MEMORANDUM

November 24, 1987

Subject: Withdrawal of PR Notice 87-8

From: Dwight A. Welch  
TSS/IRB/RD

To: Edwin F. Tinsworth, Director  
Registration Division

Thru: Herbert S. Harrison, Chief  
IRB/RD

This morning I was given the assignment from you via Herb Harrison to withdraw PR Notice 87-8. The withdrawal notice must, among other things, indicate that while the Agency believes a problem to exist, we have insufficient data to support label changes. The notice is to further state the EPA and industry will work together to study the problem and develop labeling changes as appropriate.

The purpose of this memorandum is to register my formal objection to this course of action. I believe that there is sufficient information to warrant an expeditious course of action.

CFR 40 Section 162.11(a)(6) "Additional Grounds for Issuance of Notice of Intent to Deny or Cancel Registration or to Hold a Hearing" states: "A notice pursuant to section 3(c)(6) or 6(b)(1), or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued by the Administrator with respect to any pesticide which does not meet or exceed the criteria for risk set forth in paragraph (3) of this Section 162.11(a), if the Administrator determines:

(i) That based on......such other evidence as is available to the Administrator, the pesticide poses a substantial question of safety to man or the environment...." Section 162.11 goes on further to indicate that the burden of proof is with the registrant or applicant to prove that the product(s) is (are) reasonably safe if used in a manner consistent with its labeling.
The key ideas here are "substantial question of safety" and that the burden of proof is on the registrant not on the Agency. It is the task of Agency scientists to look at data and make predictions of a substance's relative safety; not to wait until the accident and death toll rise to certain levels. To draw an analogy to this situation, a bridge inspector tries to condemn a bridge when he discovers substandard materials were used in its construction. Would the bridge building company's assertion that the bridge hasn't collapsed yet and is therefore safe be relevant?

The flame extension test measures the hazard of an aerosol stream being ignited. It is irrelevant to the hazard associated with the ignition of accumulated propellant gases. In the absence of a test to ascertain this hazard, I have suggested using the flash point of the propellant gas as a criteria. We also have information that such ignitions, fires and explosions do occur though we merely do not know the extent of such happenings. The CSMA did not submit any data to show that these propellents are non-flammable; no such data exists since they are all extremely flammable. The CSMA has not submitted any data to support the notion that the flame extension test would screen such products. Furthermore, the CSMA has no alternative approach, merely that the PR Notice should be withdrawn.

The CSMA does have a legitimate gripe. Proposed changes in regulatory procedure should go through a comment process. Not only should industry be able to comment, so should environmental and consumer groups and all other interested parties. I believe the PR withdrawal you have outlined would give the appearance of the Agency being in bed with the CSMA. They have presented no data, tried to bully us into compliance, and have succeeded. The CSMA does not regulate the pesticides industry, EPA does. EPA regulates taking into account all interested parties, not just industry.

I believe it is necessary to have a hearing on this matter. Perhaps a cancellation proceeding would be too extreme, although, it would be in order considering the above excerpt from CFR 40.

I further propose that some actual scientific data be developed. Anecdotal accident data is not necessarily a measure of the problem, it may also be a measure of information gathering abilities. If 10,000 accidents occur but we only hear of 10, this could convey the false impression that the problem is relatively minor.
To the end of developing scientific data rather than merely relying on anecdotal information, I have talked to Barbara Levin of the Center for Fire Research, of the National Bureau of Standards. Ms. Levin indicated that the Center is not only capable of performing such research, but quite interested and willing. Ms. Levin is going to generate such a proposal, including costs, for our appraisal. Since the CSMA claims to be a responsible organization, and since the burden of proof is the responsibility of the registrant, perhaps they could be persuaded to pay for the funding.

In summary my position is that we hold a public hearing, generate actual scientific data, and develop guidelines rather than mere label changes.