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COMMENTS OF BEAZER EAST, INC. TO

Proposed Human Health Ambient Water Quality Criterion For Resorcinol

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This narrative document, along with the cited documents compiled in the attached Reference Section, comprise the comments of Beazer East, Inc. ("Beazer") to the draft Ambient Water Quality Criterion [AWQC] (Human Health Criterion) proposed in the Pennsylvania Bulletin, Vol. 42, No. 27, July 7, 2012 (*"Triennial Review of Water Quality Standards").* The derivation of the proposed Human Health AWQC for Resorcinol was described in a document entitled Commonwealth Of Pennsylvania, Department Of Environmental Protection, Bureau Of Point And Non-Point Source Management, Rationale For The Development Of Ambient Water Quality Criteria; Resorcinol & Sulfonates (Revised February 2012) ("Rationale Document"), which was adopted by the Environmental Quality Board (EQB) at its April 17, 2012 meeting.

INTRODUCTION

Beazer requests that these comments and the appended documents be considered by the Department during preparation of the final Human Health Criterion for Resorcinol and be placed in the administrative record for the proposed Water Quality Standards.[1]

In the *Triennial Review of Water Quality Standards* and the Rationale Document, the Department proposes to establish (1) a human health-based AWQC for Resorcinol and (2) "site-specific" ecologically-based AWQCs for benzene metadisulfonic acid ("BDSA"), benzene monosulfonic acid ("BSA"), p-phenol sulfonic acid ("p-PSA", collectively, the "Sulfonates") and Resorcinol. Beazer's comments on the Human Health AWQC for resorcinol can be summarized as follows:

> The human health-based AWQC for Resorcinol proposed in the *Triennial Review of Water Quality Standards* is inconsistent with the Chapter 16 and Chapter 93 regulations, and it is not based upon the best available data or best available science, including data and science previously reviewed and approved by the Department and recently used by the Department and the EQB to promulgate Statewide Health Standards.

THE HUMAN HEALTH-BASED AWQC FOR RESORCINOL PROPOSED IN *TRIENNIAL REVIEW OF WATER QUALITY STANDARDS* IS INCONSISTENT WITH THE CHAPTER 16 AND CHAPTER 93 REGULATIONS, DEP'S NPDES GUIDANCE, AND WITH STATEWIDE HEALTH STANDARDS RECENTLY PROMULGATED BY THE EQB

Beazer and the Department have been engaged in a cooperative effort to establish AWQC for the Sulfonates and Resorcinol since at least 2004. However, the AWQC proposed in the *Triennial Review of Water Quality Standards* and the Rationale Document also includes a non-peer-reviewed human-health

[1] Indspec Chemical Corporation has advised Beazer that it joins in and adopts these comments and conclusions submitted by Beazer.

based criterion for Resorcinol internally developed by the Department. The human health-based criterion is not appropriate, because it ignores a valid and precedential Reference Dose ("RfD") recently used by the Department and the EQB to promulgate Statewide Health Standards for Resorcinol, and otherwise fails to use the best available data and best available science, as required by the Chapter 16 and Chapter 93 regulations.

In 2004, Beazer, through its consultant Dr. Brian Magee formerly of AMEC Earth and Environmental ("AMEC") and now of ARCADIS U.S., Inc. ("ARCADIS"), proposed soil and groundwater medium-specific concentrations ("MSCs") for Resorcinol that were submitted to the Department in furtherance of having those numbers included in the Appendix A tables of 25 Pa. Code Chapter 250, as Statewide Heath Standards. The proposed MSCs , along with the RfD that the MSCs were derived from, were submitted to and thoroughly vetted through the Department's Cleanup Standards Science Advisory Board ("CSSAB") in 2004. As reported in the December 14, 2004 report of the Risk Assessment Subcommittee ("RASC") of the CSSAB, on May 6, 2004, the Department requested that the CSSAB RASC review information related to the proposed MSCs "so that the Statewide Health standard medium-specific concentrations . . . could be developed and included in the coming proposed regulation changes." As part of this vetting process, Beazer commissioned an extensive public peer review of the RfD and the studies supporting the proposed MSCs.

This peer review was organized and administered by the independent organization Toxicology Excellence in Risk Assessment ("TERA") and included two days of rigorous peer-review panel sessions in Harrisburg on November 17-18, 2004. These sessions were attended by the Department and members of the CSSAB. The CSSAB RASC reviewed and commented on the RfD and proposed MSCs, and the RfD and proposed MSCs were discussed during at least three teleconferences of the RASC as well as at least two public meetings of the full CSSAB. The peer-reviewed RfD derived by AMEC and proposed MSCs were presented to the full CSSAB by the RASC during the CSSAB meeting on December 16, 2004, where they were unanimously approved by a vote of the CSSAB.

The proposed MSCs, approved by the CSSAB and based on the peer-reviewed RfD, were published as proposed Statewide Health Standards on March 6, 2010 (40 Pa. Bull. 1297 (March 6, 2010)). The MSCs were published by the EQB in a proposed rulemaking to amend 25 Pa. Code Section 250 to "update the Statewide health standards by using current Environmental Protection Agency (EPA) guidance and updated toxicological information."

By promulgating the MSCs, the EQB and the Department have acknowledged that the science and studies used by AMEC in developing the MSCs for Resorcinol, including the peer-reviewed RfD, are appropriate for establishment of human health-based standards. However, based on a review of the references cited in the Department's Rationale Document, neither the MSCs themselves, nor the science used to establish the peer-reviewed RfD or the MSCs, appear to have been considered by the Department in establishing the proposed human health-based AWQC for Resorcinol set forth in the *Triennial Review of Water Quality Standards*. The failure to consider and use that science, and the other errors of the Department associated with the proposed human health water quality criterion, are summarized in the next two sections.

1. The Department's Human Health-Based AWQC For Resorcinol Is Not Consistent with Chapter 16 Regulations Entitled *Guidelines for Development of Human Health-Based Criteria*

The Department's Rationale Document states that the AWQC for resorcinol was developed in accordance with the methods and procedures described in the United States Environmental Protection Agency's ("EPA") *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (EPA, 2000, the "EPA Methodology") as required by Chapter 16.32. However, close examination of the Rationale Document establishes that the Department deviated from the EPA Methodology in several significant ways.

Specifically, the EPA Methodology provides the following equation for derivation of an AWQC based on non-cancer effects for trophic level 1 fish, which is relevant to resorcinol.

$$AWQC = RfD \times RSC \times [BW / \{DI + (FI \times BAF)\}]$$

Where:

AWQC = Ambient Water Quality Criterion (mg/L)

RfD = Reference dose for noncancer effects (mg/kg-day)

RSC = Relative source contribution factor to account for non-water sources of exposure.

BW = Human body weight (default = 70 kg for adults)

DI = Drinking water intake (default = 2 L/day for adults)

FI = Fish intake (defaults for total intake = 0.0175 kg/day for general adult population)

BAF = Bioaccumulation factor, lipid normalized (L/kg)

The equation provided in the Rationale Document differs from that in the Methodology guidance cited by the Department. The Department used the following equation:

$$AWQC (ug/L) = NOAEL/UF \times RSC \times (BW / DI + (FI \times BAF) \times 1000]$$

In calculating the human health-based AWQC, the Department substituted "NOAEL/UF" (No Observed Adverse Effect Level/Uncertainty Factor) for "RfD" and defined it as "RfD Equivalent." Although "NOAEL/UF" generically defines the manner in which an RfD is defined, the distinction between the two equations is important. The EPA Methodology calls for the use of an RfD, and a peer-reviewed and Department-approved RfD for Resorcinol has been incorporated into statewide policy, and it is entirely consistent with the criteria outlined in 25 Pa. Code Chapter 16.32(d).

Pennsylvania's Chapter 16 regulations, *Guidelines for Development of Human Health-Based Criteria,* state at Chapter 16.32(d) that the sources the Department must use to obtain relevant risk assessment values for protection for threshold level toxic effects to human health include the following:

- Verified reference doses listed in EPA's Integrated Risk Information System (IRIS) and other EPA approved data sources referred through IRIS;
- EPA's Maximum Contaminant Level Goal;
- Clean Water Act Section 304(a) health criteria; or
- Teratology and other data that have been peer-reviewed and that may provide information for criteria development.

In the case of Resorcinol, there are no IRIS values or other EPA-approved values referred through the IRIS database, no Federal Maximum Contaminant Level Goals, and no Federal Clean Water Act Section 304(a) criteria. There is, however, a peer-reviewed RfD for Resorcinol that meets the criterion defined in 25 Pa. Code Chapter 16.32(d)(4) as "other data that have been peer-reviewed and that may provide information for criteria development." The peer-reviewed RfD for Resorcinol is 2 mg/kg-day.

2. The Department's Human Health-Based AWQC For Resorcinol Is Not Based Upon The Best Available Data or Science

According to the *Triennial Review of Water Quality Standards* and the Rationale Document, the proposed AWQC for Resorcinol derived by the Department is based on a NOAEL taken from *Resorcinol – Concise International Chemical Assessment Document 71* (CICAD, WHO, 2006, the "CICAD Document"). The CICAD document is a literature review and did not include a scientific weight of evidence determination. The use of this NOAEL is not consistent with 25 Pa. Code Chapter 16.32 or 25 Pa. Code Chapter 93.8a, because it is not based on the best available data or science. Specifically, 25 Pa. Code Chapter 16.32 requires that the Department develop AWQC values in accordance with the EPA Methodology, and the EPA Methodology requires consideration of "the best available data." In addition, 25 Pa. Code Chapter 93.8a states that the Department should develop and adopt AWQC values "based on approved methodologies and the best scientific information currently available" (emphasis added).

The Department's error in not using the established, peer-reviewed RfD, as outlined above, is compounded by its selection of the toxicological study from which it independently derived its NOAEL/UF. The Department used a rodent stomach tube bolus dosing study conducted by the National Toxicology Program (NTP) in 1992 (the "NTP Study"). Resorcinol studies based on gavage-administered bolus doses have become subject to substantial criticism, because that method of dosing is known to cause transient neurological artifacts. [2] These effects are not caused when relevant dosing regimens are used, such as drinking water administration. This concern is highlighted in this case, because the NOAEL/UF selected by the Department was based on the NTP Study's reported observations of transient neurological effects. Accordingly, the "RfD Equivalent" of 0.4 mg/kg-day from the NOAEL from the NTP Study as reported in the CICAD Document and the Department's composite Uncertainty Factor of 100 that the Department employed to derive the AWQC are clearly not the best available science for the assessment of human health risks posed by ingestion of water and fish that may contain Resorcinol.

[2] "Gavage" dosing is bolus dosing wherein a large single dose ("bolus") is given to the animal once a day by use of a stomach tube.

The gavage-based NTP Study has previously been subject to precisely this criticism. In 2008, the member states of the OECD (including the Unites States) objectively reviewed the NTP Study, including the NOAEL based on transient neurological effects, and determined that those effects were not appropriate for a repeated-dose NOAEL determination (see SIDS Initial Assessment Report, Resorcinol, OECD, 2008). In addition, subsequent data presented in a drinking water study referenced as Resorcinol Task Force (RTF), 2005 in the CICAD document ("RTF 2005"), was not fully presented in the CICAD Document cited by the Department. The CICAD document cited but did not fully consider the RTF (2005) report, because RTF (2005) was completed late in finalization of the CICAD document. It was not published in the peer-reviewed literature until 2008 as Welsch et al. (2008). The following text, presented in the OECD SIAP, summarizes the OECD member states' review of the data presented, including the NTP review panel's position.

> "An NTP review panel concluded that the overt CNS effects seen in the NTP studies were an acute response to treatment. The dosing method (bolus) was probably a key factor, since no CNS effects were seen when similar or higher doses were given via the drinking water."

The CICAD document itself explicitly discusses the substantial uncertainties associated with the neurological effects reported in the NTP Study:

> "[I]t should be noted that 100 mg/kg body weight when administered by drinking-water showed no effects on the CNS. It is therefore possible that these neurological effects are due to the acute effect of the gavage administration."

Based upon the overall data available, the OECD member states concluded that the NOAEL cited in the CICAD document, and derived from the NTP Study is inappropriate for human health risk assessment purposes. (See SIDS Initial Assessment Report, Resorcinol, OECD, 2008). The NOAEL used by the Department to derive an AWQC for Resorcinol cannot in any manner be considered the best available science based on best available data.

In contrast, the existing peer-reviewed RfD, which was used by the Department and the EQB to derive and promulgate the statewide standards published in March, 2010, can be considered the best available science. During that extensive peer-review process, the transient neurological effects seen in the NTP Study were explicitly considered and rejected because the effects were artifacts of the stomach tube bolus dosing method used by NTP (TERA, 2004). When deriving the RfD in 2003-2004, AMEC carefully considered the NTP Study and the 2003 RTF dose range finding study ("RTF 2003") that preceded the RTF 2005 study, and chose the RTF study as the appropriate and relevant study from which to derive a RfD. This is because the RTF 2003 study used drinking water to administer the dose. Given that drinking water is a relevant exposure pathway for humans and stomach tube bolus dosing is not, the choice was clear. The TERA peer-review panel unanimously agreed. The peer review panel's scientific decision about the relevance of the results from a stomach tube bolus dosing study is identical to the decision made by the OECD panel members, as discussed above. Thus, the TERA peer-review panel-approved RfD of 2 mg/kg-day used in the currently proposed statewide standards promulgated by the EQB constitutes the best available science.

Beazer notes that the RTF 2005 study, the full two-generation reproductive study, employed higher doses based on the results of the RTF 2003 study, the dose range finding study. The NOAEL from the RTF 2005 study, which post-dated the derivation of the peer-reviewed RfD and its approval by the EQB, was much higher. The more recent NOAEL would cause the RfD to increase from 2 mg/kg-day to 13 mg/kg-day. Thus, the peer-reviewed RfD is conservative and more health-protective than necessary.

In summary, the NTP Study-based data presented in the CICAD Document should not be the foundational basis of the Department's human health-based AWQC for Resorcinol, because a more recent, comprehensive, scientifically defensible, and thoroughly peer-reviewed assessment of Resorcinol is available. Using the peer-reviewed RfD for Resorcinol, the appropriate human-health based AWQC for Resorcinol is 13,600 ug/L, and a human-health based AWQC for Resorcinol derived from the NOAEL from the most recently published study (RTF, 2005; Welsch et al., 2008) would be 88,660 ug/L.

3. The Department's Accreditation Requirements May Make It Impossible To Demonstrate Attainment Of The Proposed AWQC

While not explicitly stated in the proposed Triennial rulemaking, the underlying "Rationale For The Development Of Ambient Water Quality Criteria" document prepared by the Department for the Environmental Quality Board (revised February 2012) states the following regarding "Analytical Test Method Requirements" for the three sulfonates and resorcinol:

> "In the absence of an EPA approved analytical test method for the sulfonates and resorcinol, the Department is requiring that analytical laboratories apply for and obtain accreditation in accordance with 25 Pa Code Chapter 252 prior to accepting and analyzing samples for these compounds, if required to do so as a permit requirement. Currently, the Department's Laboratory Accreditation Program has approved the Test America Method OR357A - DETERMINATION OF RESORCINOL and BENZENESULFONIC ACIDS BY LIQUID CHROMATOGRAPHY-TANDEM MASS SPECTROMETRY (LCMS/MS) USING MULTIPLE REACTION MONITORING (MRM)."

This requirement unduly restricts the ability of the regulated community and the Department to timely and cost-effectively conduct and/or contract for analysis of samples that may contain resorcinol or the sulfonates. The referenced method, Test America Method OR357A, is proprietary and may not be widely available for use by other laboratories. In addition, the referenced method is calibrated to a reporting limit of 1000 ug/l. In most cases, that level of sensitivity should be sufficient to evaluate for the presence or absence of resorcinol and the sulfonates in comparison to the proposed AWQC. However, Method OR357A may not be appropriate if the sample under analysis displays a matrix effect that would require a dilution to overcome the matrix effect. In such circumstances, Test America Method OR357, which provides a reporting limit of 50 ug/l, may be more appropriate as that method can be used with greater

dilution factors. At a minimum, Method OR357 should also be recognized as acceptable by the Department.

CONCLUSION

In conclusion, Beazer requests that the Department delete the proposed site-specific human health-based AWQC for Resorcinol listed in *Triennial Review of Water Quality Standards* and replace that value with the 13,600 ug/L value based on the already-accepted, Department-approved and peer-reviewed RfD (2 mg/kg-day) used to promulgate the MSCs for Resorcinol. Beazer and its technical consultants are available to meet with the Department to discuss the issues presented in these Comments, if such a meeting would be useful to the Department.

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