A RESPONSE TO TOMÁS LEÓN SICARD ET AL.

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Introduction

The following is a response to a Critique of a Panel Report "Environmental and Human Health Assessment of the Aerial Spray Program for Coca and Poppy Control in Colombia" (Solomon et al. 2005).

Whilst there might be some points raised in the Critique(León Sicard et al. 2005) that result from aspects of translation between English and Spanish, there are a series of critical points made by León et al. (2005) that require responses, as they are based on misunderstanding, a lack of knowledge, or possibly a less critical approach to the subject under discussion than is desirable. In the response that follows, reference to the scientific advisory team (SAT) report is noted as: (Panel, with reference to page numbers in the English version). The Report by Tomás León Sicard et al. is referred to as the Critique.

General comments

The critique was written by a team from the "Programa de Investigación en Impactos de Cultivos Ilicitos (PIAC)", from the National University of Colombia. This team is lead by a PhD and composed by two PhD candidates but the areas they are working on are not stated. In addition, the team has an architect, a zootechnologist, a civil engineer, and a topographic engineer. There are no members of the team with any apparent expertise in

human health, epidemiology, medicine, public health, or ecotoxicology. Clearly, some of the comments in the Critique would not have been necessary if the team had included expertise in these critical areas.

As a general observation, the comments in the Critique were not well referenced to the primary scientific literature. There are 17 references in the bibliography of the Critique but many of them can not be easily found. For example the reference of de Luengas (2005) can not be is only listed by the title. The reference of Maldonado (2003) was not listed in the bibliography and Nivia 2001 etc. on page 4 are also not properly referenced. This is in contrast with more than 350 updated references reviewed by the panel to work on the assessment.

Content, layout, objectivity, and Monsanto

First, there are a number of expectations noted in the Critique that were not met by the report. A point made several times is that the study by the SAT Panel did not encompass social, economic and political aspects of the issue. The Independent Panel (we are not "the OEA experts" and were specifically requested to be independent) took the view that a purely scientific risk assessment was a valid, indeed essential, contribution to make to a topic already clouded with misinformation. In a situation where allegation is compounded by rumour and even deceit, an appropriate response is to take an independent view of the known facts. The example of alleged effects of deposition of herbicide within Ecuador resulting from the aerial spray programme in Colombia is a case in point. There is a 5 km-wide no-spray buffer zone along the border in Colombia. The alleged incidents were 10 km within Ecuador, 15 km away. Given the characteristics of the spray droplets, the nature of the application, knowledge off-target deposition in the actual spray areas in Colombia, and other locations where similar equipment is used, deposition sufficient to cause effects in plants, the most sensitive organisms, would not be possible over this distance. There is no scientific evidence to support the allegation that significant spray drift occurs over a distance of 15 km

The Critique makes the point that the eradication programme and its effects are in the domain of sociology, politics and economics, not forgetting ecology and human health. The report clearly states that its focus was on the human health and biological science only. As such, the report contributes factual scientific information to the debate. But, by the same token, so does this Critique and its authors should be very careful in the content and manner of their writing.

The Panel's risk assessment contributed to an evaluation of the eradication programme. It is not the whole part of such an evaluation, nor was it meant to be. Similarly, the eradication programme is only a part of the whole approach to controlling illicit crops in Colombia. By design, politics and socioeconomic issues were not part of the considerations of the Panel. These issues are for the nation of Colombia and its institutions. Whilst it might be gratifying to have been expected to provide an absolute and comprehensive answer the problem of illicit crops in Colombia in a12-month study, that was never our aim. The Critique observes that the report will be used for political ends whatever. That is no excuse for subjectivity or poor science on the part of the Critique. We attempted to be as clear and as objective as we could, allowing that there were aspects of the risk assessment that would rely on expert judgement. It is therefore disappointing to have our objectivity questioned (p.3 et seq.), instead of offering a reasoned scientific argument rebutting our interpretations.

There is also an implication that we have not properly consulted the rich literature on glyphosate, or that we have been selective in our use of it. This is not so. The bibliography of the report cites about 350 references from the scientific literature as well as documents and reports known or obtained by the Panel because of their expertise and knowledge of the research and academic community in their fields. There have been a number of recent extensive reviews of the literature, including Giesy et al. (2000), Williams et al., (2000), and Solomon and Thompson (2003). We took these reviews as a good starting point, so that most of our bibliography is more recent than 2003. To dismiss the review by Williams et al. on the basis that it was commissioned by Monsanto is to ignore the fact that it was published in the peer-review literature and also ignores the reviews by national regulatory agencies in several countries (US EPA, Australian NRA, and many other countries) and international groups such as the EU and the World Health Organization. More insidiously, it implies that the Panel were somehow influenced by or in the pay of the Monsanto Company. The authors of the Critique seem unaware that glyphosate has been off-patent for some years and most of the herbicide used around the world is not sold by Monsanto.

The Critique notes that the report is not in the form of a scientific paper or report, with sections on Introduction, Methods, Results and Discussion. The difficulty in finding details of methodological approaches is alluded to. In the opening sentences of the Preface, it is clearly stated that the report is a formal risk assessment. Thus, the report is not written in the classical scientific study format, but one that takes the form appropriate to an evaluation of risks to health and the environment such as is widely used in the regulatory arena and in the literature. The writers of the Critique seem to be unaware of structure of formal risk assessments.

What is a risk assessment of a pesticide? What should it contain? Why does it not cover, for example, 8000 recorded complaints about the eradication programme?

The framework of a formal risk assessment of a pesticide, as used by regulatory authorities across the globe, characterizes, a) toxicity and, b) exposure and evaluates the likely risks with margins of safety between these. More simply, it asks - what the likely effects of a pesticide are at realistic exposures? Currently, with much greater interest in non-target effects, there are formal means of calculating toxicity-exposure ratios (TERs), based on exposures causing toxic responses in test populations, with appropriate consideration of uncertainty factors. This was the approach used by the panel and is consistent with state of art risk assessments procedures. The Panel used exposure scenarios calculated from the literature as appropriate for conditions in Colombia and

toxicity values both from the literature and from tests conducted specifically for the study.

Is a risk assessment an end in itself? No. Risk assessments should be re-evaluated regularly, in the light of new information. This is, in fact one of the recommendations of the Panel. The Panel would modify their assessments, if further information becomes available, for example in mammalian neurotoxicology, ecology, etc.

Section 2 (p.4) of the Critique suggests that a major deficiency of the report is that no account has been taken of the many complaints received by the Defensoria del Pueblo, either directly in terms of their content, or in framing the work of the Panel. The Panel was aware of this dataset and welcomes its existence. It is alleged that the data are wellsupported and that 87% of complaints refer to effects on vegetation and just short of 7% refer to health effects. This is undoubtedly the case, but the Panel needed to take a judgement on the likelihood of ascribing the true, rather than alleged, causality for the complaints received. The information given to the Panel was that, of all the complaints received only seven cases of damage to crops were proven and compensation provided. For the human health cases, the Panel required well-documented cases where the exposures and symptoms were clearly characterized. As glyphosate is excreted from the body in a few days, it is not possible to quantify exposure unless samples of urine or blood are taken shortly after exposure. This means that a robust biomarker of exposure is not available to allow causality of effects to be unequivocally ascribed to glyphosate. Bearing in mind that an unknown proportion of complaints are likely to be mischievous, the Panel took the view that work based on the complaints would be unsound and a more objective approach, given our timescale, would be to conduct a properly controlled epidemiology study. That is not to say that these complaints should not be evaluated. We would encourage a detailed investigation of all complaints but recognize that the assignment of causality may difficult to accomplish.

Further, the Critique states that "the study did not consider, or if so it was only by the side, direct and indirect risks on ecosystems and agroecosystems...." This is incorrect - the assessment of the panel also considered the effects of the entire cycle of production of illicit crops on erosion, loss of biodiversity, deforestation, and human health. The major focus was on glyphosate but these other effects were also considered.

Detailed comments by section

Section 2:

The Critique, apart from referring to the 8000 complaints (see above), also notes that there are aspects of the Panel's work on human health that are questionable. Specifically, the timescale of effects on human health would be longer than the actual study and that we did not consider aspects of genetic impacts. Both these points are ill-founded. First, time to first pregnancy (TTP) has been well validated in the literature as an indicator of fertility and was used to examine a sample time of 5 years. In other words, the data integrates exposure impacts over a significant time period prior to the study and included the years of major eradication spraying. We agree that this does not address all aspects of human health, but is does investigate a key aspect of human reproduction that can reflect exposures to threats from within the local environment. Second, the Panel Report quotes data from the published literature and that provided for registration which indicates that glyphosate is not genotoxic, mutagenic, nor carcinogenic. It is not teratogenic or developmentally toxic, except at high doses that are overtly toxic to the mother and extremely unlikely to result from the spray program (p.51). The lowest no-effect level for the purposes of risk characterization for adults is the NOEL of 175 mg/kg/bw/day, value based on the maternal toxicity at the highest dosage tested of 350 mg/kg bw/day. We trust the meaning of this in relation to glyphosate is clear. Other pesticides such as those used agriculture and also in the production of coca and poppy may be more toxic than glyphosate, however, they were not included in the this review.

The Critique questions whether the panel should be concerned regarding herbicide exposure amongst the spray mixers and operators. The panel was concerned with <u>all</u> aspects of exposure and these were addressed. To consider otherwise might be interpreted as reflecting a particular agenda, rather than an impartial scientific approach.

This section closes with a final thought, that health should also encompass mental as well as physical health and proposes, in a bizarre statement, that witnessing crop spray planes accompanied by military helicopters operating on a criminal enterprise may have adverse impacts. One might well ask the same question about the effects of cocaine or heroin addiction on family members of victims of the drug trade. As both of these are social issues, they were excluded from the assessment.

Section 3. Planning

It is alleged that the purpose of the report is not clearly stated, that the questions asked are not obvious and that the procedures followed are ambiguous. As noted above, the report is a formal risk assessment and follows a commonly used and widely recognized framework for conducting such assessments.

The Critique is also contradictory as, on the one hand it recommends that questions should be concrete and obvious, while also asking for wider and nebulous questions such as the economic and social effects of the glyphosate to be addressed.

Section 4. Methods

As there is no chapter on methods, the Critique notes that it is difficult to comprehend the approaches. It is claimed that the Panel did not examine the areas where effects were most likely to be found, but concentrated where effects were less likely. The main criticism is that the report does not address effects on plants and it is suggested that the conclusion would have been very different if effects on plant biodiversity had been studied.

As the Critique notes (p.6), glyphosate is a broad-spectrum herbicide. One of the basic assumptions in the Panel report is that glyphosate kills all plant species, if a sufficient

dose is received. This is nearly true, though certain species show degrees of resistance (Panel: pp. 71; 109). The assumption, therefore, is that glyphosate kills all plants in the target area, so it becomes a trivial question to ask what are the effects on plants in the coca fields – it kills them all. It is not a trivial question to ask what happens to plants outside the target area. This was approached in the Report in terms of likely drift and off-target deposition.

The section then makes some remarks regarding the lack of study of the process of adsorption of glyphosate on to clay in soils. Whilst this is not developed in the Panel report, the science of this process is relatively well-documented and referenced to in the Report. The Critique then introduces the important topic of soil erosion, noting that loss rates of between 15 and 25 tonnes ha-1 year-1 occur. It is not clear to us if the Critique implies that glyphosate adsorption to clay particles in soil affects erosion. This seems most unlikely, considering the rates of application compared with soil bulk density. However, it is well-understood that removal of forest cover, such as is done when planting coca or poppy, causes erosion and this is noted in the Panel report (Panel: p. 79).

The Critique makes a valuable suggestion that it would be really interesting to know the range of erosion rates in Colombia a) in virgin sites, b) in sites cleared for coca production and c) coca sites that have been sprayed with glyphosate from the air. The Panel would encourage the Institute to approach the appropriate research funding agencies to support such a project. The opinion of the Panel, based on the literature, is that erosion rates of a) are lowest and those in b) and c) would be the same, but significantly higher than a).

Section 5. Target environment

The Panel are entirely aware that extensive areas of Colombia contain significant amounts of the world's plant diversity and that there is overlap between coca and poppy production areas. This is clearly stated in the report (Panel: p. 9 - "much of the production takes place in remote areas that are close to or part of the Andean Biodiversity Hotspot"). The point made earlier is that the proportion of land area involved is relatively small.

Section 6. Off-target deposition

In the Critique, there is some confusion between results of the assessment of glyphosate use in the Canadian Forest Service (Payne et al. 1990) and the estimates of off-target damage in the eradication programme in Colombia reported by Helling (2003) (Panel: p. 33). The Canadian experience is highly relevant; nevertheless there is some confusion in the interpretation of data here. We accept that the Helling studies, which are conducted on an annual basis, present a relatively small sample of fields. A greater sampling size might be appropriate, but we also proposed that an experimental approach to measure drift should also be conducted. But to imply that 22.6% of spray sites have non-target effects is misleading. The key question is what is the likely area of non-target damage? Is it 1 m² or is it thousands of hectares? A single site out of 200 that has non-target drift

damage of hundreds of hectares could be classified, according to the Critique, as less than 1% of spray sites with drift damage. Aerial application, even with safety limits built into calculated spray paths, is more prone to drift than ground application. The upper and lower estimates of observed areas of damage (Panel: Table 5) were applied to the total area of aerial applications in each year. This provides an estimated range of the area likely to be damaged by glyphosate drift. In the last sentence of this section the Critique states that 7.1% of Colombia's area has coca crops. This number is incorrect.

Section 7. Risk scoring

The Critique questions the use of 5-point scoring systems in Figures 11 and 12, used to calculate overall measures of risk. How were the scores derived? Did the group come to a consensus?

The risk frameworks are explained in the text (Panel: pp. 34, 35). All operations associated with growing and processing coca carry some risk to humans and the environment. Sowing and fertiliser are considered in human and environmental risk frameworks, both for completeness and because there is potential for health effects, e.g. physical injury from tools or machinery. The risk scenarios were agreed to by all Panel members as a means of presenting relative risks.

When it is reported that a number of highly toxic pesticides have been seized in antinarcotic operations by the police, the Critique asks if the relatively low scores for pesticides (2) and recovery time of (0.5 of a year) are appropriate. Impact score is based on the additional impact to the clear-cut and burn and recovery is based on the need for repeated use of these products in pest management. If one were to increase the impact of pesticides to a score of 5 and increase the longevity of effect to one year, the impact score would still only be 5 and the percentage impact would only be 1%. Bearing in mind that this approach is only to evaluate relative risks over an annual cycle, the scoring system is relatively robust. This highlights an important area of risk the Panel are aware of – the use of banned pesticides in the illicit production of drugs. The discovery of the banned insecticide endosulfan in the surface water samples (Panel: p. 46, 47) means the product is being used. Our concerns have been reported to CICAD, but please note that our task was an evaluation of the use of glyphosate in the eradication programme, not the use of banned chemicals in an illegal activity.

The Critique concludes this section with the observation that POEA is not discussed and that the Panel have ignored dioxins, which are apparently impurities in the pesticides. In regard to POEA (polyethoxylate dethoxylated tallow amine), the effects of this surfactant, the main surfactant in previous formulations of the glyphosate product Roundup®, on toxicity are extensively discussed in the report (Panel: pp.53, 66, 67). The Critique seems to ignore the highly significant data summarised in Figure 17. This presents toxicity data for technical glyphosate (with no surfactants), glyphosate as Roundup® (data including POEA formulations) and glyphosate plus Cosmoflux® (as used in Colombia). There are no dioxins in glyphosate or Roundup®. Nothing in the process of its manufacture or the manufacture of the surfactants would lead to the

formation of dioxins. The authors of the Critique may be confused by a historical reference to the use of dioxane, a totally different chemical, in the manufacture of components of the formulation. It is troubling that the authors of the Critique have raised the topic of dioxins without any validation or reference. What are Leon et al. attempting? If, by innuendo, they wish to raise the issue of use of 2,4,5-T more than 30 years ago in Vietnam, then their motives may not be honourable. In so doing, they also conveniently overlook the fact that more that 86% of the glyphosate used in Colombia is in legitimate operations by agricultural and other workers in the field, rather than in the eradication programme. In addition, other surfactants such as CosmoFlux® are also used. Additionally, glyphosate is widely used in almost every other country on the planet.

Section 8. Characterising exposure

The Critique raises valid questions in regard to basing estimates of exposure to glyphosate on the literature. It may be of interest that the Panel proposed an experimental study of direct exposure to the spray, using volunteers in Colombia. Unfortunately, the experiment could not be conducted at the time because of concerns expressed by the Approval Board in Colombia. However, it is well known that there is little penetration of glyphosate through human skin. Even if exposures to the skin were greater, this would not have increased total exposures to a level of concern, even for chronic risks. The Critique points out that mixer-loaders use protective clothing. This is standard operating procedure for many pesticides and is done because these individual may be exposed to concentrated material. People exposed to spray in the field are exposed to diluted product which has lower hazard. However, the likelihood of this occurring is small as, according to standard operating procedures, fields are not sprayed if people are observed to be present.

The Critique implies that exposure is estimated on the basis of a single person, which is incorrect. Exposure was estimated in terms of the effects on a person, but is the same for however many people may be present in the field and are contaminated. The point is raised that the environmental conditions – temperature, humidity – and the health of the coca growers may be very different from those considered in the literature. Whilst the environmental conditions may impact exposure and uptake, no assumptions regarding health are made in estimating exposure as these were already included in the uncertainty factors incorporated into the reference dose to which the exposures were compared. As is pointed out in the Report, these are made even more conservative because acute exposures, such as would occur from the spray program, are compared to chronic reference doses.

The Critique alludes to the 8000 complaints and the need to design studies to investigate these. As was pointed out above, for almost all of these cases it is logistically impossible to collect confirmatory exposure data and, in many cases, the reported effects are inconsistent with those needed to establish causality. Given immediate and free access to these situations and better infrastructure, such investigation would be possible. However, the toxicity data on the sprayed formulation and experience in other regions suggests that effects, if any, would be minor and temporary.

Section 9. Environmental exposure

There are criticisms that the approach to evaluating the presence of glyphosate and its breakdown product AMPA in the environment taken by the Panel is too small a sample and that the site conditions are not described for sound conclusions. A series of questions are posed, highlighting perceived deficiencies in the work.

Whilst, as an ecologist, one might have sympathy for a number of the points raised and a desire to see a comprehensive monitoring programme for pesticides in surface waters in Colombia, it is appropriate to focus on what the aims of the task were. This exercise had two objectives: first, to determine if glyphosate was present and secondly to test whether its presence might be influenced by the eradication programme.

The Critique suggests that the methods in the epidemiological study were not clearly described. The Panel report does describe how the epidemiological study was carried out, why the places were chosen, what field work was conducted, and what analyses were conducted for assessing the association between glyphosate and TTP. The site descriptions are available in separate reports. The sites were selected as representing different land uses, though with similar environments. A number of sites were explored as potential locations for the water and sediment sampling as well as for the epidemiological study of TTP. Important factors in the final selection were accessibility and safety for the staff involved. Ultimately the sites differed in a number of ways, some of which we do not understand, as illustrated by the TTP results. Nevertheless, a detailed protocol (*note: all sampling and analytical protocols are available for inspection*) was followed, over a 22 week period with fortnightly sampling, involving the use of sample blanks and spiked samples, so that both contamination and analytical recoveries were monitored.

A valid question is: what can the data tell us? Returning to the objectives, the data clearly tell us that glyphosate is not found often in surface waters. Only two samples out of 86 contained the herbicide and then only at concentrations just above the limit of detection. On the basis that the molecule is rapidly adsorbed by soils, this is consistent with the properties of glyphosate and with observations in other locations such as were reviewed in the Panel Report.

The second objective was to test whether there was evidence that the eradication programme was influencing amounts of the herbicide in the environment away from the application areas. On the basis of the available data, there was no evidence to show this. Nevertheless, the Panel has recommended that the environmental monitoring programme is expanded in Colombia.

The Critique then proposes that there is no evidence for rapid recolonization of sprayed plots and that because there were no measurements of residues in soils, we cannot conclude lack of effects. The information on rapid replanting of coca in sprayed fields and recolonization from Helling (2003) is compelling and our own observations in the

field cannot be refuted. Similarly, there is very wide experience of lack of residual activity of glyphosate in agricultural uses, a fact that the authors of the Critique were apparently ignorant of. Leon et al. (2005) should be aware that a key factor is whether the herbicide residues in soil have biological effects. Repeated applications of glyphosate to soils may result in an increase in residue that can be found, if soils are extracted with techniques involving strong acids. However, this tells little about its biological activity in soils which, from extensive use in agriculture, is known to be minimal. The review of Racke et al. (1997) (Panel: pp. 22, 23) also indicates generally more rapid dissipation of pesticides in tropical soils.

Section 10. Effects characterisation

It is a shame that the Critique takes on a patronising tone at this point, implying that the Panel have been partisan, rather than exercising critical judgement. The authors of the Critique seem to be happy to accept the validity of articles that are not in the peer-reviewed scientific press, which is to be regretted. When we write that a risk assessment contains uncertainties, the Critique betrays a non-scientific approach in its comments, compounded by not understanding that potential cancer and neurological effects are different.

Section 11. Effects on non-target organisms

There is a lack of objectivity in the comments made here. If the authors are unhappy with the judgements made in regard to individual papers, then they should advance an alternative scientific argument, backed up with suitable references. The effects on amphibians we note is not "finally admitted", but clearly stated and developed in relation to shallow water bodies and likely contamination effects from overspray (see Figure 19). I would also refer to one of the specific recommendations (Panel: p. 95) that toxicity measures be made on amphibians, which are clearly more sensitive than other organisms to some formulations of glyphosate. The Critique refers to a report by Bigwood, not peer-reviewed, that reviews "effectos nocivos" of glyphosate. From the title alone, one would question the balance inherent in such a report.

The paper by Relyea (2005) is referenced and discussed fully in the panel report (Panel: pp. 67, 111). To quote "*The rate of application was equivalent to 16 kg/ha, a value that is unrealistic and probably the result of an error in the methods. At this concentration, glyphosate formulated with POEA would be expected to be lethal to tadpoles.*" Further, the Relyea study suffered from poor experimental design and the wild speculations regarding amphibian declines contained therein were not justified by the data.

Section 12. Effects on mammals

The Critique makes some wild statements in regard to testing effects of pesticides on mammals, betraying a lack of understanding of regulatory, experimental, and ethical issues. Perhaps León et al. (2005) might like to explain the alternative. It is the practice across the globe to evaluate chemicals, pharmaceuticals, foods, and cosmetics on

laboratory mammals, including mice, rats, rabbits, and guinea pigs. The Critique asks, is a slight to moderate eye irritant a risk to human health? The answer is, it is a risk, but so is getting soap in one's eye when washing. A little balance is required – there are a large number of substances in the home, in agriculture, and industry that are eye irritants and can be safely used.

Section 13. In summary

- The risk assessment draws sound and defensible conclusions from the literature, from field assessments, from specially conducted toxicity testing, interviews of nearly 3000 women and not least from a sound understanding of the subject.
- The peer-reviewed scientific literature was consulted exhaustively by the Panel. To suggest otherwise is disingenuous.
- The Panel have assumed that if there is spray drift, there are impacts on plant biodiversity, as glyphosate kills all plants. There is drift, so there are effects, although to a limited area. However, effort has been placed on the less obvious impacts, including human exposure and non-target organisms.
- The Critique suggests that the report should include social, political and economic aspects to the environment. In the totality of the issue, these are potentially important factors, but they do not help in providing a science-based risk assessment of a pesticide and have been intentionally not addressed, in order to improve the objectivity of the Panel Report. Should a modification to the title be appropriate, the work "risk" could be added, but no other change is necessary.
- The illicit drug problem is undoubtedly complex and it is one that is faced by a number of countries, including Colombia and Afghanistan. However, to base an evaluation on lists of complaints about an eradication programme, some of which are genuine, but which also include specious representations and even some perhaps made under duress, seems somewhat naïve. A risk assessment of part of the illicit crop control programme is entirely justified and hopefully will shed some light on the actual practices on the ground, both good and bad.

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