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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 4, 1997

MEMORANDUM

SUBJECT: Review of Waiver Request for Strychnine Data
DP Barcode D237258, Chem. No. 076901, Rereg. Case #3133

TO: Bonnie Adler, Team Manager
Reregistration Branch I
Special Review and Reregistration Division (7508W)

FROM: Jerome Blondell, Ph.D., Health Statistician
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THRU: Susan V. Hummel, Branch Senior Scientist
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The Stychnine Consortium has submitted two waiver requests:
1. GDLN 82-2-SS, 21 Day Dermal Toxicity Study.
2. GDLN 82-3-SS, Human Incident Study.
The basis for these two requests and the Health Effects Division recommendation will be presented in turn.

GDLN 82-2-SS, 21 Day Dermal Toxicity Study

The basis for the waiver request for the dermal toxicity study was the absence of accumulation of stychnine in body tissues, the lack of acute dermal toxicity, the absence of any incidents reported due to dermal exposure, and the limited use for underground baiting. The Consortium also points out that existing personal protective equipment requirements in the RED which includes chemical-resistant gloves would preclude significant dermal exposure in any case for occupational handlers. Further, the occupational handlers are the only ones likely to experience repeated dermal exposures. Other genenal use applicators do not apply these products more than a few times, thus subchronic exposure is not expected to be a concern. Nevertheless, the Consortium did recommend extending minimal PPE requirements to all strychnine products, claiming that this requirement is practical for residential users. They support this claim of practicality by noting that products registered for use for flea and tick control on pets already have such requirements.

Recommendation:
On balance the Health Effects Division finds that the justification for the waiver for the 21 Day Dermal Toxicity Study is well stated and persuasively argued. HED recommends this waiver request be granted.

GDLN 82-3-SS, Human Incident Study

The basis for the waiver request for incident data included the time and expense to collect additional incident data. Second, the Consortium noted that the request should have included only residential general use products that would be used around residential areas and that there was no concern for children getting into restricted use products. Third, the precautionary measures already proposed for residential situations were sufficient to address the concerns for incidents involving children.

Taking the second point first, there is concern that children get into restricted use pesticide products even when their use is limited soley to non-residential sites. Among 13 toxic organophosphate and carbamate insecticides with nearly all uses restricted (e.g., aldicarb, carbofuran, and methidathion) there 34 exposures per year reported to Poison Control Centers in children under age six. Infants and young children accounted for 9 percent of the calls to Poison Control Centers for these products. Therefore, restricting a pesticide to certified applicators and registering its use for only non-residential sites is not a guaranteed way to prevent exposure in young children. The request for a partial waiver based on limiting concern only to general use products should be denied.

The third point suggests that child-resistant packaging is sufficient to address concerns involving children. In general, studies of other products have shown significant reduction in poisoning and death after introduction of CRP. Careful review of the studies by Fink (1976), Sibert et al. (1977), Clarke and Walton (1979), Gross et al. (1980), and Walton (1982) all suggest that CRP can be expected to reduce poisoning incidence by about 50 percent. The range found in these individual studies varied from 30 to 67 percent. For non-drug related products placed in CRP (e.g., drain and oven cleaners, antifreeze, and lighter fluids), Walton (1982) and Gross et al. (1980) found the range of reduction varied from 50 to 67 percent. This suggests that CRP may be more effective for products not consumed intentionally by people which young children may imitate. Despite this evidence for efficacy, data suggest that at least one-third of poisonings will continue to occur despite CRP. For products where a single swallow is potentially lethal (See Blondell 1994), risk assessment requires an assessment of the number of likely exposures both for residential and non-residential products.

The first point concerned the excessive cost to fulfill this Data Call In which was estimated to be $26,000. This estimate was based on obtaining data for the years 1990-1992 in one report and for the years 1993-1995 in another report. The Office of Pesticide Programs has recently (since the Data Call In was issued) received funding that will permit it to examine the data for the years 1993 through 1996 for all pesticides including strychnine. Therefore, there is no need for the registrants to obtain data for these years and the total costs are will be cut in half. Thus the final costs for obtaining Poison Control Center Data for the years 1990-1992 would be $13,000. This should not be considered an undue cost given the potential savings from preventing loss of life.

In addition to the complete waiver for incident data, there was also a request for a partial waiver, such that data would be required only for the years 1994 through 1996. Even though some data is available to EPA for the years 1990-1993 is not sufficiently detailed and product specific. Only be examining the incidents for both non-residential and residential areas will it be possible to assess the likely hazards to young children.

Recommendation:
The Health Effects Division recommends that the waiver request for incident data be denied. Further the Health Effects Division recommends that the requests for a partial waiver either to limit the scope of products covered or to limit the years covered to 1994 through 1996 be denied. However, given that the Office of Pesticide Programs will be able to obtain data for 1993 through 1996, the Health Effects Division does recommend a waiver be granted for collecting data for these years.

References

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cc: Correspondence
Strychnine file (076901)

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