

## **Analysis of various studies of communities near the former TexPet oil operations in Ecuador**

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Starting in 1994, my colleagues and I at Cambridge Environmental have analyzed the scientific aspects of several studies of communities near the former TexPet oil operations in Ecuador. These reports have included:

- (1) *Rights Violations in Ecuador: Human Consequences of Oil Development in the Oriente* (1994) by the Center for Economic and Social Rights;
- (2) A draft document, “*Yana Curi*” *Report: Impact of Oil Activity on the Health of the Ecuadorian Amazon Basin Population* (1999) by M. San Sebastian and J. Cordoba;
- (3) A final report, *Informe Yana Curi: Impact of Oil Activity on the Health of Rural Population of the Ecuadorian Amazon* (2000) by M. San Sebastian and others;
- (4) San Sebastian *et al.*, (2001). “Exposures and cancer incidence near oil fields in the Amazon basin of Ecuador.” *Occup. Environ. Med.* 58(8):517-522;
- (5) San Sebastian *et al.*, (2001). “La salud de mujeres que viven cerca de pozos y estaciones de petroleo en la Amazonia ecuatoriana.” *Pan Am. J. Public Health* 9(6):375-384;
- (6) Hurtig and San Sebastian (2002). *Cancer en la Amazonia del Ecuador (1985-1998)* published by Instituto de Epidemiologia y Salud Comunitaria “Manuel Amunarriz,” Coca, Ecuador;
- (7) Hurtig and San Sebastian (2002). “Geographic differences in cancer incidence in the Amazon basin of Ecuador in relation to residence near oil fields.” *Int. J. Epidemiol.* 31:1021-1027;
- (8) Hurtig and San Sebastian (2002). “Gynecologic and breast malignancies in the Amazon basin of Ecuador, 1985-1998.” *Int. J. Gynecol. Obstet.* 76:199-201;
- (9) San Sebastian *et al.*, (2002). “Outcomes of pregnancy among women living in the proximity of oil fields in the Amazon basin of Ecuador.” *Int. J. Occup. Environ. Health* 8:312-319.

In what follows, I present a series of questions and answers surrounding these reports.

**1. Do these studies provide reliable scientific evidence that TexPet activities, including environmental contamination therefrom, have harmed the health of nearby populations?**

No, these studies do not provide reliable scientific evidence that the health of nearby populations has been harmed by TexPet activities or environmental pollution in the Oriente. The studies claim to show that health has been damaged in several ways: (1) that cancer rates are increased in villages or towns contaminated by TexPet activities; (2) that women in contaminated towns or villages have suffered higher rates of miscarriages; and (3) that men and women in contaminated towns or villages have higher rates of various other symptoms or illness. However, these studies are flawed in numerous respects such that their conclusions are not scientifically valid or justified. While I acknowledge and appreciate the challenges of conducting epidemiologic research in a region such as the Oriente, valid scientific conclusions require certain data and methods, many of which were lacking in this instance.

**2. What are some of the flaws in the studies claiming to find higher rates of *cancer* in contaminated areas?**

In the “Yana Curi” reports and in the published article relating the same data (document 4 listed above), cancer was assessed in only one village, San Carlos. No explanation was given for not assessing cancer experience of several “exposed” and “unexposed” communities, as was done for general health and reproductive outcomes (discussed below). Since San Carlos was not chosen at random from among exposed communities, but was investigated specifically because of concerns regarding cancer incidence, the analysis cannot be viewed as representative of exposed communities. Even if cancer were truly elevated in San Carlos for a period, this could have been due to chance.

Cancer tends to develop slowly. Cancers that are caused by chemicals (whether industrial pollutants, tobacco smoking, alcohol, or food substances) generally take several decades to develop. An exception is the blood and lymph cancers, which may develop more quickly, over a few or several years. The authors ignore the fact that exposures near in time to a cancer diagnosis probably were irrelevant to the development of disease. Indeed, it is common in cancer epidemiological studies to ignore the most recent 10 or so years of exposures when investigating whether exposure increases risk of cancer. Thus, it would be scientifically implausible to relate a newly diagnosed case of stomach cancer, for example, to an exposure that happened only one or a few years earlier. The investigators do not take this latency issue into account in their analyses.

The investigators did not discuss to what extent information on cancer incidence and mortality was likely to be complete for San Carlos, or whether the source and quality of information were comparable for San Carlos and the comparison community, Quito. Comparability of data in the two communities is critical to a valid analysis.

The study authors assume that cancer incidence rates in Quito, the capital city, are reasonable indicators of the expected incidence in Amazonian villages, but this assumption is highly questionable. The investigators do not explain whether the populations are sufficiently similar in racial make-up, relevant lifestyle characteristics, access to health care, accuracy of cancer diagnosis, accuracy of cause of death, and other germane factors to justify the comparisons.

The investigators assumed that the community was constant in population size throughout the study period. Moreover, given the relatively small population in 1998 (the first year studied), this assumption has a significant effect on the risk calculations. If the population grew over the years, then the cancer risks would be smaller than calculated. The authors should have at least commented on how different assumptions about population size during the decade would have influenced the incidence and mortality measures.

More cancer was found in men than expected, but less was found in women. Bias on the part of the investigators is suggested by their discussion of results: men are said to have an “unusually high” rate of cancer overall, but no mention is made of the fact that women apparently had an unusually low rate of cancer. Moreover, in no analysis was the *incidence* of total cancer or any specific cancer increased with statistical significance, so that elevations due to chance alone cannot be excluded. Single occurrences of cancer types were more common than multiple occurrences.

The investigators calculated a statistically significant increase in death from cancer in men, due entirely to three cases of stomach cancer. Stomach cancer, the most frequently detected cancer in San Carlos, is also the leading cause of cancer death among Ecuadorian men generally. As was described above, the mortality rate in San Carlos could be falsely inflated if the population size was underestimated.

The implied link between the single leukemia case seen in San Carlos and contamination is weakened by the facts that the case was of acute lymphocytic leukemia (ALL) in a child, and ALL is both the most frequent leukemia in children and a type of leukemia (as opposed to acute myelogenous leukemia, AML) *not* typically linked to chemical exposures.

Nothing in the “Yana Curi Report” indicates that specific cancer risk factors were explored in San Carlos (other than the statement that one person smoked). It is also fallacious to consider absence of

alternative risk factors as support for one's hypothesis about oil contamination, since, unfortunately, most cancers (other than those related to smoking) have no known cause.

Some of the same investigators conducted a larger study of cancer that involved the populations of several exposed and unexposed counties (documents 6 and 7 listed above). The study is an improvement over those criticized in that it examined a much larger population. However, significant flaws still remain, including several discussed above.

"Exposed" counties were defined as those in which petroleum activity occurred. However, there was no actual demonstration of pollution in water, air, or any other material to which people might be exposed, nor was it shown that a county's population was exposed to a similar degree, if at all, or that pollution was substantial enough to be a likely cause of any ill health.

It was assumed that the only factor pertinent to cancer and to its diagnosis that differed between exposed and unexposed counties was the so-called exposure to petroleum pollution. For some of the cancers that occurred at higher rates in "exposed" counties, there are well-known risk factors. The authors could not explore whether these risk factors differed between the two populations.

### **3. What are some of the flaws in the studies claiming to find higher rates of *miscarriage* in contaminated areas?**

Pregnancy outcomes were studied in the "Yana Curi" reports and also discussed in a published article (document 9 listed above). The environmental investigation used to identify contaminated and uncontaminated communities was inadequate for the purpose. Very little environmental data were collected in communities near to petroleum operations, and no data were collected in communities far from petroleum operations. Thus, the investigators simply assumed that the "uncontaminated" communities were uncontaminated. However, even if there were no nearby petroleum operations, there are many other ways for a community to have exposure to petroleum. For examples, oil might be used on dirt roads, or oil barrels used to collect rainwater, or fuel oils could be carelessly stored or handled. The investigators should have documented, with chemical analyses, that uncontaminated communities were truly uncontaminated.

If women in exposed communities have, through better health care, earlier confirmation of pregnancies than do women in unexposed communities, more miscarriages would likely be reported simply because a large fraction of early pregnancies terminate naturally. The investigators should have explored

possible differences in the ways by which pregnancy had been determined by women in the two communities.

In this kind of study, it is statistically and biologically incorrect to treat a woman's pregnancies as independent events, since women who miscarry once tend to miscarry again, regardless of chemical exposure. The analysis should have included only the most recent pregnancy, evaluated a larger number of women, or controlled statistically for repeated pregnancies; it could also have compared the fraction of women in exposed and unexposed communities with repeated miscarriages.

The discussion of confounding factors is incomplete. Access to health care, and prenatal care in particular, tobacco use, and alcohol use could be important factors in the risk of miscarriage.

The relative risk of miscarriage in contaminated communities was higher for earlier pregnancies than for later pregnancies. This could indicate that a risk factor used to be present but is less common now. More likely, however, was recall bias on the part of women in exposed communities. That is, women in exposed communities may be concerned about the possible effects of contamination and thus more likely than other women to remember short-lived pregnancies. A difference in the tendency of women to recall recent pregnancies, in contrast, is less likely, and would explain the absence of an increased risk of miscarriage for recent pregnancies.

#### **4. What are some of the flaws in the studies claiming to find higher rates of various *other symptoms or illnesses* in contaminated areas?**

Like the miscarriage study, the general health study of women was conducted in districts where residents were concerned about the impact of oil activities on their health. The results are discussed in the "Yana Curi" reports and in a published articles (document 5 listed above). This concern causes there to be a high potential for recall bias on the part of surveyed residents. To reduce the potential for this bias, the investigators should have selected districts with equivalent levels of contamination but without a high level of health concern, or studied clinically verifiable endpoints (which would not be subject to recall bias) rather than, or at least in addition to, subjective reports.

Also like the miscarriage study, "uncontaminated" villages were not proven to be so through any environmental data collection.

Heads of households were asked to fill out questionnaires regarding various health symptoms. However, there was no explanation for selection of specific health symptoms for analysis —

specifically, the authors did not demonstrate that, *a priori*, any of the symptoms are reasonable indicators of exposure to petroleum. What is the *basis* for inquiring about fever, frequent urination, and nose itch, for example? If the study was testing associations between exposure to petroleum and ill health, it should have focused on specific, petroleum-related symptoms.

Further, in order to detect any recall bias (or inadequate matching of communities), the investigators should have included some symptoms they felt would *not* reasonably be associated with petroleum exposure.

As for the results, relative rates of symptoms in the previous two weeks were not greatly elevated in exposed communities, as the largest adjusted estimate was 1.48. Only one symptom, skin fungi, was reported in statistical excess. Similarly, only itchy nose and throat pain occurred in statistical excess during the previous 12 months in exposed communities, with a maximum relative prevalence of 2.18. Why skin fungus, itchy nose, and throat pain might be associated with petroleum-contaminated water is not discussed.

The “Yana Curi” reports found that subjects in exposed communities were less likely than unexposed subjects to visit a doctor or take medicine in the previous two weeks, to be hospitalized in the previous 12 months, or to have a death in the home in the previous 12 months. The authors did not mention these differences (which are not statistically significant), although they could argue against the authors’ hypothesis that oil contamination adversely affected health and/or partly explain why health might be worse. In other sections of their study, the authors specifically mentioned health symptoms found to be increased among the exposed subjects, even though these differences, too, were statistically insignificant. This selective highlighting of results that favor the hypothesis, and silence regarding those that do not, is clearly inappropriate.

Overall, then, these reports fail to establish that oil operations in the Oriente have harmed health.