Regulatory Policies, Technology, and Related Factors Affecting the Use of Fumigants and Controlled Atmospheres

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Abstract

Pesticides used for the disinfestation of stored grain are receiving increased scrutiny and challenge by regulatory agencies throughout the world. In the US, several fumigant materials whose use has spanned more than 50 years (methyl bromide, chloropicrin, and aluminium/magnesium phosphide) are under intense review by the nation's Environmental Protection Agency. This paper discusses the interactions of policy, technology, and related factors which impact on fumigant use and identifies specific data requirements for their continued registration. The regulatory status of controlled atmospheres in the US is also discussed.

CHEMICAL grain fumigants have provided the principal remedial procedure used to control insect infestations in bulk stored grain for more than 50 years. Their use became an essential control measure when no other pesticide treatment could reach an infestation deep within the grain mass. Today, controlled atmosphere treatments of grain involving alteration of the proportions of the normal gaseous constituents of air (oxygen, nitrogen, carbon dioxide) to provide an insecticidal atmosphere represents the most likely direct substitute for chemical fumigation of grain. The two methods of pest control appear, however, to be following divergent paths of development.

The availability of chemical fumigants for the control of pests affecting agricultural commodities has significantly diminished over the past few years, especially in the United States. Specifically, the compound ethylene dibromide (EDB) was suspended by the U.S. Environmental Protection Agency (EPA) from all further sale, distribution, or use in February 1984 and the distribution of liquid fumigants containing admixtures of carbon tetrachloride (CCl_4), carbon disulphide (CS_2), or ethylene dichloride (EDC) was ended on 31 December 1985 (EPA 1985). These fumigant mixtures dominated the U.S. fumigant market for nearly 30 years reaching a peak annual use estimated at 5 million gallons (ca 19 million litres) in the late 1950s (Storey et al. 1986). In contrast to the cancellation of liquid fumigant mixtures, EPA established an exemption from the requirement of a residue tolerance for controlled atmospheres on all raw, dried, or processed agriculture commodities (EPA 1980, 1981) and listed the atmospheres as an alternative to chemical fumigants for insect control in harvested grains (EPA 1985).

While it is not our purpose here to explicitly document the demise of liquid grain fumigants, it may be useful to re-examine some of the factors that resulted in action against these materials in order to better understand the events now affecting the future of the three remaining fumigants—methyl bromide, chloropicrin, and aluminium/magnesium phosphide—still approved for use in the United States.

Fumigants and the Media

Although it is generally recognised that chemical fumigation will continue to play a critical role in future pest management strategies (Bond 1984; Storey et al. 1986), pesticides in general and fumigants in particular

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are receiving increased scrutiny and challenge, especially in the U.S. After decades of relative obscurity, fumigant 'incidents' have become front-page news filled with sensationalism and, in many instances, gross misinformation. An improper dockside disposal of aluminium phosphide material in a 55-gallon drum, which resulted in a minor fire, was equated to the Bhopal, India, disaster and the manufacturer of the phosphide material was misidentified as Union Carbide of India ('Dockside toxic leak controlled', Savannah News 1 March 1987). A project to treat imported wood stumps with methyl bromide was not too subtly captioned ...'Brunswick company will use a carcinogen to fumigate shipments' (Atlanta Journal /Constitution 7 July 1986). Following EPA's cancellation of EDB, a major newspaper in the central states ran a three-day series of articles examining the use, hazards, and long-term health risks associated with fumigant use and criticised the Agency's 'bogging down' in not following through with programs to adequately regulate grain fumigants ('Toxic harvest', Minneapolis Star & Tribune 2, 3, and 4 September 1984). These articles were later followed by an open advertisement in the same newspaper placed by a law firm offering to represent anyone who suspected themselves of suffering injury related to liquid fumigant exposure (Minneapolis Star & Tribune, 3 April 1985).

EPA: Lineage and Policies Affecting Fumigants

Because EPA is currently inundated with a broad range of environmental concerns encompassing such diverse problems as air pollution, water quality, acid rain, and toxic waste dumps, it is easy to lose sight of the fact that this important government agency was essentially created out of an amendment (U.S. Federal Environmental Pesticide Control Act of 1972) to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for the primary purpose of regulating the use of pesticides. This amendment to FIFRA required that all pesticides be classified for either 'general' or 'restricted' use and that individuals who use or supervise the use of restricted pesticides would require training in application as well as certification through a responsible state agency. The Federal Environmental Pesticide Control Act (FECPCA) marked the first attempt to create a national pesticide policy that would identify the potential hazards of pesticides and also provide a measure of accountability on the part of individuals using pesticides.

By the mid-1970s, EPA began issuing a series of Pesticide Policy Enforcement Statements (PEPS) to inform users and the general public of policies being adopted by the Agency involving specific aspects of pesticide use. One of these policies established a new registration guideline entitled 'Rebuttable Presumption Against Continued Registration of a Pesticide' (RPAR). This Special Pesticide Review Process was initiated against a pesticide if EPA determined that use of the pesticide exceeded or 'triggered' risk criteria in the following areas:

RPAR Triggers

1. Acute toxicity
2. Chronic toxicity (oncogenic or mutagenic effects)
3. Reproductive effects
4. Wildlife (endangered species, non-target species)
5. Non available emergency treatment or antidote

As the title of the process implies, a chemical which triggered one or more of the risk areas was prejudged unregisterable unless the registrant(s) of the chemical could provide data acceptable to the Agency which would prove the risks were within acceptable limits or were unfounded. In due course, RPARs were issued against ethylene dibromide, carbon tetrachloride, chloroform, and ethylene oxide. In most instances, the risk criteria exceeded by these fumigant materials was in the area of chronic toxicity, specifically tumor formation in test animals. To some, EPA's RPAR registration policy was a classic example of a 'Catch 22' situation in which a 'no response' resulted in cancellation of registration, or the cost of data development for response was greater than market returns, or the data submitted might be judged inconclusive or, worse still, self-incriminatory. To others, the RPAR process was a bureaucratic 'black-hole' into which data flowed, but out of which no decisions ever emerged; yet, marketing of the suspect chemical continued while the issue was debated.

The RPAR actions against the liquid fumigant components were taken nearly 20 years after

passage of the Miller Law in the 1950s which made illegal the use of any chemical which left harmful residues in the grain. Joint industry/government residue studies (Lynn and Vorhes Jr. 1957) during that period had concluded that the common fumigant chemicals would 'not carry through into finished ready-to-eat foods and that residues present in the grain immediately following treatment bore little relationship to levels which would exist at milling or feeding'. What changed with time was not the policy of 'no harmful residues', but the analytical skill in detecting residues. Today, the limits of quantitative analysis in chemistry have improved a million-fold due to advances in instrumentation and methodology. As a result, fumigant residues previously judged as not present became readily detectable at the part per billion (ppb) and part per trillion (ppt) levels.

Deregistration of EDB

Following discovery of EDB residues in groundwater associated with soil fumigations and the reporting of EDB per se, rather than as inorganic bromide residues in milled cereal grain products (Rains and Holder 1981), pressures mounted on EPA to cancel registration of the chemical compound. In fact, most of the manufactured EDB was used primarily as an additive in leaded gasoline with less than 10% of production (ca 20 million pounds or 9.1 million kilograms) used for agriculture purposes. Furthermore, about 90% of agriculture use of EDB was as a pre-plant treatment injected into the soil to protect crops from attack by nematodes. The remaining EDB was used in programs to fumigate citrus and other fruits and vegetables under quarantine programs and in admixture with other fumigant compounds for the treatment of stored grain and milling equipment. Only about one-fourth of the liquid fumigants marketed contained any EDB. When present, it generally constituted 1.2 to 7.4% by weight of the liquid mixture. The total amount of EDB formulated fumigants marketed was sufficient to treat only about 2% of the grain volume handled annually through the US grain marketing system (Storey 1983).

Although the justification for the 'emergency' nature of the action which suspended all uses of EDB is still open to question, the aftermath of the decision became all too readily visible. Nightly pesticide accounts on the evening news from each major network, TV pictures of grain-based milled products being removed from grocery shelves, and the characterisation of products as 'contaminated' following analyses of questionable reliability took a heavy toll in consumer confidence in food safety. It also placed much of the cereal food industry in a defensive position and was likely a major factor in speeding up EPA's subsequent review of the remaining fumigant materials. After decades of relative obscurity, the act of fumigation and the chemicals used in the process were suddenly thrust into public attention. Although the media blitz soon waned, the public perception of pesticide use on food was clearly affected. A survey conducted by the Food Marketing Institute on consumer attitudes toward foods revealed that concerns about pesticide residues had largely replaced previous concerns about food additives in general or such traditional food concerns as cholesterol, sugar, and salt.

EPA Fumigant Registration Requirements

Following suspension of EDB, the Agency supplemented the RPAR process with a 'Data Call-in Notice' which reviewed existing scientific data concerning fumigants and identified essential but missing information which may not have been available or required when individual fumigant materials were initially registered. The Data Call-in Notices essentially told fumigant registrants what new information would be required for continued registration of their product and of the need to establish a specific timetable for submitting the data.

EPA also developed a 'Label Improvement Program for Fumigants' designed to help minimise occupational exposure to fumigants. The program stipulated changes in fumigant label information and in fumigant use that would require two trained persons be present during the principal fumigant operation, required the use of approved respiratory devices when concentrations of fumigant exceeded a prescribed level or were unknown, and required specified direct-reading detector devices to monitor fumigant concentrations to prescribed levels as a condition of reentry into fumigated areas or following transfers of treated grain.

Data required under the Data Call-in Notice for the three major liquid fumigant components

(carbon tetrachloride, carbon disulphide, and ethylene dichloride) included product chemistry, analytical methodology and residue, teratogenicity, and reproduction and oncogenicity studies. The general reaction of most registrants of these fumigant materials was that the costs of developing the data to satisfy the registration requirements far exceeded the total profit that could reasonably be expected from these products for the subsequent 5–10 years. As a result, none of the registrants agreed to supply the necessary information and instead requested voluntary cancellation in lieu of complying with the additional data requirements. Not a shot was fired or a prisoner taken—the battle was over before it began.

When the end came for these materials their loss was not nearly as critical as it appeared. In part, because liquid fumigants had already lost a substantial share of the fumigant market to aluminium phosphide fumigants and, in part, because the ongoing EPA questions about their continued registration were being translated into rumours and a pervasive feeling of uncertainty about 'what's next on the list'. As a result, there was abandonment of pest management strategies featuring liquid fumigants well before they were 'officially' cancelled.

Guidance for Reregistration of Fumigants

Following cancellation of liquid fumigants, EPA combined information developed in the various registration programs for each of the three remaining fumigants (methyl bromide, chloropicrin, and aluminium/magnesium phosphide) into a single reregistration document for each material: 'Guidance for the Reregistration of Pesticide Products Containing Chloropicrin as the Active Ingredient, Sept. 1982; Guidance for the Reregistration of Pesticide Products Containing Methyl Bromide as the Active Ingredient, Aug. 1986; and Guidance for the Reregistration of Pesticide Products containing Aluminium or Magnesium Phosphide as the Active Ingredient, Oct. 1986.' The documents provide a step-by-step outline of EPA's assessment of the scientific database for each fumigant, evaluate the potential hazards associated with registered uses of the material, determine what additional data are required on health and environmental effects, and review the adequacy of label information.

Chloropicrin

The guidance document for chloropicrin requires that residue chemistry data resulting from postharvest use in stored grain be developed. Specific toxicology data may also be required if significant residues are detected and a residue tolerance will have to be established. Industry support for chloropicrin's use as a soil fumigant is being developed, but only one registrant has indicated a commitment to develop the necessary data for grain use. The present deadline for submitting the required residue data is 1 July 1989

Until the question of reregistration is settled, users of chloropicrin are subject to the limitations and conditions inherent in its 'restricted' classification. Furthermore, if the concentration of chloropicrin in work areas, as measured by an approved detection device, exceeds 0.1 ppm (0.7 mg/m^3) an approved air purifying respirator for organic vapours or a self-contained breathing apparatus (SCUBA) or combination air supplied/SCUBA respirator must be worn. No treatments are to be permitted when commodity temperatures are below 40°F (5°C). Finally, when treated commodities are transferred to another site without adequate aeration, warning notices must be erected at the new site until the commodity is aerated below the prescribed threshold concentration. Degassing chloropicrin fumigated commodities is a monumental task and problems have repeatedly surfaced involving rail cars of grain containing high gas concentrations but no warning notices. Demurrage costs resulting from having to set the cars aside and fines for transporting cars with no warning notices displayed may well curtail the future use of chloropicrin irrespective of EPA's eventual reregistration decision.

Methyl Bromide

A summary of the data requirements for reregistration of methyl bromide is as follows:

Methyl bromide major data 'gaps'

1. *Toxicology database*

- subchronic inhalation studies in rat and rabbit
- chronic feeding trials in rat and dog
- mutagenicity (bone marrow, DNA synthesis)
- teratogenicity in rabbits

- worker exposure monitoring (dermal and inhalation)

2. *Tolerances (residue chemistry)*

- residue data on methyl bromide, per se
- metabolism in plants
- acceptable daily intake (ADI) for methyl bromide, per se

3. *Efficacy*

- minimum application rate under high and low pest severity.

In response to these extensive requirements, the Methyl Bromide Industry Panel began negotiations with EPA for the development of alternative data and for substitution of some toxicology data already completed. Tests by the panel are also in progress to establish worker exposure information specific to bulk grain fumigation. Additionally, the panel petitioned EPA for the establishment of tolerances for methyl bromide per se in or on several commodities, including cereal grains (except maize) at 0.3 ppm (2.1 mg/m^3) and maize at 2.0 ppm (14 mg/m^3) (EPA 1986). In an effort to gain support for reregistration, the Methyl Bromide Industry Panel told user groups that the postharvest market was relatively small (ca 2 million pounds or 908 000 kg) and that limited money was available to develop the required data. Recent statements by the Methyl Bromide Industry Panel indicate that methyl bromide users are cooperating to help supply data to satisfy the 'gaps' still existing.

Interim use requirements for methyl bromide designate it a 'restricted' use pesticide and establish a guideline for respiratory protection and applicator/worker safety requiring a self-contained breathing apparatus or combination air supplied/SCUBA respirator when methyl bromide concentrations exceed 5 ppm (35 mg/m^3) or are unknown. Applications of methyl bromide require the presence of two trained persons during fumigant introduction and no treatments are allowed when commodity temperatures are below 40°F (5°C). Transfers of treated commodities require warning signs to be erected at the new site until it is established that methyl bromide concentrations have been aerated below the threshold limit.

Aluminium/Magnesium Phosphide

Aluminium/magnesium phosphide major data 'gaps' identified are:

1. *Toxicology database*

- subchronic inhalation studies in rats
- teratogenicity test in (1) animal species
- mutagenicity battery
- worker exposure information (monitoring of all work activities where exposure is possible)

2. *Generic product chemistry*

- physical and chemical characteristics (bulk density, oxidising–reduction information, flammability, storage stability).

An organisation of 'metal' phosphide registrants in the US has agreed to jointly support development of the required data and partial requirements submitted under the reregistration process are now under review by EPA.

The present operational requirements for aluminium/magnesium phosphide use establish the 'restricted' classification and require that an approved respiratory device be worn if exposure is likely to exceed the eight hour time-weighted average (TWA) of 0.3 ppm (2.1 mg/m^3) during application, or a 0.3 ppm ceiling at any time during fumigation or upon reentry into fumigated areas after they have been aerated. It is also recommended that hydrogen phosphide concentrations should be documented for each type of routine fumigation performed where worker exposure could occur. The agency originally set the exposure limit at 0.1 ppm (0.7 mg/m^3), but decided to leave the exposure at the previously established 0.3 ppm limit until a review of the required toxicology data is completed. For concentration levels up to 15 ppm (105 mg/m^3) a full-face gas mask/hydrogen phosphide canister combination may be used. Above this level or in situations where the hydrogen phosphide concentration is unknown, an approved self-contained breathing apparatus or its equivalent must be worn.

Future of Fumigant Use

The future of fumigant use may be characterised as being composed of three basic components:

- technical factors;
- regulatory policies; and
- cost/benefit/risk relationships.

Technical factors include developments in fumigant formulation and application/distribution methodology (such as presented in the conference) that provide for more effective and efficient, and safer methods of utilising fumigant chemicals. Developmental progress in these areas is absolutely essential to retaining fumigation as a primary management tool, but such technical factors alone are not the 'tail that wags the dog'.

Regulatory policies are both a bureaucratic minefield and an environmental necessity. Fumigant chemicals are indeed highly toxic and hazardous to use. And, whether out of ignorance or indifference, fumigant misuse has occurred. EPA's regulatory policies are now establishing the ground rules of what chemicals may be used, what commodities may be treated, the conditions of treatment that must be met, and the training requirements necessary for licensing individuals who apply or supervise application of fumigants. Above all else, these regulatory policies and guidelines are establishing accountability, which in many respects has been lacking in the past. EPA's fumigant regulation is also an open-ended process. Revelations in fumigant residue chemistry or toxicological links to cellular dysfunction, irrespective of its actual medical significance, can quickly escalate the 'cost' of retaining fumigant registration in terms of both monetary expenditures for data development and in public/user confidence in the safety of the fumigant material. Despite its precarious existence, fumigation is still authorised and extensively used in the U.S. We expect it to continue to be a mainstay for pest management in stored grain in the years to come. Still, nothing is forever—especially fumigant registration by the Environmental Protection Agency.

The third component of fumigant use—*Cost/Benefit/Risk Relationships*,—is perhaps the most important interacting combination of factors affecting the likely future use of fumigants. Tighter control on fumigant application procedures requiring additional investment in monitoring devices and safety equipment, together with expanded formats for training, record keeping, and misuse penalties will clearly influence both commercial and private fumigators. However, the dominant factor affecting fumigation costs and decisions on fumigant use may well be the rapidly escalating liability insurance costs for fumigant applicators and marketers. Rate increases reportedly as high as 500% have occurred in recent years and many in the fumigant industry question whether fumigation services, particularly in rural areas, will be available in the future. The attendant expenses in travel, labour, materials, safety equipment, and liability coverage involved in servicing grain storage accounts presents a situation where the 'costs' of fumigation are being pushed well beyond the current discount penalties assessed by grain buyers for the presence of insects in grain deliveries. Under marketing practices where the benefits derived from reducing insect losses and improving grain marketability are not easily recognised or tabulated in monetary terms, rationalising the increased cost of treatment may be difficult. Furthermore, the nearly exclusive emphasis on the negative risk aspects of fumigant use has justifiably raised questions of whether fumigation benefits are worth the personal and corporate 'risks' involved. It is likely a valid observation today, to suggest that fumigation decisions in the cereal food processing industry that were once the prerogative of the sanitation departments are now being made in the boardrooms and legal departments of the companies. The ghost of EDB lingers on!

Controlled Atmospheres: EPA Registration Policies

Because of the nonproprietary nature of controlled atmospheres, the Pesticide Petitions requesting exemption for carbon dioxide, nitrogen, and combustion-product gas from the requirement of a tolerance on raw, dried, and processed agricultural commodities (EPA 1980, 1981) were submitted by the U.S. Department of Agriculture rather than by individual gas companies or equipment manufactures. In response to the petitions, EPA concluded that the usual data requirements (toxicology studies, metabolism studies, analytical methods, residue data) for pesticide petitions were not applicable to the three atmospheres and would therefore be waived. Following establishment of the exempt status, gas suppliers were furnished with registration guidelines and directions for

developing labels for their specific gases. Several carbon dioxide suppliers have now registered and labelled their gases, but no nitrogen labels have been registered to date.

The original plan for registering combustion product gases was to label the use of the inert gas generator as a 'device' since generation of the atmosphere was 'on site' rather than transported to the site as with carbon dioxide or nitrogen gases. EPA concurred that the generator was indeed a device, but then further declared that, as a device, it was not subject to registration under the Federal Insecticide, Fungicide and Rodenticide Act (Miller 1982). At present, the generators and their use locations are being recorded as pesticide production sites. As the list of 'devices' (gas diffusion membranes, pressure swing adsorption units, internal combustion engines, etc.) proliferates in the future, it is likely that EPA will have to further revise its registration guideline for controlled atmospheres.

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