RE-EVALUATION OF HEAVY DUTY WOOD PRESERVATIVES: A COLLABORATIVE APPROACH TO RISK MANAGEMENT

Andrew Beyak, Health Evaluation Division, Pest Management Regulatory Agency, Health Canada, 2720 Riverside Drive, Ottawa ON, K1A 0K9

Summary

1. Introduction

Health Canada's Pest Management Regulatory Agency's (PMRA) mandate includes preventing unacceptable risks to people and the environment from the use of pesticides, as well as minimizing risks currently posed by pesticides. The PMRA also evaluates pesticides for their efficacy and their value to users, and promotes sustainable pest management.

As part of their mandate the PMRA re-evaluates currently registered pesticides on a 15-year cycle, as required by the Pest Control Products Act (PCPA). The PMRA's Re-evaluation Program applies modern science and risk assessment methods, and current regulatory requirements to older pesticides, thereby assessing if the risks associated with older pesticides remain acceptable.

Several heavy duty wood preservatives (HDWP) were re-evaluated under the PMRA's re-evaluation program. These include creosote, pentachlorophenol, chromated copper arsenate (CCA) and ammoniacal copper zinc arsenate (ACZA).

The PMRA's re-evaluation of HDWPs was conducted cooperatively with the United States Environmental Protection Agency (USEPA), particularily with respect to the science and value assessments. However, different regulatory requirements in Canada and the United States, as well as conditions unique to the wood preservation industries of each country resulted in different timelines for the finalization of each countries' respective re-evaluation/reregistration activities.

The USEPA finalized their Re-Registration Eligibility Decisions for HDWPs in September 2008 (published November 2008) and allowed reregistration with the implementation of specified mitigation measures (eg. additional personal protective equipment and engineering controls).

In October 2008 the PMRA presented an update on the re-evaluation of HDWPs at the Canadian Wood Preservation Association (CWPA annual meeting). The PMRA has subsequently addressed Canadian-specific aspects of the re-evaluation, which include the following:

- an evaluation of HDWPs under the Federal Government's Toxic Substances Management Policy (TSMP);

- the re-evaluation of a brush on formulation of creosote, not registered in the U.S.;
- consideration of the Recommendations for the design and operation of wood preservation facilities – technical recommendations document (TRD) and its relevance to both the re-evaluation risk assessment and risk mitigation options; and
- the public consultation requirements under Section 28 of the PCPA, addressed through the publication of a Proposed Re-evaluation Decision Document (PRVD) prior to a final re-evaluation decision.

The Proposed Re-evaluation Decision Document PRVD2010-03, *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)* was published in August 2010. This document identified some occupational risks of concern related to the use of HDWPs and found that these products are efficacious, have significant value (economic and socioeconomic) and few viable alternatives. The document proposed the continued registration of these products, identified mitigation measures and proposed the development of a Risk Management Plan to further reduce potential risks. A corresponding document, Re-evaluation Note REV2010-05, *Call for Risk Management Proposals for Heavy Duty Wood Preservatives (Creosote, Pentachlorophenol, CCA and ACZA)* was published to solicit input to a Risk Management Plan.

The Re-evaluation Decision RVD2011-06**,** *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)*, was published in June 2011. This decision granted continued registration to these products, while requiring changes to product labels and other additional risk mitigation measures. These measures included requiring the development of a Risk Management Plan for HDWPs and requiring that all operational procedures of wood treatment facilities be consistent with the Environment Canada document, *Recommendations for the Design and Operations of Wood Preservation Facilities –Technical Recommendations Document* (TRD).

The re-evaluation of HDWPs presented numerous challenges, which included:

- recognizing different industry practices in the United States and Canada, while conducting a cooperative re-evaluation with the U.S.;
- making appropriate regulatory decisions in consideration of evolving industry practices;
- managing risks while recognizing value; and
- obtaining expert opinion on industry.

Several risk management considerations were identified during the re-evaluation. These included:

- the implementation of industry guidelines during the re-evaluation process;
- the accuracy of the PMRA's risk assessment; and
- determining the relevance of USEPA mitigation measures to the Canadian wood treatment industry.

Addressing the above challenges and considerations led to a collaborative re-evaluation process and resulted in unique approaches to risk management.

2. Methodology

The PMRA generally conduct pesticide risk assessements by comparing exposure estimates (both human and environmental) to the toxicological properties of pesticide active ingredients. To do this, the PMRA establishes a target margin of exposure (MOE), which is the desired buffer between estimated exposures and toxicological effects. This target MOE is then compared against the estimated margin of exposure, which is the buffer between estimated exposures and toxicological effects). Low target MOEs (i.e. a smaller buffer to toxic effects) are established if there is a higher degree of certainty in toxicology and exposure data, or if the toxic effects are not severe. Higher target MOEs (i.e. a higher buffer to toxic effects) are established if toxicology and exposure data have a lower degree of certainty or if toxic effects are more severe. Some target MOEs in the HDWP assessments were low, since precise human epidemiology was available. In other cases target MOEs were higher where data sources provided less certainty with respect to toxic effects or exposures.

The re-evaluation of HDWPs evaluated the risks of their use as well as their value. The re-evaluation also and identified risk mitigation measures. In addition to the PMRA's usual re-evaluation resources, the re-evaluation of HDWPs also involved collaboration the USEPA, Environment Canada, product registrants, the wood treatment industry (e.g. Wood Preservation Canada) and expert consultants.

A major consideration in determining risk management options was the implementation of industry guideline (i.e. TRDs) during the re-evaluation. The TRDs are a voluntary code developed by industry and government (led by Environment Canada). The objective of the TRDs is to minimize worker and environmental exposure to wood preservatives. These guidelines have been adopted by >90% of Canadian wood treatment facilities and represent a substantial monetary and capital investments by industry.

In their reregistration eligibility decision the USEPA imposed additional risk mitigation requirements regarding personal protective equipment and engineering controls as part of their re-registration decision. The applicability of these mitigation measures to the Canadian wood treatment industry was unclear because

the U.S. has no program comparable to the Canadian industry's TRD program. Therefore the PMRA contracted the services of SCI Services Inc. (Konasewich and Brudderman) to compare the U.S. requirements to: the TRDs; and the current state of the Canadian industry.

3. Results and Discussion

The PMRA's value assessment determined that the HDWPs under re-evaluation were critical to the wood preservation industry because of limitations with respect to registered alternative wood treatment products and alternative materials.

The PMRA's re-evaluation risk assessment identified some risks of concern to workers using heavy duty wood preservatives in treatment plants. However, the exposure data upon which the risk assessment is based may not be representative of the present Canadian situation, where implementation of the TRDs has likely decreased exposures. Therefore the risk assessment likely overestimates exposure. That said, the degree to which risks are overestimated cannot be determined without new exposure data. Therefore potential occupational risks cannot be dismissed. Requiring new exposure data to refine the re-evaluation assessments would result in significant cost and effort to industry. Furthermore it would take significant time for the data to be generated and evaluated by the PMRA. Therefore the PMRA is requiring that a risk management plan be developed, which is builds on and is complimentary to recent industry investments in the TRDs.

Pesticides are generally regulated through a product labelling approach where conditions of use and directions are specified. Such label statements are legally binding. Therefore label requirements must be universally practicable.

A risk management plan is a plan to identify and implement additional opportunities to lower exposures and reduce risk. Such a plan may go beyond product labelling requirements and allow for continual improvement through an action plan. However, the PMRA presently considers the applicability of a risk management plan approach to be limited to situations where:

- there are few or no alternative products registered; and
- the occupational environments where the products are used are inherently manageable (eg. industrial environments are more manageble than residential/homeowner environments.)

The PMRA intends to develop a HDWP risk management plan in consultation with industry, other areas of Health Canada and Environment Canada. The PMRA will also consider the recommendations on risk mitigation provided to PMRA by SCI Services Inc. and will endeavour to work with the existing industry TRD framework, where possible.

Possible elements for consideration in a risk management plan include the following:

- Documentation/Regulation/Guidelines
    - Periodic review/ update of TRDs (currently under revision).
    - Clarifying or revising personal protective equipment requirements.
    - Enhancing coordination/communication among regulatory authorities.
    - Harmonizing regulations/guidelines (where possible).

- Technology/ Monitoring
    - Identification of engineering controls/best available technology and implementation plans.
    - Reviewing air monitoring practices.
    - Assessing ventilation approaches.
    - Developing medical, biomonitoring and air monitoring protocols.

- Compliance Promotion and Enforcement
    - Identifying HDWP treatment facilities as a priority for PMRA compliance projects.
    - Increasing PMRA-Environment Canada involvement in TRD certification process.

- Corporate Stewardship/Responsibility
    - Promoting supplier stewardship over sales of preservatives/ treated product.
    - Long-term development of alternatives.

4. Conclusions

The PMRA's re-evaluation decision for HDWPs allowed for the continued registration of creosote, pentachlorophenol, CCA and ACZA subject to certain conditions. These conditions included:

- label updates
    - to improve protection of health and the environment, and
    - to achieve consistency across labels and with the TRD;
- requiring wood treatment facilities to follow the TRD; and
- requiring the development of a HDWP risk management plan.

The re-evaluation of HDWPs demonstrates the advantages of a collaborative approach to re-evaluation. Such an approach allows for full consideration of current industry practices and takes advantage of industry expertise.

Furthermore, utilizing industry best management practices, such as the TRD, has been shown in some cases to result in better risk reduction/compliance outcomes than conventional regulatory approaches. Sound management of risks by industry allows regulators to focus on specific problems rather than the entire sector.

A collaborative approach also allows for consideration of, and coordination with, other regulators' activities.

Utilizing the knowledge and expertise of independent and impartial consultants allows regulators to provide effective and practical regulation while maintaining regulatory integrity.

5. Literature

Recommendations for the design and operation of wood preservation facilities, 2004 – technical recommendations document. Report EPS 2/WP/6. Prepared for Environment Canada National Office of Pollution Prevention by GE Brudermann, Frido Consulting.

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