MEETING REPORT - PARAQUAT LABEL REVISION

A meeting was held on March 28 and 29 to discuss proposed label changes for Paraquat that would be acceptable to Research, Marketing, Legal and ICI. Present at the meeting were: ICI - K. Fletcher, G. Jenkins and E. Schumacher; Chevron - L. Hopkins, F. X. Kamienski, W. Lewis, J. N. Ospanson, D. F. Searle, L. R. Stelzer and C. R. Tanner; SOCAL - R. D. Cavalli; IBT - F. Koyoshiba; Legal - G. M. Doppelt. A summary of the discussion is outlined below.

Meeting Agenda

The proposed agenda, copy attached, was discussed and agreed upon.

History and Background

Hopkins summarized the attitudes of the regulatory agencies toward Paraquat. It was emphasized that the regulatory people inform us that Paraquat poses a potential worker hazard we cannot afford to ignore. Our inaction to regulatory pressure could result in severe restriction of Paraquat uses. Banning of Paraquat use in the United States is considered a possible course of regulatory action. The lack of an antidote appears to be the motivating basis for the adverse attitudes toward Paraquat. Additional regulatory pressures are being felt as a result of the worker injury reports recently compiled by the State Department of Public Health. The California regulatory agencies consider these injuries as evidence of a user hazard even though the majority of the injuries are accidental and have resulted from gross misuse of the product. The California State Department of Agriculture indicates that Paraquat injuries outnumber any other single pesticide. In addition, reduced lung capacity and liver damage have supposedly been reported in workers using Paraquat.

Our present label has been severely criticized as being inadequate in that the instructions are not clear and can be misinterpreted. The regulatory and public health agencies feel that human health must be protected at all costs. The question has been raised: What health effects does continuous Paraquat exposure pose to workers? At the present time we are unable to properly respond to this question to the complete satisfaction of Public Health and Regulatory people. It was emphasized that regulatory agencies respond to emotional and political pressure rather than acting on sound scientific evidence.

Legal

Doppelt pointed out that the evidence available to the regulatory agencies implicating Paraquat to be hazardous, even though not scientific, is legally dangerous and admissible as court evidence. Searle and Doppelt felt there were many shortcomings in our present label which would be difficult to defend in a court of law. The punitive aspects of liability are not favorable at the present time. They felt that preventive measures in the form of stricter label recommendations were the best course of action.
Marketing

Our increasing percent of sales are dependent of "influencers" such as state and university cooperators, soil conservation people and field specialists. Restricted list classification doesn't appear to adversely affect sales as evidenced by the larger number of registrations. In the past, the usefulness and efficacy of Paraquat was used to offset complaints about drift problems and health hazard potential. However, with glyphosate introduction into the market these arguments will lose their emphasis.

It was pointed out that regulatory agencies and use regulations have a direct effect on sales. Some poeple could be persuaded not to have fears about Paraquat hazards while others cannot. Marketing felt that the signs are unmistakable - that people are being influenced on the hazards from Paraquat use. They felt a specific antidote for Paraquat would greatly decrease adverse pressure. Marketing did not feel that label recommendations for use of goggles and respirator would greatly affect sales. Marketing felt that the best course of action in preventing registration restrictions was to modify our present label in a way that was acceptable to the regulatory agencies.

Toxicology

It was felt that the lack of chronic inhalation toxicity information and epidemiological surveys were a definite weakness in properly evaluating the safety of Paraquat use or properly defending the safety of Paraquat. ICI indicated that the worker-hazard study now in progress in Ireland would aid in evaluating the potential hazard to Paraquat users. Dr. Fletcher felt confident that the Ireland study will demonstrate that Paraquat is safe and minimal amounts are absorbed by workers after prolonged usage.

ICI

ICI felt that there was no chronic hazard to workers from prolonged exposure to Paraquat. Their position was based on the overwhelming history of safe use in all parts of the world. ICI outlined worker safety rules which appear on their label. The worker safety rules are general rules for all pesticides and emphasize good hygiene practices. They urged Chevron to incorporate these worker safety rules in a separate "box" on our label. They pointed out that respirator and goggles need not be worn at all times when spraying as outlined in Chevron's proposed label revision. ICI felt goggles and a respirator should only be worn if there was a risk of accidental exposure. It was strongly suggested that the goggles and respirator requirement be included under worker safety rules rather than in our present poison box.

Proposed Label Changes

Based on the above philosophies and potential health hazards associates with Paraquat, the following major changes were proposed:

1. Revise front panel format to conform to Parathion label.
2. Revise poison box on side panel. Include physician's emergency telephone number.

3. Include a side panel box containing worker safety rules.

A copy of Chevron's current and proposed labels are attached for comparison. On April 5, copies were distributed to all meeting participants for immediate review and comments. Tentative plans are to submit the revised label to EPA by April 30.

**Recommendation For Future Consideration**

Attach a sticker on neck of container to read - DO NOT OPEN without reading Danger statement on label! This comment was well received by all attendees.

Recorded by

F. X. Kamienski

Attachments

cc: All Attendees
    D. B. Barlow
    A. P. Brown
    M. Wierenga