

RESPONSE TO THE COMMENTS ON THE PANEL REPORT FROM TNI

Dr. Keith R Solomon

Centre for Toxicology and Department of Environmental Biology,
University of Guelph, Guelph, ON, N1G 2W1, Canada

Dr. Arturo Anadón

Departamento de Toxicología y Farmacología
Facultad de Veterinaria,
Universidad Complutense de Madrid
Avda. Puerta de Hierro, s/n
Madrid 28040
Spain

Dr. Antonio Luiz Cerdeira

EMBRAPA, Ministry of Agriculture
Jaguariuna, SP 13820-000, Brazil

Dr. Jon Marshall

Marshall Agroecology Limited
2 Nut Tree Cottages, Barton, Winscombe,
Somerset, BS25 1DU, UK

Dr. Luz-Helena Sanin

Department of Public Health Sciences,
Faculty of Medicine, University of Toronto, Toronto, ON, M5S 1A8,
Canada, Autonomous University of Chihuahua,
and National Institute of Public Health, Mexico

This is a response to an internet posting by Ricardo Vargas from TNI¹. The TNI comments are in *Italics*; our responses are in regular type.

1. *The evaluation included no studies of the risk of direct exposure for farmers and others susceptible to the effects of aerial spraying.*
To address this point, according to the report:

"Human exposures to glyphosate were estimated from extensive and well-documented studies in other jurisdictions and are judged to be accurate with respect to bystanders who are directly over-sprayed. Exposures were judged to be small and, in all cases, considerably below thresholds of concern." (1)

The document does not identify the sources of these "extensive and well-documented studies in other jurisdictions;" given the shortcomings of this evaluation's assessment of the risk to people who have been exposed, this constitutes a basic error, as the reference is used to compensate for the lack of field studies by the authors of the report.

The report states that, for logistical reasons, i.e., safety of the persons conducting the field studies, it was not possible to directly study persons who may have been exposed to the spray in the field. It was also not possible to use biomarkers of glyphosate exposure as this substance is rapidly excreted unchanged from the body and can only be detected for a few days after exposures. This has been well documented in the literature and was referenced in the SAT Report (Solomon et al. 2005). Thus, any field research would have had to have immediate access to potentially exposed individuals (and their full and informed consent to cooperate) immediately after spraying and for a period of several days afterwards. This was not possible and could likely never be done under the conditions that currently prevail. Because of this, the SAT used data from the peer-reviewed literature on exposures measured under agricultural conditions and extrapolated this to the higher rates of application used in Colombia. This was clearly stated and referenced in the Report. To overcome some of the difficulties associated with this, we studied people from regions with different uses of glyphosate. We assessed indirect effects through a widely accepted indicator, Time to Pregnancy (TTP) for epidemiological surveillance. This is also discussed and referenced in the Report.

A question arises from the CICAD team's inference: Under what parameters is exposure considered small? And if that is the case, why are these exposures taken as a valid reference for evaluating exposure risk?

The conclusion is that the report suffers from severe shortcomings in this area, and the effort to fill the gaps reveals serious deficiencies in the use and analysis of the reference documentation, as shown by the cited text.

¹ Ricardo Vargas. 2005. A Few Comments about the OAS-CICAD Study of the Impact of Glyphosate used in the Eradication of Illicit Crops in Colombia (Versión español). TNI Website, 30 May 2005
<http://www.tni.org/drugs/>

For both human and ecological risks, the exposures were compared to toxicity studies from the literature, from studies specifically conducted for the SAT, and to internationally recognized benchmarks used for human health risk assessment. For example, the reference dose (RfD) is the daily lifetime exposure from which there is considered to be no unacceptable risk. This is used to assess exposures from many substances in a number of jurisdictions and is an important benchmark used to assess risks from exposures to all pesticides (USEPA 2000). The RfD is based on a biologically relevant No-Observed-Effect-Level (NOAEL) and incorporates a number of uncertainty factors which address extrapolation from animals to humans as well as differences between adults and the young and healthy and unhealthy persons. References to these studies are in the Report and are current to early 2005.

2. *There is no mention of field research in Colombia, in a tropical environment, on the behavior of the mixture used in the spraying; instead, the report alludes to experiments carried out in other environments, and it is not clear whether those experiments were done with the same mixture or with the ingredients and surfactants separately.*

Toxicity studies were done with the mixture of glyphosate and adjuvant (Cosmo-Flux®) as is used in Colombia. Where these studies are done is not relevant to the outcome as they are conducted to international guidelines and according to good laboratory practice. There is good evidence from the literature – cited in the Report - that pesticides, in general, are less persistent in tropical environments such as Colombia and that data based on other environments will be conservative for risks in Colombia and similar locations.

3. *Data regarding the chemicals used in coca and poppy production and processing are from the National Narcotics Office (Dirección Nacional de Estupefacientes, DNE), which to date has produced no serious study of impacts, beyond a list of the chemicals believed to be used in these processes. Nor is there updated information about the use of chemicals, an area that is constantly changing. In other words, reference is made to a source that includes many generalities and has little credibility.*

These data were incorporated into the report to illustrate that there are other risks associated with coca production and that the risks of glyphosate, the objective of this study, need to be considered in this context. It was made clear that these other risks cannot be easily quantified because exact amounts used and use practices are, unlike the spray program, not well known. A Tier-1 hazard assessment (CICAD/OAS 2004) of these substances has been conducted and a Tier II assessment (CICAD/OAS 2005) will address comparative hazards for a subset of these. Analyses showed the presence of some of these pesticides (endosulfan and 2,4-D) in surface waters from coca-producing areas.

4. *Unsupported statements are made, such as "experience with spray equipment of the type used in Colombia suggests (sic) that spray drift will be minimal," and reference is made to a document dating back to 1990, when spraying conditions, droplet size, altitude, glyphosate concentration, etc., were very different. In addition, specific information is not*

provided about how the sample, supposedly of 22 fields, used for measuring errors in spraying (in 2002) was selected. Because complaints from the affected population, which in general terms almost always refers to errors because of herbicide spraying over extensive areas of pasture and other legal crops, are not taken into consideration, this leaves much to be desired as a solid argument for "demonstrating" that there have been no major errors and that it can therefore be assumed that there never will be any. (2)

The spray equipment used in Colombia is similar to that used in spraying of glyphosate in Canadian forests. In fact the booms used on some aircraft in Colombia are made in Canada. The raindrop nozzles also produce the same droplet spectrum and the spray-drift pattern would be similar. This was the basis for the conclusion of similarity. The off-target deposition from Colombia was referenced to the Helling report, wherein the random selection of the sites is described. Because of the small sample size used, both the minimum and maximum range of off target deposition was used to estimate the range of off-target deposition likely to occur. This range of values presents a reasonable worst case scenario. In addition, and in recognition some uncertainty in these values, the Report also recommended that additional data be collected on changes in the margins of sprayed fields so that a better assessment of off-target deposition can be made. It should be pointed out that effects on food plants intercropped with coca were not considered as "off-target deposition".

5. Discussion of risks from glyphosate exposure is based on secondary sources under test conditions that certainly differ in such characteristics as the physical conditions of children and colonists, with an unbalanced diet and exposure to tropical diseases (malaria, diarrhea, fever, etc.), a scenario in which the specific health effects of exposure to the indiscriminate use of this mixture should be established. There is no in-depth analysis under these conditions, and the study refers to an ideal type of person that bears no resemblance to these characteristics.

As discussed above, the RfD to which the exposures were compared already incorporates uncertainty factors that take differences in sensitivity between humans into account. In addition, the RfD is for a daily dose and thus reflects chronic exposures, not the once or twice a year exposures that may result from the aerial applications. Compared with the acute toxicological criteria, the likely exposures from the spray program in Colombia are orders of magnitude less than acute response concentrations.

6. With regard to the impact of spraying over surface water used for consumption, the following conclusion is drawn:

"Exposures from drinking of untreated surface waters in areas where eradication spraying takes place are judged to be small and infrequent." (3)

Nonetheless, in light of the deficient sample used for the surface water analysis, that is, in areas peripheral to the zones where spraying has taken place, it is surprising that such a broad conclusion is drawn.

These shortcomings are acknowledged in the report when it states that:

"Uncertainties in the exposure characterization lie in lack of precise measurements of the proximity of sprayed fields to surface waters and the proportion of treated areas that are in close proximity to these surface waters. The sampling of the surface waters only took place for a period of 24 weeks and only 5 locations were sampled in this way. Although two of these were scheduled to be sprayed, only one location was treated during the sampling period. For logistical reasons, it was also not possible to sample close to the application sites. If sampling had been conducted at more sites closer to the sprayed fields and over a longer time period, residues may have been detected more frequently." (4)

This statement refers to the frequency of detection rather than to the risks that may result. It should be noted that the few detects that were observed were not from areas subject to aerial spraying and likely resulted from agricultural use in Colombia – use that is six-times greater than that in eradication spraying. Given the short half-life of glyphosate in water, consumption of contaminated surface water at a concentration 100-times the detection limit (25 µg/L) of the analysis would only raise the estimated single day total intake for an adult to 0.41 mg/kg/day and 1.0 mg/kg/day for a child. These are also less than the RfD (2 mg/kg/day) and do not suggest any risk, particularly as the frequency of such consumption would be low.

The study shows no correlation among the occupation of land by coca farmers, population size, the use of surface water for consumption, the relationship between crop areas and the location of this water (all of which requires mapping showing these relationships, which the study does not present), so as to develop tests based on samples of this water and arrive at conclusions that are really based on field study.

These details are in the reports of the epidemiology study which is being prepared for publication in the peer-reviewed literature. It was, however, an ecological study (in the epidemiological sense) that utilized self-reporting. Large samples were used to avoid reporting bias and this was considered in the protocol of the study. Mapping is not needed in this type of analysis. As described in the Report, analyses of data on other exposures and on confounders such as nutritional status of the mother were considered and were included in the TTP models. Thus, possible confounders or independent predictors were considered and the models were adjusted for using procedures from peer-reviewed publications.

While the reference source for establishing the effects of consumption of untreated water affected by spraying is North America, the authors believed that they had adjusted their analysis for Colombia's characteristics of Colombia merely by taking as a reference the increased dosage used in that country. Once again, characteristics of the U.S. environment are extrapolated, without taking into account environmental conditions, the health of the coca-growing population or

other factors, and these circumstances are "adjusted" only with regard to the dosage used.

It is correct that the only the exposures were adjusted. As discussed above, differences in the health of the individuals are considered in the uncertainty factors applied in developing the RfD. This comment from TNI is predicated on the assumption that people in coca-growing areas are less healthy than people in other rural areas of Colombia. This assumption is not supported by the results of the TTP study, a good indicator of reproductive health. These results did not suggest greater risk in those mothers from areas exposed to aerial spraying in the last 5 years. In other words, the health status of persons in coca producing areas is not worse than those from non-coca producing areas. Considerations regarding the use and interpretation of the TTP outcome have been discussed in more detail in a paper, which has been accepted for publication in Spanish, in the Colombian Journal BIOMEDICA from the National Institute of Health (Idrovo J, Sanin LH and Cole DC, 2005).

In addition, the concentration of glyphosate in the mixture used on illegal crops is not taken into account; this invalidates any inference drawn from the formulations used in the United States or for agricultural purposes.

This was addressed and is clearly stated in the Report. If it was not clear enough to TNI, members of the SAT would be happy to explain this in more detail, one on one.

7. *The study was done under highly politicized circumstances and under pressure to show the mixture used for aerial spraying of illegal crops in Colombia to be harmless. An attempt is made to resolve this issue under an obsolete premise of "scientific rigor," which is reduced to separating the social, economic and political problems involved on the grounds that they (in themselves) do not qualify for scientific treatment. This premise undermines the seriousness of the report. By setting this standard of scientific rigor and making an effort to measure the phenomenon, it leaves out aspects closely related to the policy, such as the serious problem of the movement of crops, which leads to expanded spraying, resulting in deforestation and the burning of fragile soil and increasing environmental damage. In other words, "science" is stripped of its objectivity and serves - in itself - as the court that will determine who is right in this debate. In practice, however, the evaluators serve as judge and jury, since the evaluation in no way constitutes an independent exercise, but, as indicated throughout this document, seeks only to establish the harmlessness of the Round Up used for spraying illegal crops.*

The Report addressed only the human and ecological risks of the use of glyphosate for the spraying of poppy and coca. This was the remit of the SAT. The report acknowledged that there were other socioeconomic issues but these were specifically and intentionally excluded. It is appropriate to conduct assessments such as this in tiers or in stages as this allows the elimination of issues of low relevance and subsequent focus on more important issues. Hopefully this will be the case. It should be noted that the use of glyphosate does not mean that growers are forced to move elsewhere. Coca can be replanted in the same field days after spraying and will survive and grow without ill effects.

We observed this ourselves in Colombia and, from field observations, it is known that the growers use glyphosate in their own fields and it is also used to a much greater extent in agricultural production across the entire country of Colombia. If growers are moving to other areas, this is not for reasons related to the use of glyphosate.

If some organizations are concerned about the psychological and social consequences of the program, they should conduct a rigorous scientific study of the issues and questions. It does little good to indulge in armchair speculations when good data and clear results from a well conducted study would provide strong arguments for appropriate actions.

8. *Finally, to suggest that the spraying program can be reduced to the act of spraying glyphosate is a glaring error. Spraying in Colombia also implies the presence of five armed combat helicopters, which could be explained by the presence of armed groups in the fields of illegal crops, but which do not justify the climate of war also being waged against farmers. Spraying occurs in Colombia within the context of the fight against terrorism, and this places it in a specific political context that affects the civilian population and discredits peaceful alternatives, such as manual eradication; this technique has been tacitly dismissed in the report, as its conclusions do not take into account this form of eradication, which is currently not used in Colombia. This type of eradication creates the least environmental and health impact for farmers and, in general, for all people exposed. This is such a "scientific" study - done in the name of alleged "neutrality" - that it ends up being extremely political, to the extent that it actually takes a position in favor of chemical warfare, completely ignoring its effects in comparison to those of other techniques, such as manual eradication.*

The remit of the SAT was to assess the risks of glyphosate, not to assess the psychological effects of helicopters or the impact of guerillas on the psyche of the population. Neither was it to compare eradication with glyphosate to the use of manual procedures, however, the SAT was made aware of these efforts. Although manual eradication may be an alternative to spraying in some situations, it is not without risk of physical injury to those doing the eradication. Since the manual eradication was started in Colombia, at least 3 people have been killed and several injured. As has been well demonstrated in agriculture in general, there are far greater health risks associated with physical activity than with the use of pesticides in general and glyphosate in particular. In field tests of manual eradication described to the SAT, upwards of 40 person days are required to eradicate one ha of coca. To do this over a wide area presents major logistical problems and rate of new plantings could easily outstrip this rate of eradication, thus negating all of the manual work and its associated risks.

Throughout its work, the SAT used all of the data available and based its conclusions and judgments on the best science. The results are data-driven and were not directed to any specific conclusion or agenda as appears to be alluded to by TNI. There was no editing of the report by OAS, the Government of Colombia, any other country, or any persons other than the SAT and scientists contracted to the SAT. From the tone of the last comment from the TNI, it would appear that TNI does have an agenda. Would they be as critical of

the Report if the science had directed the SAT to the opposite conclusion? To the SAT it would not have made any difference.

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