TO: **Honorable Members of Congress**

FROM: **Ted Schettler MD, MPH**
Science Director, Science and Environmental Health Network
Boston Medical Center, Boston MA
Greater Boston Physicians for Social Responsibility

DATE: **September 18, 2002**

SUBJECT: **Comments on U.S. Environmental Protection Agency, "Consultation Review of the Use of Pesticide for Coca Eradication in Colombia," August 19, 2002, released by the Bureau for International Narcotics and Law Enforcement Affairs, September 2002**

Title II of the Foreign Operations, Export Financing, and Related Programs Appropriation Act 2002 requires the State Department to determine and report to the Committees on Appropriations that certain conditions are satisfied by the US-sponsored crop eradication campaigns currently under way in Colombia. First, the State Department must determine that the crop eradication campaigns are "being carried out in accordance with regulatory controls required by the Environmental Protection Agency as labeled for use in the United States." Second, the State Department must determine that "the chemicals used in the aerial fumigation of coca, in the manner in which they are being applied, do not pose unreasonable risks or adverse effects to humans or the environment." EPA's assessment of the crop eradication campaigns, presented to Congress as part of the State Department's report to Congress on September 4, 2002, is intended to determine whether or not the coca spraying program in Colombia meets these conditions.

As noted by EPA, a risk assessment of this type requires, among other things, identification of the hazard (what chemicals are being used); a comprehensive toxicity assessment of these chemicals; and an assessment of exposure levels in humans and wildlife. With that information, it is theoretically possible to estimate the magnitude of risks to humans, wildlife, and non-target vegetation, including food crops.

The accuracy of a risk assessment depends on the adequacy of data for each of the components of the risk assessment process—hazard identification, toxicity evaluation, and exposure assessment. In each of these categories, EPA's assessment fails to provide information essential for conducting the requested risk assessment. The hazard identification is incomplete because chemical components of the herbicidal formulation are not fully identified. The toxicity evaluation is incomplete because EPA does not provide a comprehensive toxicological evaluation of the components separately and in their final formulation. The exposure assessment is incomplete because it is limited by unwarranted assumptions about spraying conditions and routes of exposure. As a consequence, the document provided by the EPA fails to provide data sufficient for determining the magnitude of the risks of the spray program and whether or not they are “unreasonable.” Some of the important omissions and flaws in the EPA assessment of health hazards are detailed below, following the structure of the Agency's report. Brief comments on ecological hazards are included as well.

Comments on Executive Summary

EPA's choice of reference point is inappropriate.

EPA chooses to use forestry and rights-of-way uses of glyphosate in the US as its reference points for comparison with the crop eradication campaigns.[1] However, forestry and rights-of-way uses of herbicides in the US are distinctly different from applications in food production systems. Given that the aerial spray campaigns in Colombia occur in agricultural areas, EPA's choice of reference point is inappropriate.

EPA correctly acknowledges that drift will affect non-target plants.

EPA correctly acknowledges that "phytotoxicity to non-target plants outside of the application zone would be expected, since glyphosate is a broad spectrum herbicide. Given the application method described by Department of State, offsite exposure from spray drift is probable, as it would be under similar uses in the U.S."[2]

EPA avoids commenting on aquatic risks of the tank mix.

EPA comments that dietary exposure to the active ingredient, glyphosate, is unlikely to pose a risk to birds and mammals, including livestock. [3] In this statement, EPA avoids commenting on the aquatic risks of the added surfactants or the final formulation.

Comments on Section 1: Description of Glyphosate Use in the U.S. for Comparison to Use in Colombia for Coca Eradication

Fixed wing aircraft increase likelihood of drift.

The data that EPA uses for comparison to Colombia are derived from US experiences with application of glyphosate herbicides in forestry sites. However, EPA notes that "it is not clear how closely this use approximates that for coca eradication" because glyphosate is applied to forestry sites in the US via helicopter, whereas the spray campaigns in Colombia are carried out using fixed-wing aircraft. EPA notes that helicopters applying glyphosate herbicides to forestry sites in the US travel at air speeds of "50-70 knots (about 60-80 miles per hour)," and that "application to forestry sites by fixed wing aircraft, if practiced at all, is extremely rare."[4] EPA does not specify the speed at which fixed wing aircraft travel when applying herbicide in Colombia. EPA's lack of information on or experience with herbicide application from fixed wing aircraft, and associated drift, constitutes a major gap in EPA's ability estimate exposures and to certify safety of the spray campaigns.

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[1] Executive Summary: Findings. Unless otherwise noted, footnotes in this letter cite EPA's Consultation Review of the Use of Pesticide for Coca Eradication in Colombia, as viewed online at http://www.state.gov/g/inl/rls/rpt/aeicc/13237.htm, visited September 6, 2002.
[2] Executive Summary: Findings
[3] Executive Summary: Findings
[4] Section 1 (Description of Glyphosate Use in the US): Addendum after references.

Off-target exposure assessments are necessary to assess risks from drift.

According to the protocol, spray runs are cancelled if wind speed at the airport exceeds 10 MPH. However, local wind conditions and spray altitude determine spray drift, and airport wind speeds are unlikely to represent wind speeds if the spraying is carried out in mountainous or hilly terrain. Moreover, spraying from fixed wing aircraft at considerable altitude facilitates excessive drift. For these reasons, off-target exposure assessments are essential for an adequate evaluation of risks.

Comments on Section 2: Human Health Risk Assessment for the Use of Glyphosate Herbicide as Part of the Aerial Eradication Program of Coca in Colombia

EPA's hazard identification is incomplete due to lack of full information on ingredients.

EPA's analysis of the toxicity of the glyphosate herbicide product is limited because key ingredients are considered to be confidential. The glyphosate herbicide product itself contains a surfactant that is not identified because it is considered a trade secret. In addition, the tank mix includes a surfactant that is not registered or sold in the US. The composition of this surfactant is also considered to be confidential. Without information on the ingredients of this adjuvant, it is impossible to assess the human health or environmental effects of the tank mix.

EPA has not fully evaluated the toxicity of the tank mix.

Regarding the adjuvant added to the tank mix, EPA states that "all ingredients identified as contained in this product are substances that are not highly toxic by oral or dermal routes" but "may cause mild eye and skin irritation."[5] The statement that the adjuvant is "not highly toxic by oral or dermal routes" is subjective and without guidance as to what "highly toxic" actually means. It is unclear whether the statement refers only to acute toxicity or to all forms of toxicity, including subchronic and chronic. A full evaluation of toxicity requires assessment of a variety of health endpoints, including reproductive effects, developmental effects, and carcinogenesis.

Ecological impacts must also be evaluated for a variety of health endpoints. The inhalation pathway, as well as oral and dermal exposures, must be considered. Even single or occasional exposures to toxic substances can have long term, delayed impacts if the exposure occurs during a window of vulnerability. In humans, for example, the fetus, infant, and child are often far more vulnerable to single exposures than adults. Wildlife may have similar periods of susceptibility; see the comment and reference below regarding salmon.

EPA notes that "the components of the adjuvant (Cosmo-Flux 411F), that DoS indicates have been sprayed on coca plants in Colombia have also been determined to be approved for use on food by the Agency."[6] However, this information does not clarify what the components are and what their toxicity may be. Similarly, information presented under the heading "Components of

[5] Section 2 (Human Health Risk Assessment): II (Executive Summary): "Hazard Assessment"
[6] Section 2 (Human Health Risk Assessment): III (Background)

the Glyphosate Product," part 2, cannot be evaluated without the information that has been omitted as "confidential."[7]

Similarly, the information provided on Cosmo-Flux 411 F cannot be evaluated due to omission of crucial information, labeled as "confidential." For example, if Cosmo-Flux 411F contains a polyethoxylate, ecological hazards must be considered. A polyethoxylate surfactant produced severe adverse effects in salmon smolt in New Brunswick during a spruce budworm eradication program.[8]

EPA does not provide justification for failure to quantify risks from the tank mix.

In its discussion of exposure, EPA notes that "an exposure and risk assessment is required for an active ingredient if: (1) certain toxicological criteria are triggered and (2) there is potential for exposure." EPA says that "upon review and analysis of the hazard database in total, the Agency's HIARC did not identify a hazard of concern for acute dietary, dermal, or inhalation exposures." On this basis, EPA decided not to develop quantitative estimates of risk for dietary, dermal, or inhalation exposures.[9] This decision, however, was based on characteristics of the active ingredient only, and leaves open the question of whether quantitative risk estimates should have been developed for the tank mix.

EPA's exposure assessment is based on untested assumptions.

EPA also chooses not to consider hazards from incidental hand-to-mouth exposure potentially experienced by people who are directly sprayed with the herbicide mixture. The justification for this decision is that the State Department "states that pilots are instructed not to spray fields where people are present."[10] EPA overlooks the fact that spray drift is virtually certain to lead to some direct exposures. EPA notes that, while the potential for bystander exposure exists, "the technology and other safeguards described by DoS as being used in this program are consistent with common approaches in the United States for reducing spray drift."[11] "Common approaches," however, are very different from common protocols and enforcement. EPA provides no evidence that spray drift is not occurring but merely assumes that it does not. Without a detailed evaluation of exposures as well as toxicity of the substances being used, an investigation of the spraying program is seriously flawed.

In its exposure assessment, EPA notes that according to the State Department, mixers and loaders "are trained on the label requirements for handling the chemicals in the spray mixture, first aid, and use of personal protective equipment (PPE). The required PPE according to the label includes long-sleeved shirts and long pants, waterproof gloves, shoes and socks, and protective eyewear."[12] However, label requirements are typically not followed by mixers,

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[7] Section 2 (Human Health Risk Assessment): V (Hazard Identification): "Components of the Glyphosate Product"
[8] Fairchild WL, Swansburg EO, Arsenault JT, Brown SB. Does an association between pesticide use and subsequent declines in catch of Atlantic salmon (Salmo salar) represent a case of endocrine disruption? *Environmental Health Perspectives* 107:5 (May 1999), 349-58.
[9] Section 2 (Human Health Risk Assessment): II (Executive Summary): "Exposure"
[10] Section 2 (Human Health Risk Assessment): II (Executive Summary): "Exposure"
[11] Section 2 (Human Health Risk Assessment): II (Executive Summary): "Exposure"
[12] Section 2 (Human Health Risk Assessment): VII (Exposure Assessment): "Handler Exposure"

loaders, and applicators, especially in tropical climates where high temperatures sometimes make it impractical to wear full protective clothing.

EPA fails to evaluate chronic or sub-chronic effects of the final formulation. Acute effects identified by EPA fail to meet the "unreasonable risk" standard.

Based on concern about the hazard of acute eye irritation, EPA "recommends that DoS consider using consider using an alternative glyphosate product (with lower potential for acute toxicity) in future coca and/or poppy aerial eradication programs."[13] Again, EPA emphasizes consideration of acute toxicity, and fails to mention chronic or sub-chronic effects of the final formulation in the tank mix. Moreover, the acute effects themselves fail to meet the standard of posing no "unreasonable risk."

Cosmo-Flux 411 F is not used in the United States.

In its discussion of spray drift, EPA states "the use of spray adjuvants (in this case Cosmo-Flux 411F) in pesticide product formulations and/or the spray solution is also consistent with common agricultural practices in the United States."[14] However, in fact Cosmo-Flux 411F is *not* used in the US. Thus it is not correct to refer to this use as "consistent with common agricultural practices."

EPA cannot reach valid conclusions about hazards from drift without completing a quantitative risk analysis of drift potential of the tank mix.

EPA's assessment is seriously deficient in its failure to gauge fully the hazards from drift of the tank mix. As EPA notes, the Agency "did not complete a quantitative risk analysis of the drift potential of glyphosate in the water/surfactant solution used in this program."[15] EPA states that the State Department carried out quantitative spray drift studies, but did not provide the results of these studies to EPA. Without this information, it is impossible for EPA to reach valid conclusions about the hazards from drift.

EPA possesses no valid epidemiological data from Colombia.

In its review of incident data, EPA notes that information available from the Department of Nariño "does not provide any substantial evidence of health effects due to the spraying of the glyphosate tank mixture in Colombia," although "it is possible that some cases could be related to the aerial eradication program."[16] EPA does not add to the body of knowledge on this subject by reviewing this material. The data provided from the Department of Nariño are so flawed and filled with data gaps that no conclusions are possible.

[13] Section 2 (Human Health Risk Assessment): X (Risk Characterization)
[14] Section 2 (Human Health Risk Assessment): VIII (Spray Drift)
[15] Section 2 (Human Health Risk Assessment): VIII (Spray Drift)
[16] Section 2 (Human Health Risk Assessment): IX (Incident Data Review): 1.3 (Epidemiological Monitoring System and Mandatory Notification)

Similarly, EPA notes that information provided in records of interviews with Colombian health officials in the Department of Nariño "do not add significant evidence about the health risks from the use of glyphosate tank mixture in Colombia."[17] As EPA notes, the data presented in this section are of no value for determining health risks.

Conclusion

EPA's responsibility is to determine whether the crop eradication campaigns pose unreasonable risks. To do that, EPA must fully assess the hazard(s), their toxicity, and exposure levels. Yet EPA has not completed a full assessment in any of these categories. The hazard assessment fails to fully consider, or indeed even to identify, each of the components of the final formulation. The toxicity assessment of the spray formulations fails to consider the full range of potential human and ecological impacts. Exposure assessments are similarly flawed. No attempt has been made to determine the extent of human exposures to the spray mixture applied from fixed wing aircraft under conditions of use. Thus, the existing data are inadequate to determine the safety of the program. The document does not provide information sufficient for determining the presence or absence of unreasonable risk.

[17] Section 2 (Human Health Risk Assessment): IX (Incident Data Review): 2.3 (Interviews with Nariño Department Health Officials Regarding the Spraying)