

April 2, 2003

Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget, NEOB, Room 10202
725 17th Street, NW.,
Washington, DC 20503

RE: Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, FR vol. 68, no. 22, Monday, February 3, 2003

The Office of Management and Budget (OMB) recently released a Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations (OMB 2003) and has requested public comments. The comments of Tennessee Gas Pipeline (TGP) are in response to the following two specific requests for public comments:

- Ways in which “precaution” is embedded in the current risk assessment procedures through “conservative” assumptions in estimation of risk, or through explicit “protective” measures in management decisions as required by statutory requirements as well as agency judgments.
- Examples of approaches in human and ecological risk assessment and management methods addressed by U.S. regulatory agencies (e.g., consumer product safety, drug approval, pesticide registration, protection of endangered species) which appear unbalanced.

TGP owns and operates a number of compressor stations located along its natural gas pipeline that extends from Texas to New England. As a result of discovery of historical polychlorinated biphenyl (PCB) contamination, TGP entered into an Administrative Order on Consent in 1994, which contemplated complete remediation of the compressor stations and any impacted off-facility areas within ten (10) years. Remediation of the compressor stations is almost complete. Remediation of the off-facility areas has been significantly delayed by the inability to complete engineering evaluations and costs analyses (EE/CA) required under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) due to the requirement that ecological risk assessments be conducted and due to perceived inflexibility in the interpretation and implementation of guidance for such risk assessments.

TGP is currently conducting baseline ecological risk assessments at several off-facility locations at the request of and in conjunction with U.S. Environment Protection Agency Region IV (Region 4) to evaluate the potential effects of PCBs on potential receptor species. TGP's comments are based on Region 4 recommendations, requirements, and judgments made regarding the ecological risk assessments. Whereas TGP understands and appreciates the need to be protective or conservative in the face of uncertainty, we believe that Region 4 has overlooked the equally important qualities of realism, reasonableness, scientific credibility, objectivity, and balance. As a result, we believe that the ecological risk assessments provide unrealistically conservative estimates of risk and that requiring cleanup based solely on this information is not technically defensible.

Ecological risk has been quantitatively evaluated at TGP sites using a simple hazard quotient approach. A hazard quotient (HQ) approach involves comparing exposure estimates for exposed wildlife species to adverse effects thresholds measured in the laboratory. Mathematically, the $HQ = \text{Exposure}/\text{Effects Threshold}$. A hazard quotient less than 1 indicates that the exposure estimate is below the effects threshold and, therefore, is unlikely to cause adverse effects. A hazard quotient greater than 1 indicates that the exposure estimate exceeds the effect threshold and, therefore, adverse effects are possible. Dietary exposures for wildlife species are estimated using a standard food-web exposure modeling approach.

The food-web exposure model requires selection and use of exposure parameters for each wildlife species modeled, such as body weight, food ingestion rate, home range, water ingestion rate, dietary composition, and contaminant concentrations in food. For each of these input parameters, there is a range of possible values that could be used. For example, adult body weights are variable and depend on several factors, including region of the country, habitat, and the availability of food. The home range (i.e., the size of the area used by the organism) of certain species can vary as much as an order of magnitude. Similarly, chemical concentrations in food may be measured or estimated, and can be expressed numerous ways, including maximum, mean, or as a confidence limit of the mean. Single-value point estimates have been used in TGP ecological risk assessments to calculate deterministic risk estimates, with the worst-case assumptions used to estimate each parameter of the model. Each of the parameters used in the exposure and risk models can have a tremendous impact on the exposure estimates and the resulting risk estimates (i.e., HQs), and many of them are multiplicative. This results in an unrealistic overestimate of exposure and risk.

There is considerable uncertainty regarding many of the exposure parameters for ecological risk models and, unlike human health risk assessment, standard assumptions regarding exposure models have not been developed or promulgated for ecological risk assessment. EPA determines for each assessment which assumptions will be used. In discussions with EPA regarding the balance between realism and protectiveness, an EPA representative stated, "I do not care about realism" and went on to explain that the only consideration for selection of exposure parameters for ecological risk models was protectiveness. It is the unreasonable, overprotective bias in the selection of these

exposure parameters by Region 4 that has resulted in what we believe is an unrealistically conservative estimate of risk.

TGP has worked to distinguish between the different types of uncertainty (i.e., knowledge uncertainty and uncertainty associated with natural variability) and has argued (with limited success) for the use of multiple scenarios using a range of values for parameters where there is uncertainty due to natural variability, in order to communicate to the risk manager a sense of the most probable as well as the worst-case risk levels.

Although Region 4 accepts the use of multiple scenarios, it severely constrains the range of exposure parameters allowed in the scenarios and does not permit the risk assessment to identify the most probable risk level, even when such an identification is well-supported by the scientific literature. Thus, TGP believes that none of the scenarios reflect an accurate or realistic estimate of risk, that much of the available scientific knowledge is being ignored, and that, collectively, the range of scenarios used in the assessment represents an unbalanced view of risk.

For example, the most conservative scenario in a recent ecological risk assessment involved the following conservative assumptions:

- Minimum receptor body weight (results in maximum exposure)
- Wildlife spend their entire life at the single highest concentration detected in soil or sediment
- Diet composed of 100 percent of the maximum contaminated prey item
- The lowest reproductive toxicity thresholds identified from the literature (maximum sensitivity)

These assumptions result in a scenario that is not only highly unlikely, but physically impossible. More realistic scenarios using realistic body weights, diets, food concentrations and home ranges would far better predict the likelihood of adverse effects to wildlife, yet such scenarios were not permitted in the risk assessment. Furthermore, Region 4 has forbidden the use of any qualitative adjectives to describe exposure or risk scenarios, such as “worst-case”, “most-likely” or “realistic”.

The potential impact of using only “protective” assumptions in the input parameters of baseline risk assessments is illustrated in the following example from a TGP site. TGP conducted bio-assay testing on benthic macroinvertebrates at a site along the Mississippi gulf coast where PCBs were detected in estuarine sediments up to 1.1 mg/kg. The concentration of PCBs in the sediment greatly exceeded the screening values endorsed by

Region 4 and the National Oceanic and Atmospheric Administration (NOAA), however no adverse effects attributable to PCBs were observed.

TGP tested several endpoints in benthic-macroinvertebrates, including: mortality, reproductive maturity, embryo production, embryo hatching, and DNA strand damage. The absence of any differences among the test results corresponding to PCB concentrations supports the conclusion that there were no adverse effects on sensitive reproductive endpoints due to PCBs in the sediments associated with this TGP site.

The absence of adverse effects during site-specific testing was noted at PCB concentrations substantially higher than generic screening criteria for sediment endorsed by Region 4 and NOAA. The source document used by Region 4 and NOAA predicts a threshold effects level (TEL), the concentration above which adverse effects are expected to become observable, of 0.02 mg/kg. The site-specific testing demonstrated no adverse effects at approximately 1 mg/kg, 50 times the generic screening value. The concentrations tested even exceeded the predicted probable effects level (PEL) of 0.2 mg/kg from Region 4's and NOAA's source by up to 5 times without producing any effects. The PEL is a concentration at which a significant proportion of organisms are expected to experience adverse effects. These outcomes demonstrate the level of protectiveness of the generic screening criteria for total PCBs and the importance of site-specific testing results and reasonable risk management interpretation for refining the representation of potential risks.

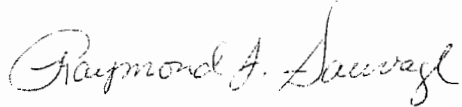
In its ecological risk assessment documents, TGP has attempted to offer what we consider to be a more realistic and reasonable characterization of ecological risks by evaluating the effect of the full range of possible assumptions (including the worst case) on the risk estimates in the uncertainty section of the risk assessment, but we remain concerned that risk-based management decisions will be driven solely by the unrealistically conservative quantitative risk estimates presented in the main body of the assessments.

The type of approach employed by Region 4 for characterizing ecological risks can lead to costly and unnecessary remediation, and this is our primary concern. This type of approach, however, can also lead to the overstatement of risks posed by environmental contaminants and the overstatement of the benefits of remedial actions. Responsible parties are concerned that overstated risk could also lead to unjustified exposure to other types of damage claims outside of the ongoing remediation. In TGP's case, the prolonged ecological risk assessment has resulted in a significant delay in the commencement of remediation. Therefore, TGP strongly urges OMB to recommend and encourage U.S. regulatory agencies to ensure that the core assumptions used to evaluate ecological risks are well grounded in science, objective, reasonable, balanced, and realistic, and need not be skewed towards the most conservative input parameters.

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Lorraine Hunt, OMB
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Tennessee Gas Pipeline appreciates the opportunity to offer constructive comments on this topic.

Sincerely,

A handwritten signature in cursive script that reads "Raymond J. Sauvage".

Raymond J. Sauvage, CHMM
Principal Environmental Scientist

Attachment

cc: Greg Odegard, El Paso Corporation
Jay Greenwalt, El Paso Corporation
Brian Black, El Paso Corporation
Kim Lesniak, El Paso Corporation
Central File, El Paso Corporation
Steve Nadeau, Sediment Management Work Group coordinator