<u>**Excerpt 20**</u>

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EPA's Summary and Evaluation Of the Human Health Risk Assessment And Screening Level Ecological Risk Assessment

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INTRODUCTION

Purpose of Human Health Risk Assessment and a Screening Level Ecological Risk Assessment

In order to determine if there are any risks (human health or ecological) associated with emissions estimated to result from the Energy Answers ("EA") proposed project ("facility" or "municipal waste combustors") both a human health risk assessment (HHRA) and a screening level ecological risk assessment (SLERA) were prepared.

Chemicals Evaluated

The following chemicals or chemical classes, which are estimated that potentially could result from municipal waste combustors, such as EA's project, were selected for detailed evaluation, in both HHRA and SLERA. In the context of the human health risk assessment these chemicals are called constituents of potential concern ("COPCs"), and in the context of the ecological risk assessment these chemicals are called chemicals of potential ecological concern ("COPEC"): polycyclic aromatic hydrocarbons (PAH), dioxins, furans, and metals (antimony, arsenic, beryllium, cadmium, chromium VI, cobalt, copper, lead, manganese, mercury, molybdenum, nickel, selenium, tin, vanadium, and zinc), and polychlorinated biphenyls (PCBs). Hydrochloric acid and hydrofluoric acid gases were included in the evaluation of the potential for adverse effects from short-term exposure.

While, some of the chemicals listed above, including dioxins, furans, PCBs, and certain metals are persistent and bioaccumalative, and therefore they are of the most interest for long -term (i.e., chronic) exposure, other chemicals, are more of a concern for short-term (i.e., acute) exposure.

Emissions from waste combustion potentially include dioxin and furan (D/F) at trace levels. The dioxins and furans emissions are comprised of mixtures of polychlorinated dibenzo-p Dioxins (PCDDs or Dioxin) and polychlorinated dibenzofurans (PCDFs or Furans) compounds. The Dioxin and Furans occur in the environment together, are highly persistent compounds, and are resistant to microbial degradation. There are 75 PCDDs and 135 PCDFs, with each individual compound referred to as a congener. However, there are 7 congeners of dioxins, and 10 congeners of furans that are considered toxic.2, 3, 7, 8-Tetrachloro Dibenzo-p-Dioxin “TCDD” is one of the most toxic congener (of the 17 congeners of D/F) and extensively studied, and serves as a prototype for toxicologically relevant or "dioxin-like" PCDDs

The toxicity of dioxin-like PCDDs is expressed as a fraction of the toxicity attributed to 2, 3, 7, 8 -TCDD. This fraction is called Toxic Equivalent Factor (TEF). The toxic potency (i.e., toxicity or TEQ) of a mixture of congeners is the sum of the products of the TEFs for each congener and its concentration in the mixture. The TEQ of the 17-dioxin and furan congers was evaluated in the human health and ecological risk assessment using 2, 3, 7, 8-TCDD TEF assigned by the World Health Organization in 2005.

Emission Rates

The emissions rates of the chemicals evaluated by the EA’s HHRA and SLERA were based on a combination of proposed project emission limits, available emissions stack test data from SEMASS Plant (Massachusetts), and the US EPA’s 2005 Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities (HHRAP)’s procedures for estimating emission rates.

Area Evaluated

USEPA guidance indicates that the most significant atmospheric deposition of emissions from waste combustion units generally occurs with 10 kilometers (km) of a combustion source. The air modeling conducted for this HHRA (which was used also for the SLERA) predicted that the highest air concentrations and areas of maximum deposition would occur within 10 km radius ("10 km") of the proposed facility. Therefore the HHRA evaluated all populations (or receptors, such as adults, children, nursing infants) living within 10 km radius (i.e., 10 km^2 receptor grid) from the project, while the SLERA evaluated all ecological receptors (e.g.., plants, animals) which could potentially be found within 10 km of the project.

HUMAN HEALTH RISK ASSESSMENT

The HHRA evaluates the potential for adverse health effects in human receptors from exposure to combined emissions estimated to result from the two proposed municipal waste combustor units (combustors).

The HHRA was prepared following the guidance and recommendations from the USEPA, including but not limited to HHRAP. The evaluation of risks and hazards associated with chemicals emitted from a combustion source (municipal waste combustor) is performed following the four steps below:

Hazard Identification – Chemicals of potential concern (COPCs) are chemicals potentially associated with facility emissions that have the potential to cause adverse health effects through direct (inhalation) or indirect (e.g., through soil, water, or food sources) exposure pathways. The COPCs identified for this HHRA are specified above.

It was assumed that the chemicals (i.e., COPCs) emitted from the combustors are dispersed and deposited as either vapors or particulates (i.e., particles or particle bound).
The AERMOD air dispersion and deposition model was used to estimate the air concentrations and deposition fluxes for vapor phase, particle phase, and particle bound COPCs that may be emitted from the combustion units. As stated above the modeling was used to estimate the concentrations and deposition of COPCs in the ambient air both near the facility and at a distance away (within 10-km^2 receptor grid). COPCs concentrations are also estimated in other environmental media (e.g., soil, surface water, and sediment) and food items (e.g., milk, beef, pork, poultry, home-grown produce, fish, etc.,) through which humans may be indirectly exposed.

Exposure Assessment - This step identifies the people that may be exposed to the COPCs and the different exposure pathways through which they may contact the COPCs. The HHRA evaluated the following receptors and exposure pathways:

- Urban Residents (adults and children) who live in Arecibo and may be exposed to COPCs in air, soil, drinking water from surface water sources, milk from local dairies, and fish from local surface water bodies.

- Suburban Residents (adults and children) who live in suburban areas surrounding Arecibo and may be exposed to COPCs in air, soil, drinking water from surface water sources, home-grown produce, milk from local dairies, and fish from local surface water bodies.

- Local Farmers (adults and children) who may be exposed to COPCs in air, soil, drinking water from surface water sources, home-grown produce, and locally-raised animal products (e.g., milk from dairy cows, beef, poultry, pork, and eggs).

- Fishers (adults and children) who rely on fish as the main source of protein in their diet. These people may be exposed to COPCs in air, soil, drinking water from surface water sources, home-grown produce, milk from local dairies, and locally-caught fish.

- Nursing Infants (urban resident, suburban resident, farmer, and fisher infants) who may be exposed to dioxins and furans that may bioaccumulate in human breast milk. This exposure scenario considers the mother's total intake of dioxins/furans and the potential for subsequent maternal transfer through breast milk fat.

Exposure to COPCs is calculated by combining the COPC concentrations in the media of concern (air, soil, drinking water, milk, beef, poultry, pork, eggs, home-grown produce (e.g., lettuce, other leafy produce, corn, peas, fruits, etc.,), fish, etc.) with exposure parameter values, such as consumption rate, body weight, exposure duration, and exposure frequency. Using these factors, a "reasonable maximum exposure" scenario is calculated which represents the highest level of human exposure that could reasonably be expected to occur. The intent is to overestimate the potential for exposure and associated health hazards to provide a conservative (health protective) evaluation.

For assessing the human exposure through food ingestion, it was assumed that 100 % of a particular type of food consumed was grown or raised within the 10 km radius of the proposed facility.
An example of a reasonable maximum exposure used in this HHRA is assuming that, a farmer drinks 1.4 liters of untreated drinking water from surface water source (Superacueducto or reservoir), and eats locally-raised beef, poultry, produce, eggs, pork, and milk, and 100% of the food is affected by COPCs from the proposed facility, for 350 days per year, and for 40 years out of a lifetime.

Exposure to milk from dairy cows is evaluated by estimating COPC concentrations in the cow's diet and through incidental ingestion of soil. It was assumed that the cow's diet consisted of forage (pasture grass and hay), grain, and silage (grain that has been stored and fermented). It was conservatively assumed that 100 % of the animal's diet is grown locally on soil that receives COPC deposition and COPCs in soil are 100% bioavailable[1], and metabolism does not decrease the COPCs concentration in fat and muscle tissue.

The drinking water ingestion pathway considers exposure to COPCs potentially associated with combustion emissions from the proposed facility that are deposited onto a surface water body used as a drinking water source (e.g. a reservoir). The main water system in the region is known as the North Coast Aqueduct System (Superacueducto), and it was modeled as a water body receptor and conservatively assumed that the potable water from it is untreated.

The fish ingestion pathway considers exposure to COPCs that are deposited onto fishable water bodies. Three fishable water bodies were selected for the fish ingestion pathway: estuary where the Rio Grande de Arecibo meets Puerto Arecibo, Cienega Tiburones, and Puerto Arecibo.

Toxicity Assessment – In this step, the types of adverse health effects associated with chemical exposures and the relationship between magnitude of exposure (dose) and severity of adverse effects (response) are determined. Potential health effects are chemical-specific and may include the risk of developing cancer over a lifetime or other non-cancer health hazards such as changes in the immune system or nervous system effects.

Risk Characterization – This step summarizes and combines the outputs of the exposure and toxicity assessments and provides a quantitative assessment of site risks for all COPCs and all exposure pathways, combined.

Cancer and Noncancer Risks

Exposures are evaluated based on the potential risk of developing cancer and the potential for non-cancer health hazards.

[1] The term bioavailable (or bioavailability) refers to the fraction of the total amount of compound in contact with a body portal of entry (e.g. gut, skin, and lung) that enters the blood stream, from which it may exert a toxic response.

The likelihood of developing cancer is expressed as a probability. For example, a 10^{-4} cancer risk means a "one-in-ten-thousand excess cancer risk"; or one additional cancer may be seen in a population of 10,000 people as a result of exposure to facility emissions.

For non-cancer health effects, a "hazard index" (HI) is calculated. An HI represents the sum of the individual exposure levels compared to their corresponding reference dose (i.e., RfD (oral) and reference concentration (i.e., RfC (inhalation). The key concept for a non-cancer HI is that a threshold (measured as an HI of less than or equal to 1) exists below which non-cancer health hazards are not expected to occur.

For each exposure pathway (i.e. air inhalation, soil ingestion, ingestion of locally -grown produce, ingestion of untreated drinking water from surface source (reservoir), ingestion of beef, milk from dairy cows, poultry, eggs, pork, fish (locally-caught fish)), cancer risks and non-cancer HIs are calculated for each COPC and then all of the individual values are added together to get pathway-specific risk value.

Since people can be exposed to COPCs through several different routes, pathway-specific cancer risks and non-cancer HIs are added together to get a cumulative risk value (total excess lifetime cancer risk and total noncancer HI). For example, in order to calculate the cancer risks and noncancer HI values for the farmer receptor all the following farmer's exposure pathways are added up: air inhalation, soil ingestion, ingestion of locally-grown produce, ingestion of drinking water from surface source (reservoir), ingestion of beef, milk from dairy cows, poultry, eggs, and pork.

For chronic (i.e., long-term) exposures, both cancer risks and non-cancer hazards were calculated in two different ways as follows:

1) Based on the maximum annual average values of air concentration and deposition fluxes of each COPC, which were predicted by the AERMOD at each receptor location (e.g., residential, agricultural). The receptors locations were established based on the local conditions (i.e., current and future land use) of the area within 10 km^2 receptor grid, and the recommendations of the USEPA guidance.

Table 1: Excess Lifetime Total Cancer Risks (across all pathways)

Excess Lifetime Total Cancer Risks (across all pathways)							
Urban Resident		**Suburban Resident**		**Farmer**		**Fisher**	
Adult	Child	Adult	Child	Adult	Child	Adult	Child
9E-08	1E-07	1E-07	2E-07	3E-07	4E-07	2E-06	2E-06

USEPA generally finds Excess Lifetime Cancer Risks between one-in-ten-thousand (10^{-4} or 1E-04) and one-in-a-million (10^{-6} or 1E-06) or less are acceptable[2].

Table 2: Noncancer Total Hazard Indices (across all pathways)

Noncancer Hazard Indices (across all pathways)							
Urban Resident		**Suburban Resident**		**Farmer**		**Fisher**	
Adult	Child	Adult	Child	Adult	Child	Adult	Child
0.01	0.01	0.01	0.02	0.02	0.05	0.2	0.5

USEPA generally finds Non-Cancer Hazard Indices of less than 1 acceptable[3].

2) Based on the maximum annual average air concentration and deposition fluxes of each COPCs which the AERMOD predicted within the entire 10 km radius, regardless of the land use. In this scenario, instead of placing the receptors according to the land use criteria, each receptor was assumed to be located at the point of the maximum annual average air concentration and deposition fluxes of each COPC.

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[2] National Contingency Plan Requirements (NCP) (40 CFR 300.430(e) (2) (i) (A)), available at USEPA Region 4 Regional Removal Management Levels for Chemicals (RMLs) webpage references the National Contingency Plan (dated 2012) http://www.epa.gov/region4/superfund/programs/riskassess/rml/rml.html.
In general, the USEPA considers excess cancer risks that are below about 1 chance in 1,000,000 (1×10^{-6} or 1E-06) to be so small as to be negligible, and risks above 1E-04 to be sufficiently large that some sort of remediation is desirable. Excess cancer risks that range between 1E-06 and 1E-04 are generally considered to be acceptable (see Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions (Memorandum from D. R. Clay, OSWER 9355.0-30, April 1991), although this is evaluated on a case-by-case basis and EPA may determine that risks lower than 1E-04 are not sufficiently protective and warrant remedial action.

[3] U.S. EPA 1989, Risk Assessment Guidance for Superfund Manual (Part A), OERR, Washington D.C. OERR 9200-6-303-894, Volume I Human Health Evaluation Manual

Table 3: Excess Lifetime Total Cancer Risks (across all pathways)

Excess Lifetime Cancer Risks (across all pathways)							
Urban Resident		**Suburban Resident**		**Farmer**		**Fisher**	
Adult	Child	Adult	Child	Adult	Child	Adult	Child
9E-08	1E-07	1.9E-07	5.3E-07	3.3E-07	5.6E-07	4.2E-06	3.6E-06

USEPA generally finds Excess Lifetime Cancer Risks between one-in-ten-thousand (10^{-4} or 1E-04) and one-in-a-million (10^{-6} or 1E-06) or less are acceptable.

Table 4: Noncancer Total Hazard Indices (across all pathways)

Noncancer Hazard Indices (across all pathways)							
Urban Resident		**Suburban Resident**		**Farmer**		**Fisher**	
Adult	Child	Adult	Child	Adult	Child	Adult	Child
0.01	0.01	0.011	0.038	0.011	0.034	0.29	0.95

USEPA generally finds Noncancer Hazard Indices of less than 1 acceptable.

As noted above, for this scenario, the cancer risk (Excess Lifetime Cancer Risks) shown in Table 3, and non cancer risk (Noncancer Hazard Indices) shown in Table 4 were estimated for each receptor and for all exposure pathways except fish ingestion and drinking water using the maximum COPC concentration and deposition fluxes within the entire area evaluated (i.e., 10 km^2 receptor grid). This approach represents the most conservative evaluation of the potential for adverse health effects.

The maximum Noncancer Hazard Index (HI) of 0.95 was predicted for the fisher child receptor that is assumed to reside at the maximum impact location, and consumes locally caught-fish from a surface water body affected by the estimated COPC concentrations from the project's emissions.

Generally, the HIs are only used in the evaluation of a mixture of chemicals that induce the same effects by the same mechanism of action. However, the HI determined in Table 4 represents the sum of individual hazard quotients (HQ) for COPCs that can have different effects.

Consistent with the USEPA guidelines for assessing risks for chemicals mixtures, the HQ can be segregated by target organ/critical effect. Consequently, because the calculated HI for the fisher child was close to the USEPA benchmark of 1, target organs were identified for each COPC for the ingestion and inhalation exposures. The maximum HI per target organ/critical effect was 0.37, which is below the benchmark of 1. In addition, the maximum combined HI, which represents the sum of the HI for the whole body effect and each individual target organ HI, is 0.49, which is below the benchmark of 1.

In conclusion, based on the assumptions and scenarios used to evaluate the potential cancer risk and non cancer hazard, the calculated Excess Lifetime Cancer Risks, and Noncancer Hazard Indices for all COPCs combined and across all exposure pathways, fall within, or are less than the acceptable USEPA range and benchmark. Therefore, adverse long term (i.e., chronic) life time cancer risk and non cancer effects are not expected to occur from the combined inhalation and ingestion exposure to the estimated project's emissions.

Dioxins and Furans Noncancer Hazard Evaluation

Table 5, below presents the estimated Dioxin and Furan (expressed as 2, 3, 7, 8- TCDD toxic equivalents "TEQ") intakes from indirect (i.e., non -inhalation) exposure (i.e., ingestion) for each adult and infant receptor, and a comparison with the national average background exposure level (USEPA 2005b) for an adult of 1 picograms (pg)[4]/kg-day and for a nursing infant of 60 pg/kg-day. In this estimate, the infant exposure to the dioxin/furans is through breast milk ingestion.

Table 5: Comparison of 2, 3, 7, 8-TCDD TEQ Exposures (Ingestion) Estimates and Background Exposure Levels

Receptor Population	**2,3,7, 8-TCDD TEQ Exposure Estimate pg/kg-day**	**National Average Background 2,37,8-TCDD TEQ[5] Exposure Level pg/kg-day**
Urban Resident Adult	0.001	1
Suburban Resident Adult	0.001	1
Farmer Adult	0.002	1
Fisher Adult	0.001	1
Urban Resident Infant	0.03	60
Suburban Resident Infant	0.03	60
Farmer Infant	0.06	60
Fisher Infant	0.03	60

As shown in Table 5 the level of exposure estimates for both the adult and infant are less than the national average background exposure level. Therefore, health effects are not expected from ingestion exposure to the estimated project's D/F emissions.

[4] Units of mass: 1 picogram (pg) = 0.001nanograms (ng) = 0. 000001 micrograms (ug) = 0.000000000001 grams (g)

[5] TCDD TEQ-Tetrachloro dibenzo-p -Dioxin toxic equivalents

Acute Exposure Evaluation

The potential for acute (i.e., short -term) exposures risks through inhalation associated with emissions estimated to result from the facility was also evaluated for off property receptors, at the location of maximum impacts within 10 km radius of the project.

This was accomplished by comparing modeled short-term 1-hour maximum ambient air concentration of COPC with the acute index inhalation exposure criterion and by calculating a non cancer hazard quotient for each COPC. The non-cancer hazard index, which represents the potential for non-cancer adverse health effects from cumulative exposure to the COPCs of 0.02, is less than the target index of 1. In conclusion, based on this analysis, adverse short-term inhalation effects are not expected to occur from exposure to the estimated project's emissions. As with the chronic non-cancer HI, acute HIs of less than 1 are considered acceptable.

Conclusion for HHRA

The analysis completed in the HHRA showed that potential risks associated with the combined emissions estimated to result from the two proposed combustors were below USEPA cancer risk range and benchmark levels for human health. Consequently, the EA's project is not expected to have an adverse impact on human health.

SCREENING LEVEL ECOLOGICAL RISK ASSESSMENT

The Screening Level Ecological Risk Assessment (SLERA) evaluates the potential ecological risks to ecological receptors from exposure to combined emissions estimated to result from the two EA's proposed combustors. The SLERA focuses on evaluating potential adverse effects to ecological receptors (e.g., mammals, birds, plants, etc.,) which potentially could be found in habitat areas located within 10 km radius[6] of the project from estimated chemicals of potential ecological concern (COPECs)[7] in soil, surface water, and sediment (within 10 km area) as a result of the estimated project's emissions.

The primary exposure pathway identified for this SLERA involves transport of COPECs from the facility via stack emissions and subsequent deposition to ecological habitat areas (i.e., open water, estuarine area, wetlands (tidal wetlands, freshwater wetlands), and upland forested habitat in the karst region, conservation areas, and natural areas). It was assumed that the chemicals (i.e., COPEC) emitted from the combustors are dispersed and deposited as either vapors or particulates (i.e., particles or particle bound).

This SLERA has been prepared following USEPA guidance, which recommends a four-step process consisting of problem formulation, exposure assessment, effects assessment, and risk characterization. A conceptual site model (CSM) identifies potentially complete exposure pathways near the facility. For an exposure pathway to be complete, it must contain a source, a transport mechanism, an exposure point, and a receptor present at the exposure point.

[6] See INTRODUCTION/ Area Evaluated of this document for the rationale used in selecting the 10 km - Radius used for evaluating the ecological risks.
[7] See INTRODUCTION/ Chemicals Evaluated of this document for details about the COPEC.

Assessment and measurement endpoints are identified during the problem formulation stage. Assessment endpoints are defined as explicit expressions of the actual environmental value that is to be protected – an ecological entity and its attributes. For this SLERA, the assessment endpoints selected are the survival, growth, and reproduction of plants, birds, and mammals. The measurement endpoints selected for this SLERA include comparisons of soil, surface water, and sediment COPEC concentrations to ecological-based screening level (EBSLs).

EBSLs are defined as media-specific COPEC concentrations above which there is sufficient concern regarding adverse ecological effects to warrant further investigation. The EBSLs used in this SLERA include USEPA Ecological Soil Screening Levels, USEPA ambient surface water criteria, and appropriate sediment values.

Several resources were used to identify ecologically sensitive areas (ESAs), where the potential ecological receptors could be found, surrounding the proposed facility including the U.S. Fish and Wildlife Service, the Department of Natural and Environmental Resources of Puerto Rico, and National Wetland Inventory maps. Within the 10 km radius, the following ESAs were identified:

- Rio Grande de Arecibo adjacent to the proposed facility

- Rio Grande de Arecibo Estuary/Priority Conservation Area

- Forested Wetlands 3 km west of the proposed facility

- Woodlands 5 km west of the proposed facility

- Woodlands at Rio Abajo State Forest 6 km southwest of the proposed facility

- Forested and Emergent Wetlands 5 km south of the proposed facility

- Woodlands at Cambalache State Forest 7 km south of the proposed facility

- Reserva Natural Cano Tiburones 2 km northeast of the proposed facility

- Puerto Arecibo

AERMOD estimated soil, surface water, and sediment concentrations in each of the ESAs listed above. The results showed that the Woodlands at Cambalache State Forest had the lowest COPEC concentrations in soil and the Forested Wetlands to the west of the proposed facility had the highest soil concentrations. The Puerto Arecibo area showed the lowest concentrations of COPECs in surface water and sediment and the Reserva Natural Cano Tiburones showed the highest concentrations.

The effects assessment compares the modeled exposure-point concentrations of COPECs in soil, surface water, and sediment to EBSLs for different classes of receptor organisms and plants. These comparisons provide information on potential impacts to ecological receptors and form the basis for assessment of ecological risk. Based on the data screening results, the following conclusions are identified:

- For soil, all of COPECs concentrations are expected to be very low and typically more than 3 orders of magnitude less than the EBSLs for a range of ecological receptors including plants, invertebrates, birds, and mammals. As a result, potential adverse effects to ecological receptors from COPEC concentrations in soil are unlikely.

- For surface water, all of the COPEC concentrations in all of the ESAs were more than one order of magnitude less than the EBSLs. As a result, the potential for risk to ecological receptors exposed to surface water is expected to be negligible.

- For sediment, all of the COPEC concentrations in all of the ESAs were more than 3 orders of magnitude less than the EBSLs. As a result, the potential for risk to ecological receptors exposed to sediment is expected to be negligible.

Ecological species (i.e., ecological receptors) such as birds (e.g., parrots), mammals, reptiles (e.g., snakes), aquatic species (e.g., turtles, fish, amphibians), and other organisms, as well as plants may be present in the above ESAs analyzed by this SLERA. The EBSLs are meant to be protective of these species of animals and plants.
As described above, the estimated concentration of all COPECs (for soil, surface water, and sediment), in the ESAs are much lower than their appropriate ESBLs screening values (i.e., more than 3 orders of magnitude less for soil and sediment, and more than one order of magnitude for surface water), and therefore, no potential for risk to ecological receptors exposed to soil, surface water, and sediment is expected.

Conclusion for SLERA

The analysis completed in the SLERA showed that based on the comparison of the estimated COPECs concentrations to the EBSLs for soil, surface water, and sediment, adverse health effects in the ecological receptors are not expected.