From:	Krasnic, Toni
To:	"John Bell"
Cc:	Caffey Norman (Squire Patton Boggs); fgraul@hsia.org
Subject:	RE: TCE Developmental Toxicity Study
Date:	Thursday, August 03, 2017 11:22:00 AM

John,

As I discussed with Caffey, TSCA §8(e) requires manufacturers (including importers), processors, and distributors of chemicals to notify EPA immediately of information obtained that reasonably supports the conclusion that their substances or mixtures present a substantial risk of injury to health or the environment. TSCA §8(e)-reportable information can come from a variety of sources including, but not limited to, draft, interim, or final written reports (e.g., study reports) or verbal reports (received at meetings or by phone) that involve, among other things, observations (including preliminary observations) from, for example, controlled or uncontrolled animal studies. EPA has emphasized that "reasonably supports the conclusion" of substantial risk is not identical to a conclusive demonstration of substantial risk. Reasonable support is typically obtained at an earlier stage of evaluation than conclusive evidence, which may require long-term health or environmental risk assessments of the subject chemical to establish certainty. A submitter only has to obtain information that reasonably supports a conclusion that a chemical substance can cause an effect of concern to demonstrate that TSCA §8(e) reporting should occur.

Companies not sure whether information should be reported under TSCA §8(e) can report the information to EPA as a "For Your Information (FYI)" submission. Within this FYI category is information not judged by the submitter to reasonably support a conclusion of substantial risk, as well as those situations where the submitter does not have a TSCA §8(e) reporting obligation (e.g., when the submitter is not a person or entity engaged in activities involving the manufacture, importation, processing, or distribution in commerce of the chemical substance or mixture). Please note, however, that timing is always relevant for filing a submission determined to contain §8(e) substantial risk information. EPA considers a person to have "immediately informed" the Agency of 8(e) substantial risk information if it is received by EPA no later than the 30th calendar day after the date the subject person obtained such information. Therefore, if a person files information as an FYI submission because the person is uncertain of whether it is substantial risk information, the submitter should file the information within the 30-day window after obtaining it in order to avoid a possible TSCA §8(e) reporting violation. EPA encourages the submission of information under this voluntary adjunct to TSCA §8(e), especially on chemicals, such as trichlorethylene, currently under review by EPA.

Please let me know if you have any additional questions.

Sincerely,

Toni Krasnic
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From: John Bell [mailto:jbell@hsia.org]
Sent: Wednesday, July 26, 2017 5:54 PM
To: Krasnic, Toni <krasnic.toni@epa.gov>
Cc: Caffey Norman (Squire Patton Boggs) <Caffey.Norman@squirepb.com>; fgraul@hsia.org
Subject: TCE Developmental Toxicity Study

Toni

Caffey Norman asked me to follow up with you regarding whether or not the draft results from our TCE drinking water study needed to be submitted to your office. He is currently out of the country and, as I was on vacation last week, I am trying to come up to speed on the issues you discussed. As I'm sure you are aware by now, CRL ran into problems with achievement of the target drinking water TCE concentrations during the study, invalidating the results. We are currently working with them to ensure that they have a workable procedure in place which will ensure that target concentrations can be reliably achieved (± 10% of target). That process begins tomorrow and should be completed next Monday. Once a suitable procedure is in place, we will work with CRL to reschedule the study as soon as possible. CRL also identified a problem within their breeding animals during the time our study was run, resulting in an unexpected spontaneous increase in fetal interventricular septal defects (IVSDs) across several developmental studies. IVSDs were essentially the only fetal effects seen in our study, raising serious questions about the role of TCE.

Given this background, we are not confident that the study produced <u>any</u> evidence of a "substantial risk" and would be very concerned about submitting the audited draft report for fear that the information in it could be misinterpreted for the reasons described above. As we fully intend to rerun the study, are we under any time constraints which would require us to submit the results of this flawed study now? Thanks and we look forward to your response.

Regards
John

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