



Statement
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Director, Department of Pesticide Regulation

Senate Committee on Food and Agriculture
June 17, 2010

Thank you for the invitation to appear before your committee today. We appreciate the opportunity to review for you our proposed decision to register methyl iodide, a replacement for methyl bromide.

In arriving at our decision, the Department of Pesticide Regulation followed a strictly defined procedure under the law. It is a complex process, which I will highlight for you today.

DPR's proposed decision follows several years of assessment and an unprecedented level of evaluation to determine if, and ensure that, methyl iodide could be used safely in California. DPR scientists examined more than 100 studies on the potential health and environmental effects of methyl iodide. Their risk assessment was peer-reviewed by our colleagues at the Office of Environmental Health Hazard Assessment and the U.S. Environmental Protection Agency (U.S. EPA). To further validate our science, we contracted with a panel of eminent scientists to conduct an independent peer review. Their comments and those of others are reflected in the final risk assessment.

Some have accused DPR of ignoring its risk assessment or, worse, of changing its conclusions. These accusations are untrue. The risk assessment was finalized by DPR's scientists and posted on our Web site months ago, in February 2010. It has not changed.

What some critics have misunderstood or ignored is the role risk managers play in the regulatory process. Risk assessments are not designed or intended to recommend registration decisions or risk mitigation options. They provide the foundation for the next step in the regulatory process – risk management.

I and other DPR risk managers considered the risk assessment and the external peer review panel's document when reaching a proposed registration decision. We also considered other information, including U.S. EPA's risk assessment and guidance issued by U.S. EPA and the World Health Organization, for these types of decisions.

This approach to risk management is one widely accepted and used by environmental and health regulatory agencies throughout the world. As U.S. EPA explains, "The scientific risk assessment and its peer review provide the sound scientific underpinnings for a decision. However, it is only one of the many factors that a decision maker considers in arriving at a final environmental decision. . . . Risk assessment provides INFORMATION on potential health risks, and risk



management is the ACTION taken based on evaluation of that and other information,” including social, economic, and legal considerations.

As DPR risk managers, we based the proposed decision on the facts presented in the risk assessment. This information helped us decide if and how exposures to methyl iodide could be kept below unsafe levels. We concluded the answer is yes, with requirements for more health-protective measures than U.S. EPA imposes. For example, California’s allowable exposure for licensed professionals who apply or handle methyl iodide will be half of what U.S. EPA allows. For others (those not handling or using methyl iodide), DPR’s allowable exposure is five times lower than the U.S. EPA level. Meeting these stricter exposure standards means that California will impose more comprehensive controls on methyl iodide than U.S. EPA or any other state imposes.

I would like to take a few minutes to address other assertions that have been made that are contrary to facts.

TRAINING: Methyl iodide will not be used by untrained farmworkers. Doing so would be a violation of state law and our comprehensive use restrictions. In California, professional applicators who would use methyl iodide must have extensive safety training, a special fumigator license, and a site-specific permit from the local agricultural commissioner who can impose further use restrictions.

AIR QUALITY: Some have said that methyl iodide will emit gases that form smog. It is true methyl iodide does emit volatile organic compounds, or VOCs. However, because of methyl iodide’s low reactivity, U.S. EPA is considering reclassifying it as a compound that does not contribute to formation of smog. Also, the use of methyl iodide and all fumigants is subject to DPR regulations that have reduced smog-producing emissions from pesticides. For example, in the San Joaquin Valley, pesticide VOC emissions have been cut by 30 percent from 1990 levels.

GROUND WATER: U.S. EPA and DPR independently assessed the potential for contamination of ground and surface water. Using computer modeling and assuming worst-case environmental conditions, the conclusion was that methyl iodide is unlikely to affect water quality. To provide an extra margin of safety, DPR is proposing added controls to protect ground water, such as buffer zones around wellheads and application limits in vulnerable areas.

FOOD RESIDUES: Methyl iodide is not applied to food crops. Rather, it is injected into bare soil before crops are planted. It leaves no methyl iodide residues in either soil or food. In extensive field studies, methyl iodide residues could not be detected in harvested fruit. In short, methyl iodide use does not present a food safety concern.

BUFFER ZONES: DPR is proposing a minimum half-mile buffer zone around occupied schools, hospitals, nursing homes, and similar sites. Neither the public nor workers can be present in a buffer zone during the application and for 48 hours afterwards. The applicator is responsible for ensuring the area remains clear of people.

Residents in buffer zones are not forced from their homes during fumigant applications. However, it is not uncommon in rural areas for applicators to arrange for residents in a buffer zone to voluntarily leave their homes for a few days so fumigation can proceed. The applicator typically pays for all lodging and expenses. These agreements are voluntary and, if residents decline, no fumigation can occur.

ENFORCEMENT: County agricultural commissioners enforce pesticide laws locally and levy penalties for violations. No other state has similar local enforcement. The commissioner also can impose additional restrictions, tailored to local conditions, over and above DPR's fumigant rules, already the strictest in the nation.

RESPIRATORS: Face-sealing respirators required when using methyl iodide are the same as those used as proven worker protection throughout the chemical manufacturing industry. The U.S. Occupational Health and Safety Administration (OSHA) has tested half-face respirators like those required for methyl iodide and found that they meet the requirement to reduce inhalation of dangerous chemicals by at least 90 percent.

DPR recently enhanced its respirator regulations to make them more stringent than federal law and ensure that pesticide applicators receive full protection and can safely use respirators. Our rules require a medical evaluation and fit testing before workers can use a respirator. The regulations prohibit workers from wearing face-sealing respirators if they have facial hair that interferes with the seal or valve. The respirators are designed so that sweating should not interfere with the seal. If a person wearing a respirator needs to remove it, they must leave the area where exposures may occur. They cannot just lift up their respirator and take a smoke break as critics have alleged.

STATUS OF METHYL IODIDE AT U.S. EPA: U.S. EPA officials stated that the agency would review the external peer review panel's report and DPR's revised risk assessment to determine whether any new scientific information was developed to warrant further examination at the federal level. However, as recently as this week, we received verbal confirmation from U.S. EPA officials that the agency does not plan to reevaluate its registration decision on methyl iodide at this time.



Mary-Ann Warmerdam
Director

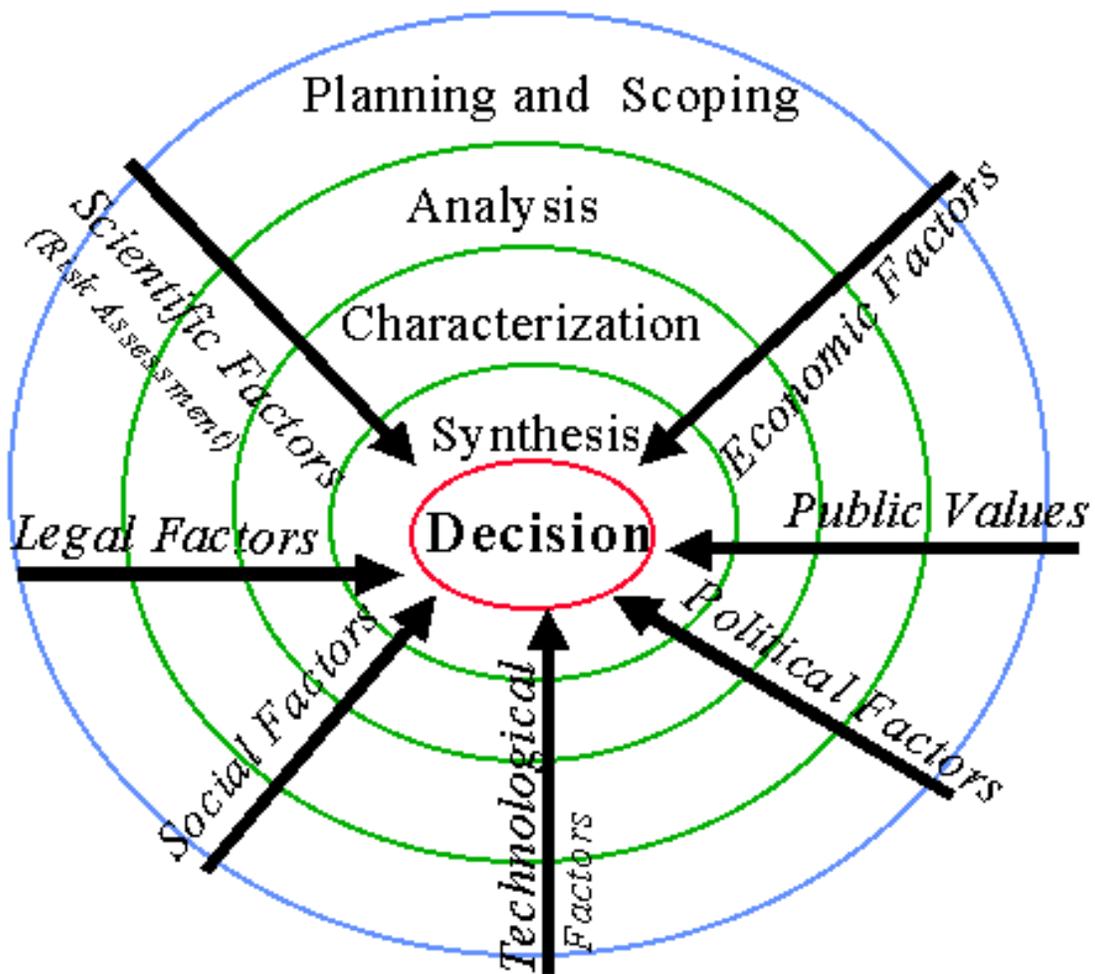
Arnold Schwarzenegger
Governor

Methyl Iodide Timeline

2002	DPR receives first applications from Arysta to register methyl iodide (also known as iodomethane) products; however, application package was not complete.
2004	After a preliminary review of toxicology studies, DPR identifies methyl iodide as having potential adverse health effects which a more in-depth appraisal of risk could examine before a registration decision. Begins risk characterization process.
October 2007	U.S. EPA grants a one-year, time-limited registration to methyl iodide products.
September 2008	U.S. EPA grants conditional registration for all methyl iodide products without time limitations. <i>(The conditions of registration were to ensure that the iodomethane registrant makes all changes to the iodomethane labels that are appropriate to ensure that all the fumigants are regulated in a consistent manner, when the reregistration process for the existing soil fumigants was concluded.)</i>
October 2008	Arysta's application package to DPR for methyl iodide products is complete.
March 2009	Following standard protocol, DPR sends its draft risk characterization document (RCD) to the Office of Environmental Health Hazard Assessment and U.S. EPA for peer review.
August 2009	Revised RCD posted online for public comment.
September 24-25, 2009	Two-day workshop held by external peer review panel convened by DPR to peer-review RCD.
February 2010	Final RCD posted on DPR's Web site, including many revisions recommended by external peer review panel.
February 2010	External peer review panel's report posted on DPR's Web site.
April 30, 2010	DPR announces proposed decision to register methyl iodide products, using nation's most stringent use controls; 45-day comment period opens.
May 19, 2010	Prompted by a high degree of public interest, DPR extends public comment period to June 29, 2010.
June 29, 2010	Comment period ends.
NEXT STEPS	After U.S. EPA approves California-specific product labels, DPR technical experts will review them to ensure all required health-protective measures are in place.
	DPR will evaluate public comments before deciding whether to proceed with registration.
	If DPR makes it decision final, the Department must first adopt regulations making methyl iodide a restricted material.



Figure 5.1 Risk Management Decision Framework. At least seven factors (represented by the arrows) affect and inform risk management decisions. Each factor passes through four analytical steps to integrate the information for a risk management decision.



Excerpted from "Science Policy Council Handbook: Risk Characterization"

U.S. Environmental Protection Agency (EPA 100-B-00-002), Office of Science Policy (2000)