

Australian Pesticides & Veterinary Medicines Authority

Special Review of EDB (Ethylene dibromide, 1,2-dibromoethane)

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EXECUTIVE SUMMARY

Review Outcomes

The NRA has completed a Special Review of the remaining uses of the agricultural fumigant, ethylene dibromide (EDB; 1,2-dibromoethane). After considering the toxicological concerns associated with the handling and use of EDB, the NRA has:

- pursuant to section 40 of the Agvet Code, cancelled the registration of all products containing EDB, and the approval of associated labels and technical grade active constituents effective from 22 December 1997;
- authorised the supply of existing stocks of EDB at retail level until 30 June 1998 and also allowed the use of EDB until no later than 30 November 1998 with a stated use regime which includes the following elements:

- a. products containing EDB only be used where stringent requirements are in place to reduce the risk of exposure to workers, including the use of closed delivery systems;
- b. registrants be required to provide resellers with technical notes explaining the hazardous nature of EDB which are to be supplied to all purchasers of EDB, and resellers to maintain records which include a written acknowledgment from purchasers that they are aware of the hazardous nature of EDB and are aware of the safety requirements for its use;
- c. registrants be required to give instructions regarding the hazards and safety requirements to users who currently hold stocks of EDB;
- d. resellers only supply EDB to users who have Farm Chemical Users Course or equivalent accreditation;
- e. a protocol be put in place by the registrant for the collection, transportation and destruction of all EDB remaining on farms and at retail outlets by 31 December 1998 – the registrant and the grower organisations to be responsible for conducting the recall according to a plan approved by the NRA;
- f. industry to be responsible for the independent auditing by a third party of the supply and use until 30 November 1998.

- resolved to withdraw maximum residue limits for EDB from 30 December 1998.

The Australian National Health & Medical Research Council (NH&MRC) identified EDB as a significant health risk in 1984, following a review of data showing that it was a potent carcinogen in rats and mice by all routes of exposure tested. The NH&MRC recommended at that time that all uses where operator exposure could not be prevented be phased out.

As a response to these recommendations, State registration authorities limited uses of EDB to soil fumigation through enclosed application systems for control of soil pests prior to sowing fruit, vegetables, cereals and ornamentals. Chamber fumigation of some fruit and vegetable commodities was also permitted as part of interstate and international quarantine requirements.

The 1994 FAO/WHO Joint Meeting on Pesticides (Core Assessment Group) reviewed the toxicology of EDB and concluded that "an exposure that would not cause adverse effects in humans after any route of exposure could not be estimated" and recommended that "all appropriate measures should be taken to eliminate or minimize human exposure to 1,2-dibromoethane".

The Australian Advisory Committee on Pesticides and Health (ACPH), supported by the then Environmental Health

and Safety Unit (EH & SU)* of the Department of Health and Human Services, subsequently recommended that the "... use of EDB as an agricultural fumigant be discontinued as soon as practicable ...". ACPH also asked the NRA to consider revising the existing MRLs for EDB to the current limit of determination and suggested that the status of these MRLs be further examined following completion of the regulatory action for the withdrawal of EDB. ** These recommendations were discussed by the NRA Board in April 1996, and the Directors recommended that the Board resolve to withdraw all uses of EDB unless procedures acceptable to public health and occupational health and safety agencies were in place to guarantee no exposure to workers or the public. A special review of EDB was formally established.

During the review, a number of submissions supporting responsible continued use of EDB were received from grower industries, in particular from Golden Circle Limited (representing the pineapple industry), the Northern Queensland Tobacco Growers' Cooperative Association, and the Australian Ginger Growers' Association. Longer phase-out periods were proposed by growers because of the long production cycle for pineapples and the necessity for growers to develop and implement alternative practices. Throughout the review, extensive consultations were held with these key user industries in an attempt to find a solution which addressed the very serious health issues associated with EDB while recognising its importance as a soil fumigant to grower industries.

Notwithstanding the information contained in the grower submissions, the TGA (supported by Worksafe Australia) reiterated their concerns, advising that unless no exposure to EDB could be guaranteed, their recommendation that EDB be phased out as soon as possible would stand.

Exposure monitoring data generated by grower industries failed to demonstrate that workers involved in the use of EDB would not be exposed to significant levels of EDB, even with the use of closed delivery systems. The NRA could therefore no longer be satisfied that the use of EDB might not be an undue hazard to workers and was obliged to cancel all remaining registrations of products containing EDB.

1. Introduction

The major use of EDB (ethylene dibromide, 1,2-dibromoethane) in agriculture in Australia is as a soil fumigant for the control of nematodes and other soil pests in crops such as vegetables, ornamentals, pineapples and tobacco.

Industrially, it is used as a lead scavenger in leaded petrol and antiknock preparations, an intermediate in the synthesis of dyes and pharmaceuticals and as a solvent for resins, gums and waxes.

EDB had been identified in the early 1980's as a significant health risk, following a review of data showing that it was a potent carcinogen in rats and mice by all routes of exposure tested. The NH&MRC recommended at that time that all uses where operator exposure could not be prevented be phased out.

More recently, ACPH reviewed the continued use of EDB in agriculture in Australia and strengthened its position on EDB, especially in the light of a review of the toxicology of EDB by the 1994 FAO/WHO Joint Meeting on Pesticides (JMP). This group concluded that "an exposure that would not cause adverse effects in humans after any route of exposure could not be estimated" and recommended that "all appropriate measures should be taken to eliminate or minimize human exposure to 1,2-dibromoethane".

On this basis, ACPH recommended to the NRA that the use of EDB as an agricultural fumigant in Australia be discontinued. The reduction of the MRL values to the current limit of determination was also requested.

2. Reasons for and Scope of the Review

The grounds for the NRA's decision to reconsider EDB were that, in the light of the toxicological concerns related to the use of EDB, it could no longer be satisfied that the chemical would not:

- be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; or
- be likely to have an effect that is harmful to humans.

In arriving at this decision, the NRA took into account recommendations from ACPH and EH&SU that the use of EDB as an agricultural fumigant be discontinued as a matter of urgency. The reduction of the MRL values to the current limit of determination was also requested.

The recommendations of the public health agencies were considered by the Registration Liaison Committee, with the Queensland and South Australian State Chemical Coordinators advising of significant uses of EDB for soil fumigation. Interstate and international quarantine uses were also noted.

The recommendations of ACPH in relation to use of EDB were first discussed by the NRA Board in April 1996, and resolved to withdraw all uses of EDB unless procedures acceptable to public health and occupational health and safety agencies were able to be established to guarantee no exposure to workers or the public.

A special review was therefore initiated in order to formalise the NRA response to the significant health issues identified in relation to EDB.

The NRA has therefore reconsidered under Division 4, Part 2 of the AgVet Code:

- the approval of the active constituent
- the registrations and permits
- the approval of all labelling

for all products containing EDB.

3. Regulatory Status in Australia

As a response to the original NH&MRC recommendations, State regulatory authorities limited uses of EDB to soil fumigation through enclosed systems for control of soil pests prior to sowing fruit, vegetables, cereals and ornamentals.

Chamber fumigation of some fruit and vegetable commodities for protection against various fruit fly species was also permitted to continue as part of interstate and international quarantine requirements. These latter uses were carried

out in accordance with individual States' use legislation, with permits/approvals applying where required. For approximately 3 months, until January 1996, a major emergency use of EDB was in chamber fumigation of fruit in North Queensland under permit from the NRA to control an outbreak of the exotic pest, papaya fruit fly, for inter-State quarantine purposes. Alternative treatments/management options have now been adopted and the permit is no longer in force.

It is noted that in some States, registered chemicals may be used for purposes other than those on the registered labels, as long as those uses are not prohibited. This is the case for South Australia and Victoria, where some quarantine chamber fumigation of fruit and vegetables may take place without the necessity of a permit. It should also be noted that there is an order in Victoria prohibiting the use of EDB except for soil fumigation and chamber fumigation of fruit and vegetables.

The following products containing EDB were registered at the time of the review:

Nufarm EDB 210 Soil Fumigant

Nufarm EDB EC Soil Fumigant

Nufarm Nemadi Nematicide

SA Rural Agencies Nemafix 2000 Nematicide

Riverland Horticultural Traders Nemand Nematicide

Another product, **Rentokil EDB Insecticide**, has previously been supplied by Rentokil Pty Ltd under permit to licensed fumigators in Western Australia. These fumigators carry out fumigation of fruit and vegetables in accordance with Western Australian requirements for interstate movement of these commodities.

4. Regulatory Status Overseas

Residues of EDB in tropical fruits, imported wheat and beans have been prohibited in Japan and use of EDB for agricultural purposes has been prohibited in Egypt, Kenya, the Netherlands, Sweden, the United Kingdom and the USA. (*Environmental Health Criteria (EHC) 177*, Dr J Sckizawa, World Health Organization, 1996).

In July 1991, the Codex Committee on Pesticide Residues decided to delete the Guideline Limits for EDB as these limits no longer reflected current GAP (Good Agricultural Practice). Where it was still used for quarantine purposes, countries were requested to send all information necessary to establish MRLs to JMP (Joint Meeting on Pesticides). JMP reviewed all data submitted at its 1994 meeting and concluded that an exposure which was safe to humans could not be estimated and that measures to eliminate or minimize exposure to this chemical should therefore be put into place as soon as possible.

EHC 177 also indicates that legislation banning the use of lead in petrol and controlling the agricultural use of EDB has reduced world demand for this substance by 75 % to approximately 30000 tonnes.

5. Notification of Review

Formal notification to all interested groups of the proposed reconsideration of the registration of EDB was forwarded early in May 1996.

The following organisations/individuals were involved in the consultation process and given opportunity to provide information, comment or data which might be relevant to the review:

- Product registrants and Permit holders
- State Departments of Agriculture/Primary Industries
- Golden Circle Limited (representing the pineapple industry)
- Australian Ginger Growers Association
- Queensland Fruit and Vegetable Growers Association
- North Queensland Tobacco Growers' Co-operative Association Limited
- Licensed fumigators in Western Australia
- Licensed fumigators in Victoria
- Licensed fumigators in South Australia
- The Australian Quarantine & Inspection Service (AQIS)

6. Responses to the Notification of Review

6.1. State Departments of Agriculture

The issue of the continued availability of EDB had been discussed at the Registration Liaison Committee meeting in April 1996 and State Departments of Agriculture given opportunity to provide comment on the recommendations made by ACPH. Only Queensland and South Australia indicated that there were sectors of agricultural production in their States which would be significantly affected by regulatory action in relation to EDB.

Queensland's concerns stemmed from the fact that alternative chemical treatments for nematodes had not yet been registered for use in tobacco and pineapple production and that the industries would be significantly affected without some form of control for these pests.

South Australia's concern also stemmed from the lack of suitable alternative treatments. Although there appear to be alternative treatments available for the glasshouse vegetable industry, they are considered to be either less efficacious or less cost effective than EDB. In particular, the main alternative fumigant in South Australia is methyl bromide, the use of which is being reduced because of environmental concerns. South Australia proposed that consideration should be given to reducing the health risks by placing stringent training and operational conditions on operators to ensure that the chemical is properly and safely handled and used. In the meantime, further effort should be focused on developing alternative chemical treatments and management strategies.

Victoria indicated that there was some chamber fumigation of fruit and vegetables for inter-State quarantine purposes, but that these uses were not considered to be significant.

A commercial practice which would be significantly affected by the non-availability of EDB is that of on-forwarding fruit and vegetables from markets in Victoria and NSW to markets in South Australia, Western Australia and

Tasmania. This practice arises because fruit and vegetables from Queensland destined for these markets do not have to be fumigated before being despatched. In fact, some farmers are accredited to be able to treat produce in the field so that the produce does not have to be fumigated or dipped in dimethoate. However, if a merchant decides to then forward the produce to another State because, for example, the prices are better, he must arrange for the produce to comply with the receiving States' quarantine regulations. The only way this can be achieved at present is by fumigating with EDB. The alternative is to dip all produce from Queensland in dimethoate.

Western Australia initially advised that use of EDB for fumigation of fruit (especially bananas from Queensland) was a very important use which, if lost, could threaten the viability of a multi-million dollar interstate trade in bananas. However, advice was subsequently received that alternative treatment or prevention methods are now available which do not require the use of EDB. The alternative chemical treatment involves dipping of fruit in dimethoate before packing for shipment, while shipping green bananas which have not matured to a stage where they are fruit fly hosts is also permitted.

In addition, Western Australian plant health inspectors have been negotiating with the Western Australian government in relation to continued inspection of commodities treated with EDB and supervision of EDB fumigations because of occupational health and safety concerns. The inspectors argued that it is impossible to guarantee that there will be no exposure to EDB during fumigation because of factors such as leaking seals, venting of fumigant and residues on fumigated produce.

In relation to the latter factor, data from the Queensland Department of Primary Industries and NSW Agriculture indicate that EDB residues can be detected in produce treated at commercial rates for some time after application.

6.2. Registrant and Supplier

The main registrant and supplier of EDB, Nufarm Limited, indicated that the only data relevant to the review and available to them was from their supplier in Israel and that these data had already been submitted to the NRA. They also requested, and were supplied with, details of the recent reassessment of EDB by health authorities. Nufarm did not wish to make further comments in relation to the review, but wished to be kept advised of the progress of the review and its outcomes. SA Rural Agencies indicated that there was a small but significant use by market gardeners in South Australia and that there had been recent use in fumigation chambers by them because of an outbreak of Mediterranean Fruit Fly in the area. They advised that they did not wish to make a submission, but requested advice on the outcome of the review.

Rentokil Pty Ltd, which had been supplying EDB under permit for chamber fumigation purposes in Western Australia, indicated that they would cease supply immediately and not seek renewal of the permit.

Riverland Horticultural Traders advised of the importance of EDB as a soil fumigant in SA.

6.3. Australian Quarantine and Inspection Service

During the period of the review, the Australian Quarantine and Inspection Service (AQIS) advised that they have been able to amend its requirements so that they are now able to fulfil their disinfestation obligations without recourse to EDB.

Initially they advised that EDB fumigation was still required for some Australian commodities entering New Zealand. This fumigation was mostly carried out in New Zealand, but there had been increased stringency in the New Zealand requirements in terms of residue limits and chamber design. The remaining EDB treatment has now been replaced with an alternative treatment and EDB is now no longer required for quarantine purposes. Recent verbal advice from New Zealand authorities confirms that fumigation of produce with EDB before supply to New Zealand is no longer approved.

In addition, some produce entering Australia from India, Fiji and the Philippines may be treated with EDB before leaving the respective countries. AQIS would have preferred to have EDB available for emergency use, in cases where produce is brought into the country and there is some doubt whether the produce has been appropriately treated in the country of origin. EDB fumigated fruit is still permitted entry from the Philippines and Fiji, and whilst NRA action would not directly affect this trade, there may be a chemical residue issue to be pursued by the appropriate agencies.

AQIS has used EDB fumigation as a backstop for product which should have been treated overseas or come from an area free of fruit fly, where the documentation does not meet AQIS requirements. This treatment (although only infrequently applied) will not be available in the future, and any consignments which do not fully comply with AQIS's quarantine requirements will be either re-exported or destroyed.

6.4. Growers' Organisations

Several submissions were received from grower industry groups, particularly the Queensland pineapple, tobacco and ginger industries. Various meetings were held between these organisations and the NRA, some involving the Queensland Department of Primary Industries, the TGA and Worksafe Australia.

The industries emphasised their view that control of nematodes was vital to the continuing viability of the pineapple and tobacco industries and that EDB was the most effective, including cost effective, treatment available at present. In addition, they indicated that considerable care was being exercised in the respective industries in relation to application of EDB through closed delivery systems to minimise exposure of operators during fumigation operations. Although research had been continuing for some time, and some progress had been made in developing alternative chemical and non-chemical control strategies, the industries were of the view that they could not yet rely on these strategies. They believed that the consistency of effectiveness of the main alternative chemical treatment available required further testing and the acceptability to neighbours because of odour was questioned. The use pattern for the alternative chemical is quite different to that of EDB and farmers would require training in different application methods and the purchase of new equipment to enable them to use it. The chemical has a higher acute toxicity than EDB, while not being a potent carcinogen.

The point was also made that EDB remains in use as a lead scavenger for leaded fuel and it was contended exposure via this route is likely to be considerably higher than through soil fumigation operations.

Golden Circle advised that, if effective nematocides (including cost effective) were not available to growers, the pineapple industry in Queensland would probably not be sustainable. Figures quoted in the industry submission claim that a loss in revenue of approximately \$7000 per ha could be expected without the use of nematocides and that the costs of using EDB and alternative treatments are \$220/ha and \$2100/ha, respectively.

7. Evaluation of Submissions

There has been clear and consistent advice from the Commonwealth Department of Health and Family Services and from Worksafe Australia that the use of EDB in agriculture cannot be supported because of the severe health risks associated with this use. EDB is known to be a potent carcinogen by all routes of exposure and no safe level of exposure can be established. The National Occupational and Safety Commission has a 'nil' exposure standard for EDB. This advice is supported by a similar recommendation from the NHMRC in 1984, and by the ACPH. It is consistent with international action relating to EDB, including its prohibition from agricultural use in countries such as the USA and UK and a call from the JMP for measures to be taken to eliminate exposure to EDB.

Various submissions arguing that EDB was essential were made by certain grower industries (particularly the Queensland pineapple, tobacco and ginger industries) and extensive consultations were held with these industries during the course of the NRA review. However, in reconsidering the registration of products containing EDB, the NRA had to be satisfied that the continued use of EDB would not be an undue hazard to the safety of the people exposed to it during its handling, and would not be likely to have an effect that is harmful to human beings (paragraphs 34(1)(a)(i) and (ii) of Agvet Code).

Monitoring data submitted by the Queensland pineapple and tobacco industries demonstrated that workers could be exposed to significant levels of EDB, even with the use of closed delivery systems. The data was considered by the NRA in conjunction with the TGA and Worksafe Australia, and it was concluded that these results did not provide assurance that there would be an adequate degree of protection to workers involved in the use of EDB.

Conclusion

After consideration of all the above factors (including the monitoring data which was submitted) the NRA was not satisfied that the continued use of, or any other dealing with, EDB would not be an undue hazard to the safety of people exposed to it during its handling and that its continued use would not be likely to have an effect that is harmful to human beings (paragraphs 34(1)(a)(i) and (ii) of the Agvet Code). Therefore, pursuant to subsection 34(3) of the Agvet Code, the NRA was not satisfied that the requirements for continued approval or registration of all products containing EDB, as set out in paragraphs 34(1)(a)(i) and (ii) of the Agvet Code, had been complied with as required by subsection 34(2) (having regard to the factors enumerated in subsections 14(4)(a), 14(5)(a), 14(5)(d), 14(5)(e) and 14(6)). Further, the NRA was not satisfied, within the terms of subsections 34(5), that the conditions to which approval or registration were then subject could be varied in such a way that the requirements for continued approval or registration would be complied with. Accordingly, pursuant to subsection 34(8) and section 40 of the Agvet Code, registration of all products containing EDB, and the approval of the associated labels and active constituents, were cancelled with effect from 22 December 1997.

8. Review Outcomes

The NRA has therefore:

- pursuant to section 40 of the Agvet Code, cancelled the registration of all products containing EDB, and the approval of associated labels and technical grade active constituents effective from 22 December 1997;
- authorised the supply of existing stocks of EDB at retail level until 30 June 1998 and also allowed the use of EDB until no later than 30 November 1998 with a stated use regime which includes the following elements:

- a. products containing EDB only be used where stringent requirements are in place to reduce the risk of exposure to workers, including the use of closed delivery systems;
- b. registrants be required to provide resellers with technical notes explaining the hazardous nature of EDB which are to be supplied to all purchasers of EDB, and resellers to maintain records which include a written acknowledgment from purchasers that they are aware of the hazardous nature of EDB and are aware of the safety requirements for its use;
- c. registrants be required to give instructions regarding the hazards and safety requirements to users who currently hold stocks of EDB;
- d. resellers only supply EDB to users who have Farm Chemical Users Course or equivalent accreditation;
- e. a protocol be put in place by the registrant for the collection, transportation and destruction of all EDB remaining on farms and at retail outlets by 31 December 1998 – the registrant and the grower organisations to be responsible for conducting the recall according to a plan approved by the NRA;
- f. industry to be responsible for the independent auditing by a third party of the supply and use until 30 November 1998.

- resolved to withdraw maximum residue limits for EDB from 30 December 1998.

* Now known as the Chemicals and Non-Prescriptive Drugs Branch of the Therapeutic Goods Administration (TGA)

** Final Report of the Ninth Meeting, Advisory Committee on Pesticides and Health, Canberra, 16 February 1996
The APVMA is the National Registration Authority for Agricultural and Veterinary Chemicals.