

Enfoque para evaluar la influencia de una planta de valorización energética: estudio de un caso en Gipuzkoa (País Vasco, España)

Abordagem para avaliar a influência de uma central de valorização energética: estudo de caso em Gipuzkoa (País Basco, Espanha)

Approach for assessing the influence of an Energy Recovery plant: A case study in Gipuzkoa (Basque Country, Spain)

Loreto Santa-Marina^{1,2,3}, Amaia Irizar^{1,3,4}, Aitana Lertxundi^{1,3,4}, Nerea Urbietta¹, Ziortza Barroeta^{1,4}, Alba Jimeno-Romero¹, Miren Begoña Zubero^{1,4}, Jesús Ibarluzea^{1,2,3,5}

¹ Biogipuzkoa Health Research Institute, Group of Environmental Epidemiology and Child Development, Paseo Doctor Begiristain s/n, 20014, San Sebastian, Spain.

² Department of Health of the Basque Government, Subdirectorate of Public Health of Gipuzkoa, Avenida Navarra 4, 20013, San Sebastian, Spain.

³ Spanish Consortium for Research on Epidemiology and Public Health (CIBERESP), Instituto de Salud Carlos III, C/Monforte de Lemos 3-5, 28029, Madrid, Spain.

⁴ Department of Preventative Medicine and Public Health, University of the Basque Country (UPV/EHU), Leioa, Bizkaia, Spain.

⁵ Faculty of Psychology, University of the Basque Country (UPV/EHU), 20008 San Sebastian, Spain.

Cita: Santa-Marina L, Irizar A, Lertxundi A, Urbietta N, Barroeta Z, Jimeno-Romero A, Zubero MB, Ibarluzea J. Approach for assessing the influence of an Energy Recovery plant: A case study in Gipuzkoa (Basque Country, Spain). *Rev Salud ambient.* 2024; 24(1):54-63.

Recibido: 25 de marzo de 2024. **Aceptado:** 21 de mayo de 2024. **Publicado:** 15 de junio de 2024.

Autor para correspondencia: Ziortza Barroeta
Correo e: ziortza.barroeta@ehu.eus

Financiación: The Gipuzkoa Provincial Council funded this research, conducted between 2017 and 2024 before and after the operation of the waste-to-energy plant, through two public tender (017/11-HH-ZE and 2020/04-HH-ZE). However, the funding source did not play any part in the study's design, data collection and analysis, or the interpretation and writing of the manuscript.

Declaración de conflicto de intereses: The authors declare the following financial interests/personal relationships, which may be considered as potential competing interests: Jesus Ibarluzea reports that Gipuzkoa Provincial Council provided financial support.

Declaraciones de autoría: L. Santa Marina: conceptualization, methodology, investigation, writing – original draft preparation, funding acquisition; A. Irizar: conceptualization, methodology, reviewing and editing, funding acquisition; A. Lertxundi: conceptualization, methodology, reviewing and editing, funding acquisition, supervision; N. Urbietta: conceptualization, methodology, investigation; Z. Barroeta: writing – original draft preparation; A. Jimeno: conceptualization, methodology, investigation; M.B. Zubero: conceptualization, methodology, reviewing and editing, funding acquisition, supervision; J. Ibarluzea: conceptualization, methodology, reviewing and editing, funding acquisition.

Resumen

En la Unión Europea, la creciente generación de residuos, junto con las dificultades para encontrar nuevos lugares para su eliminación, han llevado a optar por la incineración como alternativa a la gestión de residuos no reutilizables o reciclables, valorizándolos y generando energía. La incineración de residuos, sin embargo, genera una serie de contaminantes que se han asociado con efectos sobre la salud humana y el medio ambiente. Varios estudios han analizado el impacto que producen las plantas de valorización energética, comparando la concentración de contaminantes tanto en el aire como en muestras biológicas donadas por la población que vive cerca y lejos de estas instalaciones. Una limitación notable en la investigación existente es la escasez de datos de referencia sobre dioxinas, furanos y PCB en el aire y en la población general antes del inicio de operaciones de la planta. Estos datos facilitan comparaciones significativas con los niveles posteriores a la puesta en marcha. Este artículo delinea la metodología empleada para evaluar el impacto en la calidad del aire y la salud pública resultante de la implementación de una instalación de recuperación de energía a través de una incineración de residuos urbanos (planta de conversión de residuos en energía) en Gipuzkoa, ubicada en el País Vasco, España. Esta metodología incluye la medición de los niveles de contaminantes en el aire, el nivel de exposición de la población mediante la medición de la carga corporal de contaminantes y las concentraciones en el suelo y en los alimentos de producción local. Además, se ha evaluado el estado de salud de la población tanto a corto como a largo plazo, así como la valoración del riesgo por exposición a la contaminación atmosférica.

Palabras clave: planta de valorización energética (conversión de residuos en energía); metodología; efectos en la salud; niveles de población; niveles ambientales.

Abreviaturas: PM: Partículas; HAP: Hidrocarburos aromáticos policíclicos; PCDD: Dibenzo-p-dioxinas policloradas; PCDF: dibenzofuranos policlorados; PCB: bifenilo policlorado; ERP: Planta de recuperación de energía; WTE: Planta de conversión de residuos en energía; IRSU: Incineración de residuos sólidos municipales; IARC: Agencia Internacional para el Estudio del Cáncer.

Resumo

Na União Europeia, a crescente geração de resíduos, juntamente com as dificuldades para encontrar novos locais para sua eliminação, levaram à opção pela incineração como alternativa para a gestão de resíduos não reutilizáveis ou recicláveis, valorizando-os e gerando energia. A incineração de resíduos, no entanto, gera uma série de contaminantes que têm sido associados a efeitos sobre a saúde humana e o ambiente. Vários estudos analisaram o impacto produzido pelas unidades de valorização energética, comparando a concentração de contaminantes tanto no ar quanto em amostras biológicas doadas pela população que vive perto e longe dessas instalações. Uma limitação evidente na pesquisa existente é a escassez de dados de referência sobre dioxinas, furanos e PCB no ar e na população em geral antes do início das operações das centrais. Esses dados facilitam comparações significativas com os níveis posteriores ao início das operações. Este artigo delinea a metodologia empregada para avaliar o impacto na qualidade do ar e na saúde pública resultante da implementação de uma instalação de recuperação de energia através da incineração de resíduos urbanos (central de conversão de resíduos em energia) em Gipuzkoa, localizada no País Basco, Espanha. Esta metodologia inclui a medição dos níveis de contaminantes no ar, o nível de exposição da população através da medição da carga corporal de contaminantes e as concentrações no solo e nos alimentos de produção local. Além disso, foi avaliado o estado de saúde da população tanto a curto como a longo prazo, bem como a avaliação do risco por exposição à poluição atmosférica.

Palavras chave: Central de valorização energética (conversão de resíduos em energia); metodologia; efeitos na saúde; níveis da população; níveis ambientais.

Abreviaturas: PM: Partículas; HAP: Hidrocarbonetos aromáticos policíclicos; PCDD: Dibenzo-p-dioxinas policloradas; PCDF: Dibenzofuranos policlorados; PCB: Bifenil Policlorado; ERP: Central de recuperação de energia; WTE: Central de conversão de resíduos em energia; IRSU: Incineração de resíduos sólidos urbanos; IARC: Agência Internacional para a Investigação do Cancro.

Abstract

In the European Union, the escalating generation of waste, together with the difficulties in finding new places for its disposal, have led to choose for incineration as an alternative to the management of non-reusable or recyclable waste, recovering it and generating energy. The incineration of waste, however, generates a series of contaminants that have been associated with effects on human health and the environment. Several studies have analysed the impact produced by energy recovery plants, by comparing the concentration of pollutants both in air and in biological samples donated by the population living near and far from these facilities. A notable limitation in existing research is the scarcity of baseline data on dioxins, furans, and PCBs in air and in the general population prior to the plant's start of operations. Such data facilitates meaningful comparisons with post-start-up levels. This article delineates the methodology employed to assess the impact on air quality and public health resulting from the implementation of an energy recovery facility through an urban waste incineration (waste-to-energy plant) in Gipuzkoa, located in the Basque Country, Spain. This methodology includes the measurement of the levels of contaminants in air, the level of exposure of the population by measuring the body load of contaminants, and the concentrations in soil and locally produced food. Furthermore, the health status of the population has been evaluated in both the short and long term, as well as the assessment of the risk from exposure to air pollution.

Keywords: energy recovery plant (waste-to-energy); methodology; health effects; population levels; environmental levels.

Abbreviations: PM: Particulate matter; PAH: Polycyclic aromatic hydrocarbons; PCDD: Polychlorinated dibenzo-p-dioxins; PCDF: Polychlorinated dibenzofurans; PCB: Polychlorinated biphenyl; ERP: Energy recovery plant; WTE: Waste to energy plant; MSWI: Municipal solid waste incineration; IARC: International Agency for the Study of Cancer.

INTRODUCTION

In Europe, incineration has emerged as a solution for handling waste that is not suitable for reuse or recycling^{1,2}. In the last decades, numerous waste-to-energy plants (WTE) have been established. Despite the

inherent benefits of this waste management approach, including a substantial reduction in waste volume resulting in energy generation, incineration remains a subject of significant concern and robust social debate. This apprehension primarily stems from the health effects associated with the emissions from these facilities³.

The correlation between air pollution and health is shaped by diverse factors, encompassing the nature and concentration of pollutants, exposure duration, and individual susceptibility⁴. Particularly concerning in the context of emissions from WTE are air pollutants such as particulate matter (PM), benzo(a)pyrene, 2,3,7,8-tetrachlorodibenzo-p-dioxin, and metals (Cd, As, and Ni). These pollutants are of heightened concern as they are all classified as carcinogenic to humans by the International Agency for Research on Cancer (IARC). Exposure to these pollutants is associated with various health issues, including respiratory problems such as chronic obstructive pulmonary disease (COPD), asthma, bronchiolitis, as well as more severe conditions such as lung cancer, cardiovascular events, central nervous system dysfunctions, and skin diseases⁴.

Beyond assessing atmospheric exposure, the examination of contaminants in food, water, and soil is pivotal as it provides an indirect measure of exposure^{5,6}. The evaluation of internal exposure entails measuring the levels of contaminants present in the human body. The levels of internal exposure will allow us to directly know the level of exposure of the population. The most common method to assess internal exposure is biomonitoring in biological samples⁷, such as blood, urine or hair. By including all absorption pathways and considering all relevant exposure sources, it makes it an exemplary instrument for risk assessment by providing direct and personalized data on internal exposure levels in particular for exposure to toxic substances. Hence, it facilitates the identification of new exposures, trends, vulnerable groups, and populations with heightened exposures. Moreover, it aids in pinpointing environmental risks at specific contaminated sites⁸. This enhanced accuracy in health risk assessment ultimately facilitates, when necessary, the implementation of measures to mitigate exposure⁷. Engaging in risk assessment and risk management without incorporating Human Biomonitoring (HBM) may lead to inaccurate risk estimates and the implementation of inadequate measures⁸.

Extensive research has explored the immediate and prolonged impacts of air pollution on human health⁹. Regarding short-term effects, mortality is one of the most studied effects. The percentage change in all-cause deaths attributable to short-term particulate matter exposure has been estimated to range between 0.4 and 1.5 % for each 20 $\mu\text{g}/\text{m}^3$ increase in PM10 and 0.6–1.2 % for every 10 $\mu\text{g}/\text{m}^3$ increase in PM2.5¹⁰. The increase in hospital admissions caused by cardiovascular and respiratory disease has also been studied in relation to increasing levels of air pollution^{11,12}. Likewise, maternal exposure to air pollution has been associated with adverse effects on fertility, pregnancy, childbirth, and prenatal growth^{13,14}.

Beyond its immediate impacts, air pollution has now been proven to exert long-term effects on health, influencing health in more profound yet challenging to quantify ways¹⁵. One of the long-term effects extensively studied concerning WTE is their potential association with cancer and congenital malformations^{16,17}. A systematic review and meta-analysis¹⁸ by synthesized cohort studies investigating the link between ambient particulate matter (PM) and cancer risk. The pooled relative risks for lung cancer incidence or mortality associated with every 10 mg/m^3 increase in PM2.5 or PM10 were 1.16 and 1.22, respectively. Similarly, another meta-analysis focused on evaluating the relationship between maternal exposure to particulate matter during pregnancy and the risk of congenital anomalies. The findings revealed that each 10 $\mu\text{g}/\text{m}^3$ increase in PM10 exposure was associated with an elevated risk of 1.05 for congenital heart disease, 1.04 for neural tube defects, and 1.03 for cleft lip with or without cleft palate¹⁹.

It is crucial to highlight that evidence linking incinerator emissions to health effects primarily pertains to older incinerators characterized by inadequate quality controls and outdated technologies^{20,21}. Typically, controls are chosen based on their proximity to WTE rather than considering the atmospheric dispersion model of emissions. Additionally, Campo et al. highlighted the absence of crucial variables needed to eliminate confounding factors related to exposure, including diet, lifestyle habits (such as tobacco and alcohol consumption), medication consumption, area of residence (rural/urban), and occupational exposure, among others²². Given the absence of clear and conclusive evidence regarding the health effects stemming from these facilities, there is low public acceptance, and WTE are perceived as a health and environmental risk³. Therefore, it is imperative to conduct a thorough assessment of the health risks associated with WTEs.

In this context, the recent development of a waste-to-energy plant in Gipuzkoa, located in the Basque Country, Spain, has provided an ideal framework for conducting a study aimed at assessing the influence of the WTE on air quality and health of the local population. The study comprises environmental monitoring, human biomonitoring, and the evaluation of both short- and long-term health effects of exposure to air pollution. This endeavour seeks to outline the methodology employed and its practical implementation.

MATERIAL AND METHOD

1. STUDY AREA

The research site is situated in the northeastern part of Spain within the province of Gipuzkoa, located in the Basque Country (Figure 1). Spanning an area of 1,980 km^2 ,

Figure 1. Study area detailing the location of the WTE, the main roads and the main important industries according to the PRTR-Spain. The location of the air sampler's are also included, and the municipalities of residence of the population whose biomarkers were measured are highlighted

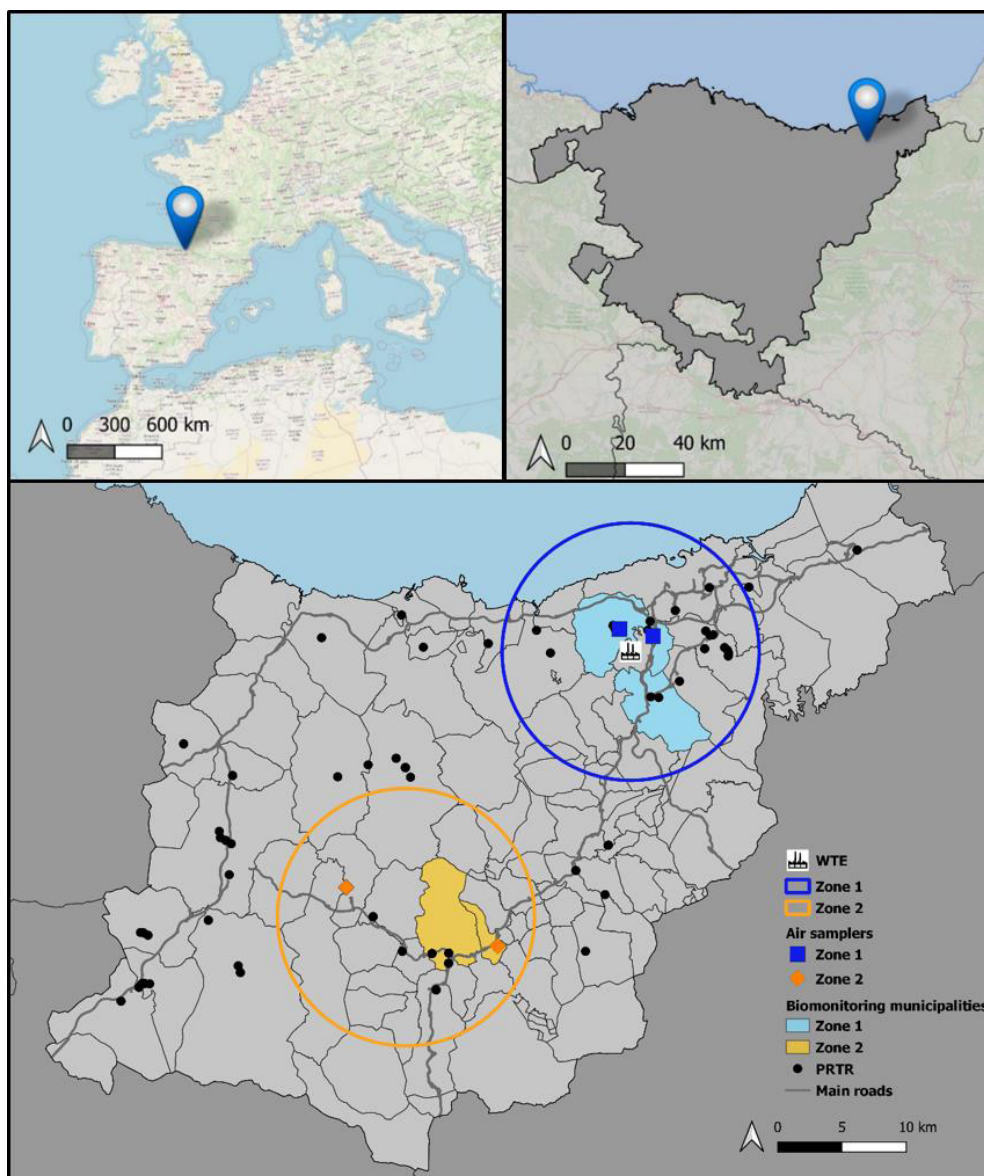


Table 1. Comparison of average daily traffic intensity in different years and the percentage of the population with each deprivation index among the study zones (Zone 1 and Zone 2)

Zone	Average daily traffic intensity					
	2017	2018	2019	2020	2021	2022
Zone 1	53842	55657	53760	42425	48144	52219
Zone 2	49440	51352	52948	43008	49779	49560

Zone	Deprivation index (% of the population)				
	1	2	3	4	5
Zone 1	22.69	11.93	42.21	15.10	8.06
Zone 2	13.13	25.62	20.41	29.95	10.89

Gipuzkoa is a densely populated region known for its high economic and social development, with a prominent industrial sector shaping its economy.

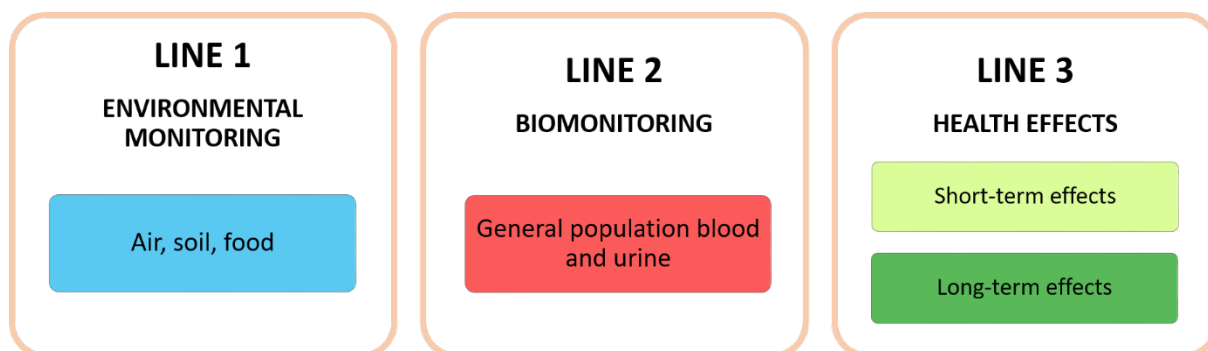
To assess the immission levels experienced by the population and analyze the extent of the impact, two comparable zones were established in terms of population density, sociodemographic characteristics (the majority of the population with a deprivation index 3 or 4), traffic intensity (average daily traffic intensity around 50 000) (Table 1) and industrial activity, documented in the Spanish Registry of Polluting Emitting Sources (PRTR-Spain) as emitters of polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/F) and dioxin-like polychlorinated biphenyls (dl-PCB): «Zone 1,» denoting the area of influence of the WTE, and «Zone 2,» designated as the control zone situated 28 km from the WTE. Air collectors were placed considering prevailing winds and air dispersion models, a potential impact zone of 15 km was defined for the WTE, with a maximum influence radius of 5 km.

2. STUDY DESIGN

This is a pre-post control-impact study that measures the impact as the difference between the situation before, and the situation after the intervention. During the period from October 2017 to February 2020, the characterization of contaminants was conducted in biological samples, as well as in air, soil, and locally produced food, establishing “baseline” prior to start-up (referred to as the pre-start-up period). This assessment encompassed both the exposed zone or “Zone 1” and the control zone or “Zone 2.” Subsequently, the analysis of contaminants in the same matrices during the post-start-up period took place between February 2020 and December 2023.

To establish the impact of the start-up of the plant three research avenues have been established, including: 1) environmental monitoring, entailing the measurement of contaminants in air, food, and soil; 2) biomonitoring of contaminants in biological samples collected from the general population; and 3) an assessment of the effects

Figure 2. Schematic diagram of the research lines of the project



on the health of the population (see Figure 2). In each line, considering the characteristics of environmental exposures, exposed population and health effects, the parameters to be determined in each line and the statistical treatment of the resulting data have been established.

Line 1: Environmental monitoring

The immission levels of dioxins, particulate matter (PM), polycyclic aromatic hydrocarbons (PAHs), and trace elements associated with PM in the air were measured in both zones and during both periods. Considering that atmospheric deposition facilitates the transfer of particles and contaminants from the atmosphere to the soil and crops, the analysis extended to include the examination of PCDD, PCDF, and dl-PCB in soil and locally produced foods across both areas and periods.

Line 1.1: Atmospheric pollutants

This study targeted atmospheric pollutants including PM₁₀, PM_{2.5}, trace elements associated with PM_{2.5}, PAHs, PCDD/F, and PCB. Active samplers, specifically DIGITEL DHA-80 for PM_{2.5} and PALAS Fidas 2005 fine particle aerosol spectrometers for PM₁₀, were utilized for PM sampling. Samplers were placed in urban areas representative of the immission levels. Providing daily information on pollutant concentrations, enabling the identification of short-term variations in pollution levels and specific pollution episodes. The collection of PCDD/F and PCB involved both active sampling using DIGITEL DHA-80 collectors and passive sampling over three-month periods with polyurethane foam filters (PUF) (diameter 10 cm x length 10 cm) positioned in the same locations as the active collectors. Twenty-four-

hour samples were collected for 22 days each month to measure PM_{2.5}, associated trace elements, and PAHs. Measurements of PM₁₀ and PM_{2.5} were conducted for one month during each season of the year (summer, autumn, winter, and spring). The collection of PCDD/F and dl-PCB was conducted actively and passively on a quarterly basis, specifically during the summer and winter months. Details regarding air sample collection and chemical analysis can be found in the work by Santa-Marina et al.²⁹ This approach aimed to capture seasonal variations. In the case of active collections, samples were collected during both weekdays (Monday-Friday) and weekends (Saturday-Sunday) to observe the potential impact of industrial activity. The methodology employed for pollutant measurements in air adhered to the specifications outlined in Spanish Royal Decree 102/2011, dated January 28, pertaining to the enhancement of air quality, and Royal Decree 39/2017, dated January 27, which brought partial modifications to the former.

The assessment of the impact resulting from the implementation of the WTE involved a comparative analysis of PM_{2.5} and trace element values before and after the implementation in both zones (Zone 1 and Zone 2). This evaluation utilized a Before-After/Control-Impact (BACI) design, a method introduced by Green and subsequently refined by Bernstein and Zalinski, Stewart-Oaten et al., Underwood, and later revised by Underwood and Stewart-Oaten and Bence²³⁻²⁸. Unlike many previous studies that often neglect the temporal trend of the data, this novel methodology takes into account the temporal intravariability, providing a comprehensive understanding of whether changes occurred in the areas and the trend of change over time. It must be pointed out that the data between 2020 and 2021 were not taken into account since they belong to the period of Covid restrictions.

Line 1.2: Food and soil

The primary route of population exposure to PCDD/F and PCB is through the diet, particularly via foods rich in fat due to their lipophilic nature. The objective of this research line was to ascertain the concentration of PCDD/F and dl-PCB in locally produced milk and eggs, as well as in the soil, of both the exposed and control areas associated with the WTE. A total of 50 samples of soil and locally produced food (milk and eggs) from both zones (Zone 1 and Zone 2) underwent analysis in the pre-start-up period and in the post-start-up period at the same locations. The results were expressed in toxic equivalence (TEQs), as defined by the World Health Organization in 2005, and in international TEQs (I-TEQ) for dl-PCBs in soil. Comparative assessments of PCDD/F and dl-PCB

levels in milk, eggs, and soil from the two areas and periods were conducted, employing non-parametric contrasts of paired samples.

Line 2: Human Biomonitoring

The internal levels of PCDD, PCDF, and dl-PCB in serum, as well as the levels of metals in urine, serum, and whole blood, have been assessed in the population residing in both zones (Zone 1 and Zone 2) during both periods (pre-start-up and post-start-up). Participants were selected through a simple random sampling method using censuses provided by the city councils of the five municipalities in the study area. The random sampling was stratified by sex and limited to individuals within the age range of 18 to 70 years. Inclusion criteria required participants to have resided in the municipality for the past five years, not to work/have worked in the last 5 years in industries associated with PCDD/F and dl-PCB, not be pregnant, and not have significant illnesses, which could affect biomarkers in blood and urine. These criteria were established to minimize potential confounding factors that could influence the study results. Between 2017 and 2018, 228 participants were recruited (122 from Zone 1 and 105 from Zone 2) during the pre-start-up period. In the post-start-up period, between 2021 and 2022, 231 participants were recruited (121 from Zone 1 and 110 from Zone 2). A total of 154 subjects participated in both periods (84 from Zone 1 and 70 from Zone 2). All participants provided informed consent, and the study received approval from the Ethics Committee of Basque Country (n°PI2016140 for the pre-start-up period and n°PI2020242 for the post-start-up period). Participants also completed a questionnaire covering sociodemographic variables, lifestyle factors, reproductive history for women, and the frequency of consumption of locally produced products. Details regarding blood sample collection, questionnaires, covariates, and chemical analysis can be found in the work by Santa-Marina et al.³⁰.

In the realm of data analysis, a descriptive examination was conducted for trace metals in urine, serum, and whole blood, as well as for PCDD/F and dl-PCB in serum. The difference in levels between areas and by period will be analyzed. The interaction between zone and period gives us an idea of the change in one zone compared to the other for each period, and in the same zone between periods.

To assess differences between the pre- and post-start-up periods, non-parametric paired sample contrasts were executed. Multiple linear regression models were employed for each contaminant, incorporating adjustments for sociodemographic factors, lifestyle variables, reproductive history and frequency of consumption of locally produced products. Several

variables, including study period (pre or post), study area, age, and sex, were retained in the models as design variables for the study.

Line 3: Health effects

This line of the study addresses the final objectives, all centred on the progression of the health status of the population resulting from the exposure to atmospheric pollution.

Line 3.1: Short-term effects: prenatal exposure

In the past decade, there has been an increasing body of evidence linking exposure to air pollution during pregnancy with adverse outcomes in fetal growth and length of gestation¹⁴. While the individual risks of air pollution on adverse pregnancy outcomes may appear relatively modest, the attributable risk at a population level (indicating the percentage of events, such as undesirable reproductive effects in this context) should not be underestimated.

To assess the impact of prenatal air pollution exposure on birth outcomes before and after WTE implementation, a retrospective follow-up study of pregnant women was conducted. The study focused on analyzing low birth weight (< 2 500 g) and prematurity (< 37 weeks) in relation to PM_{2.5} and trace element exposure. The two study areas previously described in this article were defined. Birth-related information, including sex, age, weight, height, date of birth, week of gestation, and mother's address, was obtained from the birth registry. The socio-economic variable could not be obtained from the health register, so it was decided to use the deprivation index created for each census section through the MEDEA study³¹. Two study periods were defined: the before period (births between 01/01/2018 to 01/04/2020) and the after period (births between 01/01/2021 to 21/12/2021). Births from April 2020 to December 2020 were not taken into account because it was an unusual period (COVID restriction period) that could have an impact on the results and was not related to the functioning of the WTE.

All pregnant women with births during those periods were georeferenced, and only women living within 4 km of one of the 4 study devices were selected. It is assumed that exposure to PM_{2.5} at this distance is highly correlated (see article 32). Therefore, pregnant women living in the same valley less than 4 km away have the same air device as a reference exposure. Exposure to PM_{2.5} and trace elements was estimated for each pregnant woman for each trimester of pregnancy and for the total pregnancy period.

Logistic regression models were constructed for each study area (Zone 1 and Zone 2) for each contaminant and each dependent variable, introducing the term of interaction between contaminant and period, in addition to the other covariates. Thus, it can be observed whether there is a different risk of prematurity and low birth weight depending on the period in each study area.

Line 3.2: Short-term effects: general health

In this line of work, to avoid an excess of zeros when dealing with a study area with a small population, a different methodology has been employed. In this case, the study area has been expanded to include 5 valleys, where industrial, steel, and metallurgical activities have been the predominant sources of pollution. This expansion helps mitigate the issue of excessive zeros that could arise. Each valley is equipped with a PM_{2.5} monitoring device from the air quality network.

To handle missing data, under missing at random assumption, we performed a multiple imputation by chained equations approach (MICE) ³³ by specifying for each variable with missing entries a CART model including all the other variables in the data set as predictors. We obtained 10 multiply imputed data sets fixing the MICE iterations to 30³⁴.

The health outcomes evaluated included total mortality and hospital admissions due to respiratory, cardiovascular, and cerebrovascular diseases. Mortality data were sourced from the Mortality Registry of the Basque Country (Spain), while morbidity data were obtained from the MBDS (Minimum Database Set) registry.

Poisson regression models were employed to analyse the relationship between daily events and daily exposure levels, adjusting for seasonality, meteorological variables, summer period, weekday, and influenza epidemics. The adjustment variables for the period 2010-2019 were modelled as follows: seasonality captured through "cubic spline" regression (with 7 degrees of freedom, df) + day of the week + holiday indicator + "cubic spline" regression for temperature with a delay of 0-3 days and 5 df + summer holiday indicator (July + August) + quadratic term for humidity + influenza epidemic indicator + linear term for pollutants. A delay of 0-1 days was utilized to address temporal autocorrelation and 0-3 days for hospital admissions.

The same methodology was applied to the metropolitan area of Donostia, where road traffic is the primary source of PM_{2.5}. This allowed for

the assessment of whether the risk before plant installation was consistent for individuals residing in urban versus urban-industrial areas. Consequently, estimates of the risk and impact of short-term PM_{2.5} exposure for the period 2010-2019 were obtained for both urban and urban-industrial areas.

In estimating the impact, this study calculated the potential reduction in deaths or hospital admissions if the annual average of each air pollutant studied were reduced by 20% or to the value recommended by the WHO. It should be noted that impact calculations assume a linear dose-response relationship. The subsequent step involves employing the same methodology for risk and impact estimation for the period 2021-2030.

Additionally, a sensitivity analysis for the exposure area will be conducted in this case. This analysis will assess whether the risk changes by excluding the area defined in this article as the "exposed" zone.

Line 3.3: Long-term effects: cancer and congenital malformations

The long-term effects associated with WTE include cancer and congenital malformations^{16,17}. Assessing long-term effects requires a considerably large sample size and a follow-up period of at least 10 years. As such, the incidence and mortality rates of cancer and congenital malformations at birth were evaluated as disease maps, excluding consideration of air pollution. Data for constructing disease maps were sourced from the Cancer Registry, Mortality Registry and Registry of Congenital Anomalies of the Autonomous Community of the Basque Country, Spain. All diagnosed invasive tumours, excluding non-melanoma skin cancers, were included in the analysis. For congenital malformations, information on each subject's gender, year of diagnosis or death, year of birth, and municipality was collected, specifically evaluating defects related to the heart, genitals, hips, urinary system, and nervous system. Disease maps were generated to express standardized mortality risk or standardized incidence risk, utilizing the smoothing model proposed by Besag, York, and Mollié³⁴. The smoothed risk estimation was conducted at the municipality level of aggregation. These maps depict geographic risk patterns, highlighting municipalities or areas with higher risk and assessing changes in geographic patterns of various neoplasms and malformations before and after the implementation of the WTE. If an increased risk is identified in the study area in the future, it would be prudent to consider conducting an analytical observational study. It's important to note that this line of work is solely descriptive and serves to generate hypotheses rather than establish causality.

RESULTS AND DISCUSSION

In the interest of transparency due to the concern and strong social debate generated by these facilities, the results have been made public. Hence, the public report comparing the situation before and after the operation of the WTE will soon be accessible in Spanish³⁵ and Line 3 is anticipated to be published soon, providing more detailed information regarding the methodology and pre-post evaluation, particularly in the case of reproductive effects. The assessment of health impact discussed in this article involves a comprehensive design, encompassing the simultaneous characterization of external and internal exposure in two distinct areas across two periods. The prior characterization of PCDD/F and dl-PCB concentrations in both air²⁹ and the general population³⁰ before the WTE's start of operations is crucial for establishing baseline reference levels. This aspect adds significant relevance to the study, enhancing our understanding of the potential impact of the WTE on both the environment and public health.

The study's approach, targeted to the general population, significantly enhances its relevance to public health concerns. The utilization of random sampling techniques in the recruitment process bolsters the validity of the study by minimizing bias in participant selection. The decision to analyse individual samples instead of pooling them contributes to a more precise assessment of each participant's exposure levels, enhancing the power of these data regarding precision risk assessment. Additionally, the inclusion of a reference or control area with industries emitting PCDD/F and PCB, considering the worst-case scenario related to incinerator plant pollutants, provides valuable insights into the baseline exposure levels of the population to these pollutants before the start-up of the WTE.

It is important to highlight that the methodology employed for comparing contaminant levels in air before and after start-up using the Before-After/Control-Impact (BACI) design could not be applied to PCDD/F and PCB due to the lack of a sufficiently extensive time series to discern trends over time, with the primary limiting factor being the high cost of completions. Within Line 3, there are several important limitations to mention. All three sublines of work rely on data collected from health records, which means that variables crucial for improving risk estimation may be missing. For example, in Line 3.1 and 3.2, confounding variables such as socio-economic status and smoking were unavailable. We attempted to address this issue in the reproductive effects study by incorporating the MEDEA deprivation index, which provides information on socio-economic status at an aggregate level, by census tract. In Line 3.2, apart from the use of register data, it's essential to recognize that this is an analysis based on aggregated data. This means that the unit of analysis is not the individual but rather

the number of admissions/deaths per day. Consequently, the results obtained could potentially suffer from the ecological fallacy. In such studies, it's not feasible to account for confounding variables at the individual level. Stratifying the analyses by factors such as sex and age could be considered, but this approach often leads to a reduction in sample size. Estimating risk over a 10-year period helps to achieve consistency in results. If there are no changes in the study population, consistent risk estimates with the same systematic error can be expected. Therefore, under the absence of other influencing factors, the two risks are expected to be similar. In the case of Line 3.3, as noted in its section, it is currently a descriptive study. The aim is to describe the pattern of smoothed risk and monitor its evolution. If variations in the exposure area are observed, consideration should be given to conducting an analytical observational study.

CONCLUSION

The comprehensive approach, combining external and internal exposure assessments, provides a thorough understanding of the environmental and health implications associated with the WTE's activity. The characterization of contaminant levels in air, soil, and locally produced food, along with biomonitoring of the general population, establishes a solid foundation for evaluating the potential impact on public health. The use of a BACI design for air quality assessment and a targeted analysis of individual samples enhance the precision and reliability of the study. Despite some limitations, such as the unavailability of a complete time series for PCDD/F and dl-PCB, the methodology applied here significantly enhances the possibilities for better determining the potential effects of WTEs' activities on the nearby population, thus being a valuable tool to be implemented in routine risk assessment analysis for policymakers. By considering spatiotemporal variations and demographic factors, this study contributes key insights into the factors influencing exposure levels. The random sampling technique and individual sample analysis strengthen the validity of the study, while the inclusion of a control area with known pollutant sources provides crucial baseline data. In essence, this study design has overcome inherent challenges, offering a comprehensive and reliable evaluation of the impact of the WTE on both environmental and public health. The results generated from this research are poised to contribute substantially to the broader understanding of the consequences of WTE operations, aiding in the formulation of evidence-based policies and interventions to safeguard community health.

ACKNOWLEDGEMENTS

The authors express their gratitude to the municipalities for their cooperation in allowing the placement of air collectors and ensuring their proper

functioning. As well as, to all the participants who selflessly donated their blood and to the personal healthcare centers of the municipalities where the blood samples were taken. This study would not have been possible without their support.

REFERENCES

1. European Commission, 2020. Circular Economy Action Plan. For a cleaner and more competitive Europe. Available in: https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en.
2. European Parliament, 2017. Amendments adopted by the European parliament on 14 March 2017 on the proposal for a directive of the European parliament and of the council amending directive 2008/98/EC on waste (COM(2015)0595 e C8-0382/2015 e 2015/0275(COD)). Strasbourg.
3. Subiza-Pérez M, Santa Marina L, Irizar A, Gallastegi M, Anabitarte A, Urbieto N, Babarro I, Molinuevo A, Vozmediano L, Ibarluzea J. 2020. Explaining social acceptance of a municipal waste incineration plant through sociodemographic and psycho-environmental variables. *Environ. Pollut.* 263, 114504.
4. Manisalidis I, Stavropoulou E, Stavropoulos A, Bezirtzoglou E. 2020. Environmental and health impacts of air pollution: a review. *Front. Public Health.* 8, 14.
5. Martí-Cid R, Perelló G, Domingo J L. 2009. Dietary exposure to metals by individuals living near a hazardous waste incinerator in Catalonia, Spain: temporal trend. *Biol. Trace Elem. Res.* 131, 245-54.
6. Mari M, Díaz-Ferrero J, Schuhmacher M, Nadal M, Domingo JL. 2013. Health risks of environmental exposure to PCDD/Fs near a hazardous waste incinerator in Catalonia, Spain. *Journal of Risk Analysis and Crisis Response.* 3(2).
7. Louro H, Heinälä M, Bessems J, Buekers J, Vermeire T, Woutersen M et al. 2019. Human biomonitoring in health risk assessment in Europe: Current practices and recommendations for the future. *Int. J. Hyg. Environ. Health.* 222(5), 727-37.
8. Angerer J, Ewers U, Wilhelm M. 2007. Human biomonitoring: state of the art. *Int. J. Hyg. Environ. Health.* 210(3-4), 201-28.
9. Folinsbee LJ, Raven P. 2001. Air pollution: acute and chronic effects. *Proceedings of Marathon Medicine 2000.*
10. Mannucci PM, Harari S, Martinelli I, Franchini M. 2015. Effects on health of air pollution: a narrative review. *Intern. Emerg. Med.* 10, 657-62.
11. Colonna KJ, Koutrakis P, Kinney PL, Cooke RM, Evans JS. 2022. Mortality attributable to long-term exposure to ambient fine particulate matter: insights from the epidemiologic evidence for understudied locations. *Environ. Sci. Technol.* 56(11), 6799-812.
12. Liang R, Chen R, Yin P, van Donkelaar A, Martin RV, Burnett R et al. 2022. Associations of long-term exposure to fine particulate matter and its constituents with cardiovascular mortality: A prospective cohort study in China. *Environ. Int.* 162, 107156.
13. Gheissari R, Liao J, Garcia E, Pavlovic N, Gilliland FD, Xiang AH, et al. 2022. Health outcomes in children associated with prenatal and early-life exposures to air pollution: a narrative review. *Toxics.* 10(8), 458.
14. Keplac P, Locatelli I, Korosec S, Kunzli N, Kukec A. 2018. Ambient air pollution and pregnancy outcomes: A comprehensive review and identification of environmental public health challenges. *Environ. Res.* 16, 144-59.

15. Schwartz J. 2000. Harvesting and long term exposure effects in the relation between air pollution and mortality. *Am. J. Epidemiol.* 151(5), 440-8.
16. Baek K, Park JT, Kwak K. 2022. Systematic review and meta-analysis of cancer risks in relation to environmental waste incinerator emissions: a meta-analysis of case-control and cohort studies. *Epidemiology and Health.* 44.
17. Parkes B, Hansell AL, Ghosh RE, Douglas P, Fecht D, Wellesley et al. 2020. Risk of congenital anomalies near municipal waste incinerators in England and Scotland: Retrospective population-based cohort study. *Environ. Int.* 134, 104845.
18. Yu P, Guo S, Xu R, Ye T, Li S, Sim MR et al. 2021b. Cohort studies of long-term exposure to outdoor particulate matter and risks of cancer: A systematic review and meta-analysis. *The Innovation,* 2(3).
19. Yu G, Chen Y, Tang J, Lin Z, Zheng F, Zheng C et al. 2021a. Meta-analyses of maternal exposure to atmospheric particulate matter and risk of congenital anomalies in offspring. *Environ. Sci. Pollut. Res.* 28(40), 55869-87.
20. Bena A, Gandini M, Cadum E, Procopio E, Salamina G, Oreggia, M et al. 2019. Risk perception in the population living near the Turin municipal solid waste incineration plant: Survey results before start-up and communication strategies. *BMC Public Health.* 19 (1): 1-9.
21. Zhang X. 2021. Conflicts and order: controversies over municipal solid waste incineration in China. PhD Thesis.
22. Campo L, Bechtold P, Borsari L, Fustinoni S. 2019. A systematic review on biomonitoring of individuals living near or working at solid waste incinerator plants. *Critical Reviews in Toxicology,* 49(6), 479-519.
23. Green RH. 1979. Sampling design and statistical methods for environmental biologists. John Wiley & Sons.
24. Bernstein BB, Zalinski J. 1983. Optimum sampling design and power tests for environmental biologists. *J. Environ. Manage.* 16(1), 35-43. United States.
25. Stewart-Oaten A, Murdoch WW, Parker KL. 1986. Environmental Impact Assessment: "Pseudoreplication" in Time? *Ecology.* 67(4), 929-40.
26. Underwood A. 1992. Beyond BACI: the detection of environmental impacts on populations in the real, but variable, world. *J. Exp. Mar. Bio. Ecol.* 161(2), 145-78.
27. Underwood A. 1993. The mechanics of spatially replicated sampling programmes to detect environmental impacts in a variable world. *Austral. Ecology.* 18(1), 99-116.
28. Stewart-Oaten A, Bence JR. 2001. Temporal and Spatial Variation in Environmental Impact Assessment. *Ecol. Monogr.* 71(2), 305-39.
29. Santa-Marina L, Barroeta Z, Irizar A, Alvarez JI, Abad E, Muñoz-Arnanz J, Jimenez B et al. 2023a. Characterization of PCDD/F and dl-PCB levels in air in Gipuzkoa (Basque Country, Spain). *Environ. Res.* 115901.
30. Santa-Marina L, Irizar A, Barroeta Z, Abad E, Lertxundi A, Ibarluzea J et al. 2023b. Serum levels of PCDDs, PCDFs and dl-PCBs in general population residing far and near from an urban waste treatment plant under construction in Gipuzkoa, Basque Country (Spain). *Environ. Res.* 236, 116721.
31. Domínguez-Berjón MF, Borrell C, Cano-Serral G, Esnaola S, Nolasco A, Pasarín MI et al. 2008. Construcción de un índice de privación a partir de datos censales en grandes ciudades españolas (Proyecto MEDEA). *Gaceta Sanitaria,* 22, 179-87.
32. Lertxundi A, Martínez MD, Ayerdi M, Álvarez J, Maiztegi M, Basterrechea, et al. 2011. Prenatal exposure to PM_{2.5} and its relationship with low birth weight in the inma-gipuzkoa cohort. In *ISEE Conference Abstracts 23* (Vol. 2011, No. 1).
33. Van Buuren S, Brand JP, Groothuis-Oudshoorn CG, Rubin DB. 2006. Fully conditional specification in multivariate imputation. *Journal of statistical computation and simulation,* 76(12), 1049-64.
34. Besag J, York J, Mollié A. 1991. Bayesian image restoration, with two applications in spatial statistics. *Annals of the institute of statistical mathematics,* 43, 1-20.
35. Diputación foral de Gipuzkoa: <https://www.gipuzkoa.eus/es/web/ingurumena/residuos-urbanos/infraestructuras>.