Critique of Barenys et al. (2014)  
“Heavy metal and metalloids intake risk assessment in the diet of a rural population living near a gold mine in the Peruvian Andes (Cajamarca)”

Introduction

Barenys et al. (2014) surveyed a group of rural Peruvians in 11 different areas within about 10 kilometers of a gold mine in Cajamarca, Peru. Based on reported food intake and concentrations of metals in food samples, they calculated dietary intakes of several metals, and compared these intakes to European Food Safety Authority (EFSA) standards. The authors’ overall conclusions are (1) the population’s health is at serious risk due to dietary exceedances of EFSA standards for arsenic (As), cadmium (Cd), and lead (Pb), and (2) intakes of As and Pb increase the closer the population is to the gold mine.

The data and methodology used by Barenys et al. (2014) are fundamentally flawed. Even if they were adequate, they do not support the authors’ conclusions; indeed, they contradict them. The authors’ assertion that there are “serious concerns for the population’s health” and recommendation that “it is reasonable to advise to La Pajuela population not to drink from the water sources in their area” are scientifically unsubstantiated.

Key Points

- Comparison of the Barenys et al. (2014) results with typical dietary intakes cited in EFSA scientific opinion documents indicates that sampled Cajamarca area residents are exposed to As, Cd, and Pb at levels similar to those of the general population of Europe. Thus, what the Barenys et al. (2014) study actually shows is that sampled Cajamarca residents have no greater dietary exposure to these metals and are at no greater risk of toxicity than are average Europeans.

- Because the existence of complete exposure pathways between the gold mine and various study locations was not established, Barenys et al.’s assumption that the gold mine is the source of metals in food items is invalid. Metals are naturally present everywhere in the environment, including in food, and the mine was not shown to be the source of metals in food samples or the cause of any adverse health effects.
• The group studied was not representative of the population. No rationale was provided for subject selection, and the very small study group does not reflect local demographics because:
  o The surveyed group consists primarily of teenaged males, who are unlikely to be able to provide dietary recall information that is accurate or generally applicable.
  o Women are severely underrepresented in the sample.
  o There is a mismatch between locations where food was sampled versus where dietary recall questionnaires were administered. Importantly, the dietary habits of residents of La Pajuela, the settlement closest to the mine which Barenys et al. purport to show is most affected by releases from the mine, were not determined.

• The very few food and water samples collected do not provide an adequate basis for exposure assessment for several important reasons:
  o The source of the sampled food items was not identified. The fact that a sample was obtained from a given location does not necessarily mean that it was produced there.
  o Establishing the mine as a significant source of metals in food items would require extensive environmental sampling (air, water, soil, sediment) – which was not performed.
  o Quantification of metals in sampled materials requires careful and thoroughly documented collection and transport methods, including field and trip blanks. The omission of critical details regarding sampling locations and methodologies precludes validation of Barenys et al.’s results.
  o Seasonal changes in dietary composition were apparently not considered. For example, certain plant and animal food items may be more or less available in different seasons.

• Because metals are naturally occurring and present everywhere in the environment, human exposure must be evaluated with respect to typical background (or reference area) exposures – that is, on a comparative basis. The absence of a reference area in this study precludes meaningful interpretation of calculated exposures. This is particularly true for the naturally mineralized zone being studied.

Specific Comments

Data
• Barenys et al. (2014) did not present the primary data underlying their calculations – the concentrations and forms of metals detected in food and water samples, detection frequencies, individual intake rates, and body weights. The study therefore fails to meet basic scientific standards in a critical respect: their calculations cannot be reproduced. This raises
questions about the effectiveness of the peer review that presumably occurred before acceptance for publication.

• Few food and water samples were collected for metals analysis (Table A^2). Although water was asserted to be the major dietary source of lead and arsenic (Table 1), very few water samples were collected, and no description of the sources or sampling procedures was provided (such as type of water (surface water, groundwater, spring), sampling location, well depth, productivity, piping materials (perhaps containing lead?), and number of people served).

Table A. Summary of Data Collected by Barenys et al. (2014)

<table>
<thead>
<tr>
<th>Collection site*</th>
<th>Number of people surveyed</th>
<th>Number of water samples</th>
<th>Number of food samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>La Pajuela</td>
<td>0</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Tual</td>
<td>10</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>La Ramada</td>
<td>4</td>
<td>4</td>
<td>36</td>
</tr>
<tr>
<td>Porcón Bajo</td>
<td>7</td>
<td>4</td>
<td>35</td>
</tr>
<tr>
<td>Cajamarca market</td>
<td>0</td>
<td>0</td>
<td>32</td>
</tr>
</tbody>
</table>

*Increasing distance from gold mine

• While there were 36 people included in the overall dietary survey, only 21 individuals lived in locations that also had food and water sampling. As noted previously, the origin of collected foods was not verified. Body weights were apparently only measured for 25 of the 36 subjects, further reducing the accuracy of daily intake rates.

• Barenys et al. (2014) did not identify the origin of the food sold in the markets, so cannot assume that metals released from the mine were present in that food. No indication was provided of the proportion of diet obtained from home gardens or local growers vs. the regional market in Cajamarca city. The fact that no subjects lived in, and few food samples were obtained from, La Pajuela, undercuts Barenys et al.’s conclusions that this area is most affected by alleged releases of metals from the mine.

Methodology

• Health regulatory agencies throughout the world have agreed on a consensus conceptual framework and methodology for assessing potential toxicological risks. This framework is described in many standard textbooks of occupational/environmental medicine and toxicology (e.g., Sullivan and Krieger 2001; Klaassen 2013) and integrated into numerous international

^2 Please note that figures and tables from the Barenys et al. (2014) paper are referred to by their numbers, while those presented as part of these comments are labeled alphabetically.
regulatory guidance documents (e.g., U.S. Environmental Protection Agency (EPA) (1989, 1992, 2014 and many others), World Health Organization (WHO) (1999, 2000, 2010 and many others). According to this consensus approach, a scientifically defensible conclusion that a chemical exposure caused a given health effect, or that any individual or group is at significantly increased risk of adverse effects from a certain chemical exposure, requires rigorous elucidation of each element of the logical sequence:

**Source → Exposure → Dose → Health Effect(s)**

Thus, an investigation to determine that an illness or health effect has been or could be caused by exposure to chemicals must proceed in a logical fashion that (1) establishes the presence of a complete exposure pathway\(^3\) linking a chemical source(s) to the human receptor, (2) estimates the concentration(s) of any source-related chemical(s) under investigation at the receptor’s location via measurements or modeling over the exposure period, (3) calculates or measures the dose received by the individual(s) at the exposure point, and (4) characterizes the potential health effects of the chemical(s) under investigation based upon the route of exposure and chemical-specific dose-response relationship(s). Because Barenys et al. (2014) did not establish these linkages, they cannot credibly associate exposure with the gold mine or any other specific source.

- No spatial analysis was done to substantiate the authors’ conclusion of a mine-related exposure gradient for As, Cd and Pb. La Pajuela, the site stated to be closest to the mine, is the only sampling location north of the mine.

- To be reliable, a survey study must establish that its subjects are representative of the general population of interest. Barenys et al. (2014) did not define their population of interest. Their study not only lacks any measure of how representative of the population the subjects examined are, no information is given regarding subject recruitment, and no characterization of any of the 11 locations where the subjects were drawn from is provided (save location and distance from the mine).

- Cajamarca is one of the few Peruvian regions in which the rural population outnumbers the urban population. Males slightly outnumber females, but the age structure of the population is the same for both sexes (Figure A).\(^4\)

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\(^3\) Defined as “the course a chemical or physical agent takes from a source to an exposed organism.” A complete exposure pathway includes a source or release from a source, an environmental transport/exposure medium (or media), an exposure point (location of potential contact between an organism and a chemical or physical agent), and an exposure route (i.e., ingestion, inhalation, dermal contact) (EPA 1989).

\(^4\) Cajamarca population data from Instituto Nacional de Estadística e Informatica (INEI) Perú (http://knoema.com/ocjysee/Perù-regional-dataset-december-2013). Note that Cajamarca population percentage totals are less than 100% because only relevant age groups are shown.
Of the very small population sample examined by Barenys et al. (n = 36), the majority were males aged 12 to 17 (n = 20) – proportionally one of the smallest age groups in the population (Figure A), while only eight were female (22%). This bias towards young males is also problematic as it is unlikely that young males would have accurate knowledge of and/or involvement in day-to-day food preparation. It is likely to result in an overestimate of intake by adults, who consume less per unit body weight than adolescents. Moreover, females typically consume less food per unit body weight than males (EPA 2011).

- Given that metals are naturally occurring and human exposure to them ubiquitous throughout the world, the lack of a defined background or reference site in this study limits interpretation

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5 Although the under-30 age ranges provided by Barenys et al. (2014) for their subjects (12-17 and 18-29) do not precisely match the corresponding INEI age structure intervals (12-16 and 15-29), they are sufficiently close for the qualitative comparisons illustrated in Figure A.
of the measured metals concentrations in different foods and calculated intakes. The widespread presence of metals in rice and other foods in many areas of the world is well established (e.g., Williams et al. 2007). The authors’ statement, “…the gold mine cannot be excluded as the origin of this contamination [of rice]” is more correctly expressed as there is no evidence that the gold mine was the source of any metals in rice sampled in the Barenys et al. study. No rice is grown in the vicinity of the mine. In fact, most of the food items identified are not likely to be produced anywhere near the mine.

**Metal Exposure and Risk Assessment**

**Arsenic**

- The only exceedance of As guidelines in food or drinking water samples were reported in water samples from La Pajuela, by an unspecified margin (Table 3). Given the conservatism of these standards, the authors’ omission of both the concentration detected in water and the degree of exceedance is surprising. A rough estimate of the As concentration in water can be made from the data in Figure 3. Water appears to contribute around 15 ug As/day in La Pajuela; dividing by the water intake rate of 1,153.7 g water/day (Table 1), the As concentration in water is roughly 0.013 mg/L (15 ug/day÷1,153.7 g water/day) – only slightly above the standard of 0.01 mg/L (WHO 2011), typical of many water supplies in the U.S. (Focazio et al. 2000).

- According to EFSA (2009), inorganic As consumption from food and water in Europe ranges from 0.13 to 0.56 ug/kg-day for average consumers, and from 0.37 to 1.22 ug/kg-day for 95th percentile consumers. As shown in Figure B, these ranges are very similar to the estimated ranges for both study subjects in La Pajuela (Table 4) and estimates based on Instituto Nacional de Estadística e Informática (INEI) dietary intakes (Table 5) (INEI 2012). Importantly, all are within the benchmark dose lower 1% confidence limit (BMDL01) range calculated by EFSA (2009). (Barenys et al. (2014) do not appear to understand that the EFSA standard is in fact a range, and not only its lower bound.) Thus, the sampled Cajamarca residents are exposed to As levels similar to the general population of Europe, and are not at increased risk of As toxicity.

**Lead**

- Food guidelines for Pb were reported to be exceeded in milk and oca samples from Tual, and the WHO drinking water guideline was exceeded in a water sample from La Pajuela (Table 3). Neither detected concentrations nor degrees of exceedance were reported. As indicated in Figure 3, virtually all of the lead exposure appears to be from the La Pajuela water sample. Food concentrations, although not reported, are clearly very low. The marked difference
between lowerbound and upperbound\textsuperscript{6} calculated intakes in Table 4 indicates the dominance of non-detect results in dietary samples.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure_b.png}
\caption{Comparison of European and Estimated Peruvian Dietary Arsenic Intakes with BMDL\textsubscript{01} Range}
\end{figure}

- According to EFSA (2010), dietary Pb intake in Europe ranges from 0.36 to 1.24 ug/kg-day for average consumers, and from 0.73 to 2.43 ug/kg-day for high consumers. These ranges are similar to the estimated ranges for study subjects in La Pajuela (Table 4), and higher than ranges for other study areas (Table 4) and estimates based on INEI dietary intakes (Table 5). Thus, it appears that the rural Cajamarca residents are at lower risk of Pb toxicity than the general population of Europe. It is noteworthy that while Europeans typically exceed the neurodevelopmental BMDL01 of 0.5 ug/kg-day (EFSA 2010), the Peruvian subjects do not.

\textsuperscript{6} Defined by Barenys et al. (2014) as calculated using the detection limit for results lower than the detection limit.
Cadmium

- The only exceedance of Cd guidelines in food or drinking water samples were reported in rice and carrot samples from the regional market in Cajamarca city (Table 3). The source of these foods is unknown, and neither the concentrations of metals detected nor the degree of exceedance was specified. According to Figure 3, the major contributor to Cd intake was rice. As acknowledged by the authors, no relationship of Cd intake with the mine can be established.

- According to EFSA (2012), mean Cd consumption from food and water in Europe ranges from 0.16 to 1.12 ug/kg-day. This range exceeds the estimated ranges for both study subjects in all areas (Table 4) and estimates based on INEI dietary intakes (Table 5). Thus, there is no basis for the conclusion that residents of any sampled area are at any greater risk of Cd toxicity than the population of Europe.
References cited


NewFields’ Summary Critique of Barenys et al. (2014)