

Risk and Decision: Evaluating Pesticide Approval in California

A review of the methyl iodide registration process

Abstract

Fumigant pesticides are widely used in agriculture in California and other states to control soil pests for high-value crops such as strawberries, peppers, tomatoes, and stone fruits. This report focuses on one fumigant—methyl iodide—and the story of its approval for use in California by the Department of Pesticide Regulation (DPR) in a process known as registration.

Methyl iodide (used in combination with chloropicrin) was introduced as a substitute for methyl bromide, a widely used fumigant slated for phase out by 2015 due to its ozone-depleting nature. While the methyl iodide/chloropicrin mixture was a promising alternative in terms of performance, it raised substantial human health issues, including neurotoxicity, carcinogenicity, and developmental toxicity. The high volatility and high application rates used for soil fumigation guarantee significant exposure for workers and those living and working near a fumigation site. As a result, the approval of the methyl iodide/chloropicrin mixture as a fumigant pesticide was the subject of substantial controversy at both the Federal and state levels.

This report uses methyl iodide as a case study to explore the limitations of the risk governance approach reflected in California's registration process. Risk governance refers to the social, legal and institutional decision-making processes used in identifying and responding to risks facing society. In evaluating the scientific, social, and legal dimensions of registration, the report draws upon reports, letters, hearing transcripts and other documents generated as part of the registration process. From existing literature, it identifies best practices for the relevant elements of risk governance—Problem Identification/Framing; Risk Assessment; Evaluation/Option Selection; and Stakeholder Communication—and assesses the methyl iodide registration process against them.

That assessment identified a variety of deficits in the pesticide registration process, implicating four general themes underlying risk governance. Effective risk governance should be realistic when framing and assessing risk, taking into account multiple and cumulative risks facing individuals. It should be based on the best available science and data, and should deal cautiously and conservatively with data gaps, uncertainty, and variability. It should take the concept of prevention seriously, carefully considering the availability of safer alternatives. Finally, it should be a transparent and interactive process, involving all stakeholders in a meaningful way. The report concludes by presenting recommendations to improve pesticide risk governance in light of these themes, drawing in large part from new approaches offered by the National Research Council (NRC) in 2009 as a way forward.

The risk governance deficits included:

- Failing to require adequate data regarding developmental neurological toxicity, neurotoxicity, potential groundwater impacts, and anticipated emissions of methyl iodide from farm fields;
- Using incomplete risk assessment methods: limited attention to case studies, inadequate study design, inadequate study methods and faulty assumptions;
- Framing the registration review too narrowly by considering only the risks of methyl iodide, rather than focusing on cumulative exposure to the methyl iodide/chloropicrin mixture that would be used in practice;

- Relying upon unrealistic assumptions in estimating worker exposure to fumigant emissions;
- Inadequately engaging stakeholders other than the applicant in the process of registering new pesticides;
- Failing to consider safer chemical and non-chemical alternatives to the fumigant,
- Lacking clear, complete description of how the risk managers reaching the decision to register methyl iodide, particularly regarding how acceptable exposure levels were determined;
- Revising the scientific conclusions of the risk assessment regarding acceptable exposure levels under circumstances that suggest that the revised levels were selected so as to support economically acceptable mitigation measures; and
- Selecting acceptable risk values that exceeded staff and SRC recommendations by a factor of 100 thus providing inadequate protection.

The following recommendations respond to the specific deficits and advance the four themes of effective risk governance described above. The recommendations assume that the basic structure of pesticide regulation and agricultural policy more generally in California remains essentially intact. The pervasive use of chemical fumigants is a consequence of modern conventional agriculture, going hand in hand with such elements as intensive tillage, monoculture, and the application of inorganic fertilizer. Achieving sustainable agriculture which, among other things, would likely minimize the dependence on chemical pesticides, would require more fundamental changes that are beyond the scope of this report.

- ***Realistic Framing and Assessment of Risk***

Develop realistic framing of the problem, taking into account the actual context. DPR framed the problem as exposure of workers and residents to methyl iodide, when in fact those individuals would be exposed to mixtures of methyl iodide and chloropicrin. This frame drove the data collection, risk assessment and ultimately the registration decision.

Perform cumulative risk assessments, taking into account all active ingredients in the pesticide under review, as well as exposures affecting the relevant population. Implement a phased-in approach to consider chemicals under a unified dose-response assessment framework that includes a systematic evaluation of background exposures and disease processes, possible vulnerable populations and modes of action that may affect human dose-response relationships.

- ***Use of Best Available Science/Data and Exercise of Caution***

Develop procedures for early identification of mandatory testing. DPR should identify data gaps and the necessary testing early in the process, requiring a comprehensive data set from the applicant.

Improve uncertainty and variability assessment to accurately reflect all known factors. This would include the context in which the chemical is intended to be used, and would account for unknowns by increasing uncertainty factors. It is particularly important to address exposure assessment and dose-response in the context of uncertainty and variability.

Develop a robust, conflict-free peer review process to ensure the best science is used in developing risk assessments. The peer review process should include scientists with particular knowledge of the most important toxicological and health endpoints.

Incorporate state of the art risk assessment methods into the registration process. Going forward, DPR should take full advantage of OEHHA's expertise to help integrate new risk assessment methods into DPR's registration process. This would include making use of advanced methods for dose-response assessment including the benchmark dose approach, and considering linear dose response models as representative of the most health protective approaches.

Develop procedures for consultation and concurrence of risk assessors. DPR policy should be modified to require consultation with and concurrence of the Medical Toxicology and Worker Health and Safety branches on any revisions to the conclusions of the risk assessment. This recommendation is consistent with existing policy that prevents registration where any reviewing DPR branch recommends against registration because of inadequate data, unacceptable studies or unmitigated adverse effects.

- ***Embracing Prevention of Risk***

Include identification and evaluation of chemical and non-chemical alternatives as part of the registration review. Existing law and regulations require consideration of alternatives as part of the registration decision. Failure to include the existence and viability of alternatives as part of the problem undermines DPR's ability to do so. DPR should rather require the applicant to provide such information subject to DPR oversight, or independently generate the information as part of the review process.

Develop guidance on alternatives analysis. DPR policy should be modified to explicitly integrate analysis of alternatives—either by the applicant or the agency—into the registration process. As part of these modifications, DPR should develop standard methodologies for performing alternatives analyses, and include relevant stakeholders and experts in alternatives analysis in the development process.

- ***Engaging in Transparent, Interactive Decision-Making***

Review public participation practices. DPR should engage in a structured review of its public participation process, identifying additions and modifications intended to enhance meaningful participation by all relevant stakeholders in the registration process.

Develop requirements for record of decision, providing a more extensive description of the basis of decision. DPR should address the lack of transparency in the decision-making by fully documenting and explaining the bases of its decisions in the publically available Notice of Proposed Decision and Notice of Final Decision. Agency guidance should be modified to articulate specific performance standards for the notices providing for specific discussion of the assumptions, data and reasoning relied upon in approving registration, setting exposure levels and establishing mitigation measures.