/17/2017 3:30:27 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: CERCLA 108(b)-Hardrock Mining Financial Assurance
Attachments: The Mosaic Company Comments CERCLA Section 108(b) Docket EPA-HQ-SFUND-20....pdf

Nancy—I wanted to share with you Mosaic's comments that we submitted last week in the CERCLA 108(b) Financial Assurance rulemaking.

We believe the comments and attached technical documents provide strong record support for a phosphate and potash exemption.

Please let me know if you have any questions. We're happy to come in anytime to discuss further.

Lorine

Mosaic
Lorine D. Card |Federal Government Affairs
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Nancy Case
Vice President - EHS

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E-mail:
Nancy.Case@mosaicco.com

July 11, 2017

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

Mr. Barnes Johnson
U.S. Environmental Protection Agency
Office of Resource Conservation and Recovery
Mail Code 5303P
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Attn: Docket ID No. EPA-HQ-SFUND-2015-0781

Re: Financial Responsibility Requirements under CERCLA Section 108(b) for Classes of Facilities in the Hardrock Mining Industry; 82 Federal Register 3388, January 11, 2017; 82 Fed. Reg. 12333 (March 2, 2017) (extending comment period through July 11, 2017)

Dear Mr. Johnson:

The Mosaic Company (Mosaic), on behalf of its subsidiaries Mosaic Fertilizer, LLC (Mosaic Fertilizer) and Mosaic Potash Carlsbad Inc. (Mosaic Potash), submits these comments in response to the United States Environmental Protection Agency's (EPA) proposal to establish specific financial responsibility requirements applicable to certain classes of mines and associated mineral processing facilities which it describes as being within the so-called hardrock mining sector under Section 108(b) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as amended, 42 U.S.C. § 9608(b). *See* 82 Fed Reg. 3388 (Jan. 11, 2017); 82 Fed. Reg.12333 (March 2, 2017) (extending Comment Period through July 11, 2017) (hereinafter the "Proposed Rule").

Mosaic Fertilizer is one of the world's largest producers of manufactured phosphate products with 15% of world phosphate production. For more than a century, Florida's phosphate industry has been a major economic driver in central Florida. Mosaic Fertilizer currently owns or controls more than 350,000 acres of land and has approximately 3,600 employees in central Florida (with an additional 2,200 contractors working at Mosaic Fertilizer's Florida sites). Mosaic Fertilizer also owns fertilizer manufacturing plants in Louisiana with approximately 400 employees. As of March 2017, Mosaic and its subsidiaries have a total of 4,655 employees in the U.S., including 414 employees at the Carlsbad, New Mexico, potash mine and the corporate office in Plymouth, MN.

Mosaic is proud to be a competitive producer with strong customer relationships, and has the financial strength to invest in growth and innovation. Mosaic has led the industry in

developing high-quality premium products that help farmers succeed, while demonstrating its shared commitment to good corporate citizenship in all of its operating communities. Mosaic's products nourish about 65% of the nation's crops, helping to maintain a stable and reliable food supply.

Mosaic is a member of The Fertilizer Institute (TFI) and incorporates by reference comments of this national trade association. In addition, we support comments submitted by the National Association of Manufacturers, of which Mosaic is a member, and the National Mining Association.

Executive Summary

EPA's proposal to include phosphate and potash mining, phosphate mineral processing and phosphate fertilizer manufacturing[1] in the definition of "hardrock mining" as sectors that present the "highest level of risk" and require evidence of financial assurance (FA) under CERCLA § 108(b) is inconsistent with governing statutory and regulatory requirements, and is unsupported by the relevant facts and the rulemaking record.

The comments that follow, and the attached Technical Memoranda,[2] support that position and establish the following: First, phosphate and potash mining sectors are different from the

[1] For clarification, the following definitions accurately describe Mosaic's phosphate, phosphate mineral processing (phosphoric acid manufacturing), and phosphate fertilizer manufacturing operations and will be used throughout these comments: (1) "Mining" includes extraction by shallow surface (phosphate) and underground (potash) mining techniques; (2) "Beneficiation" includes physical separation and sizing to physically separate the phosphate ore/potash from associated earthen materials, mostly sand and clay (phosphate) and co-present minerals such as clays and salts (potash); (2) "Mineral Processing" (phosphoric acid manufacturing) follows beneficiation and occurs at separate manufacturing plants that chemically convert phosphate rock into a "first salable product" under RCRA, in this case, phosphoric acid, and (3) "Phosphate Fertilizer Manufacturing" is the production of phosphate fertilizer using phosphoric acid as feedstock. EPA's use of the term *"mineral processing"* in the rulemaking appears to include processes that are (physical) beneficiation and (chemical) manufacturing. This is confusing and inconsistent with the way the Agency has traditionally viewed "mineral processing" in the regulatory context. In the phosphate sector, "mineral processing" is considered to include the steps *following* beneficiation up to the point of producing a "First Saleable Product" (here, phosphoric acid). *See*, EPA, "Final Technical Background Document-Identification and Description of Mineral Processing Sectors and Waste Streams," at 503 (Apr. 1998). EPA views everything after the production of the phosphoric acid, which includes most fertilizer manufacturing, as chemical manufacturing. *Id.* at 506. For purposes of these comments, Mosaic's use of the term, "mineral processing" will be consistent with EPA's definition of the term created solely for this rulemaking. We will use the term "phosphate mineral processing " when referring to EPA's existing regulatory definition applicable to phosphate.

[2] For a detailed description of Mosaic Fertilizer's phosphate mining operations and how they differ from hardrock mining, *see* Technical Memorandum from Environmental Consulting & Technology, Inc., to

hardrock mining that is the focus of the rulemaking. EPA has erroneously included phosphate and potash within the hardrock mining sector[3] based on a misunderstanding of the characteristics and practices employed by these industries and the risks associated with them. As will be discussed more in this document, phosphate and potash mining are low risk and more comparable to the 59 excluded commodities than traditional hardrock mining. Second, phosphate fertilizer manufacturing is not "mining." EPA's rule is over-inclusive, extending the Proposed Rule to separate, independent, manufacturing facilities that are engaged in chemical manufacturing, not mining operations, a category EPA has acknowledged should not be considered part of the term "hardrock mining."[4] EPA's Proposed Rule and accompanying model for estimating the amount of FA are metal-mining focused and an implausible fit for phosphate and potash sectors. Third, if EPA nonetheless – improperly – includes phosphate and potash mining and phosphate fertilizer manufacturing within the rule's reach, these sectors should be exempted, like the commodity sectors EPA has excluded from the rule, because, similarly, they are: (a) not high risk or (b) already covered by substantial Resource Conservation and Recovery Act (RCRA) and/or state law FA requirements. For these reasons, there is little risk of unfunded future releases, no plausible basis for characterizing them as high risk, and consequently no additional FA obligation is justified under the requirements of 108(b).

EPA's authority to impose FA requirements under CERCLA 108(b) is limited. CERCLA § 108(b) is focused on minimizing the risk that the cost of future corrective actions will require expenditure of public funds. That authority extends only to those facilities that represent the highest risk that the cost of remediation will fall on the public. The statute is also clear that authority to impose FA requirements does not extend to facilities already subject to RCRA or other federal laws.[5] EPA seeks to exceed these statutory limitations by imposing FA

Mosaic Fertilizer, LLC *Technical Analysis – Justification Analysis for Exempting Mosaic Fertilizer, LLC, from CERCLA §108(b) Requirements* (2017), (incorporated herein by reference) (hereinafter the "ECT Phosphate Justification"), Attachment A. For a detailed discussion of Mosaic Potash's potash operations and how they differ from hardrock mining practices, *see* Technical Memorandum from Arcadis U.S., Inc., to Mosaic Carlsbad Potash Inc., *Technical Analysis, - Justification for Potash Exclusion from CERCLA §108(b) Requirements* (2017) (hereinafter, "Arcadis Potash Justification"), Attachment B.

[3] EPA's rulemaking analysis is focused on those industrial sectors that have been traditionally defined as "hardrock mining" to include those ores containing metals, gold, silver, copper, nickel zinc, lead, and molybdenum. Mosaic's comments make use of the term "traditional HRM" when referencing these metal-mining sectors traditionally considered hardrock mining.

[4] *See Evidence of CERCLA Hazardous Substances and Potential Exposures at CERCLA 108(b) Mining and Mineral Processing Sites*, p. 11 (Sept. 23, 2016) ("Some mineral processing is categorized as chemical manufacturing and, thus, would be outside the scope of the proposed 108(b) regulations for mining and mineral processing.").

[5] *See* 42 U.S.C. § 9608(b)(1). The plain language of the statute is clear that consideration of whether FA requirements are needed is limited to facilities that are not already covered by RCRA or other federal laws. Both phosphoric acid and phosphate fertilizer manufacturing facilities are subject to RCRA and, as

requirements on facilities, such as Mosaic Fertilizer's phosphate mining and phosphate mineral processing operations and Mosaic Potash's potash mining operations, that each exhibit a low level of risk, and Mosaic Fertilizer's phosphate fertilizer manufacturing facilities, which are already addressed under RCRA, including in consent decrees addressing operational practices, closure and post-closure care and substantial FA. Finally, EPA has considerable discretion under CERCLA §108(b) to determine acceptable risks in establishing requisite FA amounts, and the "zero risk" approach reflected in EPA's proposed rule is both unnecessary and inappropriate, and it cannot be supported in the context of a fair and accurate analysis of the costs imposed and benefits derived.

I. Background

CERCLA § 108(b) directs EPA to develop regulations that require classes of facilities to establish and maintain evidence of financial responsibility consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.[6] Section 108(b)(1) directs EPA to focus the rulemaking on "those classes of facilities … that the President determines present the highest level of risk."[7]

As of 2009, EPA interpreted its obligations under CERCLA § 108(b) as "discretionary because Section 108(b) does not specify a date-certain deadline for completion of either requirement [i.e., promulgating financial responsibility requirements and subsequently imposing those requirements on applicable entities]."[8] U.S. District Court Judge William Alsup agreed with EPA, holding that "the duty to promulgate and impose financial responsibility regulations under CERCLA is discretionary based on the combination of the absence of a date-certain deadline and CERCLA's legislative history."[9]

On July 28, 2009, EPA published a Priority Notice of Action identifying classes of facilities in the "hardrock" mining industry for development of CERCLA § 108(b) financial

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such, they fall outside of the scope of CERCLA § 108(b) by virtue of the plain language of the statute, read in its proper context, that is, of addressing risk. Even if EPA views this language differently, and instead adopts a position that the shield is limited only to facilities already subject to FA requirements under these laws, EPA should recognize that Mosaic's facilities are subject to robust cradle- to- grave regulatory schemes designed to minimize potential danger to human health and the environment.

[6] 42 U.S.C. § 9608(b).

[7] 42 U.S.C. § 9608(b)(1).

[8] *Sierra Club v. Johnson*, 2009 WL 2413094, at *3 (N.D. Cal. Aug. 5, 2009) (where EPA also argued that CERCLA's legislative history supported its position "because Congress rejected a proposed amendment to add a date-certain deadline for the promulgation of financial responsibility requirements").

[9] *Id.* at *4.

responsibility requirements.[10] "Hardrock mining" was defined for purposes of the Priority Notice as the extraction, beneficiation or processing of metals (e.g., copper, gold, iron, lead, magnesium, molybdenum, silver, uranium, and zinc) and, arbitrarily, non-metallic, non-fuel minerals (e.g., asbestos, phosphate rock, and sulfur).[11] EPA also identified certain classes of facilities that it exempted from the rulemaking, even though they fell within the above definition of "hardrock mining."[12] EPA compared the types and amounts of chemicals from 59 non-fuel hardrock commodity sectors, noting that the amount and types of releases were significantly lower than, and do not pose as significant a risk as, other hardrock commodities.

In August 2014, various environmental groups filed a lawsuit in the U.S. Court of Appeals for the District of Columbia Circuit seeking a writ of mandamus requiring issuance of CERCLA § 108(b) financial responsibility rules for the hardrock mining industry and three additional industries. Following oral argument, EPA and the petitioners submitted a Joint Motion for an Order on Consent, filed on August 31, 2015, which included an ambitious schedule for further administrative proceedings under CERCLA § 108(b). The court order granting the motion was issued on January 29, 2016.[13] Pursuant to the court's order, EPA must publish a final rule by December 1, 2017. The D.C. Circuit also made clear that while EPA had to act, the final action could be no rule at all: "[T]he proposed joint order 'does not *require* EPA to promulgate a new, stricter rule. At most, it 'merely requires that EPA conduct a rulemaking and then decide whether to promulgate a new rule – the content of which is not in any way dictated by the [proposed order on consent] – using a specific timeline."[14]

In January 2017, EPA published the Proposed Rule and subsequently extended the comment period to July 11, 2017.[15] EPA's rule seeks to impose FA obligations on hardrock mines, "mineral processing" facilities and certain chemical manufacturing plants that it claims present the highest level of risk and those that are also not covered by other federal programs.

EPA has determined, solely for purposes of this rulemaking, that phosphate and potash mining sectors and phosphate mineral processing operations should be included in the rulemaking as "hardrock mining." Mosaic contends that EPA has erroneously included all of those sectors based on a misunderstanding of the characteristics and practices employed by these

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[10] *Identification of Priority Classes of Facilities for Development of CERCLA Section 108(b) Financial Responsibility Requirements*, 74 Fed. Reg. 37,213 (July 28, 2009).

[11] *Id.* at 37,214.

[12] Stephen Hoffman & Shahid Mahmud, U.S. Environmental Protection Agency, Memorandum to the Record: *Mining Classes Not Included in Identified Classes of Hardrock Mining* (hereinafter "2009 Excluded Classes Memo").

[13] *See In re Idaho Conservation League*, 811 F.3d 502 (D.C. Cir. 2016).

[14] *Id.* at 514 (quoting *Defenders of Wildlife v. Perciasepe*, 714 F.3d 1317, 1324) (emphasis added).

[15] 82 Fed. Reg. 3388 (January 11, 2017); 82 Fed. Reg. 12333 (March 2, 2017).

industries and the risks associated with them. The attached Technical Memoranda provide EPA with an accurate and complete description of the practices employed by these sectors and an assessment of the associated risks under the criteria EPA used to exempt 59 industry sectors from the rule, which shows the similarities of Mosaic's operations to the exempted sectors.

EPA also was improperly over-inclusive in including phosphate fertilizer manufacturing plants in a rule described on its face as addressing mining. Phosphate fertilizer manufacturing is chemical manufacturing, not mining or mineral processing. Indeed, EPA recognized that "some mineral processing is categorized as chemical manufacturing and, thus, would be outside the scope of the proposed 108(b) regulations for mining and mineral processing." Nonetheless, EPA swept in Mosaic Fertilizer's phosphate fertilizer manufacturing facilities that are, without question, chemical manufacturing. EPA's proposal and accompanying model for estimating the amount of FA is metal-mining focused and applying it to phosphate fertilizer manufacturing is arbitrary and not defensible. Even if EPA decides to include these manufacturing facilities in the hardrock mining sector, any final rule must recognize that additional FA requirements are unwarranted where any risks associated with these operations are already addressed under RCRA Subtitle C regulations and Consent Decrees under EPA's RCRA National Enforcement Initiative.[16] The language of CERCLA § 108(b) is clear that EPA's authority to promulgate FA requirements extends only to "facilities in addition to those under Subtitle C of the Solid Waste Disposal Act [42 U.S.C.A. § 6921 et seq.] and other Federal law."[17] Where, as in the case of Mosaic Fertilizer's phosphate fertilizer manufacturing facilities, facilities are already subject to RCRA, EPA has no authority under CERCLA § 108(b). Any final rule must be consistent with the clear language of the Act.

EPA's improper inclusion of these sectors likely resulted from misapplication of data unrelated to risk addressed under CERCLA 108(b). EPA improperly construed the type of risk CERCLA 108(b) is intended to address, resulting in an overly broad universe of covered facilities. CERCLA § 108(b) is designed to minimize the risk that the cost of future corrective actions will require expenditure of public funds. It is indisputable that Congress was interested in ensuring that owners and operators of facilities would have funds available to cover the cost of recovery actions due to any future releases from those facilities. EPA's analysis used to identify industry sectors that would be included in the regulated universe as "hardrock mining" has erroneously included data and information that fall outside this narrow focus to include: 1) releases from historical operations (pre-1990) that predate when environmental regulatory programs were instituted; 2) closed or abandoned operations that are not within the intended CERCLA 108(b) focus on the ability of current owners and operators to cover the cost of any

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[16] *See* EPA, National Enforcement Initiative: "Reducing Pollution from Mineral Processing Operations", available at https://www.epa.gov/enforcement/national-enforcement-initiative-reducing-pollution-mineral-processing-operations.

[17] 42 U.S.C. § 9608(b)(1).

future releases from active operations; 3) releases not associated with "hazardous substances" as defined by CERCLA § 101(14) or that are federally permitted and also outside the scope of CERCLA § 108(b) authority; 4) releases from facilities that are not mining facilities at all but instead are chemical manufacturing facilities and EPA itself acknowledged should not be included in the proposed regulation; and 5) releases from facilities that are already subject to EPA's RCRA National Enforcement Initiative, including state and federal negotiated consent decrees addressing operational practices, closure and post-closure care and substantial FA requirements.

It appears that EPA's inclusion of phosphate and potash mining facilities in the Proposed Rule's regulated universe may be the result of EPA's misapplication of data and information completely unrelated to the risk that can be addressed under CERCLA § 108(b). When analyzed properly, taking into consideration Congress' clearly expressed limitations -- requiring that the focus should be on risk that public funds would be needed and on releases that are within the scope of a CERCLA recovery action-- it is clear that EPA relied on improper data to sweep phosphate and potash sectors into the rulemaking. EPA should recognize this error and consider it as a basis for excluding these sectors from any final rule.

II. EPA's Inclusion of Phosphate and Potash Mining in the Proposed Rule is Arbitrary and Capricious.

i. Phosphate and Potash Mining Sectors Are Not Like "Hardrock Mining."

EPA has not established any factual basis for concluding that the phosphate and potash mining sectors should be included within the "hardrock mining" sector EPA determined represents the "highest level of risk" for purposes of CERCLA § 108(b).[18] EPA's proposal to include these two sectors is without any credible record support. Phosphate and potash mining practices and features are not like the hardrock mining practices EPA erroneously attributed to these sectors in assuming high risk.

As a general principle, EPA correctly recognized that facility characteristics and practices employed will differ even within the same commodity sector, such that an entire sector of an industry may not present the same level of risk under EPA's analysis.[19] Accordingly, EPA requested comments on whether there may be additional mining sectors that present a lower level

[18] On the question of whether EPA has appropriately identified the hardrock mining industry as representing the "highest risk" for purposes of CERCLA § 108(b), Mosaic agrees with and incorporates by reference the comments of the National Mining Association submitted in response to EPA's request for comments, 82 Fed. Reg. 3388 (Jan. 11, 2017).

[19] 82 Fed. Reg. at 3,456.

of risk for purposes of CERCLA § 108(b) based on "facility characteristics and operations."[20] Specifically, EPA requested comment on whether there is evidence to support excluding the phosphate mining sector. Notably, in its Final Report on EPA's Planned Proposed Rule, the Small Business Administration's Office of Advocacy requested that EPA solicit comments on whether such classes of mines, defined based on facility characteristics, could potentially encompass iron ore, **phosphate**, and uranium mines.[21] These comments and Technical Memoranda provide technical support to document that phosphate *and* potash mining are not like the hardrock mining sectors EPA analyzed for application of the rule, and that there is ample evidence to support an EPA determination that these two sectors should be exempted like the 59 commodity sectors EPA appropriately determined should be excluded.

It is incorrect as a technical matter for EPA to analyze the phosphate and potash mining sectors under the same lens used for hardrock mining. With regard to phosphate, EPA's inclusion of that sector appears to be largely based on a 2004 EPA Office of Inspector General (OIG) Report on the "Nationwide Identification of Hardrock Mining Sites" (the "2004 OIG Report"),[22] but this report does not support EPA's conclusion. First, that OIG Report is wholly inaccurate with respect to Florida phosphate mining operations. Notably, the 2004 OIG Report indicates that EPA believed there was a "likelihood of acid mine drainage" (AMD) at phosphate mines that Region 4 was failing to consider in its cost estimates.[23] However, this position further demonstrates EPA's fundamental misunderstanding of phosphate mining operations like Florida phosphate operations. There is *no* likelihood of AMD at these sites, as explained by Florida state environmental authorities.[24] This belief -- false at least as to Mosaic Fertilizer's operations — nonetheless led to a conclusion in the 2004 OIG Report that cleanup costs at each of these sites could total over $100 million to address AMD, and that the total cleanup costs for 22 Florida phosphate mining sites could range from $2.2 billion to $11 billion.[25] These

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[20] *Id.*

[21] *See* Letter from Darryl DePriest, U.S. Small Business Administration, *et al.* to The Honorable Gina McCarthy, EPA, re: "Report of Small Business Advocacy Review Panel" on EPA's Planned Proposed Rule Financial Responsibility Requirements for the Hardrock Mining Industry under CERCLA 108(b) (Dec. 1, 2016); Comments of U.S. Small Business Administration re Financial Responsibility Requirements for the Hardrock Mining Industry (Jan.19, 2017); *see also* Comments of the American Exploration & Mining Association, CERCLA 108(b) SBREFA Panel.

[22] U.S. Environmental Protection Agency Office of Inspector General, Evaluation Report, Nationwide Identification of Hardrock Mining Sites, Report No. 2004-P-00005 (March 31, 2004) (hereinafter "2004 OIG Report").

[23] *Id.* at 49.

[24] *See* Letter from John C. Coates, Florida Department of Environmental Protection, to Linda Barr, U.S. Environmental Protection Agency, (Aug. 19, 2016), Attachment C.

[25] OIG Report, at 49, 69 (noting that "[t]his is a major difference in total costs").

estimates are clearly off-base. In actual fact, because there is no risk of AMD at Florida phosphate mining sites, no AMD-related potential cleanup costs should be considered.

The State of Florida has formally expressed concerns with regard to EPA's incomplete understanding of and erroneous conclusions about the phosphate industry.[26] The Florida Department of Environmental Protection (FDEP) stated that "inclusion of Florida phosphate mining in EPA's financial assurance requirements for the hardrock mining industry would be based on a misunderstanding of and confusion about operations for phosphate extraction, beneficiation, and processing in Florida. Phosphate mining in Florida is not 'hardrock mining' nor are the operations and actual risks sufficiently similar to warrant EPA's inclusion under regulations specifically designed to address hardrock mining concerns."[27] With regard to phosphoric acid and fertilizer manufacturing, FDEP stated that "any risks that do exist, particularly related to mineral processing facilities, are already comprehensively addressed in Florida by a unique combination of existing state and federal laws and regulatory actions."[28] Furthermore, FDEP stated that, as a result, there is already both state and federal oversight and financial assurance requirements covering the potential for related hazardous substance release[29] and that FDEP believes EPA's rule could weaken and frustrate Florida's efforts to ensure that phosphate mining in Florida is accountable for both land reclamation obligations, and for operating in a manner that protects the state's land and water resources.

EPA's risk analysis in support of the proposed rule is weighted towards metals mining. This makes sense because EPA's initial analyses, Phase I (Feb. 2009) and Phase II (July 2, 2009)[30] Reports, targeted those metal mining sectors known as "hardrock mining," specifically, gold, silver, copper, nickel, zinc, lead and molybdenum sectors. The hardrock mining analyses appropriately focused on mining and beneficiation, in contrast to "mineral processing." This approach was consistent with Congressional intent that facilities already addressed under RCRA or other federal laws would not be the focus of CERCLA 108(b) (inasmuch as phosphate mineral

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[26] *See* Letter from John A. Coates, P.E. Director, Division of Water Resource Management, Florida Department of Environmental Protection, to Linda Barr, Office of Resource Conservation and Recovery, U.S. Environmental Protection Agency (August 19, 2016) (sharing details about FEDP's concerns with inaccurate risk information that is referenced in the rulemaking's supporting documentation, and the potential for adverse impacts to and preemption of existing state regulatory requirements for phosphate mining in Florida).

[27] *Id.* at pg. 2.

[28] *Id.*

[29] *Id.* at pp. 2-4.

[30] *See* U.S. Environmental Protection Agency, CERCLA Section 108(b) Financial Responsibility: Phase I: Preliminary Analysis (Feb. 2009) (EPA-HQ-SFUND-2009-0265-0033); U.S. Environmental Protection Agency, CERCLA Section 108(b) Financial Responsibility: Phase II Preliminary Analysis (July 2, 2009) (EPA-HQ-SFUND-2009-0265-0020).

processing facilities typically employ practices such as solid waste land disposal or use hazardous substances that are subject to RCRA and other federal environmental laws, and produce Bevill exempt waste streams[31] that Congress specifically excluded from CERCLA recovery actions).[32]

Without any change in the statute or explanation from EPA, in 2009, EPA issued a Notice of Proposed Rulemaking announcing an expansive and arbitrary definition of hardrock mining that would represent the classes of facilities subject to EPA's CERCLA 108(b) rulemaking.[33] In addition to adding new mining sectors, including phosphate, that would be considered hardrock mining for the sole purpose of the CERCLA 108(b) rulemaking, EPA expanded the scope of applicability to include phosphate mineral processing facilities and redefined key terms in order to capture a broad swath of facilities and operations, even including those that are chemical manufacturing and not mining at all. According to the notice, for purpose of this rulemaking only, EPA decided to include non-metallic, non-fuel minerals, e.g., asbestos, phosphate rock, and sulfur.[34] EPA did not invite public comment on its unprecedented expansion of the traditional use of the term "hardrock mining" at the time of its announcement in 2009, and the Agency specifically foreclosed any such opportunities in the January 11, 2017 notice.[35]

EPA's 2009 notice also announced the decision to exclude certain mineral commodity sectors, similar to phosphate and potash, based on the Agency's conclusion that these commodities represent lower risk.[36] Notably, at the time, Mosaic understood that potash, while not specifically mentioned, fit within the salt category that was subject to the exclusion, along with salt brine evaporation, crushed and broken limestone production, sand and gravel, and kaolin and ball clay, which EPA decided to exclude from further analysis. A comparison between potash operations and each exempted commodity is provided in the attached, Arcadis

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[31] In 1980, Congress enacted both CERCLA and amendments to the Solid Waste Disposal Act commonly known as the Bevill Amendment. The Bevill Amendment explicitly exempts fossil fuel combustion waste; waste from the extraction, beneficiation, and processing of ores and minerals (including phosphate rock and overburden from uranium ore mining); and cement kiln dust from regulation under the RCRA until such time as comprehensive studies of these wastes and their adverse effects could be completed.

[32] *See infra* pp. 18-20; *see also* Comprehensive Report: An Overview of Practices at Hardrock Mining and Mineral Processing Facilities and Related Releases of CERCLA Hazardous Substances, Final Report, at 153 n.637 (Nov. 30, 2016) (acknowledging that petroleum is specifically excluded as a CERCLA hazardous substance, so is not subject to CERCLA response authority and liability).

[33] 74 Fed. Reg. 37, 213 (July 28, 2009).

[34] *Id.* at 37,214.

[35] *See* 92 Fed. Reg. at 3455 ("EPA is not seeking comment on the 2009 *Priority Notice*.").

[36] *See* 2009 Excluded Classes Memo.

Potash Technical Memoranda at Appendix B. This analysis shows that potash, which involves soft rock mineral salts mining, is in all relevant respects similar to the excluded commodity sectors and nothing like hardrock mining as it is traditionally known.

Prior to January 11, 2017, EPA did not make known its intent in any way to include potash mining as a covered sector. Indeed, had the potash industry been aware, the industry would have marshalled resources to educate EPA on the similarities between potash mining and salt mining, an excluded sector, and explain that inclusion of potash was unsupported and improper. Furthermore, EPA did not mention potash mining in its required consultation with the state of New Mexico where Mosaic Potash's potash mining operations (85% of U.S. production) are located. There is no evidence in the record that the state had any knowledge EPA intended to include the potash commodity sector within the scope of the rule.[37] Among other reasons why this is important is the fact that EPA's summary report[38] on New Mexico's state hardrock mining regulatory program did not recognize that New Mexico's hardrock mining regulations expressly *exclude* "potash mining" and no separate analysis addressing potash regulation was completed. Notably, New Mexico considers potash production to be comparable to sand, gravel, caliche, borrow dirt and quarry rock, and exempted these sectors from regulation under the New Mexico Mining Act Reclamation Program.[39] Moreover, New Mexico's silence as to potash is in stark contrast with its vigorous warning to EPA of the negative consequences from imposing duplicative FA requirements on the hardrock mining sector and supports Mosaic's view that EPA's decision to include the potash sector was arbitrarily decided and never communicated to state authorities, contrary to EPA's obligations under the statute.[40]

ii. EPA has Provided No Relevant Evidence to Support High Risk

EPA has not identified any Florida phosphate mining or potash damage cases. EPA's analysis identified common features or processes employed at hardrock mining and mineral

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[37] *See* Letter from William C. Olson, Chief, Ground Water Quality Bureau and Charles de Saillan, Assistant General Counsel, New Mexico Environment Department, to James R. Berlow, U.S. Environmental Protection Agency (February 28, 2011); Letter from William Brancard, General Counsel, New Mexico Energy, Minerals and Natural Resources Department, Office of the Secretary, to James R. Berlow, U.S. Environmental Protection Agency (Feb. 28, 2011); Bill Brancard, General Counsel, New Mexico Energy Minerals and Natural Resources Department, Presentation, New Mexico: Financial Assurance for Hard Rock Mines; EPA State Mining Program Summary.

[38] U.S. Environmental Protection Agency, *Summary of New Mexico State Financial Responsibility Requirements Applicable to Classes of Potential CERCLA 108(b) Hardrock Facilities*, October 2012.

[39] *See* 69 NMC Section 36-3.H.

[40] *See* Letter from William Brancard, General Counsel, New Mexico Energy, Minerals and Natural Resources Department, Office of the Secretary, to James R. Berlow, U.S. Environmental Protection Agency (Feb. 28, 2011).

processing facilities that EPA predicts typically result in federal CERCLA expenditures. Under EPA's analysis, where these features are found, EPA assumed evidence of risk of unfunded responses warranting FA coverage would occur. In identifying the relevant features, EPA relied on "damage cases" found in each mining sector.[41] However, none of the cases referenced by EPA involved Florida phosphate or any potash mining operations. Of the entire list, EPA identified only two Western phosphate mine sites; however, neither of these cases is a proper indicator of risk of future unfunded response actions. First, in both cases, the release is associated with historical mining practices no longer employed or authorized at Western phosphate mining sites, and both are owned by well-funded companies that are already addressing the relevant environmental issues. Because of that, there is little risk of future unfunded response actions from either of these Western phosphate mining operations. Therefore, there are no phosphate mining operations that could properly be considered by EPA to pose high risk much less the "highest level of risk" which EPA must target for purposes of CERCLA §108(b) FA. Similarly, EPA also has provided no evidence of damage from potash mining features and processes.

In an attempt to create perspective of high risk, EPA has improperly relied on four examples of releases from Florida phosphate fertilizer manufacturing facilities. [42] But none of these facilities are "mining" sites. In addition, even if the examples were mining-related incidences, they do not present the type of risk CERCLA 108(b) is intended to address. Properly characterized, all of the Florida examples fall into the following categories, none of which is appropriate for establishing risk under CERCLA § 108b: 1) historical or legacy sites -- facilities were constructed and releases were from operations conducted using older, pre-1990- practices no longer employed or authorized under any permit. These facilities are either closed or they have been incorporated into ongoing operations and the current operator has assumed responsibility and cost of remediation; 2) no hazardous substance was involved – where there is no hazardous substance released, there is no risk for purposes of CERCLA § 108(b); or 3) associated with facilities already covered under RCRA (contrary to the plain language of CERCLA § 108(b)), making additional FA obligations unnecessary and duplicative. None of these situations would be addressed under EPA's Proposed Rule because they are not the type of releases Congress intended CERCLA § 108(b) would cover. EPA should exclude the use of these "damage" cases for purposes of the final rule analysis.

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[41] *See* U.S. Environmental Protection Agency, Damage Cases and Environmental Releases from Mines and Mineral Processing Wastes (April 1998).

[42] CF Industries, Inc. Bartow Phosphate Complex; Cargill Fertilizer, Inc. Fort Meade Mine; IMC Agrico Hopewell Phosphate Mine; and, IMC Agrico New Wales Chemical Complex are addressed in detail in comments of The Fertilizer Institute.

iii. Risk from Phosphate and Potash Mining is Low, Similar to the Excluded Commodity Sectors.

A closer examination of the record shows that phosphate and potash mining are more similar to the excluded commodity sectors than to the traditional hardrock mining industries identified in the Proposed Rule. As explained more fully in the attached Technical Memoranda; like the excluded sectors (and unlike traditional hardrock mining), the phosphate and potash mining operations of Mosaic conduct shallow surface (Florida phosphate) and underground (New Mexico potash) mining operations that use no chemicals or hazardous substances during the extraction process.[43] Instead, like the excluded sectors, these operations utilize simple physical separation methods to separate out the target mineral.[44] Like the excluded sectors, there are no phosphate or potash mining sites listed on the National Priorities List (NPL) as a result of mining operations.[45] And like the excluded sectors, EPA has not used any CERCLA funds for remedial activities associated with any phosphate and potash mining operations.[46] Additionally, these excluded sectors are, like phosphate and potash mining, listed under NAICS category 2123 ("Nonmetallic Mineral Mining and Quarrying") and not, like the traditional hardrock mining industries included in the Proposed Rule, under NAICS category 2122 ("Metal Ore Mining").

It becomes even clearer that EPA erroneously and arbitrarily did not include phosphate mining in the list of exempted sectors when one considers the "commonly employed practices and . . . commodity-specific issues and processes" that EPA identified as potential sources and releases of CERCLA hazardous substances in the Proposed Rule.[47] These practices and issues include:

> (1) surface and underground mining; (2) non-entry (in-situ leaching or solution) mining; (3) physical, gravity, and magnetic processing; (4) flotation; (5) cyanidation; (6) acid leach, solvent extraction, and electrowinning; (7) pyrometallurgical processes; (8) Bayer process for refining alumina; (9) ion exchange in uranium and phosphoric acid processing; (10) mine-influenced water; (11) waste rock piles; (12) tailings management; and (13) mining processes leaks and spills.[48]

Mosaic's phosphate and potash mining operations, like the sectors excluded from the Proposed Rule by EPA, involve primarily surface (phosphate) and underground (potash) mining,

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[43] 2009 Memo at 1-3.
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] 82 Fed. Reg. at 3471.
[48] *Id.* at 3471-72.

and beneficiation by physical gravity processes and flotation. However, like the excluded sectors and unlike traditional hardrock mining, these sectors do not involve the majority of the remaining practices EPA identified. Specifically, and contrary to EPA's conclusions, these operations do not employ ion exchange in phosphoric acid processing and do not create waste rock piles, acid mine or elevated selenium mine-influenced water. With respect to tailings management, both potash (clay and salts) and phosphate (sand and clay) tailings are benign and are either stacked or used in reclamation.[49]

Not a single Florida phosphate mining site has been listed to the NPL since CERCLA's passage 36 years ago, and no federal expenditures have been made to mitigate the release of hazardous materials from Florida phosphate mining facilities. In addition, contrary to the 2004 OIG Report, there is no risk of acid mine or for that matter, elevated selenium drainage, at any Florida phosphate mining sites. Similarly, as discussed extensively in the Arcadis Technical Memorandum, potash mining and beneficiation has a 120 year history in the United States. The sector includes some of the longest running mining operations, such as Mosaic Potash's operations in New Mexico, which have been ongoing for over 75 years. There are no potash mining sites on the NPL and no CERCLA Superfund expenditures associated with them. Accordingly, there is no credible basis to contend that there is high risk of future unfunded response actions within the phosphate and potash mining sectors.

iv. Existing Laws Provide Sufficient Risk Management and Financial Assurances.

Existing laws already provide more than sufficient oversight and assurances with respect to these sectors, rendering § 108(b) FA requirements wholly unnecessary. For example, the State of Florida has enacted multiple statutes and regulations governing the phosphate mining industry, including groundwater permitting and a groundwater zone of discharge program that includes corrective action standards. These regulations further reduce the minimal risk posed by Mosaic Fertilizer's phosphate mining operations.[50] Technical Memoranda (Attachments A and B) provide a complete explanation of the comprehensive regulatory regimes the phosphate and potash mining sectors operate under in Florida and New Mexico.

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[49] *See* ECT Phosphate Technical Memorandum at 7, ("Clay Settling Areas are not the equivalent of "tailings impoundments" at hardrock mines."); Arcadis Technical Memorandum at 5.

[50] *See also* ECT Justification Analysis, at pp. 12-14 (discussing Florida's regulatory scheme, including the "Zone of Danger" requirements for discharges to groundwater).

III. Phosphate Fertilizer Manufacturing Should Not Be Subject to CERCLA Financial Assurance Requirements under the Proposed Rule.

The Proposed Rule's inclusion of phosphate fertilizer manufacturing facilities among covered sectors is misguided and not supported by the record or real-world conditions. As explained more fully below, phosphate fertilizer manufacturing operations are not like phosphate mining operations, nor are they a part of the mining operation. Instead, these facilities are within the chemical manufacturing industry sector, with operations and facilities completely independent from phosphate mines. Moreover, these separate manufacturing facilities are already addressed under RCRA which already has imposed, or will impose, extensive financial assurance requirements on them.

i. Phosphate Fertilizer Manufacturing is not Hardrock Mining.

EPA has recognized that "some mineral processing is categorized as chemical manufacturing, and, thus, would be outside the scope of this regulation for mining and mineral processing."[51] But the Proposed Rule is in direct conflict with this statement. The Proposed Rule fails to recognize important distinctions between those industries that are considered phosphate rock *mining*, identified as NAICS Code 212392, and industries that are engaged in phosphate fertilizer *manufacturing,* identified as NAICS Code 32531. The different industries are also covered by different point source categories in the federal regulations.[52] EPA overlooks this critical distinction by choosing, for purposes of the Proposed Rule only, to sweep it all into one convenient category, hardrock mining. Importantly, the 2004 OIG Report also fails to distinguish phosphate mining operations from subsequent processing/manufacturing facilities. These processing/manufacturing facilities are, however, most certainly not mining operations.

While phosphate mining facilities extract and beneficiate phosphate ore, Mosaic Fertilizer's manufacturing plants chemically convert phosphate rock into phosphoric acid and convert phosphoric acid into phosphate fertilizer products. After beneficiation, the phosphate is conveyed to the manufacturing facilities where it is used as a feedstock in the production of phosphoric acid and, from there, used to manufacture phosphate fertilizers. Phosphoric acid production and phosphate fertilizer manufacturing do not occur at the mine site or at a co-located manufacturing facility; rather, the phosphate ore is transported to the manufacturing facility, miles away. The manufacturing facilities are completely separate operating units with independent utility as evidenced by the fact that they often receive phosphate ore from a variety of unrelated sources for use in manufacturing. The Proposed Rule fails to acknowledge or discuss any of these distinguishing factors.

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[51] *See supra* fn. 4.

[52] *See* 40 C.F.R. 436, Subpart R; 40 C.F.R. § 422; 40 C.F.R. § 418.

EPA also appears to have confused phosphate fertilizer manufacturing with phosphate mineral processing associated with mining, blurring important, longstanding regulatory distinctions. For example, in the RCRA context, EPA considers those activities following the beneficiation (e.g., crushing, grinding, sizing, etc.) of phosphate rock up to the production of the "first salable product" (phosphoric acid) as phosphate mineral processing. Using that construct, activities that follow the point at which phosphate mineral processing ends are chemical manufacturing. EPA's Proposed Rule overlooks this important regulatory distinction and inappropriately sweeps chemical manufacturing (not intended to be addressed in the hardrock mining rule) into EPA's newly defined, "mineral processing" activities covered by the rule. EPA's indiscriminate approach in the Proposed Rule results in an improper implementation of CERCLA § 108(b) by imposing FA obligations on facilities, like Mosaic's fertilizer manufacturing plants. Beyond that, Mosaic Fertilizer's phosphate fertilizer manufacturing operations are already subject to strict obligations under RCRA Subtitle C.

That EPA's overly broad approach is improper as applied to phosphate fertilizer manufacturing is further illustrated when one attempts to apply the formulaic model that EPA intends to be used to calculate the required amount of FA.[53] The formula has no relevance in the context of phosphate fertilizer manufacturing facilities. For example, the proposed formula has three different components for: (i) response actions; (ii) a health assessment; and (iii) natural resource damages. The response component is based on response costs from NPL and non-NPL CERCLA response actions associated with certain activities conducted at certain sites, none of which are Florida phosphate fertilizer manufacturing facilities.[54] EPA determined that 13 site features served as the source of release[55] and used those features to create 13 different "response category equations," including: (1) solid and hazardous waste disposal category; (2) open pit category; (3) underground mine category; (4) waste rock category; (5) heap/dump leach category; (6) tailings category; (7) process pond and reservoir category; (8) slag pile category;

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[53] 82 Fed. Reg. at 3461.

[54] *Id.* EPA's focus on the Simplot Don facility, Idaho, is misplaced. The releases associated with this facility occurred at the co-located former FMC Corporation elemental phosphorous facility, a facility that produces neither phosphoric acid nor phosphate fertilizers and has no relevance to the analysis of risk from these facilities.

[55] EPA has inappropriately decided that 1980 marks the advent of the "modern mining era" and, as such, considers releases occurring 1980 and beyond representative of releases that could occur at currently operating mines. This approach is incorrect and has skewed EPA's analysis. All significant regulations under which mining is regulated, including the Clean Air Act, Clean Water Act, Safe Drinking Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Endangered Species Act, and the National Environmental Policy Act, were promulgated after the passage of CERCLA § 108(b) in 1980. In fact, there was almost no comprehensive regulation of surface and groundwater discharges prior to 1990. *See* Joseph H. Baird, *Hardrock Mining Through Changing Values, Changing Laws and Experience: A Federal and State Regulatory Success Story* (June 30, 2013).

(10) interim O&M category; (11) water treatment category; (12) short-term O&M and monitoring category; and (13) long-term O&M monitoring category.[56]

To implement the formula, a facility must input various pieces of information into the model; however, when considering these inputs, it becomes clear that the majority of these categories are completely inapplicable to phosphate fertilizer manufacturing, which does not involve open pits, underground mining, waste rock, heap/dump leaching, slag piles, etc. Thus, attempting to apply this formula to phosphate fertilizer manufacturing makes no sense, and it appears that EPA was likely not considering phosphate fertilizer manufacturing when developing the Proposed Rule.

Additionally, when developing the Proposed Rule, EPA also identified specific current hardrock mining, mineral processing, and associated waste management practices that EPA determined would likely lead to future CERCLA cleanup actions, including: (1) surface and underground mining; (2) non-entry (in-situ leaching or solution) mining; (3) physical, gravity, and magnetic processing; (4) flotation; (5) cyanidation; (6) acid leach, solvent extraction, and electrowinning; (7) pyrometallurgical processes; (8) Bayer process for refining alumina; (9) ion exchange in uranium and phosphoric acid processing; (10) mine-influenced water; (11) waste rock piles; (12) tailings management; and (13) mining processes leaks and spills.[57] Of these, ion exchange is not employed in Mosaic's phosphoric acid processing and only tailings management and mining processes leaks and spills are relevant to phosphoric acid processing, not fertilizer manufacturing. However, neither is relevant for purposes of EPA's rulemaking because these practices are already addressed under RCRA or other federal statutes, and not within EPA's jurisdiction under CERCLA § 108(b). Therefore, application of EPA's formula, tailored largely for traditional hardrock mining activities, is meaningless and inappropriate for phosphate fertilizer manufacturing.

By assuming an overly broad regulatory reach, EPA oversteps its jurisdiction under CERCLA. Mosaic's Technical Memoranda addresses this important distinction in more detail, however, for purposes of the Proposed Rule, EPA should revise any final rule such that the use of key regulatory terms is consistent with RCRA and excludes chemical manufacturing facilities.

ii. Risk from Fertilizer Manufacturing Is Already Addressed.

Like phosphate mining, the Proposed Rule fails to adequately justify the inclusion of phosphate fertilizer manufacturing based on the corresponding level of risk (or lack thereof). The Proposed Rule primarily references phosphate fertilizer manufacturing facilities with respect to issues identified by recent consent decrees that were entered into pursuant to EPA's National

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[56] 82 Fed. Reg. at 3466.

[57] *Id.* at 3471-72.

Enforcement Initiative for Mining and Mineral Processing under RCRA, including recent consent decrees between EPA, the FDEP, and Mosaic Fertilizer, concerning five facilities in Florida,[58] and between EPA, the Louisiana Department of Environmental Quality (LDEQ) and Mosaic Fertilizer concerning two facilities in Louisiana.

These consent decrees resolved regulatory allegations about the management of waste under RCRA; they are not a justification for finding such facilities to be high risk and imposing significant § 108(b) FA requirements. To the contrary, they show that these facilities are adequately regulated and provide for extensive FA coverage. These consent decrees build upon state regulatory analogues and impose extensive requirements and obligations, including operational requirements, corrective action standards and design, construction, operation, closure and post-closure standards for phosphogypsum stacks. Importantly, the consent decrees also include significant FA requirements as Mosaic Fertilizer established a $630M trust and will issue a $50M letter of credit in support of obligations to close and care for the phosphogypsum stacks. The Mosaic Company (Mosaic Fertilizer's parent company) also agreed to guarantee any cost difference between the amounts held in trust and estimated closure and long-term care costs.

Aside from these consent decrees, phosphate fertilizer manufacturing facilities are extensively regulated under laws in Florida and Louisiana, which further mitigates the likelihood of releases. For example, Florida phosphate fertilizer manufacturing facilities are regulated under Florida Statutes §§ 403.4154–55, which impose various obligations related to the complete life cycle of phosphogypsum stacks at these facilities and also require FA. Like those state and local laws applicable to phosphate mining, these preexisting requirements could be preempted by § 108(b) FA requirements based on the language found in CERCLA § 114(d).[59] Moreover, their very existence makes FA requirements under § 108(b) duplicative and unnecessary.

IV. The Proposed Rule Exceeds EPA's Authority under CERCLA.

i. EPA May Not Impose Financial Assurance Requirements on Facilities and Wastes Congress Excluded from the Statute.

EPA's authority under CERCLA to impose FA requirements under § 108(b) is limited.[60] That authority is by its terms limited to the highest risk categories of facilities. Consistent with this limitation, Congress was clear that authority to impose FA requirements did not extend to

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[58] *United States v. Mosaic Fertilizer, LLC*, No. 8:15-cv-02286 (M.D. Fla, 2016); *United States v. Mosaic Fertilizer, LLC*, No. 2:15-cv-04889 (E.D. La. 2016).

[59] *See, e.g.*, Letter from John A. Coates, P.E. Director, Division of Water Resource Management, Florida Department of Environmental Protection to Linda Barr, Office of Resource Conservation and Recovery, U.S. Environmental Protection Agency, Attachment A p.5 (Aug. 19, 2016).

[60] 42 U.S.C. § 9608(b)(1).

facilities already subject to RCRA Subtitle C and other federal laws.[61] Furthermore, Congress determined certain, high volume, low toxicity wastes from the extraction, beneficiation and mineral processing are not hazardous substances subject to CERCLA.[62] The Proposed Rule completely ignores the plain language of the statute and exceeds these limits by seeking to impose FA obligations on fertilizer manufacturing facilities already subject to RCRA and other federal laws, and on certain phosphate and potash mining and beneficiation wastes that have been determined to be low risk and exempt from CERCLA under RCRA's Bevill Amendment.

In 1980, Congress enacted both CERCLA and amendments to the Solid Waste Disposal Act commonly known as the Bevill Amendment.[63] The Bevill Amendment explicitly exempts waste from the extraction, beneficiation, and processing of ores and minerals (including phosphate rock), under RCRA Subtitle C. Congress also included corresponding language extending the Bevill Amendment's mining waste exclusion to CERCLA's definition of "hazardous substances."[64]

In a subsequent report, EPA addressed "high-volume, low-toxicity" mineral processing wastes and concluded that the available data showed that regulation under RCRA Subtitle C is unwarranted for *inter alia* process wastewater from phosphoric acid production; [and] phosphogypsum from phosphoric acid production[.]"[65] An important factor in EPA's justification for not imposing federal Subtitle C regulation was Congress' expressed concern that any costs imposed by regulation must not threaten the continuance of a viable mining industry.[66] EPA now proposes to impose at least $7.1 billion in FA obligations on the same industry sectors under CERCLA 108(b).[67] EPA's proposal is completely void of any recognition of this relevant history regarding how best to manage the risks from mining, including these important Bevill

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[61] *Id.*

[62] 42 U.S.C. § 9601(14) defines hazardous substance to not include any waste that has been exempt from regulation by Congress.

[63] Solid Waste Disposal Act Amendments of 1980, Pub. L. 96-482, 94 Stat. 2337 (to be codified at 42 U.S.C. § 6921).

[64] 42 U.S.C. § 9601(14)(C).

[65] U.S. Environmental Protection Agency, Report to Congress on Special Wastes and Mineral Procession (July 1990), p. 11.

[66] 42 U.S.C.A. § 6921(b)(3)(A).

[67] *See* 82 Fed. Reg. at 3392; *see* Comments of the National Mining Association incorporating by reference the independent economic analysis completed by OnPoint Analytics, Inc., finding EPA substantially underestimated the cost of the rule by several orders of magnitude. Specifically, OnPoint concludes that the cost of the Proposed Rule could be as high as $39.4 billion on a net present values basis, 18 times the total amount EPA estimated in the Regulatory Impact Analysis developed for the Proposed Rule.

studies and subsequent regulatory determinations, and disregards Congress' expressed concern with the economic impact on the mining industry from any regulatory burdens imposed.

Moreover, a related Senate Report explicitly rejected the notion that Bevill wastes may be treated as CERCLA "hazardous substances" even if they contain hazardous constituents,[68] and therefore clearly expresses Congress's intent that Bevill wastes would not be considered hazardous wastes under CERCLA. Thus, imposing CERCLA FA obligations on Bevill Amendment wastes is not only completely unnecessary in light of the minimal risk associated with these wastes as determined by EPA, but is also beyond EPA's statutory authority.

ii. EPA May Not Consider Federally Permitted Releases in Determining the Necessary Amount of Financial Assurance.

EPA has inappropriately used data from federally permitted releases to represent risk from mining operations. In addition to exempting Bevill wastes from designation as a hazardous substance under CERCLA, Congress clearly prohibited cost recovery for federally permitted releases. Under CERCLA § 107(j), recovery "for response costs or damages resulting from a federally permitted release shall be pursuant to existing law in lieu of" CERCLA.[69] This exclusion applies for all releases covered by then-existing law (*e.g.*, under the Clean Air Act (CAA), Clean Water Act (CWA), and RCRA).[70] The exclusion was contained in the Senate version of CERCLA (S. 1480) as well as the legislation that was ultimately enacted.[71] And numerous federal courts have recognized that federally permitted releases are not subject to CERCLA.[72]

By factoring in federally permitted releases to the collection of "risks" requiring FA, EPA is essentially creating a methodology that allows it to recoup costs which would otherwise be

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[68] S. Rep. No. 848, 96th Cong., 2d Sess. 28 (1980) ("It should be noted that any substance or material for which regulation is specifically suspended by Act of Congress under the Solid Waste Disposal Act is excluded from designation as a hazardous substance for the purpose of S.B. 1480 [CERCLA], notwithstanding the presence in such substance of any hazardous or toxic chemical.").

[69] 42 U.S.C. 9607(j).

[70] *Id.*

[71] *Id.*

[72] *See, e.g., Blankenship v. Consolidation Co.*, 850 F.3d 630 (4th Cir. 2017) (mining releases authorized by National Pollutant Discharge Elimination System (NPDES) permit could not serve as basis for cause of action under CERCLA); *Reading Co. v. Philadelphia*, 823 F. Supp. 1218, 1230 (E.D. Penn. 1993) (discussing exemption); *Iron Mt. Mines*, 812 F. Supp. at 1540 (same); *U.S. v. Washington State Dep't of Transp.*, 716 F. Supp. 2d 1009, 1016 (W.D. Wash. 2010) (same); *Horsehead Industries, Inc. v. St. Joe Minerals Corp.*, 1996 WL 33415778, at *20 (same).

exempt from CERCLA recovery actions. EPA must not extend any FA requirements to those releases Congress has expressly exempted from CERCLA recovery actions.

iii. EPA Has Failed to Properly Exercise Its Discretion.

CERCLA does not require that EPA set the appropriate level of financial responsibility such that there is "zero risk" involved for the relevant activity. Instead, as EPA notes in the Proposed Rule, "CERCLA § 108(b)(2) directs that the level of financial responsibility shall be initially established, and, when necessary, adjusted to protect against *the level of risk that EPA in its discretion believes is appropriate* based on the payment experience of the Fund, commercial insurers, courts settlements and judgments, and voluntary claims satisfaction." (Emphasis added.) CERCLA is therefore clear: EPA has discretion to determine the appropriate amount of FA commensurate with the level of risk involved.

EPA has, however, failed to exercise its discretion appropriately and has instead taken an extremely conservative approach in developing the Proposed Rule. A system in which the amount of financial responsibility required must cover *all* possible (even those that are only remotely possible) risks (i.e., "zero risk" coverage) is overly conservative and cannot be justified under a proper assessment of the costs imposed and benefits derived.

EPA relies on data from NPL sites of certain mining sectors and extrapolates these costs as a basis for determining the necessary assurance requirements for all mining sectors. However, NPL sites are, by their very nature, the worst possible scenarios, and this approach leads to FA requirements that are grossly excessive in comparison to what is actually necessary for the majority of mines, particularly the limited number of existing phosphate mines. Again, there are no Florida phosphate mines listed on the NPL and likewise, there is no payment history relevant to Florida phosphate mining. Furthermore, EPA improperly relies on data based on releases from historical operations (pre-1990) permitted before environmental regulatory programs were instituted as well as releases that are statutorily excluded from the scope of EPA's CERCLA authority.

By imposing grossly inflated FA requirements that are based on worst-case scenarios taken from different types of mining and other inappropriate sources of data, EPA is imposing extraordinary costs that are completely disproportionate to the risks presented. EPA should not use CERCLA as a back door means for imposing costs that may threaten the viability of these important industries. To avoid such an outcome and to more appropriately follow the statutory intent of CERCLA, EPA should exercise its discretion in a manner that is commensurate with the risks posed.

V. General Comments

i. EPA Has Created a De Facto Mining Regulatory Regime.

The Proposed Rule includes a formula that facilities would use to determine a FA amount that would be required to insure their facilities. EPA also proposes to allow owners or operators to reduce the response cost component of the FA formula by demonstrating that risk reducing mechanisms are already required at the facility.[73] On its face, this seems like a reasonable approach, that the existence of enforceable, risk mitigating practices could be recognized by EPA and used to offset or avoid the need for additional FA. However, rather than EPA's providing offsets for existing federal and state risk reducing and FA requirements, EPA has developed entirely new, "specific minimum standards" that must be met.[74] EPA refers to these standards as "performance standards" and "future engineering controls and practices" intended by EPA to reduce risks associated with hazardous substances at the site."[75] But that is exactly what the federal land management and state mining regulatory programs are designed to do. EPA exceeds its authority under CERCLA by attempting to promulgate new performance standards, engineering controls and practices for hardrock mining operations, usurping the authority of the federal and state agencies Congress intended to regulate mining on federal lands and within the states.

Under the guise of implementing CERCLA § 108, EPA has created a new role for itself as "regulator-in-chief" over mining operations, devoid of statutory authority or regulatory due process. EPA's prescriptive, specific minimum performance standards are designed to replace the existing federal and state standards, essentially installing a de facto EPA-led regulatory scheme. This is true because EPA, and not these recognized mining regulators, sets the criteria. EPA decides whether or not a facility meets the criteria, and EPA decides when an eligible facility becomes ineligible for cost reductions. Nowhere in EPA's discussion of cost recovery reductions, is any consideration given to the standards and criteria that already exist at these facilities and that were developed under precise, site-specific analysis. Nor has EPA recognized that these federal and state programs will likely be displaced because the Proposed Rule

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[73] *See* 82 Fed. Reg. at 3504-09; 40 C.F.R. § 320.63 (proposed).

[74] *See* 40 C.F.R. § 320.63(c)(3) (proposed).

[75] *See* U.S. EPA, Office of Land and Emergency Management, *Financial Responsibility Requirements Under CERCLA 108(b) for Classes of Facilities in the Hardrock Mining Industry Proposed Rule: Financial Responsibility Reductions Technical Support Document*, Dec. 1, 2016, at pg. 1.

establishes a system where a facility has one of two choices: comply with EPA's newly devised performance standards or satisfy staggering FA requirements that are disproportionate to the risks. Moreover, EPA's unauthorized jurisdiction attaches even when a facility meets all of the relevant cost recovery criteria (highly unlikely considering the high bar proposed by EPA) because fixed-fee requirements would still apply (despite being totally unnecessary in light of the negligible risk involved for such facilities).

CERCLA was not intended to give EPA this type of almost infinite regulatory authority over ongoing business concerns. It was established instead to accomplish two primary goals: "(1) to ensure the prompt and effective cleanup of waste disposal sites, and (2) to assure that parties responsible for hazardous substances bear the cost of remedying the conditions they created."[76] Therefore, by creating these specific minimum performance standards, EPA is exceeding its statutory authority once more.

ii. The Proposed Rule is Not Consistent with the Principles Embodied in Executive Orders 12866, 13771, and 13777, and Should be Reviewed and Conformed to those Directives.

The Proposed Rule was published in early January 2017, before the issuance of Executive Orders 13771 of January 30, 2017, on *Reducing Regulation and Controlling Regulatory Costs*[77] and 13777 of February 24, 2017, on *Enforcing the Regulatory Reform Agenda.*[78] These Executive Orders (EOs) establish principles intended to "manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations" and ensure that rules regulate only to the extent necessary, minimize adverse impacts on jobs, and are fully cost justified. EO 13777 specifically requires conformity with EO 12866 of September 30, 1993,[79] on *Regulatory Planning and Review*, which directs that "Federal agencies should promulgate only such regulations as ... are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people."

The Proposed Rule pays lip service to the requirements of EO 12866, but a closer look reveals its deficiencies, particularly given the higher expectations instilled by EOs 13771 and 13777. Notably, EO 13777 directs federal agencies to target for revocation regulations that "(i) eliminate jobs, or inhibit job creation; (ii) are outdated, unnecessary, or ineffective; [or] (iii) impose costs that exceed benefits...." These same criteria apply with equal force to new rules,

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[76] *Pakootas v. Teck Cominco Metals, LTD.*, 830 F.3d 975, 981 (2016).

[77] 82 Fed. Reg. 9339 (Feb. 3, 2017).

[78] 82 Fed. Reg. 12285 (March 1, 2017).

[79] 58 Fed. Reg. 51735 (Oct. 4, 1993).

since it would make no sense to repeal nonconforming existing regulations yet allow new ones with the same flaws to go into force. The Proposed Rule fails this test in numerous ways.

Despite a lengthy preamble and 200-page Regulatory Impact Analysis (RIA), the Proposed Rule falls well short of the analytical rigor required by EOs 12866, 13771, and 13777. For example, the RIA's discussion of impacts on employment is cursory and amounts to a shrug of the shoulders over a task deemed too laborious to pursue: "EPA did not have sufficient data to model and quantify the potential changes in facilities' employment levels as a result of the proposed regulation. Potential countervailing impacts on labor demand in both the mining and financial sectors make the direction of change unknown."[80]

Further, as detailed above, EPA's failure to take into account existing FA obligations and other factors specific to the phosphate and potash mining sectors, which make new requirements duplicative, is contrary to EO directives against unnecessary regulation. And finally, the inadequacy of EPA's cost benefit analysis, particularly as to these sectors, establishes no credible record that EPA has carried its burden of demonstrating the benefits of new FA requirements would outweigh their costs, on the basis of a careful review consistent with the principles set forth in EO 12866 and OMB Circular A-4, which defines best practices for regulatory analyses.[81]

For all these reasons, EPA must conduct a far more demanding analysis of the Proposed Rule's compliance with governing Executive Orders, and finalize only those portions, if any, that can credibly withstand a best practices-compliant benefit-cost review.

iii. EPA's Rule is Based on a Flawed Model.

EPA's model for calculating FA amounts is fatally flawed. First, the model is flawed as applied to phosphate and potash sectors because it was developed using almost solely metal-mining inputs and EPA has said nothing about its intent to tailor the model to fit these non-metal mining sectors.[82] As Mosaic's Technical Memoranda point out, non-metal mineral mining extraction and beneficiation employ very different practices as compared to metal-mining

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[80] EPA, Office of Land and Emergency Management, *Regulatory Impact Analysis of Financial Responsibility Requirements under CERCLA § 108(b) for Classes of Facilities in the Hardrock Mining Industry Proposed Rule,* at E-13 (Dec. 1, 2016). The two pages devoted to this analysis in the full RIA are no more rigorous, *id.* at 6-4 to 6-6.

[81] Office of Management and Budget Circular A-4 (Sept. 17, 2003), available at https://www.whitehouse.gov/omb/circulars_a004_a-4.

[82] *See* MDB, Inc., Hardrock Mining Peer Review-Combined Documents, November 23, 2016, Comment of Reviewer #4, pg. 3 ("Generally the extraction and processing of industrial minerals has very different environmental effects from the extraction and processing of metals. … I have trouble with EPA's methodology not having separate formulas for industrial minerals … .").

operations and similarly, the environmental effects and the cost of recovery will also differ. EPA's methodology imposes cost recovery amounts derived from metal and other mining sectors on Mosaic's Florida phosphate and potash operations. This overly-simplistic approach is not defensible.

Next, under the Proposed Rule, the amount of FA a facility must obtain is determined by a formulaic model that evaluates a number of different input variables to produce estimates of recovery cost.[83] The model adopts a generic, "one-size-fits-all" approach, and fails to consider important, site-specific information that can have a profound impact on cost of recovery at a specific facility. EPA's simplistic approach has been rejected by the federal lands management agencies and most states for its lack of precision,[84] and EPA agreed, acknowledging that a site specific approach is the most precise approach.[85] Rejecting this advice, acquired by mining regulators over decades, EPA developed a model based on this flawed approach.

EPA obtained peer review of this approach from just four reviewers. Of them, only one provided meaningful commentary on EPA's formulaic model, and was largely critical of it, indicating grave concerns with the integrity of the data as collected and recommending EPA could benefit from interaction with industry professionals to address the impression that there is a stark lack of understanding of the workings of the industry that the EPA is tasked with regulating[86] Furthermore, this reviewer stated that he was "astounded" the independent reviewers did not find these same errors in EPA's dataset.[87] Finally, the reviewer concluded that those collecting the primary data from the source documents did not correctly understand the information in the documents or mine reclamation in general.[88] The remaining reviewers expressed uncertainty over the model and the data they were reviewing. One reviewer indicated [he/she] "got lost" several times despite the fact that [he/she] was taking notes while reading the report, and in some places "[he/she] just [could not] follow the logic of the Agency."[89]

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83 82 Fed. Reg. at 3460-70.

84 Comment submitted by Leslie A. C. Weldon, Deputy Chief, National Forest System, U.S. Forest Service, Department of Agriculture at 5 (Apr. 18, 2017); BLM Presentation, "Hardrock Reclamation Bonding" June 2016 Small Business Entity meeting; Comment submitted by Beth A. Botsis, Deputy Executive Director, Interstate Mining Compact Commission (Aug. 16, 2016); Comment submitted by Wyoming Governor Matthew H. Mead and Montana Governor Steve Bullock, Chairmand and Vice Chair of Western Governs Association ()March 29, 2016).

85 82 Fed. Reg. at 3460.

86 MDB, Inc., Hardrock Mining Peer Review–Combined Documents, November 23, 2016, Comment of Reviewer #4, pp. 4-9.

87 *Id.* at pg. 4.

88 *Id.*

89 *Id.* at Reviewer #3, pg. 1

Additionally, [he/she] expressed uncertainty over "[w]hich dataset was used to run the regressions[,]" explaining that [he/she] thought it was two different datasets during two different readings of the report before [he/she] "had literally no idea the third time around. **Help**!"[90] (Emphasis added.) Lastly, Reviewer #2 stated that EPA assumes all sites will eventually need source control; in practice, however, the CERCLA data show that source control is not always used, so this assumption overstates the true expected future response costs.[91]

Such comments are not entirely surprising as EPA provided the reviewers with only initial figures that were then grossly inflated based on a "smearing factor" and "source control assumption."[92] EPA did not provide the reviewers with model results to compare with associated closure and reclamation costs.[93] And this limited and confusing information made the peer review process incredibly difficult, if not entirely meaningless. Mosaic has reviewed and incorporates by reference a detailed analysis of EPA's Cost Estimate Formula prepared by SRK Consulting, Inc. for the National Mining Association. The SRK report addresses a number of errors with EPA's methodology and concludes that the formula is fatally flawed.[94]

Moreover, EPA ignored important procedural steps intended to ensure the objectivity and quality of scientific information the agencies intend to disseminate. Specifically, EPA disregarded OMB Information Quality Bulletin M05-3 that requires "scientific information" considered "highly influential" must be peer reviewed before being disseminated by EPA or other federal agencies.[95] EPA's failure to comply with OMB Information Quality criteria also violates EPA's "Scientific Integrity Policy" that requires adherence to the OMB Information Quality Bulletin for Peer Review.[96]

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90 *Id.*

91 *Id.* at Reviewer #2 at pg. 1.

92 *See* Review of Cost Estimate Formula for EPA's CERCLA 108(b) Proposed Rule, SRK Consulting (U.S.), Inc. (2017), Sections 4.5, 4.5.1, 4.5.2.

93 MDB, Inc., Hardrock Mining Peer Review–Combined Documents, November 23, 2016, Comment of Reviewer #4, pp. 10-11.

94 *See* Review of Cost Estimate Formula for EPA's CERCLA 108(b) Proposed Rule, SRK Consulting (U.S.), Inc. (2017).

95 Executive Office of the President, Office of Management and Budget, *Final Information Quality Bulletin for Peer Review*, M05-3, December 16, 2004.

96 *See* U.S. Environmental Protection Agency *Scientific Integrity Policy*, 2008, available at http://www.epa.gov/irmpoli8/21060.pdf; *see also* U.S. Environmental Protection Agency (2006) *Peer Review Handbook, Third Edition*, available at http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf.

These important peer review policies require peer review prior to disseminating scientific information, such as EPA's FA model, that will have a "clear and substantial impact on important public policies or important private sector decisions."[97] The term "scientific information" is defined to include "factual inputs, data, models, [and] analysis … related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physics sciences."[98] The term "highly influential" means "the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest."[99]

There is no question that EPA's formulaic model is both scientific information and highly influential. Therefore, EPA was required to comply with the OMB Bulletin's peer review requirements. These requirements call for a peer review that is conducted earlier in the process, is public, and is performed by peer reviewers that are objective and independent from the agency.[100] Federal agencies must also "provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers."[101]

Instead of following these requirements, EPA conducted an expedited, EPA-directed "peer review" that failed to conform to the recognized guidelines. EPA's shorthand review involved just four peer reviewers and information was not made available to the public until *after* the information had already been disseminated. This is hardly the "extensive review process" the Information Guidelines contemplate.[102] Moreover, because the process was rushed, EPA did not make any changes to the Proposed Rule. Instead, EPA indicated it will make corresponding changes to the formulaic model when it publishes a final rule, but this approach violates the Administrative Procedures Act by failing to take public comment on the model that EPA actually intends to use.[103]

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97 OMB Bulletin at 8.

98 *Id.* at 10-11.

99 *Id.* at 23.

100 *Id.* at 19-23.

101 *Id.* at 22.

102 *See* Executive Office of the President, Office of Management and Budget, *Office of Management and Budget Information Quality Guidelines,* Oct. 1, 2002, available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/iqg_oct2002.pdf.

103 Response to Peer Review Comments: CERCLA 108(b) Financial Responsibility Formula for Hardrock Mining Facilities Background Document.

Given the numerous failures with EPA's model development methodology and peer review process, any final rule mandating its use would be inappropriate.

iv. EPA Should Not Include Fixed Cost Requirements for Natural Resource Damages and Health Assessments under CERCLA § 108(b).

CERCLA § 108 contemplates that FA should be established commensurate with the risk that releases will result in costs of CERCLA response actions falling to the public. EPA proposes to require FA to cover the cost of response actions, and, in addition, a requirement for natural resource damages (NRD) fixed at 13.4 percent of the total response amount and a fixed $500,000 flat fee to cover health assessments. The inclusion of these fixed amounts for NRD and health assessments is beyond EPA's statutory authority and should be eliminated from any final rule.

First, with respect to health assessments, it is simply not the case that a health assessment will be required at every hardrock mining site. Whether a health assessment is part of a cost recovery action depends on site-specific variables such as whether there are any health risks or resident populations associated with the site. EPA's assumption that such an assessment will be required in every case is overly conservative and not supported. Indeed, EPA admitted the record does not support this claim when it relied on non-mining assessments to calculate the fixed fee amount, finding insufficient data associated with mining-related actions.[104] The Proposed Rule does not establish an adequate basis for imposing a fixed fee amount for health assessment costs for every hardrock mining site.

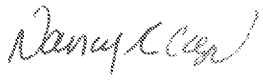
EPA's Proposal to include a fixed, 13.5% of the response cost, NRD amount in the FA formula is even more egregious. NRD is specifically addressed under CERCLA § 107(f) and is not within the scope of CERCLA § 108 response costs.[105] Instead, NRD claims are separate actions brought by government natural resource trustees under § 107(f) for imposing punitive damages. Recovery is limited to trustees, including the Federal Government and states or Indian tribes, EPA is not an appropriate trustee eligible to recover costs. Moreover, use of any recovered funds is also limited by statute. CERCLA § 108(b) was not intended to interfere or duplicate the direct action provision that already exists in § 107(f). Furthermore, EPA's proposal waives a facility owner/operator's right to legally challenge or raise defenses against any such actions. For these reasons, EPA should eliminate consideration of including fixed amounts for health assessments and NRD from any FA requirements in the final rule.

VI. Conclusion

[104] *See* 82 Fed. Reg. at 3465.
[105] *See* 42 U.S.C. 9607(f).

Mosaic appreciates your consideration of its comments on the Proposed Rule. For the reasons set forth above, Mosaic respectfully requests that the final rule recognize the inappropriateness of including the phosphate and potash mining and fertilizer manufacturing sectors within any § 108(b) final rule that relates to hardrock mining, and formally exclude these sectors from the scope of the rule. Should you wish to discuss these comments further, please do not hesitate to contact me.

Sincerely,



Nancy Case
Vice President - EHS

Phosphate Technical Analysis- Attachment A

ECT Environmental Consulting & Technology, Inc.

To: Mosaic Fertilizer, LLC

From: Gary Uebelhoer and Iyan Nance

Date: July 3, 2017

Re: Technical Analysis – Justification for Exempting Mosaic Fertilizer, LLC, from CERCLA §108(b) Requirements

The U.S. Environmental Protection Agency (EPA) has proposed to adopt Title 40 of the Code of Federal Regulations Part 320 (40 CFR 320) (the "Proposed Rule") to implement Section 108(b) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) at hardrock mining facilities.[1] As currently drafted, the Proposed Rule would apply to Mosaic Fertilizer, LLC (Mosaic) phosphate mines and manufacturing plants, although EPA solicited comments whether phosphate mine facility characteristics and operations present a lower level of risk of injury and, therefore, should be excluded.[2]

Mosaic retained Environmental Consulting & Technology, Inc. (ECT) to analyze its phosphate facilities and operations and to compare the potential risk of injury against the more traditional hardrock mining operations analyzed in the preamble to the Proposed Rule. While Mosaic's phosphate facilities and operations fit within EPA's definitions of "extraction", "beneficiation", and "mineral processing", the processes utilized and the features associated with Mosaic's mines and plants do not resemble traditional hardrock extraction, beneficiation, or mineral processing facilities and operations and, therefore, do not correlate with the response categories of the financial assurance model. Of the mining sectors analyzed by EPA, Mosaic's phosphate mines most closely resemble sand and gravel mines, which EPA has excluded from regulation. Further, EPA and Mosaic have reached agreement on the amount of financial responsibility that is appropriate for Mosaic's mineral processing plants under the Resource Conservation and Recovery Act (RCRA).

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[1] 82 Federal Register (FR) 3388-3512.

[2] 82 FR 3456.

Therefore, regulation of Mosaic's mineral processing facilities under the Proposed Rule would be redundant.

1. ANALYSIS OF MOSAIC'S FACILITIES AND OPERATIONS

Mosaic owns or controls approximately 611 million short tons of recoverable phosphate rock reserves in central Florida as of December 31, 2016.(3) Mosaic has applied for regulatory and land use approvals to extract and beneficiate sufficient reserves to meet its needs beyond 2030[4], with the remaining reserves to be permitted in the future.

These reserves lie within a sedimentary re-worked marine deposit composed of carbonate-fluorapatite, including phosphatic fossil remains (e.g., fish scales, bones, teeth, shells). Fluorapatite consists of Ca_{10} $(PO_4)_6$ F_2. Also present are aluminum phosphates [AL_3 $(OH_3)(PO_4)_2$]. Minor amounts of iron, magnesium, uranium, vanadium, arsenic, silicon, and carbon may be present, all as oxides. A typical phosphate rock sample is comprised of tri-calcium phosphate, iron and aluminum as oxides, lime as CaO, and silica; no sulfides are present.

The phosphate ore was deposited on historic marine terraces, which are major sand and gravel sources in the Atlantic and Gulf Coastal Plains.(5) Large sand mines are operated within 50 miles of Mosaic's ore reserves. The Florida marine deposits do not contain minerals that are the sources of contamination at hardrock mines.

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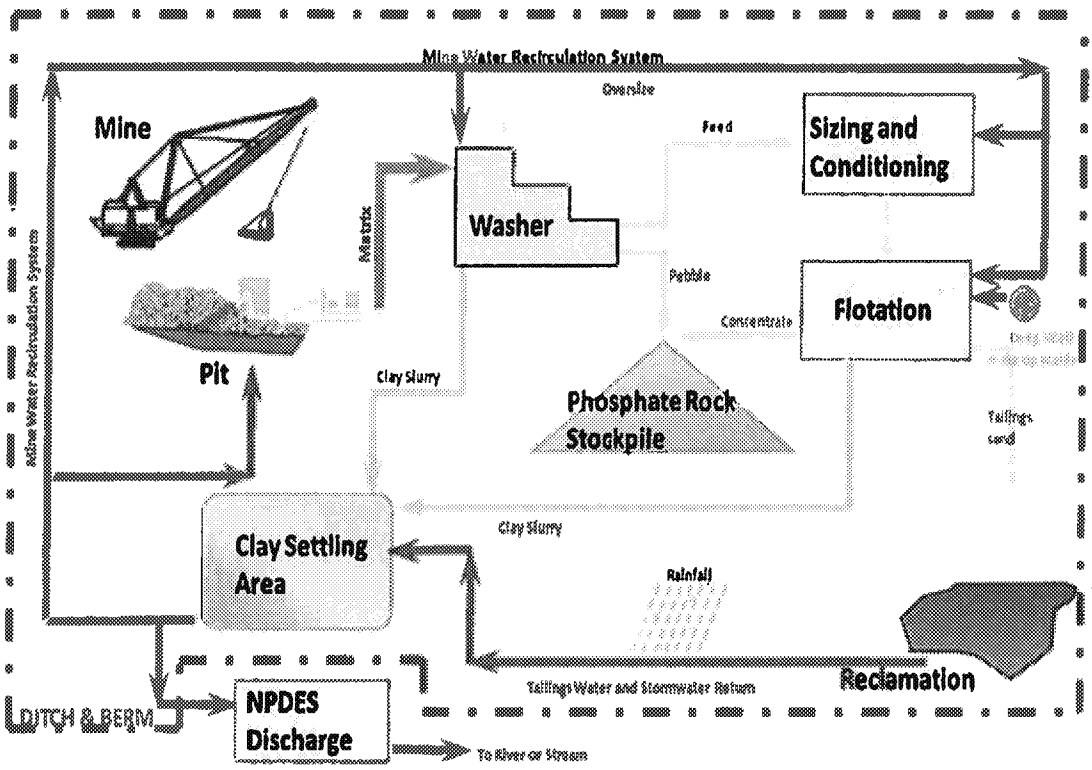
[3] The Mosaic Company. Securities and Exchange Commission Form 10-K, February 2017.
[4] U.S. Army Corps of Engineers. 2013. **Final Areawide Environmental Impact Statement on Phosphate Mining in the Central Florida Phosphate District.**
[5] Society for Mining, Metallurgy, and Exploration. 1990. **Surface Mining, Second Edition.**

In sharp contrast, traditional hardrock mines extract and beneficiate ores from volcanic, igneous, or metamorphic consolidated rock formations. The ore is present in veins, thereby requiring crushing and grinding to talcum powder consistency to expose the target mineral to recovery techniques. Typically, hardrock ores containing specific desirable metals (e.g., copper, silver, or gold) also contain undesirable elements such as lead and mercury.[6]

1.1 EXTRACTION AND BENEFICIATION

Operations meeting EPA's definitions of "extraction" and "beneficiation" are conducted at Mosaic's Four Corners, South Fort Meade, South Pasture, and Wingate Creek Mines. All of these mines consist of similar facilities and processes.



[6] 82 FR 3471.

Prior to commencing ore extraction, mining areas and pipeline corridors are isolated, or severed, from their watersheds by the installation of perimeter secondary containment berms (the mined voids provide primary containment). These structural best management practices (BMPs) minimize the risk of uncontrolled releases to the environment.

1.1.1 Extraction

At the Four Corners, South Fort Meade, and South Pasture Mines, large, electrically-powered draglines are used to first remove 10 to 40 feet of unconsolidated overburden soils and sands that overlie the ore matrix and place the excavated overburden into adjacent mined areas for subsequent use in reclamation. Then, the ore matrix, which also is typically 10 to 40 feet thick, is extracted by the same dragline and placed into a shallow pit dug in an adjacent unmined area.

The ore in the adjacent pit is converted into a slurry by disaggregation using high pressure water jets (similar to placer mining). The resulting slurry is pumped through pipelines to the beneficiation plant for ore separation.

At the Wingate Creek Mine, both overburden removal and ore extraction are completed using a separate dredge for each function. Use of dredges is preferred at Wingate Creek because that overburden thickness is more than 40 feet across much of the mine.

Being of sedimentary origin, the overburden and ore matrix are excavated without the need to blast prior to mining. Disaggregation of the ore matrix is accomplished solely by water pressure. Crushing or grinding is not required.

The ore matrix is comprised of a mixture of phosphate rock product, barren quartz sand, and clay-sized particles, which are physically separated at the beneficiation plant. The phosphate rock product is then shipped offsite to Mosaic's mineral processing plants.

The quartz sand and clay-sized particles are returned to mined areas via slurry pipelines to backfill the mined voids. Of the total mined area at each mine, approximately 60 to 75 percent is backfilled with sand and approximately 25 to 35 percent is backfilled with clay-sized particles in clay setting areas (CSAs). The sand backfill landform can be reclaimed into a variety of land uses. A CSA is an area contained by engineered retaining dams where water separates by gravity from the slurry after beneficiation, leaving a consolidated clay surface suitable for reclamation as agricultural land. Where insufficient sand volumes are available, the available overburden is graded to form lakes and shore lines with littoral zones.

Sand and gravel extraction uses similar dragline and dredge mining techniques. Hydraulic excavators are also used.(7) The mining depths are similar – typically less than 100 feet. Overburden is used to form the shorelines of the lakes that result, with residuals from ore washing and screening deposited in the mine pits.

Traditional hardrock mining seldom occurs at depths of less than 100 feet, with most deposits occurring hundreds to thousands of feet below land surface. Drilling and blasting are required to break the rock into sizes that can be moved from the mine to the mill. According to the preamble, these operations results in waste rock piles, acid mine drainage, and contaminated soils and sediments, all of which have led to CERCLA response actions.(8)

In contrast, Florida law requires all lands disturbed by phosphate mining to be reclaimed to a variety of productive uses. The U.S. Geological Survey and the U.S. Army Corps of Engineers (USACE) have found ground and surface waters on, beneath, adjacent, and downstream of Mosaic's phosphate mines meet applicable water quality standards.[9]

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[7] National Stone, Sand and Gravel Association. 2013. **The Aggregates Handbook, Second Edition.**
[8] 82 FR 3472.
[9] U.S. Geological Survey. 1993. **Hydrology and Water Quality of Unmined and Reclaimed Basins in Phosphate-Mining Areas, West-Central Florida.**

USACE also has found Mosaic capable of mitigating wetland impacts through land reclamation. [10]

Mosaic's Florida phosphate mining operations result in reclaimed lakes-type landforms on up to five percent of the mined areas. Reclaimed lakes typically have depths of 40 feet or less; littoral zones of 25 percent of the shoreline are required by rules adopted by the Florida Department of Environmental Protection (FDEP), as are four feet horizontal to one-foot vertical (4H:1V) slopes to depths of six feet for safety reasons. Reclaimed lakes result in highly desirable residential developments. Reclaimed lakes in Polk, Hillsborough, and Hardee Counties are used as public recreation areas and often produce trophy-sized largemouth bass.

Unlike the mine pit lakes resulting from extracting sulfide ores, reclaimed phosphate lakes are not acidic. A comprehensive study[11] of 12 reclaimed lakes produced the following findings with respect to EPA's contaminants of concern addressed in the preamble:

- Barium concentrations were low relative to natural surface waters;
- Chromium concentrations were well below standards to protect freshwater aquatic life;
- Arsenic concentrations did not exceed state standards;
- Cadmium concentrations were similar to natural lakes;
- Mercury concentrations generally were lower than in natural lakes;
- Lead concentrations were well below state standards; and
- Selenium concentrations were extremely low.

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[10] U.S. Army Corps of Engineers. 2013. **Final Areawide Environmental Impact Statement on Phosphate Mining in the Central Florida Phosphate District.**

[11] Environmental Science and Engineering, Inc. 1985. **Ecological Considerations of Reclaimed Lakes in Central Florida's Phosphate Region.**

The low levels of trace elements found in reclaimed lakes provides EPA with data to distinguish Mosaic's Florida phosphate operations from traditional hardrock mining open pits.

CSAs at a phosphate mine are not the equivalent of "tailings impoundments" at hardrock mines. There are important differences between CSAs and tailings impoundments at hardrock mines that clearly distinguish the levels of risk of injury at each:

- Height – CSA dams are less than 75 feet tall during use as compared to tailings impoundments that measure hundreds of feet tall;
- Terrain – CSAs are located on relatively flat terrain away from riparian valleys as compared to tailings impoundments that are sometimes placed in stream valleys in steep terrain;
- Drainage/watershed area – The rainshed of a CSA is limited to acreage within the perimeter of the dams (i.e., no stormwater runoff from surrounding land can enter the elevated impoundment, which limits the potential for overtopping), as compared to tailings impoundments that have watersheds consisting of the land and stream watershed upstream of the dam;
- Materials of construction – CSA embankments are engineered earthen dams whereas tailings impoundments are constructed with tailings; and
- Reclamation – Upon completion of filling, a CSA consolidates to approximately 10 to 15 feet in height over a period of about five years, after which the embankment is reclaimed to a similar elevation and outlet channels are excavated to prevent further water impoundment, thereby eliminating the risk of a dam failure. In contrast, tailings impoundments retain their original height, and are intended to remain in their operating form in perpetuity, posing over time a risk of breach.

1.1.2 Beneficiation

The term "beneficiation plant" refers to the facilities and related processes used to physically separate the phosphate rock from the quartz sand and the clay-sized particles in the ore slurry pumped from active mine areas. Two sizes of phosphate rock are recovered at beneficiation plants: pebble, which measures larger than about 1/16-inch in diameter, and sand-sized concentrate, which measures less than 1/16-inch in diameter.

Physically separating the phosphate rock is completed using the following process:

- Washer – Slurried ore matrix from the mine is screened and separated into course reject, pebble-sized product, sand-sized feed for flotation, and clays. The pebble product is usually an acceptable product ready for shipment to the mineral processing plants, while the sand-sized particles are transferred to the flotation section. Clay and coarse reject sizes are pumped to the CSAs. The washing process that separates the clay-sized particles from the large-sized pebble product and the sand-sized flotation feed material is completely physical; only screening to segregate the various particle sizes is required. No chemicals are used in the washer.
- Flotation – In the flotation process, certain reagents are added to the feed, then vigorously aerated to physically separate – as described below – the phosphate rock product from the sand. The process consists of two sequential stages: a "rougher" first stage floats virtually all the phosphate and some sand, while the "cleaner" second stage floats the remaining sand, leaving the phosphate rock concentrate product. The residual sand tailings are then pumped to mined areas for use as reclamation backfill.

Flotation recovery of the concentrate product occurs by sand-sized particles becoming attached to air bubbles floating through and to the top of the water in a flotation cell, where the froth is recovered. Because neither phosphate nor silica sand particles naturally adhere to the air bubbles, reagents are added as described below.

The selective flotation of phosphate or silica sand relies on the surface electric charge of the particles. The surface of silica sand is negatively charged. Thus, to attach to a silica sand particle, a positively-charged (i.e., cationic) reagent must be applied. In contrast, phosphatic minerals are positively charged. Flotation of the phosphate rock is, therefore, accomplished using negatively charged reagents (i.e., anionic).

Phosphate flotation is a physical, not a chemical process. The flotation reagents do not chemically react with the phosphate rock or quartz sand to result in different compounds. As explained below, phosphate flotation reagents rely solely on electrostatic forces to separate phosphate rock from quartz sand.

Fatty acids are anionic negatively-charged compounds that readily adhere to the cationic positively-charged calcium phosphate particles. Fatty acids are monocarboxylic (i.e., COOH chains) acids, many of which are naturally occurring waxes and essential oils. Examples include oleic acid and linoleic acid, which are essential fatty acids required by the human body that must be obtained from the food supply. Example sources of foods containing fatty acids include butter, corn oil, olive oil, and sunflower oil.

The fatty acids used to float the phosphate particles include oleic acid, linoleic acid, and rosin (abrietic acid) extracted from pine trees when making paper. They are commonly referred to as "tall oil". Tall oil is approved by the Food and Drug Administration for use in packaging food for human consumption (i.e., coating food containers).

In the flotation circuits, fuel oil works in conjunction with fatty acids to "enhance" flotation. The anionic fatty acid coats the cationic calcium phosphate particle (but not the sand, which does not contain calcium), and the fuel oil sticks to the fatty acid – similar to wax on a painted surface. This mixture repels water like a rain bubble on a waxed car, which allows the phosphate particle to be encapsulated by the bubble and "float" to the surface where it can be skimmed off.

The electrical attraction between the fatty acid and the calcium phosphate particles is optimized in water with a pH level of 8.5 to 9.0 standard units (s.u.). Soda ash is a non-toxic natural mineral (i.e., sodium carbonate) that is added to raise the pH level in the flotation circuits. Soda ash is commonly used to make baking soda; to treat water in swimming pools; and in water softeners.

The first phase of flotation using fatty acid, fuel oil, and soda ash produces what is known as "rougher concentrate". The concentrate contains about 10 to 20 percent silica sand, which is too impure to process in the mineral processing plants. As a result, the rougher concentrate is subjected to a second stage of flotation.

Before the second stage of flotation begins, however, the residual fatty acid and fuel oil on the surface of the rougher concentrate particles must be removed. This is accomplished by washing the particles with a mixture of recycled water and sulfuric acid, followed by rinsing in water. The pH of the acid wash water is between 3.0 and 4.0 s.u.

The second stage of flotation is accomplished by applying a positively-charged (i.e., cationic) flotation reagent that belongs to a family of "amines". As noted earlier, the silica sand particles are negatively-charged (i.e., anionic). The positively-charged cationic amines electrostatically adhere to the anionic silica sand particles and to the air bubbles to float to the surface while the calcium phosphate particles do not, which results in the complete separation of the sand the phosphate particles.

Amines are common compounds we experience daily. Among them are the amino acids lysine and methionine that are essential protein ingredients in the human diet. Proteins are amino acid residues.

The risk of releases of hazardous substances from one of Mosaic's beneficiation plants is low. Spill prevention, control, and countermeasures plans provide structural and non-structural BMPs to prevent and contain releases of reagents. In addition, the State of Florida has adopted regulations that govern the design, construction, and operation of above-grade petroleum and mineral acid storage tanks. These rules, facilities, and BMPs are protective against releases of fuel oil, surface acid or concentrated reagents.

Mosaic has evaluated the life cycle of reagents used in beneficiation and through those efforts has developed a mass balance of reagent distribution in the rock product, sand, and clay sized fractions.[12] A mass balance is one that accounts for all of the mass, or pounds, of a substance added to a process and in the products and residuals generated by the process.

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[12] BCI Engineers and Scientists, Inc. 2001. **Fate and Consequences to the Environment of Reagents Associated with Rock Phosphate Processing.**

In the case of a reagent mass balance, the reagents added must end up in the phosphate rock product (except the pebble which is recovered prior to flotation), in the sand tailings, or in CSAs. The following table shows results of the mass balance analysis at one of Mosaic's beneficiation plants:

	Fuel Oil (percent)	Fatty Acid (percent)	Amine (percent)
CSAs	65 – 75	65 – 85	60 – 80
Sand Tailings	10 – 25	5 – 10	15 – 20
Product	5 – 10	10 -15	15 - 20

The organic reagents end up in the CSAs because the water generated by the flotation steps is pumped to CSAs for clarification and storage prior to re-use, with the exception of the water used to pump sand tailings to mined areas for backfill. Even the water recovered at tailings backfill sites is subsequently returned to CSAs.

Within the CSAs, the water is clarified as suspended particles settle to the bottom, leaving the decanted water available for re-use. Reagents electrostatically adhere to particles and remain so, such that the reagents settle with the associated particles. In addition to this physical process, the amines and fatty acids both bond readily with the calcium in the clay particles. This bonding is due to the presence of carboxylate groups in both the amines and the fatty acids.[13] Water quality data demonstrate the CSAs and mine process water systems are very effective in treating the process water to reduce the concentrations of residual reagents through *in situ* biodegradation, evaporation, and photooxidation processes.

[13] Id.

The fate of the inorganic flotation reagents, specifically sulfuric acid and soda ash, is well understood. Both dissolve into the process water and are found as sodium from the soda ash and sulfate from the sulfuric acid in the process water recirculation systems. Process water concentrations of sodium typically average 100 - 125 mg/L and concentrations of sulfate typically average 200 - 300 mg/L.[14] Various concentrations of sodium and sulfate also are added by the groundwater well withdrawal make-up water supplies. The acidity is neutralized by the soda ash and clay particles, such that the pH of water in the recirculation systems is close to neutral.

While there are no federal or state surface water quality standards for either sodium or sulfate, DEP has established groundwater standards for sodium at 160 mg/L and sulfate at 250 mg/L. Groundwater monitoring near CSAs (where these minerals would most likely be found if they were to migrate from the CSAs) has not produced evidence of exceedances of either the sodium or sulfate standard.[15]

1.1.3 Framework of Regulations

The State of Florida has adopted a comprehensive framework of regulations that minimize the risk of impacts from Mosaic's extraction and beneficiation operations. The principal permits and approvals that implement the regulatory structure are the Industrial Wastewater/National Pollutant Discharge Elimination System (IW/NPDES) permit, the Environmental Resource Permit (ERP), and the Conceptual Reclamation Plan (CRP) approval.

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[14] Mosaic Fertilizer, LLC. 2011 **Ona Mine Application for a Section 404 Federal Dredge and Fill Permit Application.**

[15] Mosaic Fertilizer, LLC. 2017. **Annual Operating Report for the South Pasture Mine.**

1.1.3.1 IW/NPDES Permit

Mosaic's mine discharge water consists of "process generated wastewater" from washing and flotation and water generated by "mine dewatering" from active mining and reclamation areas. Both of these wastewater types are regulated by FDEP rules published in Chapter 62-671, F.A.C., which incorporate and expand upon the effluent limitations guidelines and new source performance standards published by EPA in 40 CFR 436. FDEP rules define "process generated wastewater" as water used for slurry transport of the ore matrix or the sand and clay residuals; recovery of the phosphate rock by washing and beneficiation at the beneficiation plant; and any other water that becomes commingled in the mine water recirculation system.[16] "Mine dewatering" means any water that is impounded or collects in the mine areas (i.e., water from surficial aquifer, rainfall collected stormwater) that is pumped into the mine water recirculation system.[17] Once water produced by "mine dewatering" enters the mine water recirculation system, it is considered "process generated wastewater.[18]

Discharges are authorized by NPDES permits. In addition to authorizing installation and operation of the surface water outfalls, the FDEP permits authorize and regulate discharges to the surficial aquifer, which consist of rehydrating the aquifer during backfilling of mined voids with sand tailings or clay and downward seepage beneath and adjacent to CSAs.[19]

The FDEP permits and regulations require all water discharged to receiving streams to meet applicable surface water quality standards at the point of discharge (i.e., without the use of mixing zones) and aquatic life criteria. Mosaic compliance monitoring data was independently examined by USACE and was found to comply with these standards.[20]

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[16] Florida Department of Environmental Protection. 2016. **Industrial Wastewater Facility Permit No. FL 0037958; Mosaic Fertilizer, LLC; South Fort Meade Mine.**
[17] Id.
[18] Id.
[19] Id.
[20] U.S. Army Corps of Engineers. 2013. **Final Areawide Environmental Impact Statement on Phosphate Mining in the Central Florida Phosphate District.**

Discharges to groundwater are required to meet Safe Drinking Water Act standards beyond the "Zone of Discharge" under Rule 62-420.465, F.A.C., which extends 100 feet horizontally beyond the boundary of the discharge area (e.g., sand tailings backfill sites and CSAs) and to the base of the surficial aquifer. USACE independently evaluated Mosaic compliance monitoring data and found groundwater contamination is not present at Mosaic's mines and beneficiation plants.[21]

1.1.3.2 ERP/CRP

The ERP and CRP regulate land disturbance associated with ore extraction. Chapter 62-330, F.A.C., requires the ERP applicant to demonstrate the proposed ore extraction will not cause or contribute to any excursions from Florida water quality standards, both ground and surface waters. The ERP also constitutes the Section 401 federal Clean Water Act certification.

The CRP requires all lands disturbed by mining operations to be reclaimed to safe and productive land uses following ore extraction. Rule 62C-16.0051, F.A.C., imposes reclamation performance standards, including the requirement that water draining from reclaimed land meets water quality standards. Rule 62C-16.0075, F.A.C., establishes financial responsibility requirements.

In addition, the state of Florida has adopted rules that protect against releases of hazardous substances that all apply to all holders of ERP and IW permits as well as reporting and remediation of releases of hazardous substances. This comprehensive regulatory structure and program is designed to prevent sites from being listed under EPA's CERCLA program. Therefore, EPA has assurance that any releases of hazardous substances from Mosaic's Florida phosphate mining operations, while demonstrated to be a low risk above, would be

[21] Id.

reported, assessed, and remediated on a timely basis, thereby precluding the need for action by EPA under CERCLA.

1.2 PROCESSING AT CONCENTRATES PLANTS

Mosaic's phosphate concentrates (mineral processing) plants located at Bartow, New Wales, Plant City, and Riverview, Florida and Uncle Sam, Louisiana utilize similar processes to chemically convert phosphate rock into phosphoric acid and to chemically convert phosphoric acid into fertilizer and animal feed ingredients finished products. At these facilities, insoluble phosphate rock is transformed into a suite of water soluble, biologically-available products.

Each of the manufacturing plants consist of one or more sulfuric acid plants, one or more phosphoric acid plants, and one or dry products plants.[22] A sulfuric acid plant burns elemental sulfur to produce sulfur dioxide and then converts sulfur dioxide into sulfuric acid. In the phosphoric acid plants, phosphate rock is reacted with sulfuric acid to produce phosphoric acid and calcium sulfate (also referred to as phosphogypsum). In the dry products plants, ammonia or limestone is reacted with phosphoric acid to produce fertilizer or animal feed ingredients products.

Mosaic has worked cooperatively with EPA to assess under RCRA whether any of its five manufacturing plants have experienced releases that resulted in contaminated soils, surface waters, or groundwater on, beneath, or have migrated offsite. These investigations, coupled with groundwater monitoring plans implemented pursuant to the manufacturing plants NPDES permits, while not yet complete, have not discovered contamination that would rise to the level of a CERCLA response action.

[22] Mosaic also operates sulfuric acid plants at its South Pierce Florida facility.

In addition, as noted in the preamble to the Proposed Rule, EPA and Mosaic have reached agreement on funding closure of the manufacturing plants and post-closure operation and maintenance costs.[23] This agreement provides additional assurance that a CERCLA response action will not be necessary in the future at the manufacturing plants.

These actions under RCRA effectively address the financial responsibility concerns EPA is attempting to address in the Proposed Rule under CERCLA. Because EPA is the lead agency, EPA's concerns about the effectiveness of other regulatory programs do not apply.

2. EPA'S FINANCIAL ASSURANCE FORMULA DOES NOT CORRELATE WITH MOSAIC'S LOW-RISK FLORIDA PHOSPHATE MINING OPERATIONS

Section 1.1 above provides documentation to support a finding by EPA that Mosaic's Florida phosphate mining operations do not pose risks similar to those documented by EPA at historical CERCLA NPL sites or current hardrock mining operations. Section 1.2 provides documentation for EPA to find that the State of Florida has implemented a comprehensive multi-media regulatory structure that is protective of the environment and minimizes the risk that one of Mosaic's Florida phosphate mines could require response actions by EPA under CERCLA.

The proposed financial responsibility formula in the Proposed Rule is based upon historical CERCLA response costs at hardrock mine sites with consideration of current practices and processes emphasized. Because no Florida phosphate mines have required CERCLA response actions, EPA's formula cannot take into consideration historical and current processes at Florida phosphate mines. The following discussion explains why the input variables do not correlate to Mosaic's Florida phosphate mining operations.

[23] 82 FR 3478.

2.1 INPUT VARIABLES

EPA's formula for total financial responsibility is based on a calculated estimate of the response cost, which is then adjusted for inflation. The response cost is the sum of 13 input variables. The applicability or inapplicability of each input variable is addressed below.

2.1.1 Open Pit Category

In the preamble, EPA cites examples of traditional open pit hardrock mines causing groundwater contamination due to precipitation coming into contract with sulfide ores, often also resulting in low pH acid mine drainage. Metals were most often cited as the constituents of concern. There are multiple reasons why Mosaic's Florida phosphate mines should not be similarly categorized.

First, traditional open pit mines are single excavations that reach at least 100 feet and often thousands of feet below land surface. Upon completion of ore extraction, the pits become "closed basins" that fill with water. In sharp contrast, Mosaic's Florida phosphate mines are shallow excavations that rarely reach 100 feet in depth. As explained in Section 1.1 above, nearly all of the mine excavations are backfilled with clay, sand and overburden such that only a small percent of mined area is reclaimed as lakes. The "reclaimed lakes" contain pH levels that are near neutral and contain low levels of constituents of concern to EPA.

Second, the vast majority of examples cited by EPA were sulfide ore veins within metamorphic rock formations. In sharp contrast, Section 1.1 documents the ore mined by Mosaic is a marine oxide deposit of sands and clay.

Third, Section 1.1 provides citations from an extensive body of research and monitoring results that document soil and ground and surface water quality on, adjacent, and downstream of Mosaic's Florida phosphate mines meet applicable standards and do not require risk-based corrective action.

2.1.2 Underground Mine Category

Section 1.1 documents Mosaic's Florida phosphate mines do not fall within the underground mine category.

2.1.3 Waste Rock Category

Section 1.1 documents Mosaic's Florida phosphate mines do not generate waste rock piles. As described in Section 1.1, the phosphate ore is overlain by unconsolidated soils, sands, and clays of marine origin, which is referred to as overburden. The overburden, along with tailings sand, is used to backfill the mine excavations and provide the reclaimed land forms.

2.1.4 Head/Dump Leach Category

Section 1.1 documents Mosaic's Florida phosphate mines do not recover phosphate rock using a heap leaching process.

2.1.5 Tailings Category

The CSAs described in Section 1.1 are not tailings impoundments and should not be compared to tailings impoundments for purposes of determining whether the Proposed Rule should apply to Mosaic's Florida mining operations. As explained therein, CSAs differ from conventional tailings impoundments at hardrock mines where CERCLA response actions have been required.

2.1.6 Process Pond and Reservoir Category

CSAs also provide storage for storm and process water. The CSAs are addressed under tailings impoundments above.

2.1.7 Slag Pile Category

Section 1.1 documents Mosaic's Florida phosphate mines do not generate slag. Therefore, the slag pile category is not applicable.

2.1.8 Solid and Hazardous Waste Disposal Category

Mosaic does not dispute that its Florida phosphate mines generate solid waste and are registered as small quantity generators of hazardous wastes. Such wastes include office trash and garbage and spent batteries, fluorescent bulbs, and fluids and solvents from mobile equipment repair, many of which are recycled.

Since the enactment of CERCLA in 1980, Mosaic and other Florida phosphate mine operators have closed 18 beneficiation plants, including demolition and removal of all mineral processing equipment, facilities, structures, and wastes. The owners/operators completed this work without imposing any costs on the taxpayer. Combined with the absence of any Florida phosphate mines requiring CERCLA response actions, this track record demonstrates Mosaic's Florida phosphate mines do not fall within this risk category.

2.1.9 Drainage Category

Section 1.1 documents that at Mosaic's Florida phosphate mines, all drainage from active mine areas is contained within the ditch and berm systems; discharged to the environment only through federal Clean Water Act Section 402 NPDES outfalls; and uncontrolled drainage only resumes after reclamation is complete and water quality has been documented to meet Florida water quality standards. Due to this regulatory structure and current operating practices, Mosaic's Florida phosphate mines do not fit within the drainage category described by EPA in the background document.

2.1.10 Interim O&M Category

The interim O&M category is not applicable for the reasons cited in the heap leach and tailings categories above.

2.1.11 Water Management Category

The water management category is not applicable because Mosaic's Florida phosphate mines do not fit within the in-situ leach category.

2.1.12 Short-Term O&M Monitoring Category

Mosaic's Florida phosphate mines do not fall within this category for the same reasons the drainage category is not applicable.

2.1.13 Long-Term O&M Monitoring Category

Mosaic's Florida phosphate mines do not fall within this category for the same reasons the drainage category is not applicable.

2.2 CONCLUSIONS

An extensive bibliography of publicly and privately funded environmental multi-media data, analyses, and scientific and engineering evaluations is provided in Chapter 7 of the USACE Areawide EIS.[24] to support the following findings by EPA:

1. Extraction of oxide deposits in central Florida and physical ore separation (i.e., beneficiation) closely resembles extraction and physical ore separation of oxide sand and gravel deposits found by EPA to have a low degree and duration of risk of injury.
2. Mosaic's Florida extraction and beneficiation operations are not comparable to traditional hardrock mines in terms of types of ores extracted and beneficiated, processes used to beneficiate the target minerals, uses of hazardous materials, and historic and current releases of hazardous substances, which forms the underlying basis for the Proposed Rule.

[24] Id.

3. Mosaic's Florida extraction and beneficiation operations do not require the features or operations/processes that generated the environmental releases addressed in EPA's evaluation. EPA's "modeled universe" did not include Florida phosphate ore extraction or beneficiation sites because none have required CERCLA response actions.
4. Based upon EPA's criteria for exemption, Mosaic's phosphate ore extraction and beneficiation facilities and operations should be excluded from regulation under the Proposed Rule.
5. Mosaic's phosphate mineral processing (fertilizer manufacturing) facilities and operations have financial responsibility amounts and instruments in place under RCRA. Regulation under the Proposed Rule would be redundant.

Potash Technical Analysis- Attachment B

ARCADIS Design & Consultancy for natural and built assets

TECHNICAL MEMORANDUM

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Mosaic Carlsbad Potash Inc.

From:

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June 1, 2017

Arcadis Project No.:

05749034.0000

Subject:

Technical Analysis – Justification for Potash Exclusion from CERCLA § 108(b) Requirements

1.0 Background

The US Environmental Protection Agency (EPA) has published proposed changes to 40 CFR Part 320 in a proposed rule (the Proposed Rule)[1] entitled *Financial Responsibility Requirements Under CERCLA § 108(b) for Classes of Facilities in the Hardrock Mining Industry*, in the Federal Register (FR) of January 11, 2017. Mosaic Potash Carlsbad Inc. (Mosaic) has requested that Arcadis provide this technical analysis of EPA's basis for inclusion of potash mining as one of the classes of "hard rock mining" to be regulated under the proposed Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) 108(b) rulemaking.

2.0 Purpose for This Analysis

EPA cites its 2009 *Identification of Priority Classes of Facilities for Development of CERCLA Section 108(b) Financial Responsibility Requirements* (Priority Notice)[2] as the basis for identifying and prioritizing the classes of facilities within the hardrock mining industry, as defined by EPA, for which EPA would first develop regulations for financial responsibility. The Priority Notice stated that the classes of mines to be prioritized for regulation were determined based on its consideration of the elements used in evaluating risk to human health and the environment, such as probability of releases, type and duration of exposure, and toxicity of releases.

[1] US EPA 2017
[2] US EPA July 2009

The preamble to the Proposed Rule also cited EPA's June 29, 2009 Memorandum, *Mining Classes Not Included in Identified Hardrock Mining Classes of Facilities* (the 2009 Memorandum)[3]. In this Memorandum, several categories of commodities were exempted based on EPA's review of 2007 TRI data, which indicated that these categories released "many orders of magnitude less hazardous substances into the environment than do other classes of hardrock mining." EPA compared the types and amounts of chemicals from 59 non-fuel hardrock commodity sectors, noting that the amount and types of releases were significantly lower than, and do not pose as significant a risk as, other hardrock mining commodities. As a result of their evaluation, EPA exempted the list of 59, which included salt, salt brine evaporation, sand, gravel, limestone, and kaolin. In the Proposed Rule[4], EPA solicits comments to justify the exclusion of additional classes of mining with low risk under 40 CFR § 320.62, stating:

> "EPA solicits comments on whether it would be feasible and appropriate to identify additional classes of hardrock mining facilities as presenting a lower level of risk of injury, particularly classes of mines that differ in their operations and associated risk from more tradition *[sic]* hardrock mining operations."

This analysis responds to EPA's request, and provides deep justification for the Agency to exclude potash mining from the scope of the proposed rule. The analysis included herein provides a basis for determining that the potash industry poses a "Lower Level of Risk of Injury Consistent with other Classes Not Included in the Proposal," and should therefore be excluded from regulation under the Proposed Rule. Specifically, the analysis demonstrates that:

1. Potash extraction and beneficiation consists of the same types of activities as other commodities, which EPA has specifically excluded from the current rulemaking due to their low level of risk of environmental impact.

2. The potash sector is not comparable to the other mining sectors included for regulation under the Proposed Rule and that potash extraction and beneficiation does not include the types of activities and features that have a history of releases, liabilities and costs evaluated by EPA as a basis for regulation under the rulemaking.

3. The "modeled universe," which served as EPA's basis for assessment of compliance cost for hardrock commodities, did not include and was not reflective of soft rock mining commodities like potash.

4. The potash sector in New Mexico, which accounts for 85% or more of potash production in the US, is strictly regulated, and has operated for multiple decades with no history of releases, environmental risk, or financial liabilities to federal regulatory agencies or the public.

The Proposed Rule[5], cites the 2009 Priority Notice as the basis for its definitions of "hardrock mining" and its component activities: "extraction "beneficiation" and "processing." The Priority Notice defines hardrock mining as:

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[3] US EPA June 2009
[4] 82 Fed. Reg. p3456
[5] Ibid. p3390

> "the extraction and beneficiation of rock and other materials from the earth that contain a target metallic or non-metallic mineral. Mineral processing separates and refines mineral concentrates to extract the target material."

Per the Priority Notice,

> "Extraction means the sequence of activities intended to physically gain access to and remove ore or a mineral body."
>
> "...beneficiation involves separating and concentrating the target mineral from the ore." EPA's definition describes beneficiation as the steps in which separation of the target mineral from waste occurs and in which size reduction or enlargement to facilitate processing occurs. EPA identifies both flotation and leaching as the most common beneficiation techniques in practice, and defines the waste remaining after separation of target minerals as "tailings."
>
> "Processing is the refining of ores or mineral concentrates after beneficiation to extract the target material." EPA's definition considers pyrometallurgical techniques such as smelting to be typical of processing/mineral refining.

The Proposed Rule relies on those definitions in describing the component activities of hardrock mining and their impacts. While the mining industry does not define or use the above terms in exactly the same way as EPA does in its Rulemaking, for the sake of clarity, this analysis will utilize EPA's terminology to the extent possible.

3.0 Overview of Potash Extraction and Beneficiation

Potash is a term currently used to refer to several potassium minerals including muriate of potash or potassium chloride (KCl), potassium sulfate (K_2SO_4), potassium magnesium sulfates (K-Mags), and potassium nitrate (saltpeter)[6]. Prior to discovery of natural potash mineral deposits in these mineral forms, potash was produced by evaporation of potassium carbonate leached from wood ashes. Potash has been produced in the United States primarily from harvesting of ores since 1930, following the discovery in 1925 of sylvinite (potassium chloride ore) and langbeinite (potassium magnesium sulfate ore) in the Carlsbad, New Mexico area.[7]

Like the exempt salt mining sector, all commercial potash mineral deposits result from evaporites, water soluble minerals crystallized from aqueous solutions and deposited, typically at depth, from sea water in ancient inland oceans or lakes. Deposits which have been economically developed in the US include Searles Lake in California; the Bonneville Salt Flats in Wendover, Utah; Sevier Dry Lake area of Paradox Basin in southeastern Utah; Delaware Basin in southeastern New Mexico; Holbrook Basin in east-central Arizona; and the Michigan Basin, as well as surface and near surface potassium brines from Great Salt Lake, Utah.

Underground potash deposits in the form of potassium chloride are found in the Great Salt Lake and Sevier Dry Lake areas of Utah, within in the Paradox Basin, approximately 3,000 feet below ground, as well as in the Michigan Basin at 7,000 to 8,000 feet below ground.[8]

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[6] Gary, et. al. 1974
[7] Austin 1984
[8] International Potash Institute 2017

Potash minerals, generally as potassium sulfates, are also present at economical concentrations in the North Arm of Great Salt Lake, in Utah. Production of potash and halite (sodium chloride or common salt) from Great Salt Lake salt brine evaporation began in the late 19th century.

The only potash deposit currently mined by underground methods is the Carlsbad deposit in New Mexico. Thick sections of salt and evaporite minerals were deposited and continually replenished during the Ochoan period in the Permian Basin in west Texas and southeastern New Mexico. The potash-containing minerals were concentrated in a small area on the west side of Permian Basin in what is known today as the Carlsbad Mining District. Approximately 85% of US production of potash minerals originates in New Mexico, and the Carlsbad deposits have been mined nearly continuously for over 75 years, making this one of the longest-operating underground potash mining areas in the US.

Evaporite mineral deposits and host rock are considered sedimentary rock, or "soft rock"[9], as opposed to other minerals found in igneous and metamorphic, or "hard rock." As discussed further in Sections 3.1 through 3.3, potash is extracted from its deposits in the host formation or media by one of three mining methods: deep shaft mining, in-situ solution mining, or salt brine evaporation (evaporation of naturally occurring surface or subsurface brines).

3.1 Conventional Extraction and Beneficiation

All potash mines in and to the east of the Carlsbad Mining District are underground mines with mine shaft depths varying from 650 to 1,750 feet. The relatively flat ore zones are mined with modified coal-mining equipment, in room and pillar or similar workings.[10]

Potash mines in the Carlsbad Mining District are deep shaft mines, usually consisting of two or more shafts: a service shaft for transport of personnel and equipment, and a production shaft for hoisting of the excavated ore. The potash is present in multiple, nearly flat or shallowly-sloped continuous beds that can be mined by using continuous mining machines. Because the potash minerals are present as extensive continuous beds of excavatable soft rock mineral salts, no explosive blasting of host rock to expose mineralized surfaces is required, as it is in traditional hard rock mining. In addition, because the potash minerals are not interbedded with non-mineralized rock, the segregation of non-mineralized waste rock, and the associated production of low-grade ore piles and waste rock dumps, does not occur.[11]

Groundwater is typically scarce in the entire region. When groundwater is present, the ore zones and mine workings are typically below the water table. In the case of Mosaic's New Mexico mining works, a hydraulic head exists between the water table and the base mining elevation.

Mosaic's Carlsbad, New Mexico potash facility, which is typical of potash mining and beneficiation in the region, consists of an underground mine and surface mill that produces potash products from langbeinite ore (K_2SO_4*$2MgSO_4$). The major steps associated with the operation are simple manual/mechanical underground mining with above ground separation and size grading, accomplished by physical equipment for crushing, screening, granulation, drying, storing, and loading. Langbeinite ore is hoisted 900 feet from the underground mine to the surface and conveyed to a crushing circuit, where it is screened. Undersized

[9] Gary, McAfee and Wolf, 1974
[10] Yager 2016
[11] Austin 1980

material goes to a fine ore bin while oversized material is crushed in an impact crusher and rescreened. The fine ore is transported by belt to a wet purification circuit where impurities are removed from the ore, by contact with water and magnetite, a non-hazardous iron mineral. After the wet circuit, the langbeinite material is dewatered over a belt filter and dried in a rotary dryer. The dried langbeinite is sized by several screens in a screening tower, and the various size grades are dispatched to warehouses and sold as either granular, standard, or a premium blend of potassium magnesium sulfate (known as K-Mag®). Approximately 30-50% of the langbeinite product is transferred to a granulation circuit, finely ground in two Raymond mills, injected into a rotating drum granulator with binder material, consisting of non-hazardous oils, amines and urea, to form uniform granules, and dried in a rotary dryer. The dried product is sized by screening, and the optimally sized product is dispatched to a warehouse. Over- and undersized product is recycled through the granulation circuit.

The above sequence of operations, in practice at Mosaic's New Mexico location, does not use acid, caustic or cyanide leaching agents. Further, no synthetic organic chemical reagents or extraction solvents are added. The operations have typically been small quantity generators of the types of wastes regulated under the Resource Conservation and Recovery Act (RCRA) from use of small quantities of reagents in on-site assay or quality control laboratories. Hence, the facility is a small quantity generator under RCRA and New Mexico's hazardous waste regulations.

Like the exempt salt mining sector, extraction and beneficiation of conventionally-mined potash produces relatively benign tailings composed of clay, soils, and sodium chloride from the mined deposit, which is accumulated on site. Cuttings are hoisted from the mine to the surface and transported to a screening and crushing circuit. Oversized material is crushed and recycled to the screen, while the appropriately-sized material is slurried with water and pumped to the tailings area.

At the Mosiac New Mexico operation tailings, containing salts and clays, are deposited in a management area referred to as the "salt stack." Larger or heavier clay particles and salts settle in the salt stack, and a clear brine containing fine clay is transferred to the clay settling area. Following fine clay settlement, clear brine is transferred by pipeline to Laguna Grande, where salt is harvested for commercial reuse in man-made evaporation recovery ponds, in an operation run by third parties. As discussed below, salt brine evaporation has been exempted from regulation under the Proposed Rule.

Because the beneficiation of potash, , does not involve digestion with mineral acids, caustics or cyanide solutions, the resulting tailings from current operations are not corrosive, do not contain dissolved heavy metals, and do not generate a leachate.

Most potash mining in New Mexico occurs in remote, sparsely populated areas, with moderate to very dry climate, and minimal precipitation.

3.2 Solution Mining Extraction and Beneficiation

As is done in the exempt salt mining sector, solution mining methods are used when the potash ore is deposited at depths too great for conventional mining techniques, or to recover ores left behind after the cessation of conventional mining. The deposit formerly mined at Hersey, Michigan was developed as a solution mine, and the former conventional mines at Cane Creek, Utah and northeast of Carlsbad, New Mexico have been converted to solution mines. Solution mining involves injection of heated natural salt brine solutions into the underground ore body to dissolve the potash-containing minerals. Before being

surfaced, potash brine solutions may be pumped initially to underground caverns for additional residence time to allow additional dissolution of the potash minerals. Brine solutions laden with dissolved potash minerals are pumped to surface evaporation ponds or above-ground equipment where salts are crystallized, and potash minerals are subsequently separated from brine salts by flotation.[12,13]

3.3 Potash Salt Brine Evaporation

In the North Arm of Great Salt Lake in Utah, potash is also produced by salt brine evaporation of naturally-occurring surface and subsurface brines, which contain high levels of sodium chloride, magnesium chloride, and potassium sulfate. In this situation, potash in the potassium sulfate form is produced from the same source, in the same facility and equipment as common salt, from salt brine evaporation, which EPA has exempted from regulation under the Proposed Rule.

3.4 Processing or Refining

Potash production does not involve "processing" or "refining" of mineral concentrates as defined by EPA in the Proposed Rule and its supporting studies. Because potash minerals exist in nature in substantially the same chemical form in which they will be marketed, and because they can be separated from co-present minerals with simple mechanical operations, potash production does not involve the types of processes or features which EPA determined to be the key causes of environmental risk and CERCLA liability from processing or refining. Specifically, because potash production does not involve the thermal purification of solid metals, it requires no solvent extraction, no calcining and no smelting; and therefore, produces no waste solvents, no furnace residues or smelter slags, and no thermal equipment stack scrubbing solutions. Because potash production does not require the creation of a metal product, it does not involve casting, forming, machining, or metal finishing, and does not produce any of the wastes associated with those processes.

In summary, potash extraction and beneficiation, including the New Mexico conventional mining operations:

- Generate no waste rock dumps, spent ore, or low-grade stockpiles piles;
- Do not involve explosives and blasting (although many mining classes in the list of 59 exempted by EPA do involve blasting);
- introduce no acid, caustic or cyanide leaching solutions;
- Are limited to physical and mechanical operations for sizing, separation, and product classification;
- Does not involve; and therefore, does not transfer leaching solutions or heavy metals to the surface impoundments;
- Produce only minimal quantities of laboratory-generated hazardous waste as defined in RCRA;
- Produce benign tailings comprised of residual constituents from the native mineral deposit. (Solution mining and surface brine evaporation generate no tailings, but do produce residual mineral salts); and,

[12] Kent et. al 2007
[13] Yager 2016

- Because the tailings, where produced, are non-acidic with no heavy metals, they do not produce acid mine runoff.

4.0 Potash Production Consists of the Same Activities as other Commodities which EPA has Exempted from the Current Rulemaking Due to Low Risk of Environmental Impact

As mentioned in Section 2.0, above, EPA cited its 2009 Priority Notice as the basis for identifying and prioritizing the classes of facilities within the hardrock mining industry for which EPA would first develop regulations for financial responsibility. The Priority Notice defined hardrock mining facilities as those which extract, beneficiate, and process metals, and non-metallic, non-fuel minerals.

In the preamble to the Proposed Rule[14], EPA states that, in addition to excluding coal mining operations from a list of potentially regulated facilities,

> "EPA also removed 44,845 mines associated with 59 non-fuel hardrock commodities to conform with the scope of those classes of facilities identified in the 2009 Priority Notice."

The preamble to the Proposed Rule also cited EPA's June 29, 2009 Memorandum, *Mining Classes Not Included in Identified Hardrock Mining Classes of Facilities* (the Memorandum). As described in the Memorandum, several categories of commodities were exempted from regulation after EPA reviewed 2007 TRI data, which indicated that these categories released "many orders of magnitude less hazardous substances into the environment than do other classes of hardrock mining." These included mining and quarrying of crushed and broken limestone, crushed and broken granite, other crushed and broken stone, and the mining of kaolin and ball clay, and clay and ceramic refractory minerals. These commodities were exempted from regulation based on TRI data indicating that they released 164,000 pounds of hazardous substances into the environment in total, which EPA considered immeasurably smaller than the rest of the hardrock mining universe. It should be noted that in comparison, the potash industry released significantly lower amounts than those identified by EPA above. For example, releases from Mosaic's New Mexico operations have historically been and remain so low that they fall below the modest reporting thresholds established for TRI reporting and have been considered de minimus .

EPA compared the types and amounts of chemicals from 59 non-fuel hardrock commodity sectors, noting that while some do release some of the same types of hazardous substances as the hardrock mining universe, the amount and types of releases were significantly lower and do not pose as significant a risk. As a result of their evaluation, EPA also exempted the list of 59 which, in addition to the commodities listed above, included salt, salt brine evaporation, sand, and gravel.

As will be discussed in the following sections, potash extraction and beneficiation is comparable to, and in some cases identical to, the following mining classes and commodities, each of which EPA has categorically excluded from regulation under the Proposed Rule because they pose a much lower environmental risk than other hardrock commodities: salt and salt brine evaporation, crushed and broken limestone production, sand and gravel, and kaolin and ball clay. A comparison between potash operation and each exempted commodity is provided in the remainder of this section, and summarized in Table 4-1 at the end of this section.

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[14] 82 Fed. Reg. p3390

4.1 Salt and Salt Brine Evaporation

Like potash, sodium chloride (common salt) is an evaporite, crystallized and deposited from sea water in ancient inland oceans or lakes in the same locations and in the same geologic periods. As would be expected, economic mineral deposits of salt and potash minerals are frequently co-located. In underground deposits they are usually intermixed or stratigraphically adjacent at depth in soft rock host formations. In the North Arm of Great Salt Lake, they are co-present as dissolved minerals.[15]

In the salt brine evaporation of lake brines, the sodium chloride product and the potash minerals are simultaneously recovered in evaporation ponds or crystallizers, then separated by flotation.

EPA concluded from review of three Society of Mining, Metallurgy and Exploration (SME) texts[16,17,18] that salt and salt brine evaporation is one of 59 commodities that "are produced by simple physical methods which separate the product from overburden." EPA also noted that the 59 commodities do not appear, at this time, to routinely use hazardous substances to produce a final product.

As described above, potash mining uses the same simple physical methods to separate product from natural materials, and potash production does not routinely use hazardous substances to produce a final product. Moreover, in potash recovery from lake brines, the potash product is sequentially harvested from the same equipment in the same salt brine evaporation facilities which EPA has exempted from regulation under the Proposed Rule.

4.2 Limestone

Crushed and broken limestone production were included in the 59 commodities which EPA exempted from regulation under the Proposed Rule because of their low environmental risk, as stated in the 2009 Memorandum.

EPA concluded from review of three SME texts that limestone quarrying is one of 59 commodities that "are produced by simple physical methods which separate the product from overburden." EPA also noted that the 59 commodities do not appear at this time to routinely use hazardous substances to produce a final product."

Like the quarrying of crushed and broken limestone, potash production involves the recovery of an alkaline mineral resource from a sedimentary host rock, and the mineral resource exists in continuous strata in the native material in essentially the same chemical form in which it will be marketed. Hence, both limestone and potash production involve simple physical beneficiation processes focused on the removal of impurities from the native mineral deposit via flotation or other physical processes, and classification/size segregation via mechanical equipment (i.e., grinding, screening). Likewise, under current practices, neither limestone quarrying nor potash production require acid, caustic or cyanide leaching, chemical conversion, or thermal processing to achieve a marketable product.

As in limestone mining, the tailings from potash mining are composed solely of residuals of native materials from the host rock, such as silica, clay and iron, which do not generate a leachate.

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[15] Peters 1978
[16] Hartman 1992
[17] Kennedy 1990
[18] Weiss 1985

As described above, potash mining uses simple physical methods to separate product from natural materials, and potash production does not routinely use hazardous substances to produce a final product.

As EPA has identified from review of the SME texts, all of the potash produced in the US is recovered either from deep underground bedded ore zones, or from two-well solution mining, solar evaporation, and selective crystallization. No open pit, strip mining, or other surface mining techniques are employed in the current potash industry. Potash recovery, therefore, produces far fewer impacts to the land surface than the exempted limestone mining, which most commonly employs open pit/surface mining of shallow formations of limestone, marble, chalk, or dolomite. Hence potash recovery does not involve the environmental effects and risks associated with:

- pit high wall safety issues,
- disruption of natural surface hydrologic features,
- incursion of groundwater into surface workings, and
- consumption of backfill material sources for reclamation,

which accompany the exempted limestone open pit/surface mining operations.

EPA's review of TRI data for 2007 indicated that "11 facilities in the crushed and broken limestone category released 67,525 pounds of chemicals, primarily lead and mercury."". In comparison, releases from Mosaic's New Mexico operations were even lower than from the limestone category; they remain below the reporting thresholds for TRI reporting and are considered de minimus, EPA considered limsetone operations, even in combination with 58 other categories, to "release many orders of magnitude less hazardous substances into the environment than other classes of hardrock mining. Additionally, EPA did not identify any limestone quarries that were placed on the National Priorities List (NPL) due to contamination from operations at the site; therefore, EPA has spent no CERCLA public funds on the cleanup of such sites.

Similarly, there are no potash sites on, or proposed for inclusion on, the NPL. Unlike limestone, potash operations do not release lead or mercury.

4.3 Sand and Gravel

Sand and gravel were included in the 59 commodities that EPA exempted from regulation under the Proposed Rule because of their low environmental risk, as stated in the 2009 Memorandum.

Sand and gravel deposits found along surface water bodies and channels are primarily quartz (silicon dioxide or SiO_2) remaining after the weathering of granite, from either igneous rock or the metamorphic re-melting of sedimentary rock. Quartz remaining after the weaker components of granitic rock have weathered away are deposited at beaches, stream beds, and deltas. Sands and gravels are typically mined from surface features by mechanical equipment such as front-end loaders, scrapers, and bulldozers, or by hydraulic dredges. Mechanically excavated sands and gravels are hauled to the recovery plant by truck, while hydraulically dredged material can either be pumped, or stockpiled and trucked. Because the product is a native material that does not require chemical extraction, conversion, purification or refining, recovery plants involve only physical steps such as washing, size-screening, and conveying.

Like the quarrying of sand and gravel, potash production involves the recovery of a mineral resource that exists in continuous strata in the native material in essentially the same chemical form in which it will be marketed. Hence, both sand and gravel operations and potash production involve simple physical

beneficiation processes focused on the removal of impurities from the native deposit, and classification/size segregation via mechanical equipment (i.e., grinding, screening, washing, conveying). Likewise, neither sand and gravel quarrying nor current methods of potash production require acid, caustic or cyanide leaching; chemical conversion; or thermal processing to achieve a marketable product.

Wastes from sand and gravel quarrying are residual native materials such as non-silica components and sediments from the excavation or dredging. Likewise, wastes from potash mining are composed solely of residuals of native materials from the host rock, such as silica, clay and iron, which do not generate a leachate.

In-stream, near-stream, and sand and gravel mining can be associated with environmental impacts such as changes to the sub-channel sediment load ("sediment budget"), degraded stream habitats, loss of riparian (streamside) habitats, changes in aquatic species balances, and loss of land. Nonetheless, EPA has considered the impacts from sand and gravel operations not to be as significant as those from other types of hardrock mining, and these operations have been exempted from regulation under the Proposed Rule. It should be noted that potash recovery from deep mineral deposits, whether by deep mining or solution mining, do not generate the impacts associated with surface channel mining.

EPA did not identify any sand and gravel operations that were placed on the NPL due to contamination from operations at the site; therefore, EPA has spent no CERCLA public funds on the cleanup of such sites.

Likewise, there are no potash mining facilities on the NPL, and no CERCLA public funds have been spent on the cleanup of potash mine sites.

EPA concluded from review of three SME texts that sand and gravel is one of 59 commodities that "are produced by simple physical methods which separate the product from overburden." EPA also noted that the 59 commodities do not appear at this time to routinely use hazardous substances to produce a final product.

As described above, potash mining uses simple physical methods to separate product from natural materials, and potash production does not routinely use hazardous substances to produce a final product.

4.4 Kaolin and Ball Clay

Kaolin and ball clay were included in the 59 commodities that EPA exempted from regulation under the Proposed Rule because of their low environmental risk, as stated in the 2009 Memorandum.

Kaolin (China clay or hydrated aluminum silicate) and ball clay (kaolinite clays containing mica and quartz) are typically extracted from open-pit mines ranging from tens to hundreds of thousands of dry metric tons produced per year. Beneficiation and purification of kaolin is accomplished by either the dry/air flotation process (to control particle size) or the wet/water wash process (to control particle size and color).

Dry or air float kaolin recovery transports crude kaolin to a dry mill where it undergoes size reduction in roll or other type crushers, and rotary drying. The dried material is fed to an air-floating circuit for pulverization. Pulverized material is fed to an air separator where fine particles are segregated and collected as product, and oversize particles are returned for re-pulverization.

The majority of kaolin in the US is mined from the central Georgia mining belt and refined through a wet process. In these operations, raw kaolin is dispersed in water for grit removal. De-gritted slurry is

centrifuged to segregate fine, intermediate, and coarse particle size fractions. These fractions may be ozone or chemically-bleached to oxidize iron-based coloration, which is removed by magnetic separation, flocculation, or froth flotation. De-pigmented product is dewatered by filtration, then rotary-dried, apron-dried, spray dried, or in some cases calcined in furnaces.

Many components of dry and wet kaolin beneficiation are identical to the mechanical/physical size reduction and size segregation steps of potash recovery operations and use the same types of equipment, including crushing, screening, drying, conveying, and loading equipment.

However, kaolin recovery, which has been exempted by EPA from the current rulemaking, incorporates a number of high temperature, chemical reagent introduction and thermal processing steps that are not required in potash recovery such as:

- Blunging (high-energy mixing with water) to form slurries,
- Centrifugation to product particle size,
- Reductive chemical leaching, ozone oxidation, and
- Calcining furnaces.

Nonetheless, based on the criteria described in the 2009 Memorandum. EPA has determined the kaolin commodity to be of low enough environmental risk to be exempted from regulation under the current rulemaking.

EPA's review of TRI data for 2007 indicated that there were "2 facilities in the kaolin and ball clay category which released 31 pounds of chemicals, primarily lead and mercury". EPA considered these operations, even in combination with 58 other categories, to "release many orders of magnitude less hazardous substances into the environment than other classes of hardrock mining. In comparison, releases from Mosaic's New Mexico operations were even lower than from the kaolin and ball clay category; they remain below the thresholds for TRI reporting and are considered de minimus, Additionally, EPA did not identify any kaolin and ball clay operations that were placed on the NPL due to contamination from operations at the site; therefore, EPA has spent no CERCLA public funds on the cleanup of such sites.

EPA concluded from review of three SME texts that kaolin and ball clay is one of 59 commodities that "are produced by simple physical methods which separate the product form overburden." EPA also noted that the 59 commodities do not appear at this time to routinely use hazardous substances to produce a final product.

Potash mining has not been associated with the release of lead or mercury, and releases from Mosaic's New Mexico operations have historically been and remain so low that they fall below the modest reporting thresholds established for TRI reporting, and have been considered de minimus.
Additionally, there are no potash mining facilities on the NPL and no CERCLA public funds have been spent on the cleanup of potash mine sites.

As described above, potash mining uses simple physical methods to separate product from natural materials, and potash production does not routinely use hazardous substances to produce a final product.

The State of New Mexico, which has the US's most extensive experience with the regulation of potash production, considers potash production to be comparable to each of the mining categories discussed

above. The above categories, including potash, were collectively exempted from regulation under the Mining Act Reclamation Program (MARP)[19]. MARP was created under the New Mexico Mining Act of 1993 to regulate hard rock mining reclamation activities for all minerals except the exploration and extraction of potash, sand, gravel, caliche, borrow dirt and quarry rock used as aggregate in construction, which were considered to be of low risk and suitable for regulation under other programs, as discussed in Section 9.0, below.

Table 4-1
Comparison of Potash Operation to Commodities Exempt from Proposed Rule

Operation	Salt	Limestone	Kaolin	Sand and Gravel	Potash
Requires surface mining?	No	Yes	Yes	Yes	No
Beneficiation limited to physical methods?	Yes	Yes	No	Yes	Yes
Requires acids, caustics or cyanide leaching?	No	No	No	No	No (per current methods)
Requires smelting or metal refining?	No	No	No	No	No

[19] 69 NMC § 36-3.H

5.0 The Potash Sector is Not Comparable to the Other Mining Sectors Included for Regulation Under the Proposed Rule

As mentioned in Section 3.4 above, because potash minerals exist in nature in substantially the same chemical form in which they will be marketed, and because they can be separated from co-present minerals with simple mechanical operations, potash production does not involve the types of processes or features that EPA determined to be the key causes of environmental risk and CERCLA liability from hardrock mines. The differences between potash production and other mining sectors included for regulation under the Proposed Rule are discussed in this Section, and summarized in Table 5-1.

Specifically, potash production requires no blasting, no heap leaching, no dump leaching, and typically no introduction of mineral acids or cyanide and, based on current methods of production, produces no acid tailings or acid runoff. As mentioned in Section 3.1 above, current potash recovery produces tailings composed only of residual natural materials from the mined deposit, which do not generate a leachate. Because potash production does not involve the thermal purification of solid metals, it requires no smelting; and therefore, produces no smelter emissions, slags, or smelter stack scrubbing solutions.

As mentioned in Section 2.0 above, multiple times in the Preamble to the Proposed Rule, EPA cited its 2009 Priority Notice as the basis for identifying and prioritizing the classes of facilities within the hardrock mining industry for which EPA would first develop regulations for financial responsibility. The Priority Notice defined hardrock mining facilities as those which extract, beneficiate, and process metals, and non-metallic, non-fuel minerals. The Priority Notice also stated that the classes of mines to be prioritized for regulation were determined based on its consideration of the elements used in evaluating risk to human health and the environment, such as:

> "probability of releases, type and duration of exposure, and toxicity of releases."

As defined in the Priority Notice,

> "Toxicity is reflected in the designation of substances as CERCLA hazardous substances."

Based on a review of materials employed in potash extraction and recovery, and comparison to the CERCLA Hazardous Substances List, potash recovery does not introduce any materials defined by EPA as reflecting "toxicity." As described in Section 3.1, potash recovery employs only limited quantities of a few reagents, as extractants and standards for assays and quality control testing, in on-site laboratories – none are used in production.

As further detailed in the Priority Notice, EPA chose to evaluate the following factors, which per EPA can relate to the probability of a release of a hazardous substance:

> "(1) annual amounts of hazardous substances released to the environment; (2) the number of facilities in active operation and production; (3) the physical size of the operation; (4) the extent of environmental contamination; (5) the number of sites on the CERCLA site inventory (including both National Priority List (NPL) sites and non-NPL sites); (6) government expenditures; (7) projected clean-up expenditures; and (8) corporate structure and bankruptcy potential."

Key factors from the above list are addressed below.

- Annual amounts of hazardous substances released to the environment: Potash mining does not release CERCLA listed hazardous substances to the environment.

- Number of sites on the CERCLA site inventory, including both NPL and non-NPL sites: There are no potash facilities on the CERCLA site inventory.

- Government expenditures: To date there have been no government expenditures associated with remediation of releases or environmental impacts from potash mining.

- Projected clean-up expenditures: As potash operations do not use hazardous substances, projected expenditures for cleanup of hazardous releases is zero. Projected expenditures for restoration of potential environmental disturbances, particularly in New Mexico operations, are addresses by reclamation plans and surety under the New Mexico Mining Act, as discussed in Section 9.0.

EPA's additional conclusions from the 2009 Priority Notice are addressed below.

EPA states in its Priority Notice that EPA's past experience leads it to concluding that hardrock mining facilities are likely to present a substantial financial burden requiring "enormous expenditures" by the federal government. In support of this claim, EPA cites a Government Accountability Office (GAO) study, which reported that the US government spent over $2.6 billion to remediate hardrock mining sites from 1998 to 2007, with EPA spending the largest amount at $2.2 billion. However, in this study, which EPA argues as a rationale for regulation of hardrock mines, none of the sites were potash mines or potash recovery facilities.

EPA states that the agency itself has spent $2.7 billion between 1988 and 2007 on mining sites proposed, listed, or deleted from the NPL and sites with Superfund alternative approach agreements in place. However, there are no potash facilities on or proposed for the NPL, and no potash facilities requiring Superfund alternate approach agreements.

EPA identified that as of April 2009, 90 hardrock mining sites have been listed on the NPL and 20 additional hardrock facilities have been proposed for inclusion on the NPL. Again, none of these 110 facilities are potash facilities.

EPA additionally cited, as justification for regulation, the fact that bankruptcies in the hardrock mining industry, particularly in operations held by foreign owners, have resulted in government expenditure of funds for mining reclamation. The examples cited include Summitville Mine, Edge Mine, Zortman Landusky Mine, and an ASARCO mine in Idaho/eastern Washington. Again, none of the examples were potash operations.

Table 5-1
Comparison of Potash Production to EPA Criteria for Regulating Hardrock Mining

EPA Criterion from Priority Notice	Potentially Regulated Universe	Potash Production
Introduce materials defined as toxic per CERCLA Hazardous Substances List	Yes	No
Associated with reported releases of hazardous substances to the environment	Yes	No
Some sites on or proposed for NPL?	Yes	No
Federal government has incurred expenditures for cleanup (due to bankruptcy or other causes)?	Yes	No
Based on past expenditures, federal government projects financial burden for cleanup?	Yes	No

6.0 The "Modeled Universe" that Served as the Basis for EPA's Assessment of Compliance Cost Did Not Include, and Was Not Representative of, Potash Mining

In the Proposed Rule[20], EPA requested comments on using the "modeled universe" to estimate the overall costs to comply with the Proposed Rule. EPA's assessment of compliance cost was based on a "modeled universe" of just "49 facilities". Review of Draft Table X-1 of the Proposed Rule Preamble demonstrates that:

a) None of the 49 facilities in the modeled universe were potash facilities.
b) Over 75% of the facilities in the modeled universe (38 out of 49) were surface mines. No potash is recovered from surface mines in the US.

As discussed in Section 3 above, brine extraction and processing bears many operational similarities to potash extraction. However, the six brine extraction/production facilities potentially to be regulated were represented by zero facilities in the "modeled universe."

EPA also states that they extrapolated the results from analyzing the subset of facilities and applied them to the full set, or universe, of potentially regulated facilities under the Proposed Rule.

As discussed above, the features used to develop the compliance cost are not representative of potash facilities.

In the Proposed Rule[21], EPA describes the use of data collected from 438 operable units at 88 NPL or Superfund alternative hardrock mining sites, stating that there was a relationship between 13 site features of mining sites and releases or threatened releases of hazardous substances and to remedies that incurred response costs. The thirteen site features are specified in the footnotes on page 3461. Dr. Gary Davis, one

[20] 82 Fed. Reg. p3391
[21] Ibid. p3461

of four academic peer reviewers contracted by EPA to review the cost responsibility formula, in his SME 2017 Annual Conference paper[22], presented the source data and extrapolation curves used by EPA to develop the costs for two of the site features in the formula: "open pits/pit lakes" and "waste rock or overburden." The curves were extracted from the Background Document[23] cited by EPA on page 3461 and described in the Response Component Regression Analysis on page 3463.

In the case of both of those site features, EPA arbitrarily included a singularly high cost outlier case as "typical" of costs (e.g., EPA included the Phoenix Mine with a remediation cost 20 times higher than the industry average rate for pit back-filling as typical of contamination costs from open pits) and captured the outlier costs in regression lines, which EPA argues on page 3463 are "the best fit possible for the data."

It can also be argued that the cost extrapolation process was similarly unrepresentative, not just of potash operations, but in the case of certain mine features and of operator managed response action costs in general.

In describing their response component cost data collection[24], EPA states that they obtained a sample of 63 facilities' reclamation and closure plans engineering cost data from mines identified by the Mine Safety and Health Administration (MSHA) and the United States Geological Survey (USGS), exclusive of the commodities exempted in the 2009 Memorandum. EPA states that:

> "This 63 facility subset was representative of the frequency of states and commodities identified in the full universe of 354 potentially regulated mines. Thus, EPA expected it would be representative of the larger group of facilities."

However, although potash mining is retained in the universe of 354 potentially regulated mines, not a single potash mining facility was included in the 63-facility subset. Hence, the subset is not representative of potash mining, and its costs extrapolation to the potash industry in the potentially regulated universe of 354 regulated mines is unfounded.

EPA incorporated supporting information[25] to justify applicability of the Proposed Rule to the universe of facilities, regardless of whether they have no prior history of releases. EPA cites their "Office and Land and Emergency Management Memorandum, *Releases from Hard Rock Mining*", which discusses:

> "30 recently or currently operating mines and mineral processing facilities with no previous significant legacy issues, with releases to the environment subsequently mitigated under CERCLA."

The facilities identified as having no history of releases prior to requiring response action under CERCLA included gold, silver, copper and zinc; however, the memorandum does not identify a single potash facility.

On FR page 3475, EPA based their assessment of risk from releases of hazardous substances, in part, on the "Evidence of CERCLA Hazardous Substances" report, which looked at 30 sites in operation in 2009 and concluded the same practices are in use at other sites, especially those with the same commodities. The

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[22] Davis and Yang, 2017
[23] EPA 2015
[24] 82 Fed. Reg. p3463
[25] Ibid. p3471

reviewed sites included aluminum, copper, lead, zinc (16 sites), precious metals (10 sites), and lithium (1 site). None of the sites were potash facilities, and the operations at the majority of the facility types, such as acid leaching, cyanide leaching, smelters, calcining furnaces, and acidic tailings ponds, differ significantly different from potash operations. The extension of the assumption that the same practices are used at potash facilities is unjustified.

EPA concludes that:

> "Overall the compiled information demonstrates that sites requiring cleaned up [sic] under Superfund in the past, and sites operational in 2009 share characteristics related to the potential release of CERCLA hazardous substances and the exposure of human and ecological receptors, and illustrates the applicability of EPA's CERCLA experience to evaluating currently operating mines and processors."[26]

A review of the source documents demonstrates that neither the sites cleaned up in the past, nor any of the 2009 current sites considered in the comparison, were potash facilities. Thus, while the generalization regarding "shared characteristics" between past celanups and operative sites may be appropriate for facilties of the same commodity, it can not be accurately extended to potash operations.

On FR page 3477, EPA described their examination of TRI data and its use as a basis to estimate hazardous substance releases from currently operating facilities in the hardrock mining industry. EPA's 2010 through 2013 TRI data indicated that the metal mining industry reported onsite releases of hazardous substances averaging nearly 1.7 billion pounds per year. EPA states further that the metal mining sector accounted for 47% of the releases for all industries and 7% of the of the on-site land disposal for all sectors. However, EPA describes the metal mining industry as including gold, lead, zinc, copper, and like metals, none of whose operations are comparable to potash. Moreover, the list of 20 specific hazardous substances of concern released by mining facilities are not released at potash facilities. Hence, the use of either the nature or quantity of these reported releases as a basis for estimation of releases at potash operations is meaningless.

EPA, in considering the total remediation costs and other expenditures from other NPL sites to develop total (past and future) response costs for incorporation into the formulas,

> "estimates that the historical response costs total 12.9 billion at 243 hardrock mining and mineral facilities for which data were available at the time of the analyses." "... or an average of $103 million per site."[27]

However, as in all the other subsets of cost data, potash sites are not included. There have been no potash NPL or CERCLA sites; therefore, extension of any cost estimates derived from these historical costs to potash operations is unfounded.

7.0 Potash Mining Site Features Do Not Correlate with the Response Categories of the Financial Assurance Model or With Reasonable Industry Costs for the Response Categories

[26] 82 Fed. Reg. p3475
[27] Ibid. p3479

EPA's Proposed Rule sets forth a formula that develops the total financial responsibility amount for a facility by totaling the response category amounts for 13 categories of site features specified on page 3505 of the FR. While potash mining is currently regulated under the Proposed Rule, unlike the other types of hardrock mining, the majority of the site features/response categories are not found on; and therefore, inapplicable to potash mines, as listed below. Each Roman numeral listed below is one of the specific response components in the Proposed Rule, Section 320.63, page 3505 of the FR.

Open pit category (i) – Potash mining does not employ open pits.

Waste rock category (iii) – Potash mines produce no waste rock dumps.

Heap and dump leach category (iv) – Potash mines do not employ heap leaching or dump leaching.

Tailings category (v) – It is inappropriate to compare potash tailings, or their potential for hazardous releases or cleanup costs, to other hardrock mining types. Potash mining produces tailings of native clay, soils, and halite (salt), which are non-hazardous, contain no leach agents or extractants, and do not produce leachate or release hazardous substances.

Process pond and reservoir category (vi) – It is inappropriate to compare potash surface ponds, or their potential for hazardous releases or cleanup costs, to other hardrock mining types. Potash operations do use tailings retention ponds and salt recovery ponds, However, because potash operations do not use leaching agents, chemical extractants, or other hazardous materials, the potash tailings ponds or salt ponds do not receive, and therefore cannot release, these hazardous substances. .

Slag pile category (vii) – Potash operations produce no slag.

Solid and hazardous waste disposal category (viii) – No hazardous chemicals are used in potash production and typically no hazardous waste treatment, storage, or disposal units are operated on site. Potash operations are small quantity generators of materials shipped and managed off site.

8.0 The Potash Sector in the US Has Operated for Multiple Decades with No History of Releases, Risk, or Financial Liabilities to the Federal Government or Public

As mentioned above, potash mining and beneficiation has a history of over 120 years in the US. The sector includes some of the longest running conventional mining operations in the US, such as Mosaic's Carlsbad operations, which have continued over 75 years. If potash mining is evaluated by the types of criteria described by EPA in the Preamble, several facts must be considered.

- All currently operating conventional underground potash mines are located in New Mexico, yet there are no New Mexico potash mines on CERCLIS.
- There are no potash mining sites on the NPL or proposed for the NPL.
- There have been no past CERCLA Superfund expenditures on potash mining sites in any state.
- Mosaic's Carlsbad mine, which is one of the longest continual mining operations of any type in the US, has been in operation for 75 years and has produced no discharges or disturbances that required a CERCLA investigation or response action.

9.0 New Mexico Environmental Department (NMED) Heavily Regulates Potash Mining to Minimize Potential Environmental Risk

The New Mexico Environmental Department's (NMED's) framework for regulation of mining facilities in New Mexico includes its authority through the following regulations in the New Mexico Statutes Annotated (NMSA) and their implementing regulations in the New Mexico Administrative Code (NMAC):

• Air Quality Control Act	NMSA 1978, §§ 74-2-1 to-17
• Environmental Improvement Act	NMSA 1978, §§ 74-1- 1 to-17
• Ground Water Protection Act	NMSA 1978, §§ 74-6B-1 to-14
• Hazardous Waste Act	NMSA 1978, §§ 74-4-1 to-14
• Radiation Protection Act	NMSA 1978, §§ 74-3-1 to-16
• Solid Waste Act	NMSA 1978, §§ 74-9-1 to-43
• Water Quality Act	NMSA 1978, §§ 74-6-1 to-17

The Mining Environmental Compliance Section of NMED regulates mining of all types, including hard rock and other recoverable resources. As described in the New Mexico Mining Environmental Compliance Section (MECS) page of the NMED website:

> "The Mining Environmental Compliance Section (MECS) conducts all of the permitting, spill response, abatement and public participation activities for mining facilities in New Mexico in accordance with the Water Quality Control Commission (WQCC) Regulations (20.6.2 NMAC). In addition, the MECS participates in the implementation of the New Mexico Mining Act and Non Coal Mining Regulations by reviewing and commenting on mine permits and closeout plans, coordinating environmental protection requirements at mine sites with the Mining and Minerals Division of the Energy, Minerals and Natural Resources Department, and providing determinations that environmental standards will be met after closure of New Mexico mining operations. Currently the MECS manages over 55 active mining permits."

These include the permits under which all potash producers in New Mexico operate.

The Mining and Minerals Division of the Energy, Minerals and Natural Resources Department regulates mining activities in New Mexico, including potash, through the New Mexico Mining Act (NMMA). The NMMA requires the development and approval of new mining operating permits for proposed operations and requires that at the time of application,

> "the mine be designed to meet without perpetual care all applicable environmental regulations imposed by the New Mexico Mining Act and regulations adopted pursuant to that act and other laws following closure."

Therefore, the Division may only approve mining plans which, by design, will not produce releases that require post closure remedial actions.

The NMMA likewise requires the development of a closeout plan for each existing operation, which specifies the activities that will,

> "reclaim the physical environment of the permit area to a condition that allows for the reestablishment of a self-sustaining ecosystem on the permit area following closure."

NMED's success in regulating the potash industry is demonstrated by the fact that while New Mexico regulates the largest potash mining operation in the US, and potash is the second largest employer in the New Mexico mining industry, in the history of potash mining in the state, there have been no releases warranting response actions or federal remedial intervention of any kind.

10.0 Conclusions

From the information presented in the foregoing sections, it can be concluded that:

1. Potash recovery resembles, in the nature of its operations, limited environmental effects, and low risk, the commodities which were exempted from regulation in the 2009 Memorandum.

2. The potash sector is not comparable to the other mining sectors retained for regulation because, as discussed in Section 4.0 above, it does not use the types or volume of hazardous materials, and does not release more than de minimus quantities any of the hazardous substances, which EPA anticipates will produce a risk of future clean-up actions.

3. The potash sector is not comparable to the other mining sectors included for regulation because it does not contain the types of features which resulted in environmental releases in EPA's evaluation. More than half of the types of features which generated environmental releases, and the types of features which generated the most significant releases, are not present on potash sites.

4. The "modeled universe," which served as the basis of EPA's cost estimation, did not include potash production or any commodities comparable to it. None of the sites cleaned up in the past, and none of the sites currently undergoing cleanup, from which EPA developed its estimates of remediation costs, were potash facilities, nor could they be, because potash operations have never been associated with a CERCLA cleanup.

5. The existing regulatory framework in states like New Mexico, has been sufficiently stringent to maintain the number of federal government cleanups at potash facilities at zero over its history.

6. Based on the criteria applied in the 2009 Memorandum for exemption, and the criteria applied in the Priority Notice as risk-based justification for regulation, potash production should be excluded from regulation under the Proposed Rule.

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Letter from Florida Department of Environmental Protection – Attachment C

Florida Department of Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Rick Scott
Governor

Carlos Lopez-Cantera
Lt. Governor

Jonathan P. Steverson
Secretary

August 19, 2016

Linda Barr, Office of Resource Conservation and Recovery
Barnes Johnson, Director, Office of Resource Conservation and Recovery
United States Environmental Protection Agency
Attention: Docket ID Nos. EPA-HQ-SFUND-2009-0265
and EPA-HQ-SFUND-2009-0834
Mailcodes 5305T and 5301P
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Barr.Linda@epa.gov
Johnson.Barnes@epa.gov

RE: Florida Department of Environmental Protection - Federalism Consultation Comments CERCLA Section 108(b) Docket ID No. EPA-HQ-SFUND-2009-0265 and EPA-HQ-SFUND-2009-0834

The Florida Department of Environmental Protection (Department) is the executive agency for the State of Florida with primary responsibility for implementing land reclamation, surface water, ground water and related environmental protections for phosphate mining and associated land reclamation activities. The Department is also responsible for ensuring cleanup and rehabilitation of sites contaminated with hazardous substances within the state, and for implementing related programs to prevent pollutant discharges and to control exposure and potential risk of exposure to humans and the environment.

The Department appreciates the opportunity to comment on the Office of Resource Conservation and Recovery (ORCR) efforts to develop appropriate and enforceable financial responsibility requirements under the authorities of the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). These comments on EPA's planned rulemaking share details about our concerns with inaccurate risk information that is referenced in the rulemaking's supporting documentation, and the potential for adverse impacts to and preemption of existing state regulatory requirements for phosphate mining in Florida. Our comments also provide you with input for your Federalism Consultation as requested in the July 7, 2016, "CERCLA 108(b) Proposed Rulemaking for Hardrock Mining," call with states.

It is our understanding that EPA is considering including phosphate mining in Florida under proposed regulations that would require financial responsibility for hardrock mining industries,

and that EPA is required to publish a proposed rule by December 1, 2016[1]. The Department appreciates the ORCR's intent to ensure that financial responsibility requirements are provided to address risks from hazardous substances. However, the Department has critical concerns about the decision making basis to include Florida phosphate mining with hardrock mining, and the similar overlap with and preemption of state regulations that are currently providing environmental protections and financial assurances. Such preemption could lead to a reduction in protections for Floridians.

Inclusion of Florida phosphate mining in EPA's financial assurance requirements for the hardrock mining industry would be based on a misunderstanding of and confusion about operations for phosphate extraction, beneficiation, and processing in Florida. Phosphate mining in Florida is not "hardrock mining," nor are the operations and actual risks sufficiently similar to warrant EPA's inclusion under regulations specifically designed to address hardrock mining concerns.

The Department has discovered that relevant supporting information in EPA's records related to operations and risks is inaccurate and mischaracterizes phosphate mining in Florida. Importantly, any risks that do exist, particularly with respect to related mineral processing facilities, are already comprehensively addressed in Florida by a unique combination of existing state and federal laws and regulatory actions.

In addition, inclusion of Florida phosphate mining in the proposed rules presents federalism concerns by interfering with the state's right to implement effective environmental protection programs, and could specifically preempt state's rights given the provisions under Section 114(d) of CERCLA. Given our discovery of the fundamental misunderstanding of operations and associated risk in EPA's supporting information, and our concerns regarding unintended impacts to Florida's laws and existing protections, direct consultation with the Department is warranted and should be done in advance of any proposal of CERCLA financial responsibility rules for any mining activities in Florida.

Attached are Florida's comments summarizing the concerns we have identified to date. Our general comments are included in Attachment A. Attachment B offers comments in response to the questions provided in EPA's July 7, 2016, call with States as part of the Federalism Consultation.

We hope these comments are informative. We appreciate the intent of the proposed rulemaking to provide protections for cleanup liability and related hazardous substance response actions. In this case, we believe that the proposed rule simply is not warranted in Florida, and could negatively impact the comprehensive and rigorous existing requirements under state and federal programs that are currently providing important environmental protections and benefits in this

[1] EPA slides from May 17, 2016, webinar on, "CERCLA Section 108(b) Financial Responsibility," for hardrock mining, from https://www.epa.gov/superfund/superfund-financial-responsibility, July 2016.

state. If you have any questions on these comments, please contact me at your convenience at (850) 245-8709, or by email at john.coates@dep.state.fl.us.

Sincerely,

John A. Coates, P.E., Director
Division of Water Resource Management
Florida Department of Environmental Protection

Attachments: As noted.

cc: Sonya Sasseville, Director, EPA ORCR
Anna Krueger, EPA ORCR
Paula Cobb, Deputy Secretary, Regulatory Programs, FDEP
Joseph Ullo, Director, Division of Waste Management, FDEP
Franklin Hill, Director, Superfund Division, EPA Region 4
Anita Davis, Enforcement Branch Chief, Superfund Division, EPA Region 4

The Florida Department of Environmental Protection (Department) offers the following general comments and preliminary observations in response to the requested Federalism Consultation:

Inaccurate Information on Risk and Conclusions

- EPA appears to be preparing to regulate phosphate mining in Florida as a type of hardrock mining. The Department strongly believes that this classification is not technically supportable, and is based on a fundamental misunderstanding of Florida phosphate mining and mineral processing risks. The Department also believes it will lead to unintended consequences that could weaken and frustrate Florida's efforts to ensure that phosphate mining in Florida is accountable for both land reclamation obligations, and for operating in a manner that protects our state's land and water resources. Phosphate mining in Florida is conducted by excavation of pebble phosphate deposits and does not involve many of the activities that are primarily associated with the hardrock mining industry. It is critical that EPA acknowledge that phosphate mining in Florida does not involve those activities such as blasting, and in-situ chemical treatments that are often relevant to the evaluation of risk for those activities commonly associated with the hardrock mining sites.
- EPA's 2009 Federal Register (FR) Notice (74 FR 37213) relied on information in an earlier 2004 EPA Office of Inspector General Report that provided background information for EPA's proposed nationwide identification of hardrock mining sites and associated risks[2] (2004 Report). The underlying information is unfortunately incorrect in regards to phosphate mining in Florida. Please note the following concerns:
    - A review of EPA's agency responses in the 2004 Report indicates that there was an incorrect belief that there is a "likelihood of acid mine drainage" at phosphate mining sites in Florida. This represents a critical misunderstanding about these mining sites in Florida. There is no amount or potential for acid mine drainage given the nature of the pebble phosphate deposits that occur and are mined in Florida. Accordingly, any conclusions about potentially elevated risks due to the erroneous conclusion that there is a "likelihood of acid mine drainage" at Florida phosphate mining sites is factually incorrect. As stated previously, phosphate mining in Florida is not hardrock mining and does not involve many of the operations that would commonly be associated with such activities. This is a significant difference where Florida phosphate mining does not have the particular

[2] See "Evaluation Report, Nationwide Identification of Hardrock Mining Sites," Report No. 2004-P-00005, March 31, 2004, United States Environmental Protection Agency Office of Inspector General.

risks that may otherwise be associated with true hardrock mining operations, and as such warrants EPA's reconsideration of whether or not to incorporate Florida phosphate mining in regulations intended for the hardrock mining industry.

- This incorrect information led to additional false conclusions in the 2004 Report, including the belief that hazardous substance related cleanup costs at each phosphate mining site could be on the order of $100 million or more because of the false expectation that there could be acid mine drainage at each of these mines in Florida. Since acid mine drainage is not a possibility, let alone a risk at Florida phosphate mines, assigning risk and any associated cost liability for cleanup of acid mine drainage and any associated hazardous substances responses is fundamentally incorrect.
- Finally, the 2004 Report inappropriately attributes these costs to 22 phosphate mining sites that were then identified in EPA's inventory for Florida, indicating that the total for cleanup costs could range from $2.2 to $11 billion, a difference of $8.8 billion between the low and high end according to EPA's analysis. In reality, there is essentially zero risk and no associated liability for acid mine drainage at Florida phosphate mining sites.

- The plans for proposed rules would also cover beneficiation of phosphate in Florida. However, it is not apparent on review of the underlying information sources referenced in EPA's July 9, 2009 Notice whether EPA has properly evaluated existing information that evaluates the relative risk of phosphate beneficiation in Florida. The Department has conducted its own studies related to the potential or release of hazardous substances from phosphate beneficiation facilities. The Department encourages EPA to further discuss and review this information to better understand the low level of risk and current regulations that are applied to these activities in Florida.

Direct Conflicts with State and Other Federal Laws Relating to Hazardous Substances

- EPA's plans to promulgate CERCLA 108(b) financial assurance regulations for extraction, beneficiation, and processing of phosphate as part of regulations for the hardrock mining industry would adversely impact both state laws and federal requirements related to protections for liability connected to the release of a hazardous substance.
- CERCLA Section 114(d) provides that an owner or operator of a facility which establishes and maintains evidence of financial responsibility under section 108(b) cannot be required under state law, "to establish or maintain any other evidence of financial responsibility in connection with liability for the release of a hazardous substance..." The Department is gravely concerned that EPA's planned rulemaking could adversely impact Florida's state laws, and our existing environmental protections related to such financial responsibility requirements.

- The phosphoric acid processing (aka, mineral processing) facilities in Florida, are separate and distinct operations from phosphate mining sites. Indeed, these mineral processing facilities do have the potential for releases of hazardous substances; however, they are significantly fewer in number and size than phosphate mining sites. As a result of the potential for release of hazardous substances, these mineral processing facilities have been extensively regulated under Florida laws including Sections 403.4154 and 403.4155, F.S. Regulations implemented under these laws include extensive construction, operational, closure and associated financial responsibility obligations under Department rules that are focused on preventing and addressing the liabilities related to potential releases of hazardous substances. Establishment of an overlapping and duplicative CERCLA financial responsibility obligation would at least cause an unnecessary regulatory burden on the State of Florida and the Department when having to resolve conflicts between state and duplicative federal requirements for the same purpose. At worst, the state's existing regulatory programs could be severely restricted or pre-empted by the provisions of CERCLA Section 114(d).
- As correctly noted in the 2004 Report, the State of Florida did determine that its then existing financial assurance requirements needed strengthening after the 2001 bankruptcy of a company that mined and processed phosphate in Florida. In 2005, the State of Florida completed that rulemaking and adopted revised state financial assurance rules that strengthened requirements for financial responsibilities including important provisions to provide more accurate cost estimates for treating hazardous substances and nutrients in acidic process water at these facilities. The Department has not found any evidence in the record to suggest that EPA has reviewed or had any concerns with Florida's revised regulations for financial assurances. Most importantly, without such review, EPA would not be able to accurately evaluate risk for the Florida phosphate mineral processing in the absence of the planned CERCLA Section 108(b) financial responsibility rulemaking.
- In Florida, the mined phosphate rock is utilized in separate phosphoric acid and fertilizer manufacturing facilities where acidic process water is stored and reused in open impoundments. It is apparent that the 2004 Report incorrectly attributed the potential for releases of acidic process water to phosphate mining sites when the consideration would only be relevant for the separate mineral processing facilities. The 2004 Report does not appear to properly differentiate between potential risks at phosphate mining sites and those applicable to mineral processing facilities. This misunderstanding is critical since hazardous substance risks at the mineral processing facilities have already been addressed by state rules and are also addressed by actions being taken under EPA's National Enforcement Initiative for Mining and Mineral Processing. During the intervening 12 years since the time of the 2004 Report, EPA's Resource Conservation and Recovery Act (RCRA) program staff in Region 4 and EPA Headquarters have been extensively engaged in federal regulatory activities under EPA's RCRA National Enforcement Initiative for Mining and Mineral Processing. As a results of those activities, EPA and the Department have been negotiating RCRA settlements related to the operational, closure, and financial

assurance requirements that are also directly, "in connection with liability for the release of a hazardous substance," as referenced under Section 114(d) of CERCLA. Both Florida and EPA are parties to the settlements that have been reached to date in Florida. As a result of these settlements under federal RCRA regulations, there is already both state and federal regulatory oversight and financial assurance requirements covering the potential for related hazardous substance releases. Accordingly, efforts to include Florida phosphate mining in the upcoming CERCLA financial assurance rulemaking would be duplicative, is unnecessary to effect further environmental protection, and potentially frustrates and preempts the effectiveness of existing state and federal regulatory programs designed to address the potential hazardous substance releases and financial responsibilities for the referenced mineral processing facilities. Accordingly, efforts to include Florida phosphate mining in the upcoming CERCLA financial responsibility rulemaking would be duplicative, is unnecessary to effect further environmental protection, and potentially frustrates and preempts the effectiveness of existing state and federal regulatory programs designed to address the potential hazardous substance releases and financial responsibilities for the referenced mineral processing facilities. The Department believes that EPA should update the 2004 Report to correct inaccurate Florida specific information and to address relevant Florida developments that occurred since 2004, particularly if EPA chooses not to reconsider the risk factors as discussed in our comments. The Department is available for direct consultation and believes such is warranted prior to publication of any proposed rule that would include mining activities in Florida.

- We have serious concerns that EPA's plan to include Florida phosphate mining in the CERCLA section 108(b) rulemaking will undermine the Department's ability to enforce state regulatory programs in accordance with related settlement agreements. The most recent settlement under EPA's National Enforcement Initiative for Mining and Mineral Processing (Civil Action No. 8:15-cv-0286-JDW-TBM) was just entered by the United States District Judge for the Middle District of Florida on August 5, 2016, and includes important provisions for Florida to act under related state law provisions. The Department notes that because of Section 114(d) of CERCLA, where an owner or operator would be required under CERCLA to establish evidence of financial responsibility in accordance with section 108(b), such an owner or operator could not be required under any state or local law "to establish or maintain any other evidence of financial responsibility in connection with liability for the release of a hazardous substance from such vessel or facility." The settlements under EPA's National Enforcement Initiative for Mining and Mineral Processing in Florida each contain carefully negotiated provisions that bind the United States and the Department, and which rely heavily on the Department's ability to implement state laws and regulations related to the potential release of hazardous substances from these mineral processing facilities. EPA's plans to include Florida phosphate mining in the CERCLA financial responsibility rulemaking may very well preempt Florida's ability to effectively implement state laws

that are incorporated into these settlements for the facilities covered thereunder, and preempt implementation of state regulations at similar facilities that are not covered under the settlements.

Relationship to Other State Regulations that also Relate to Hazardous Substance Risks at Mining Sites

- Florida's Environmental Resource Permitting (ERP) requirements are applicable to any new phosphate mining and phosphate reclamation areas in the state. The statutory and regulatory requirements under the state's ERP program (see Part IV, Chapter 373, F.S., and Chapter 62-330, F.A.C.) are extensive and require critical water quality protections for both surface water and ground waters in the state. As such, both phosphate mining activities and mandatory reclamation activities are required to be planned and implemented in a manner that does not violate the state's water quality standards, including those for hazardous substances, for both surface water and ground water. Accordingly, the combination of state mandatory mine reclamation and state water resource protections are already in place for any newly permitted mining activities, and work to ensure that hazardous substances are not a significant or meaningful risk for phosphate mining in Florida.
- In accordance with Part II, Chapter 378, F.S., and Chapter 62C-16, F.A.C., new lands mined for phosphate after July 1, 1975, and after July 1, 1984 for lands used for clay settling areas, are subject to mandatory reclamation requirements. As such, they are also subject to corresponding financial responsibility requirements designed to ensure that reclamations activities are completed in a timely manner. Since the application of these state reclamation and financial responsibility requirements also addresses the potential for hazardous substance related risks through state permitting requirements, additional financial responsibility to address hazardous substance related liabilities is unnecessary in Florida for such new mining or reclamation areas. In addition, the Department is very concerned that imposition of CERCLA financial responsibility requirements for phosphate mining in Florida would potentially interfere with or preempt the state's phosphate reclamation financial responsibility requirements.
- The ORCR's inclusion of Florida phosphate mining in the rule to be proposed for the hardrock mining industry would also appear to be duplicative of state laws intended to address liabilities and damages for the release of hazardous substances, including financial responsibility provisions for facilities under Sections 376.308 and 376.309, F.S., and additional liability provisions under Section 403.727, F.S.
- Although EPA's rulemaking is intended to be forward looking, the imposition of CERCLA financial responsibility rules is also unnecessary to address reclamation activities that would be done in the future, on lands that were mined for phosphate prior to the state's mandatory reclamation requirements that first became effective in 1975.

Florida's legislatively established program continues to provide state funding from a portion of Florida's phosphate severance taxes for the purpose of funding reclamation of those historically mined lands so that they may be returned to beneficial uses (see Part I, Chapter 378, F.S., and Chapter 62C-17, F.A.C.). The applicable regulatory requirements include provisions specifically for addressing applicable water quality standards, and any health or safety hazards on the land. In addition, reclamation done under this existing state funding program is also required to be conducted in accordance with the ERP regulatory criteria that require compliance with state surface water and ground water quality criteria. Therefore, these regulations also require that any risks from hazardous substances also be addressed as part of state funded reclamation on pre-1975 phosphate mined lands. Accordingly, Florida's regulatory programs address both historical and current mining related operations.

The responses below are provided by the Florida Department of Environmental Protection (Department) in an attempt to provide constructive input specifically related to the actual environmental circumstances and existing regulatory programs that are being implemented in Florida for phosphate mining. We encourage EPA to consult further with the Department prior to any proposal of rules for the hardrock mining industry, if EPA intends to include Florida phosphate mining, beneficiation, or processing in the proposed rules.

1. Since states have raised concerns about potential preemption or duplication of state hardrock mining financial assurance requirements, we would like to give you the opportunity to discuss those concerns with us, or any other concerns with or questions about the CERCLA 108(b) hardrock mining financial assurance rulemaking. We are forwarding letters we received regarding the CERCLA Section 114(d) preemption provision, from the states of Alaska, Arizona, Colorado, and New Mexico in 2011, and would like to give the state participants an opportunity to elaborate on or discuss current state thinking on this issue.

   Florida has provided information related to these concerns in our general comments in response to the requested Federalism Consultation. Based on our review of the relevant information, we strongly recommend that additional and direct consultation is needed with the Department to provide a full understanding of the level of risk associated with Florida phosphate mining, beneficiation, and processing operations, particularly given the interplay of exiting state and federal regulatory actions in this state.

2. How do your programs apply on mines located on land with shared federal-state ownership?

   Florida has extensive regulatory programs that apply to extraction activities, beneficiation, associated mineral processing facilities, and to corrective actions in response to releases of hazardous substances. These programs apply regardless of ownership type. Our general comments show the interdependence of our regulatory programs that have a connection with the release of hazardous substances in Florida.

3. How does your state approach spills or releases of hazardous substances from a mining site? Does your state require financial responsibility specifically for such releases?

   The Department's laws under Chapter 376, F.S., and Chapters 62-780 and 62-777, F.A.C., are applicable to any releases of hazardous substances, including those from a mining site in Florida. In addition, the regulations cited in our general comments, in conjunction with additional regulatory authorities implemented under our state's authorized Resource Conservation and Recovery Act (RCRA) and Clean Water Act National Pollutant Discharge Elimination System (NPDES) permitting programs are also

utilized to regulate potential sources of pollutants, including hazardous substances, at mining extraction, beneficiation, and processing facilities in Florida.

4. What reporting requirements do you have for mining facilities, either related to mine operations or maintenance of their financial instruments? Do you have any difficulties with compliance with these requirements?

   Reporting requirements apply to each of the required state regulatory programs that are referenced in the Department's general comments and in these question responses. The Department relies on these reporting requirements in conjunction with our various regulatory inspections programs and do not have any unaddressed or overriding difficulties with compliance with these requirements.

5. How frequently has your state needed to take enforcement actions against a mining entity for violations relating to financial assurance? How would you characterize the types of violations that trigger enforcement?

   The Department closely oversees and ensures compliance with applicable requirements for financial assurance. With respect to financial responsibility related to hazardous substances at phosphate mineral processing facilities, the Department has issued three orders since the state financial assurance requirements were strengthened in 2005, not including the referenced mineral processing settlements that were discussed for the Florida phosphate industry in our general comments.

6. Does your state require third party certification for assessing mine site features or to verify the calculation of cost estimates related to your state programs? If so, we would be interested in hearing about your experience with these approaches.

   The Department requires that cost estimates be certified by a third party engineer in relation to financial responsibility for phosphate related mineral processing facilities in Florida. The Department would be happy to further discuss any questions with EPA.

7. What is your experience with Environmental Management Systems, ISO certification, third party inspection programs, or similar types of programs in reducing risk from mining operations?

   The Department does not currently rely on Environmental Management Systems, or ISO certifications in its regulatory programs. Our regulations often require inspections by a qualified and licensed professional engineer where appropriate for compliance and safety related evaluations.

Message

From: Scott Herndon [sherndon@americansugarbeet.org]
Sent: 5/17/2017 11:33:29 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Graham, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26722dfde5b34925b0ad9a8dd4aff308-Graham, Amy]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Cassie Bladow [Cassie.Bladow@beetsugar.org]
CC: Peterson Laura USWS [laura.peterson@syngenta.com]; Janis McFarland (janis.mcfarland@syngenta.com) [janis.mcfarland@syngenta.com]
Subject: Section 18 for Chlorothalonil

Dr. Beck,

I would like to connect you with Laura Peterson and Janis McFarland who work for Syngenta. The American Sugarbeet Growers Association had a great call with Janis and Laura and their team yesterday about the Section 18 requests from MN, MI and ND and their desire to be helpful.

On behalf of our 10,000 family farmers in all 11 producing states, we sincerely appreciate all the help from EPA and Syngenta with this crisis!

Thanks again!

My cell is Ex. 6

Scott Herndon
Director of Biotechnology and Regulatory Affairs
American Sugarbeet Growers Association
1155 15th Street NW #1100
Washington, DC 20005
Ex. 6

Message

From: Bostick, Thomas [TBostick@dna.com]
Sent: 6/22/2018 7:00:43 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; Huff, Karen [KHuff@dna.com]
Subject: Re: EUP
Attachments: ATT00001.txt

Nancy, adding Karen to assist with arranging the call.

Thank you,
Tom

Sent from my iPhone

On Jun 22, 2018, at 13:31, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

> Hi Tom,
> I'm looping in Derrick to see what the art of possible is. I think next Friday may likely be best, but he will surely find the best time.
>
> Regards,
> Nancy
>
> ---
> Nancy B. Beck, Ph.D., DABT
> Deputy Assistant Administrator, OCSPP
> P: 202-564-1273
> M: Ex. 6
> beck.nancy@epa.gov
>
> **From:** Bostick, Thomas [mailto:TBostick@dna.com]
> **Sent:** Friday, June 22, 2018 10:40 AM
> **To:** Beck, Nancy <Beck.Nancy@epa.gov>
> **Subject:** RE: EUP
>
> Nancy, would it be possible to have a call to discuss our EUP sometime next week?
>
> If so, it can be one-on-one, or if possible, I would include Brad Shurdut, our regulatory lead.
>
> Have a nice Friday and weekend.
>
> Best,
> Tom
>
> ---
> Nancy B. Beck, Ph.D., DABT
> Deputy Assistant Administrator, OCSPP
> P: 202-564-1273
> M: Ex. 6

beck.nancy@epa.gov

From: Bostick, Thomas [mailto:TBostick@dna.com]
Sent: Saturday, June 2, 2018 11:13 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: EUP

Dear Nancy, greetings and trust that you and the EPA team are well.

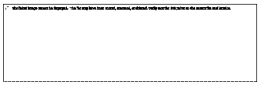
I appreciate the ongoing efforts by EPA to process our EUP and Section 3 requests. Given all of the comments on the EUP, I wanted to be sure that you saw the attached letter from Health Secretary Pedro Mello from Piracicaba, Brazil. Following submission to the EUP docket, Secretary Pedro Mello provided my team with this courtesy copy that I'd also like to share with you. As noted in Secretary Mello's letter, we have successfully and safely deployed our OX513A mosquitoes in Piracicaba over the last few years.

Thank you again!

Best,
Tom

Thomas P Bostick, PhD, PE, NAE

Chief Operating Officer
intrexon
20374 Senaca Meadows Pkwy | Germantown, MD 20876
M: Ex. 6 O: XXX-XXX-XXXX | tbostick@dna.com



www.dna.com

Message

From: Card, Lorine - Virtual US [Lorine.Card@mosaicco.com]
Sent: 6/26/2017 6:24:29 PM
To: Stuart, Eileen H - Tallahassee [Eileen.Stuart@mosaicco.com]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: RE: Thank you
Attachments: 2017-05-10 EPA Reg Reform - Mosaic.pdf

Flag: Flag for follow up

Nancy—As promised here is the letter we submitted in May in response to the call for "Evaluating Existing Regulations." As we mentioned in our meeting last week, we focused largely on CERCLA 108 (b) proposed rule on hardrock mining, CWA Section 404 existing regulation, and the Risk Management Program (RMP) existing rule.

Let us know if you have any questions on our submission and as Eileen said, we look forward to working with you over the coming months.

Lorine

Mosaic
Lorine D. Card |Federal Government Affairs
The Mosaic Company | 300 M Street SE | Suite 402 | Washington, DC 20003
P: Ex. 6 M: Ex. 6 E: lorine.card@mosaicco.com | www.mosaicco.com

From: Stuart, Eileen H - Tallahassee
Sent: Monday, June 26, 2017 9:08 AM
To: beck.nancy@epa.gov
Cc: Card, Lorine - Virtual US <Lorine.Card@mosaicco.com>
Subject: Thank you

Nancy,

Thank you very much for your time last Tuesday. Joc, Lorine and I appreciated the opportunity to meet with you and introduce you to Mosaic. Lorine will send you a copy of the comment letter we submitted to EPA in May. Please let us know if there are particular issues on which we may be able to be of assistance or work together. We would also welcome the opportunity to provide you with a tour of our Central Florida operations, so you can get a sense of the critical role our industry plays regionally, domestically and globally.

Thanks again for your time. We look forward to working with you.
Eileen

Mosaic
Eileen H. Stuart | Vice President, Public Affairs - Phosphates
The Mosaic Company | 215 South Monroe Street | Suite 730 | Tallahassee, Florida 32301
P: Ex. 6 | C: Ex. 6 | F: 850.205.3186 | E: eileen.stuart@mosaicco.com | W: www.mosaicco.com

We help the world grow the food it needs.

Deedra Allen, P.E., J.D.
Director, Regulatory Affairs

Mosaic Fertilizer, LLC
13830 Circa Crossing Drive
Lithia, FL 33547
www.mosaicco.com

D: [redacted]
C: [redacted]
E-mail:
Deedra.Allen@mosaicco.com

Ex. 6

May 10, 2017

Submitted via www.regulations.gov

Ms. Sarah Reese
Office of Regulatory Policy and Management
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

RE: Comments on EPA's "Evaluation of Existing Regulations"
Docket #: EPA-HQ-OA-2017-0190

Dear Ms. Reese:

Mosaic Fertilizer, LLC (Mosaic) appreciates the opportunity to submit the following comments regarding "Evaluation of Existing Regulations." This Request for Information was published in the *Federal Register* on April 13, 2017 at 82 FR 17793. In that notice, comments were requested to be posted to the regulations.gov website by May 15, 2017.

This letter focuses on items of high priority. For more comprehensive comments, please review the comment letter submitted to this docket by The Fertilizer Institute (TFI).

Scope of U.S. Phosphate Operations

Mosaic is one of the world's largest producers of manufactured phosphate products with 15% of the world phosphate production. For more than a century, Florida's phosphate industry has been a major economic driver in central Florida. We currently own or control more than 350,000 acres of land and have approximately 3,600 employees in central Florida (with an additional 2,200 contractors working at our Florida sites). We also own two fertilizer manufacturing plants in Louisiana with approximately 400 employees. *

According to a 2015 study released by Port Tampa Bay, phosphate accounts for nearly 71 percent of the Port's $17.2 billion annual economic activity. In addition, the phosphate industry supports more than half of the Port's 85,000 direct, indirect and related jobs.

We are proud to be a competitive producer with strong customer relationships, and have the financial strength to invest in growth and innovation. We've led the industry in developing high-quality premium products that help farmers succeed, while demonstrating our shared commitment to good corporate citizenship in all of our operating communities. Our products nourish about 70% of the nation's crops, helping to maintain a stable and reliable food supply.

* *As of March 2017, Mosaic Fertilizer LLC and its parent, The Mosaic Company have a total of 4,655 employees in the U.S., including 414 employees at the Carlsbad, NM potash mine and the corporate office in Plymouth, MN.*

Comments

The following information regarding repeal, replacement or modification of regulations is being submitted in your suggested format.

1. **CERCLA 108(b) – Proposed Regulation**
   a. Regulation: 40 CFR Part 320; Published in the Federal Register 82 FR 12333; Docket #: EPA-HQ-SFUND-2015-0781-2379
   b. Potential Impact:
      Annual cost: >$500,000/ year for additional (duplicative) financial assurance
   c. Recommendation: Remove phosphate and potash mining from the definition of Hard Rock Mining or cancel the proposed rulemaking altogether.
   d. Summary of Concern:

The proposed CERCLA rule with respect to phosphate and potash mining is unnecessary and duplicative, as confirmed in a review by the Small Business Administration and Small Business Regulatory Enforcement Fairness Act panel (SBRFA). Phosphate and potash mining operations present very low risk with respect to hazardous material use and risk of releases, and do not employ practices used by Hard Rock Mining (HRM) enterprises (*i.e.,* gold or copper). During the development of the proposed CERCLA 108(b) rule, 59 mined commodities—as matter of policy—were excluded due to low risk. Phosphate mining is similar to excluded commodities and is unlike HRM in material respects. For example, in Florida both phosphate mining and aggregate mining (an excluded commodity) involve shallow pits (< 100 ft) of unconsolidated materials and use only physical separation processes in beneficiation (no chemical reaction or leachate). There are no phosphate mines on the CERCLIS list.

With respect to potash, potash is a salt. Salt mining is among the 59 mining commodities excluded from the scope of the CERCLA rule as being low risk, and potash mining employs the same processes as salt production. Because it is a salt, potash should be categorized as a salt, and thus exempt.

While phosphate mining presents low risk from its use of hazardous materials, Mosaic has a financial responsibility to complete reclamation—to return mined land to beneficial use. To guarantee this, bonds are the mechanism typically used to provide the assurance of adequate funding. For example, one Mosaic Florida mine posts bonds in the amount of about $40 million, based on actual costs, to assure reclamation is completed. The costs and bonds are verified and updated annually. To compare this to the liability generated in the CERCLA 108(b) formula—an almost impossible exercise because the HRM assumptions and processes don't correlate to phosphate mining—the CERCLA formula yields a financial assurance requirement in the amount of about $400 million for the same mine – an order of magnitude greater. Maintaining bonds on all Mosaic phosphate mining operations at this level would increase Mosaic's costs by well over $500,000 per year, provided the marketplace has such capacity, and would underwrite a risk that is wholly unsupported.

This proposed rule also includes fertilizer manufacturing in the HRM category. Fertilizer manufacturing is akin to chemical manufacturing, not HRM. Chemical manufacturing is a separate category which may

be subject to future rulemaking. The main environmental risks associated with Mosaic's fertilizer manufacturing operations have already been evaluated and addressed under RCRA settlement agreements. EPA has deemed the bulk of wastes from those operations to be "high volume/ low toxicity" and subject to RCRA's Bevill exemption. Notably, those settlements required Mosaic to place $630 million into trust to backstop the company's commitment to close and care for phosphogypsum stack systems, which store a by-product generated during our fertilizer production process.

2. Clean Water Act Section (404) – Existing Regulation

a. Regulation: 40 CFR Part 230; (and companion ACOE regulations 33 CFR 320) , including the 2008 Mitigation Rule

b. Potential Impact:

Due to the 6 to 8 year time frame experienced for issuance of a large 404 permit, mine plans may have to be changed and adjusted to maintain, to the extent possible, production while awaiting permit issuance. The unpredictability of the permitting process results in tremendous uncertainty in production planning, adds significant costs to both production and permitting, and may unjustifiably delay a project for years.

c. Annual cost: Several million dollars/ year in inefficiencies typically occur for permit processing times in excess of 6 years.

d. Recommendation: Add streamlining/ time efficiency provisions, clarify the meaning of various concepts, and reduce the complexity of delegation of the program to the states.

e. Summary of Concerns: Issues with the 404 Permit Program include:

- Lack of fixed time frames for agency reviews – This allows the permit process to drag out for years, with no urgency on the part of agency staff to finalize. Issues may be reviewed and revisited several times during this process whether by a single reviewer, or when agency staff turnover occurs. It is recommended this process be amended to mirror regulations such as those in the State of Florida, 62-330 Florida Administrative Code. For example, upon application submittal, the Florida Department of Environmental Protection (FDEP) has 30 days to review and submit a formal Request for Additional Information (RAI). The applicant then has 90 days to respond. Either party may request a time extension if more time is needed for complex review or response. Upon receipt of the additional information response, the process repeats. This process allows state permit applications, with essentially the same review criteria, to be processed in about half the time it takes to process a federal 404 application.

- Uncertainty due to EPA permit veto authority – Mine development requires the commitment of significant resources. EPA's authority to veto a permit after issuance puts that investment at risk. It is recommended that the rule be changed to provide certainty that a final, effective permit is, in fact final, subject to customary re-openers.

- Overlap between the Army Corps of Engineers and EPA and program delegation – The 404 process is complicated by the need to interact with multiple federal agencies that may not have the same objectives. Delegation of the 404 process to the State of Florida would significantly streamline the permitting process. Care, however, should be taken not to overly complicate the state assumption process. For example, an overbroad scope of waters remaining subject to federal authority under Section 10 of the Rivers and Harbors Act may make assumption impractical. Delays could also ensue without a clear definition of the boundary between federal and state jurisdictional waters. A process that is too subjective, becomes vulnerable to challenges and delays.

- Waters of the U.S. – Mosaic supports revising the Waters of the U.S. rule using Scalia's standard defining the extent of federal jurisdiction through "relatively permanent waters." This will remove much of the subjectivity from federal wetland delineations, improving efficiency, and being closer to the original focus of the regulation on navigable waters.

- Beyond that, the permitting process is manifest with confusing, seemingly arbitrary interpretations. Here are examples we have encountered with the EPA and ACOE under the 2008 Mitigation Rule.

    - Example 1: Compensatory Mitigation Sustainability

Ex. 1: 33 CFR 332.7(b) states - *Sustainability.* Compensatory mitigation projects shall be designed, to the maximum extent practicable, to be self-sustaining once performance standards have been achieved. This includes minimization of active engineering features (e.g., pumps) and appropriate siting to ensure that natural hydrology and landscape context will support long-term sustainability. Where active long-term management and maintenance are necessary to ensure long-term sustainability (e.g., prescribed burning, invasive species control, maintenance of water control structures, easement enforcement), the responsible party must provide for such management and maintenance. This includes the provision of long-term financing mechanisms where necessary.

Summary of the Issue (Compensatory Mitigation Sustainability): This provision has been interpreted to require funding into perpetuity, even for systems without active engineering features. Natural systems are considered self-sustaining and once performance standards have been achieved for permittee responsible mitigation (with no engineering features), these systems are also self-sustaining. Natural, undisturbed wetlands evolve, *e.g.,* in vegetation composition, over time due changes in natural conditions. The ACOE's interpretation of its rule in this manner—not mandated by the rule or underlying statute—seeks to prevent such natural evolution in favor of mandating intervention to maintain an unnatural static system. Even so, the codified Conservation Easement itself (*i.e.,* 33 CFR 332.4(c)(4) Site Protection Instrument) provides assurance of perpetual protection in natural condition, regardless of current and future owners of the property, through the agency's right to enforce baseline conditions. Therefore, the interpretation of this provision that a perpetual funding arrangement is required, is both unreasonable in interpretation, and also adds unreasonable time and expense to permit processing and long term project costs.

- Example 2: Grazing and Long Term Management

Ex. 2: 33 CFR 332.7(a)(2) states - The mechanism providing long-term protection of the compensatory mitigation site (*i.e.,* management plan or real property instrument) must, to the extent appropriate and practicable, prohibit incompatible uses (e.g., clear cutting or mineral extraction) that might otherwise jeopardize the objectives of the compensatory mitigation project. Where appropriate, multiple instruments recognizing compatible uses (e.g., fishing or grazing rights) may be used.

Summary of the Issue (Grazing and Long Term Management): The ACOE/ EPA recently interpreted this provision as a prohibition against grazing. Grazing, however, particularly in accordance with best management practices (BMPs) has an important and beneficial role in ensuring wetland mitigation sites remain sustainable, with grazing fulfilling an important ecological maintenance function on many state of Florida conservation lands (See also Fla. DACS Publication P-01280, Best Management Practices for Florida Cow/ Calf Operations, 2008). Grazing can also create economic activity on large expanses of land that reduces management needs, as well as creates a funding source for other management—such as fencing and clean-up of unauthorized trash dumping. Grazing is compatible with the easement because it helps control invasive plants and maintains lower height of ground cover plants, desirable for a number of species of protected wildlife. Without grazing, more intense chemical treatment (herbicide) may be required which adds chemicals to the soil column.

The beneficial use of grazing has also been recognized by the U.S. Department of Agriculture (USDA) in its Wetland Reserve Program, where the USDA worked with ranchers to protect, restore and enhance private property wetlands. Regardless of how one comes down on the ultimate policy question of grazing or no grazing, it is so fundamental to rural property use that a decision to prohibit grazing should either be done at the congressional level or—at a minimum—through specific rulemaking. Thus, in accordance with the provision above, grazing should be considered consistent with the plain language of the rule, and particularly compatible with large rural compensatory mitigation sites (over 1,000 acres) that have been grazed for generations yet are still in excellent condition.

3. EPA – RMP Rule – Existing Regulation

a. Regulation: 40 CFR Part 68; Comment Period open until 05/19/2017 in re: Extending Effective Date to 02/19/2019
Docket #: EPA-HQ-OEM-2015-0725-0760

b. Potential Impact: This rule increases the administrative burden on operating companies and local first responders without a corresponding or measurable increase in safety or benefit. Creates extra expense through recordkeeping and production, rapid turnaround times and potential security risks with respect to record production, hiring of 3rd party auditors with no direct facility knowledge to lead incident audits/ investigations, and mandated five (5) year Safer Technology and Alternative Analysis (STAA) reviews.

c. Annual Cost: Annual costs reflect the addition of administrative recordkeeping time at an estimated cost of about $60,000/year per facility.

d. Recommendation: Repeal the rule as unfounded with respect to significant increases to operator costs without correlating benefits.
e. Summary of Concerns:

These regulations require public release of sensitive materials related to potential facility vulnerabilities which can increase, not decrease, risk by mandating a facility to provide any information deemed relevant by local emergency planners, with no exemptions or protection of confidential business or security related information. This increases the potential that such information may be used for an unlawful purpose, posing risks to the facility and host community. The rule also expands the incident auditing process, requires the process to be led by a 3rd party auditor with no direct knowledge of the facility. It requires a "Safer Technology and Alternatives Analysis" (STAA) to be performed every five (5) years and even if findings support the use of current equipment as the best economically feasible technology, General Duty Liability can be enhanced if an incident occurs.

In addition there is duplication and overlap of the Occupational Safety and Health Administration's (OSHA) Process Safety Management (PSM) program and the EPA's Risk Management Program (RMP). These programs have separate recordkeeping and reporting obligations and separate teams of federal agency officials involved in administration and enforcement. These programs should be consolidated into one to improve efficiency.

4. Matters Pending from Previous Administration
   a. **EPA Conductivity Guidance**
      i. Regulations: Draft guidance document entitled: *"Field-Based Methods for Developing Aquatic Life Criteria for Specific Conductivity"*, released on December 23, 2016, 81 FR 94370; Docket Number: EPA-HQ-OW-2016-0353
      ii. Potential Impact: Technical flaws in this guidance would result in more complex stream standards without a corresponding environmental benefit to the protection of sensitive aquatic life.
      iii. Comment Letters: See Florida Department of Environmental Protection (FDEP) Comment letter EPA-HQ-OW-2016-0353-0044 and Cardno Comment Letter regarding Florida environmental concerns EPA-HQ-OW-2016-0353-0038
      iv. Recommendation: Withdraw the draft Conductivity Guidance

b. NPDES Permit Update

i. Regulations: Proposed regulation entitled: *"National Pollutant Discharge Elimination System (NPDES): Applications and Program Updates"* released on May 18, 2016, 81 FR 31344; Docket Number EPA-HQ-OW-2016-0145

ii. Potential Impact: Revising 40 CFR 123.44(k) to allow EPA broad discretion to intervene in certain "Administratively Continued Permits" by reclassifying them as "Proposed Permits" would result in more process and delay, without corresponding benefits to water resources. Because in Florida, there is an interrelationship between NPDES permits and solid waste management approvals, if EPA were to usurp the state's NPDES permitting authority, it would result in increased administrative burden to the applicant to obtain a separate solid waste management approval. Further, this expansion of EPA authority is contrary to its own expressed opinion (See EPA's Response to Petition for Mandamus, *in re Sierra Club, Case No 12-1860 (1st Cir. March 14, 2013, pg 10-12)*), where EPA claimed that due to permit complexities and the need in some cases for detailed analyses, states are in the best position to set priorities and allocate resources.

iii. Comment Letters: See FDEP Comment letter EPA-HQ-OW-2016-0145-0111 and The Fertilizer Institute (TFI) Comment Letter EPA-HQ-OW-2016-0145-0167

iv. Recommendation: Withdraw the proposed NPDES Permit Update Rule

We appreciate the opportunity to provide this information. Please let me know if we can provide further assistance. My contact information is provided above.

Sincerely,

Deedra M Allen

Deedra M. Allen, P.E., J.D.
Director – Regulatory Affairs

Message

From: Bostick, Thomas [TBostick@dna.com]
Sent: 6/2/2018 3:12:43 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: EUP
Attachments: Ofício Oxitec PDF.PDF

Dear Nancy, greetings and trust that you and the EPA team are well.

I appreciate the ongoing efforts by EPA to process our EUP and Section 3 requests. Given all of the comments on the EUP, I wanted to be sure that you saw the attached letter from Health Secretary Pedro Mello from Piracicaba, Brazil. Following submission to the EUP docket, Secretary Pedro Mello provided my team with this courtesy copy that I'd also like to share with you. As noted in Secretary Mello's letter, we have successfully and safely deployed our OX513A mosquitoes in Piracicaba over the last few years.

Thank you again!

Best,
Tom

Thomas P Bostick, PhD, PE, NAE

Chief Operating Officer
intrexon
20374 Senaca Meadows Pkwy | Germantown, MD 20876
M: Ex. 6 | O: XXX-XXX-XXXX | tbostick@dna.com

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Prefeitura do Município de Piracicaba

Secretaria Municipal de Saúde

Estado de São Paulo - Brasil

SECRETARIA DE SAÚDE DE PIRACICABA

Dear Administrator Pruitt,

I am writing in reference to the OX513A Friendly™ Mosquito that is currently going through the U.S. regulatory process and to support an expedited review and approval of Oxitec's pending Experimental Use Permit (EUP).

The risk of vector borne disease transmission by mosquitoes is, and continues to be, a real, pervasive and escalating threat to public health and citizens globally. Advancing and deploying new innovative tools as soon as possible is absolutely critical to our fight against these vector borne diseases. As Secretary of Health of Piracicaba, Brazil, I oversaw and approved the successfully deployment the OX513A mosquitoes for the last 3 years. During that time, we have experienced a greater than 80% suppression of *Aedes aegypti* mosquitoes in areas that received Oxitec mosquitoes.

By releasing male Friendly™ Aedes mosquitoes carrying a self-limited gene, Oxitec's biological control technology has effectively suppressed wild mosquito populations to levels not achievable by conventional methods. This same technology was successfully authorized and can be deployed throughout Brazil following a thorough review of its health and safety by our federal expert biotech body, CTNBIO.

Oxitec's technology has also been well accepted by the community as there is a keen understanding that the approach provides a favorable alternative to less effective control measures, particularly given that Oxitec mosquitoes do not persist in the environment and have no negative impact on the environment, animals or health. This makes Oxitec mosquitoes a great tool in the battle against dengue, Zika, and chikungunya.

As a public health advocate who has seen the successful introduction and deployment of this novel value-added technology in recent years, I

Prezado Administrador Pruitt,

Estou escrevendo em referência ao mosquito OX513A Aedes do Bem™ que está atualmente passando pelo processo regulatório nos EUA e para apoiar uma análise e aprovação aceleradas da Permissão de Uso Experimental (EUP) requerida pela Oxitec e que se encontra pendente.

O risco de transmissão de doenças transmitidas por mosquitos é, e continua a ser, uma ameaça real, generalizada e crescente à saúde pública e aos cidadãos em todo o mundo. Avançar e implantar novas ferramentas inovadoras o quanto antes é absolutamente essencial para nossa luta contra essas doenças transmitidas por vetores. Como Secretário de Saúde de Piracicaba, Brasil, supervisionei e aprovei a implantação bem-sucedida dos mosquitos OX513A nos últimos 3 anos. Durante esse período, tivemos mais de 80% de supressão dos mosquitos *Aedes aegypti* nas áreas que receberam os mosquitos da Oxitec.

Ao liberar mosquitos macho Aedes do Bem™, portadores de um gene auto limitante, a tecnologia de controle biológico da Oxitec suprimiu efetivamente as populações de mosquitos selvagens em níveis não alcançáveis pelos métodos convencionais. Essa mesma tecnologia foi autorizada com sucesso e pode ser implantada em todo o Brasil após uma revisão completa em termos de saúde e segurança por nosso órgão federal especializado em biotecnologia, a CTNBIO.

A tecnologia da Oxitec também foi bem aceita pela comunidade, pois há um claro entendimento de que a abordagem oferece uma alternativa favorável a medidas de controle menos eficazes, particularmente dado que os mosquitos da Oxitec não persistem no meio ambiente e não têm impacto negativo no meio ambiente, nos animais ou na saúde. Isso faz dos mosquitos da Oxitec uma ótima ferramenta na batalha contra a dengue, Zika e chikungunya.

encourage others to continue to advance novel vector control technologies as quickly as possible, especially when the public's health is at stake. The results obtained so far show that Friendly™ Aedes works and is able to control a serious public health issue that has been affecting the health of Brazilian citizens for decades.

We are not only investing in the expansion of Friendly™ Aedes because its success to date, but also because it is a safe, sustainable and an environmentally-friendly tool that has undergone rigorous review by Brazilian and global regulators.

A timely review and approval of the pending Experimental Use Permit in the United States for the OX513A Friendly™ Mosquito will help our collective efforts to manage mosquito-borne diseases in the Americas and around the world.

Sincerely

Dr. Pedro Antonio de Mello
Secretary of Health Piracicaba

Como defensor da saúde pública que assistiu à introdução e implantação bem-sucedidas dessa nova tecnologia de valor agregado nos últimos anos, incentivo os outros a continuar avançando o mais rápido possível em novas tecnologias de controle de vetores, especialmente quando a saúde pública está em jogo. Os resultados obtidos até agora mostram que o Aedes do Bem™ trabalha e é capaz de controlar uma grave questão de saúde pública que vem afetando a saúde do cidadão brasileiro há décadas.

Não estamos apenas investindo na expansão do Aedes do Bem™ por conta do sucesso atingido até a presente data, mas também porque é uma ferramenta segura, sustentável e ecologicamente correta que passou por uma revisão rigorosa dos órgãos reguladores brasileiros e globais.

Uma revisão e aprovação oportuna da Permissão de Uso Experimental pendente nos Estados Unidos para o mosquito OX513A Aedes do Bem™ ajudará nossos esforços coletivos no manejo de doenças transmitidas por mosquitos nas Américas e em todo o mundo.

Atenciosamente,

Dr. Pedro Antonio de Mello
Secretário Municipal de Saúde de Piracicaba

Message

From: Schwab, Justin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EED0F609C0944CC2BBDB05DF3A10AADB-SCHWAB, JUS]
Sent: 5/5/2017 2:56:00 PM
To: Joe Bischoff [JBischoff@cgagroup.com]
CC: Bernadette Bern Rappold, Esq. [rappoldb@gtlaw.com]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Tim Lust [tim@sorghumgrowers.com]
Subject: Re: Sorghum Oil Update

Thank you, we look forward to that. Everyone have a good weekend. I hope Bernadette is on the mend!

Sent from my iPhone

On May 5, 2017, at 10:23 AM, Joe Bischoff <JBischoff@cgagroup.com> wrote:

> Thank you Justin.
>
> On the chemical issues we are making progress in gathering the, "case studies" on the modeling and EFED issues we discussed last week. These topics are pretty far in the weeds but incredibly impactful for growers access to crop protection tools. We expect to have you and Nancy the necessary information by the middle of next week.
>
> — Joe

Joe Bischoff, PhD | Senior Vice President
Cornerstone Government Affairs

Annapolis | Atlanta | Austin | Baton Rouge | Chicago | Des Moines
Houston | Jackson | Richmond | Springfield| **Washington**

Ex. 6 mobile | Ex. 6 direct
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From: "Schwab, Justin" <schwab.justin@epa.gov>
Date: Friday, May 5, 2017 at 6:50 AM
To: Tim Lust <tim@sorghumgrowers.com>
Cc: "Bernadette Bern Rappold, Esq." <rappoldb@gtlaw.com>, Joe Bischoff <jbischoff@cgagroup.com>
Subject: Re: Sorghum Oil Update

Tim,

Thank you for this message. We will take the appropriate steps to make sure the process works properly here and that all avenues are considered in line with our authority and prior practice.

And to the extent that you have not already, please send in electronic form both the original briefing materials you brought and any additional citations to authority and case studies of how you feel the process can and has worked in previous cases, to better highlight the options that you consider as available but not being satisfactorily explored in your case.

On chemicals, when you do reach out on that, please copy Nancy Beck (beck.nancy@epa.gov), a new arrival to our team who has joined OCSPP.

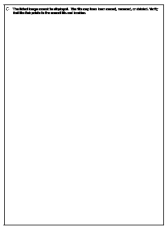
Best,

Justin

Sent from my iPhone

On May 5, 2017, at 12:37 AM, Tim Lust <tim@sorghumgrowers.com> wrote:

> Justin,
>
> Thank you again for your time last week. I need to update you on the sorghum oil pathway. We had a discussion with EPA staffers Sharyn Lie and Aaron Levy (both are OTAQ staff) on Thursday on yet one last technical question on the value of DDG without oil that we answered for the 4th time. I actually got Aaron Levy to admit that oil increased the score on corn so it is not an issue with sorghum as sorghum already had a better score than corn and that our email should be the last technical item needed. When we ask about the approval process Sharyn went political and said first it was a new feedstock so it had to go through rule making. Then she said that executive order 13771 said no new rules unless two are removed...so who knows how long. Our attorney does not believe that executive order 13771 applies to this as it doesn't cost anything when it is approved. Sharyn didn't mention the executive order on energy independence which should help get this approved even faster.
>
> The other option mention by EPA staff was a facility specific approach that would still require a federal register notice and a comment period as was required by the RFS. If there were not negative comments then it could move forward more quickly but under either approach we were looking at 1.5 to 2 years for approval. I ask about approval by letter and she said no because it's a new feedstock. This goes again what EPA staff have told us in the past that this could be approved by letter and it did not have to be considered a new feedstock. This goes totally against what was done on fiber in the legal example that we provided you where all grain fibers were approved as part of the July 2014 RFS pathways II rule (I have included this below). The rule identified corn kernel fiber as a crop residue feedstock and acknowledged the similarity between corn kernel fiber and other grain kernel fibers.
>
> "The impacts of fiber on the digestion of ruminants, swine, and poultry are extremely similar, regardless of what grain that fiber came from, because all grain fiber is virtually 100 percent cellulosic. Therefore, we are confident that diverting that fiber to a fuel production stream would have similarly insignificant market and other GHG impacts to those of corn kernel fiber . . . ." Environmental Protection Agency; Regulation of Fuels and Fuel Additives: RFS Pathways II, and Technical Amendments to the RFS Standards and E15 Misfueling Mitigation Requirements, 79 Fed. Reg. 42,150 (July 18, 2014).
>
> Eighteen months to two years is totally unacceptable to our industry and we need to find a way to approve this in a more simple manner. Perhaps you can reach out to Chris Grundler, Director of OTAQ and find another way to approve this quicker. Thanks for your leadership and help. I will provide you examples on the chemical side in a separate email next week. Regards, Tim



Tim Lust
Chief Executive Director
Ex. 6 office
cell
sorghumgrowers.com
Sorghum: The Smart Choice.



Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 5/17/2017 4:06:07 PM
To: Peterson Laura USWS [laura.peterson@syngenta.com]
CC: McFarland Janis USGR [janis.mcfarland@syngenta.com]
Subject: RE: Section 18 for Chlorothalonil

Thank you both for coming in and for making the time in the future if we have questions. It is greatly appreciated!

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6
beck.nancy@epa.gov

From: Peterson Laura USWS [mailto:laura.peterson@syngenta.com]
Sent: Wednesday, May 17, 2017 8:24 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: McFarland Janis USGR <janis.mcfarland@syngenta.com>
Subject: RE: Section 18 for Chlorothalonil

Dear Dr. Beck,

Thank you for your time, and it was so nice to see you earlier this week with Erik. We greatly appreciated your and Administrator Pruitt's perspectives and willingness to chart a path for sensible solutions on the FIFRA-ESA consultation process. Please do not hesitate to contact us any time for more assistance on ESA or on the nuances of this sugarbeet issue. Janis, cc'ed here, is who I mentioned to you from our team- our expert. We look forward to seeing you again soon.

Kind regards,
Laura

Laura Peterson
Ex. 6

From: Scott Herndon [mailto:sherndon@americansugarbeet.org]
Sent: Wednesday, May 17, 2017 7:33 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; Graham, Amy <graham.amy@epa.gov>; Palich, Christian <palich.christian@epa.gov>; Cassie Bladow <Cassie.Bladow@beetsugar.org>
Cc: Peterson Laura USWS <laura.peterson@syngenta.com>; McFarland Janis USGR <janis.mcfarland@syngenta.com>
Subject: Section 18 for Chlorothalonil

Dr. Beck,

I would like to connect you with Laura Peterson and Janis McFarland who work for Syngenta. The American Sugarbeet Growers Association had a great call with Janis and Laura and their team yesterday about the Section 18 requests from MN, MI and ND and their desire to be helpful.

On behalf of our 10,000 family farmers in all 11 producing states, we sincerely appreciate all the help from EPA and Syngenta with this crisis!

Thanks again!

My cell is Ex. 6

Scott Herndon
Director of Biotechnology and Regulatory Affairs
American Sugarbeet Growers Association
1155 15th Street NW #1100
Washington, DC 20005
Ex. 6

Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 6/26/2017 8:58:14 PM
To: Card, Lorine - Virtual US [Lorine.Card@mosaicco.com]; Stuart, Eileen H - Tallahassee [Eileen.Stuart@mosaicco.com]
Subject: RE: Thank you

Lorine and Eileen,
Thank you for the letter and for coming in to chat with us—it is really helpful to hear from stakeholders. And for sure if the Administrator is heading to Florida, I will think of your facility to see if a visit is possible.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6
beck.nancy@epa.gov

From: Card, Lorine - Virtual US [mailto:Lorine.Card@mosaicco.com]
Sent: Monday, June 26, 2017 2:24 PM
To: Stuart, Eileen H - Tallahassee <Eileen.Stuart@mosaicco.com>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Thank you

Nancy—As promised here is the letter we submitted in May in response to the call for "Evaluating Existing Regulations." As we mentioned in our meeting last week, we focused largely on CERCLA 108 (b) proposed rule on hardrock mining, CWA Section 404 existing regulation, and the Risk Management Program (RMP) existing rule.

Let us know if you have any questions on our submission and as Eileen said, we look forward to working with you over the coming months.

Lorine

Mosaic
Lorine D. Card |Federal Government Affairs
The Mosaic Company | 300 M Street SE | Suite 402 | Washington, DC 20003
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From: Stuart, Eileen H - Tallahassee
Sent: Monday, June 26, 2017 9:08 AM
To: beck.nancy@epa.gov
Cc: Card, Lorine - Virtual US <Lorine.Card@mosaicco.com>
Subject: Thank you

Nancy,

Thank you very much for your time last Tuesday. Joc, Lorine and I appreciated the opportunity to meet with you and introduce you to Mosaic. Lorine will send you a copy of the comment letter we submitted to EPA in May. Please let us know if there are particular issues on which we may be able to be of assistance or work together. We would also welcome the opportunity to provide you with a tour of our Central Florida operations, so you can get a sense of the critical role our industry plays regionally, domestically and globally.

Thanks again for your time. We look forward to working with you.
Eileen

Eileen H. Stuart | Vice President, Public Affairs - Phosphates
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Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 6/4/2018 12:21:09 PM
To: Bostick, Thomas [TBostick@dna.com]
Subject: RE: EUP

Thank you Tom.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
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beck.nancy@epa.gov

From: Bostick, Thomas [mailto:TBostick@dna.com]
Sent: Saturday, June 2, 2018 11:13 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: EUP

Dear Nancy, greetings and trust that you and the EPA team are well.

I appreciate the ongoing efforts by EPA to process our EUP and Section 3 requests. Given all of the comments on the EUP, I wanted to be sure that you saw the attached letter from Health Secretary Pedro Mello from Piracicaba, Brazil. Following submission to the EUP docket, Secretary Pedro Mello provided my team with this courtesy copy that I'd also like to share with you. As noted in Secretary Mello's letter, we have successfully and safely deployed our OX513A mosquitoes in Piracicaba over the last few years.

Thank you again!

Best,
Tom

Thomas P Bostick, PhD, PE, NAE

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