Cleanup Standards Scientific Advisory Board Risk Assessment Subcommittee Teleconference Meeting September 22, 2004

The Risk Assessment Subcommittee held a conference call on Wednesday September 22, 2004 at 9:30 a.m. in the Rachael Carson State Office Building (PADEP) in Harrisburg.

Attendees:

Subcommittee Members:

Kevin Reinert Rohm & Haas, CSSAB (chair, RASC)

Randy Shuler ERM

DEP Staff:

Samuel Fang Land Recycling

Public:

Paul Anderson AMEC
Jane Handler AMEC
Jane Patarcity Beazer East
Joe Reinhart BCCZ

Bill Shade Rohm & Haas

Tim Wolfson BCCZ

Resorcinol-related documents for the development of RfD value

Kevin Reinert opened the discussions by indicating that a letter from Resorcinol Task Force (RTF) was distributed to subcommittee members. The RTF supported AMEC's decision to use dose range-finding (DRF) study in the absence of other more reliable, targeted studies. He noted that the WIL report which was distributed to the subcommittee members by email was a DRF study, not two-generation (2G) study. The 2G study is still ongoing and its conclusions will be reported in the Spring of 2005.

Kevin outlined the purposes of the conference call and timeline for the development of the MSCs for resorcinol: This conference call will not determine definitely the RfD and MSCs for resorcinol. Instead, the subcommittee will provide short discussions on the RfD of resorcinol during the CSSAB meeting on Friday (9-24-2004). The RfD for resorcinol will be determined after the November peer-review meeting by Toxicology Excellence for Risk Assessment (TERA). The RfD and MSCs for resorcinol will be determined definitely by December of this year and will be available as part of the

proposed regulations package to EQB in the first quarter of 2005 (pending no changes resulting from the TERA review)..

Kevin then summarized the AMEC RfD report for resorcinol. The development of the RfD was based on the WIL range-finding study with the resorcinol concentrations ranged from 0 mg/L to 360 mg/L. He noted that the proposed RfD in the AMEC report could range from 0.5 mg/kg/day to 2 mg/kg/day, depending upon whether the 360 mg/L is a LOAEL or NOAEL. Bill Shade questioned the use of combined average daily dose (ADD) of 47.7 mg/kg/day as LOAEL instead of the NOAEL of 33.6 mg/kg/day, which is the lowest total ADD reported in either group of 360 mg/L males or in the 360 mg/L females. The use of the NOAEL of 33.6 mg/kg/day would derive an RfD of 1 mg/kg/day using the uncertainty factor (UF) of 30. Paul Anderson explained that the rationale to use the combined dose of 47.7 mg/kg/day could be found in the AMEC report.

Since the AMEC RfD values were derived from the WIL range-finding study, not 2G study, Kevin asked if the draft data from the 2G study could be available earlier than the Spring of 2005, how the conclusions from the 2G study could affect the AMEC's RfD values and what concentrations of resorcinol were used in the 2G study. Paul indicated that he did not know all the details of the 2G study. However, he did know that the concentrations of resorcinol used in the 2G study would be higher than the range-finding study. The 2G study would be likely to have the similar NOAEL and LOAEL. Once the 2G study is available, the UF_D of 3 would be removed. Since Brian Magee, who is in charge of the AMEC resorcinol project, was not on the conference call but will attend the CSSAB meeting on Friday, Kevin will ask Brian these questions again during the CSSAB meeting.

Randy Shuler indicated that methanol also had an RfD of 0.5~mg/kg/day. The cleanup goal for resorcinol based on an RfD of 0.5~mg/kg/day would be very similar to that of methanol. It wouldn't matter too much whether the RfD for resorcinol was 0.5~or~2~mg/kg/day. Randy indicated that the UF of 100~would not be appropriate for the NOAEL of 33.6~mg/kg/day (30~would be appropriate). Tim Wolfson pointed out that the last TERA peer-review meeting suggested an RfD range for resorcinol of 0.03-1~mg/kg/day. Kevin stated that the AMEC report suggested an RfD range of 0.5-2~mg/kg/day for resorcinol and 1~mg/kg/day was very strongly suggested by the range-finding data.

MSCs for resorcinol

Based on the oral RfD of 0.5 mg/kg/day, Kevin indicated that the soil direct contact numeric values for resorcinol would be 110,000 mg/kg for residential and 190,000 mg/kg for nonresidential. The soil-to-groundwater numeric values would be 250 mg/kg for residential and 700 mg/kg for nonresidential. The groundwater MSCs for resorcinol would be 18 mg/L for residential and 51 mg/L for nonresidential. Because the RfD value for resorcinol may be different from 0.5 mg/kg/day as a result of the TERA peer-review

meeting in November, additional RASC review and CSSAB meeting on December 16, 2004, the actual determination of MSCs for resorcinol is on hold.

Tim Wolfson confirmed that the TERA peer-review meeting will be held at Hilton Hotel in Harrisburg on November 17–18, 2004. He invited all persons on the conference call to attend.

Kevin indicated that the RASC will need to have another conference call in early December right after the TERA meeting in November. If necessary, additional meeting will be held after the release of the 2G study report by RTF in Spring of 2005.

The call ended at 10:05 AM.

S. Fang 28 September 2004