

BRIEF OVERVIEW OF ENDOSULFAN REVIEW

Endosulfan is an insecticide which has been widely used in Australia for over 30 years. The agricultural industry and State agricultural authorities advise that endosulfan is extremely important to agriculture, and for some crop/pest situations there are no alternatives at all or none which work as well.

Endosulfan is an organochlorine chemical, but unlike most other members of this class, it largely disappears from soil in 3 to 6 months and does not remain in the bodies of animals or humans. Numerous scientific studies have not found any evidence of involvement in cancer, birth defects, damage to genetic material, disruption of the endocrine hormone system or other long term effects due to chronic, low level exposure. However, endosulfan has a high acute or immediate toxicity to humans which is a matter of concern for agricultural workers. In addition, endosulfan is quite toxic to fish and other aquatic organisms.

Although endosulfan concentrations in surface waters in areas of intensive use routinely exceed ANZECC criteria recommended to protect aquatic ecosystems, there is not yet clear evidence that endosulfan is causing long term harm to the general environment or biological communities. However, it is known that during parts of each year in the rivers and creeks of these regions, endosulfan reaches concentrations which are lethal to important species of native fish and native macroinvertebrates when tested under laboratory conditions. Regular attainment of such concentrations of endosulfan in regional surface waters is not acceptable on an ongoing basis. Concern over this problem is increased by predictions of some authorities that acreage of cotton, the main user of endosulfan, is likely to increase significantly in the next few years in some regions.

A simple ban of endosulfan could lead to other problems. This is because endosulfan has relatively low toxicity to many species of beneficial insects, mites and spiders (that is, ones which prey upon or parasitise damaging insect pests). Other chemicals, necessarily substituted for endosulfan, would kill beneficial insects leading to population explosions of damaging pests which in turn would require more frequent sprays of harsher chemicals than if endosulfan had been used in the first place. In addition, because endosulfan is from a different chemical class than almost all other available insecticides, its use is very important for slowing the development of insecticide resistance to the other chemicals. Loss of endosulfan would, therefore, also lead to more insecticide use due to increasing resistance among insect pests. The net result is greater overall danger to agricultural workers and to the environment.

To address the above concerns, the National Registration Authority has taken steps to manage the use of endosulfan on an interim basis while more data on worker safety and commodity residues are developed to determine specific requirements in those areas necessary for ongoing use. In addition, the NRA has taken steps designed to reduce the inappropriate use of endosulfan and to reduce the amount of endosulfan which is carried off farms into creeks and rivers. The results of environmental monitoring and an assessment of use patterns over the next three years will be examined to determine whether endosulfan can continue to be used.

The complete Review Outcomes are presented on the following pages.

ENDOSULFAN REVIEW OUTCOMES

IMPORTANT NOTICE

Key Date

Certain Review Outcomes require the development of additional data as specified below. These data will be eligible for data protection (as appropriate) in accordance with Part 3 of the Agvet Code. Those choosing to submit such data must confirm a commitment to do so (and submit a plan for generating the data) by 31 December 1998. If no such commitment is provided by that date, then the use related to that data requirement may be cancelled.

**31 December
1998**

Those outcomes marked with # require the submission of further data, plans, standards or label changes as specified in the following table:

Review Outcome	Due Date	Requirement
2	30/11/1998 30/06/2001	<ul style="list-style-type: none"> • Development of plan for monitoring environmental contamination. • Demonstration of reductions in environmental contamination
3	30/06/1999 31/12/1999	<ul style="list-style-type: none"> • Worker exposure data in greenhouses • Worker exposure data in industries which require continued use of endosulfan
4	30/06/2000	<ul style="list-style-type: none"> • Residue data
5	30/06/2000	<ul style="list-style-type: none"> • Residue data
8	31/12/1999	<ul style="list-style-type: none"> • Re-entry data (Exposure of workers to in-crop residues)
12	30/06/1999	<ul style="list-style-type: none"> • Material Safety Data Sheets
16	30/06/1999	<ul style="list-style-type: none"> • Upgraded guidance on safe flagging procedures
17	30/06/1999	<ul style="list-style-type: none"> • All TGACs required to demonstrate compliance with the NRA standard.
1,8,9,10,11,13,14	30/06/1999	<ul style="list-style-type: none"> • All changes and amendments to labels

Restrictions on use

Environmental concerns raised as a result of the review necessitate that endosulfan can only be used according to new limitations designed to reduce environmental contamination.

It is therefore recommended that:

Review Outcome

Key Date

1.# The following additional limitations must be included on all labels immediately following the statement “NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION”

30 June 1999

THIS PRODUCT CAN ONLY BE USED IF RECORDS OF SPRAYS ARE KEPT IN ACCORDANCE WITH GUIDELINES OF FARMCARE ACCREDITATION OR ANOTHER GUIDELINE ACCEPTABLE TO THE NATIONAL REGISTRATION AUTHORITY. RECORDS OF SPRAYS WILL BE SUBJECT TO AUDIT BY AUTHORISED INSPECTORS.

EXCEPT FOR ORCHARD CROPS, ALL OTHER CROPS (INCLUDING COTTON) ARE LIMITED TO A MAXIMUM OF 2 SPRAYS OF THIS PRODUCT PER CROP PER GROWTH SEASON (OR EQUIVALENT OF 2 SPRAYS IN ACTIVE INGREDIENT PER HECTARE) UNLESS IRRIGATION TAILWATER AND STORM RUN-OFF WATER CAN BE CAPTURED ON FARM (FOR ISOLATED RAINFALL EVENTS UP TO AT LEAST 25MM OF RAINFALL).

IN ADDITION TO THE LIMITATION ABOVE, WHEN USED ON COTTON THIS PRODUCT MUST BE USED IN ACCORDANCE WITH THE LATEST (AT TIME OF USE) AUSTRALIAN COTTON INDUSTRY BEST MANAGEMENT PRACTICES MANUAL. BEST MANAGEMENT PRACTICES WHICH SPECIFICALLY CONCERN IRRIGATION DO NOT APPLY TO NON-IRRIGATED COTTON.

	<u>Review Outcome</u>	<u>Key Date</u>
2.#	Endosulfan may be further restricted or withdrawn if demonstrable reductions in its release to the environment are not achieved. Reductions will be assessed principally against measured endosulfan concentrations in surface waters of regions the NRA considers to be at risk. For other areas, reductions in the quantity of endosulfan used will be accepted as evidence of reduced environmental exposure. Acceptable baselines and reduction targets will be established by the NRA in consultation with respective State authorities responsible for water quality. Plans defining such baselines and targets are to be completed by 30 November 1998 and monitoring results will be assessed by the NRA by 30 June 2001 .	30 November 1998

Occupational health and safety (OH&S) concerns raised as a result of the review necessitate that certain uses of endosulfan can only continue on a temporary basis until additional worker exposure data is obtained. Because of the acute toxicity of the chemical, worker exposure data generated under actual Australian conditions is required for these uses.

It is therefore recommended that:

	<u>Review Outcome</u>	<u>Key Date</u>
3.#	The following requirements will be met:	
	<ul style="list-style-type: none">• Worker exposure data for greenhouse workers must be generated by 30/06/1999. Unless worker exposure data are provided for occupational health and safety assessment and the risks to workers are shown to be acceptable to the NRA, use in greenhouses will be discontinued from 31/12/1999. In addition, studies designed to determine a safe re-entry period for greenhouses are to be accomplished within the same time frame.	30 June 1999
	<ul style="list-style-type: none">• Certain other industries which require use of endosulfan for work practices specified below must generate worker exposure data by 31/12/1999 to enable the NRA to establish permanent acceptable use patterns for the respective industries. Those uses which are not supported by worker exposure data will be withdrawn on 30/06/2000. Work practices which require Australian data are:<ul style="list-style-type: none">▪ Mixer/loaders in ground and aerial applications▪ Orchard ground spray applicators▪ Broadacre ground spray applicators▪ Manual flaggers for aerial applications▪ Workers using hand directed spray applicators	31 December 1999

Residues (Note: Additional recommendations which impact on residues are included under 'Labelling')

Residue and trade concerns raised as a result of the review necessitate that certain uses of endosulfan can only continue in the long term if data supporting maximum residue limits (MRLs) are provided to the NRA.

It is therefore recommended that:

Review Outcome

Key Date

- 4.#** Residue trial data for uses currently without adequate Australian data (See Recommendation 5 below) must be submitted to the NRA for evaluation by **30/06/2000**.

30 June 2000

Uses which are not supported by adequate MRL data will be removed as from **31/12/2000**.

All residue trials should be conducted in accordance with Residue Guidelines which have been published in the NRA Gazette. Residue trials must address the maximum treatment regimes.

The following data are considered essential:

- Animal feeds - Forages, fodder or hays of such plants as cereals (including sorghum and maize), pastures, canola, sunflower, legume vegetables, potato, peanuts, and legume crops for pulse production.
- Human food – All commodities which have been assigned a temporary MRL in the table above.
- Processing studies - Cereals, fruits (citrus and apple), cotton and other oilseeds and grapes.
- Animal commodities: Animal transfer study in cattle including milk analysis and poultry feeding studies including analysis of eggs.

Review Outcome

Key Date

- 5.#** It is recommended that the current MRLs in Table 1 of the MRL Standard, be amended as follows:

30 June 2000

The following MRLs are to be deleted:

Code	Food	MRL (mg/kg)
VR 0577	Carrot	0.2
MO 0812	Cattle, Edible offal of	0.2
MM 0812	Cattle meat [in the fat]	0.2
GC 0080	Cereal grains	0.2
VD 0526	Common bean [navy bean]	1
OC 0691	Cotton seed oil, crude	0.5
PE 0112	Eggs	0.05*
	Fruits	2
VO 0050	Fruiting vegetables, other than cucurbits	2
MO 0814	Goat, edible offal of	0.2
MM 0814	Goat meat [in the fat]	0.2
VD 0545	Lupin (dry)	1

ML 0106	Milks [in the fat]	0.5
VD 0536	Mung beans (dry)	1
SO 0088	Oilseed	1
VA 0385	Onion, Bulb	0.2
SO 0697	Peanut	1
VR 0589	Potato	0.2
PO 0111	Poultry, Edible offal of	0.2
PM 0110	Poultry meat [in the fat]	0.2
GC 0649	Rice	0.1
MO 0822	Sheep, edible offal of	0.2
MM 0822	Sheep meat [in the fat]	0.2
VD 0541	Soybean (dry)	1
VO 0447	Sweet corn (corn-on-the-cob)	0.2
VR 0508	Sweet potato	0.2
DT 1114	Tea, Green, Black	30
TN 0085	Tree nuts	2
VO 0448	Tomato	2
	Vegetables [except carrot; common beans; lupin (dry); mung bean (dry); onion, bulb; potato; soybean (dry); sweet corn (corn-on-the-cob); sweet potato]	2

* the limit of analytical quantitation

The following MRLs are to be set:

Code	Food	MRL (mg/kg)
FT 0005	Assorted tropical and sub-tropical fruits - edible peel	T2
FT 0006	Assorted tropical and sub-tropical fruits - inedible peel	T2
FB 0004	Berries and other small fruits	T2
VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	T2
GC 0080	Cereal grains	T0.2
FC 0001	Citrus fruits	T2
OC 0691	Cotton seed oil, crude	T0.5
	Curcurbits	T2
PE 0112	Eggs	T*0.05
VO 0050	Fruiting vegetables, other than cucurbits	T2
VL 0013	Leafy vegetables (including Brassica leafy vegetables)	T2
VP 0034	Legume vegetables	T2
MM 0095	Meat (mammalian) [in the fat]	0.2
ML 0106	Milks [in the fat]	T0.5
SO 0088	Oilseed	T1
VA 0385	Onion, Bulb	T0.2
FP 0002	Pome fruits	T2

PO 0111	Poultry, Edible offal of	T0.2
PM 0110	Poultry meat [in the fat]	T0.2
VD 0070	Pulses	T1
GC 0649	Rice	T0.1
VR 0075	Root and tuber vegetables	T2
VA 0388	Shallots	T2
VS 0017	Stalk and stem vegetables	T2
FS 0003	Stone fruits	T2
DT 1114	Tea, Green, Black	T30
TN 0085	Tree nuts	T2

* - the limit of analytical quantitation

T - temporary MRL

IMPORTANT NOTE: The temporary MRLs above will be withdrawn on 31/12/2000 unless data are submitted to support these MRLs by 30/06/2000.

Review Outcome

Key Date

6. The Table 4 MRL of 0.3 mg/kg for Primary animal feed should remain. Unless strategies are established to accommodate residues higher than 0.2 mg/kg in meat (mammalian)[in the fat], or residue data are generated for individual animal feed commodities, the MRL should stay unchanged.

Not Applicable

In relation to any future applications for registration, it is strongly recommended that residue data on any likely animal feeds [forage, fodder or hay, processed wastes from raw commodities such as citrus pulp, apple pomace, cotton meal, cotton seed, rice hull, vegetable wastes], be generated by addressing the maximum treatment regimes (ie. application rate, number of applications, and intervals between re-applications). The time course of the residue decline should be demonstrated in all trials.

7. All future Australian residue data should be submitted by registrants or applicants to Codex Alimentarius Commission for review, so that Codex MRLs for endosulfan can encompass Australian use patterns. It is noted that endosulfan has been scheduled for periodic review by Codex in 2000.

**December 31
1999**

Labelling

	<u>Review Outcome</u>	<u>Key Date</u>
8.#	An interim re-entry period of two days is required on labels by 30/06/1999 . Collection and assessment of Australian re-entry data for different crop types will enable an appropriate permanent re-entry period to be confirmed. Protocols for development of re-entry information must be acceptable to the NRA. Data showing the likely exposure of workers to in-crop residues for different crop types/situations must be submitted by appropriate industries by 31/12/1999 . In the case of crop types for which no data is provided or can be extrapolated, those crops will be subject to a 3 day re-entry period after the deadline of 31/12/1999 . In the case of crop types where data was provided, a decision will be made by 30/06/2000 . The following label statements are required:	30 June 1999
		31 December 1999
		30 June 1999

Re-entry period

Do not allow entry for 2 days after treatment unless wearing cotton overalls buttoned to the neck and wrist and elbow length PVC gloves. Clothing must be laundered after each day's use.

Hand weeders:

Do not allow entry into treated areas for 2 days after treatment. After this period, it is recommended to wear shoes or boots, socks, long trousers, long sleeved shirt, gloves and hat.

	<u>Review Outcome</u>	<u>Key Date</u>
9.#	A statement promoting the preferred use of enclosed vehicle cabs for ground spraying equipment over reliance on personal protective equipment is to be included on the label below the Safety Directions as follows: To minimise exposure, a vehicle equipped with an enclosed cab should be used for ground spraying operations when practicable.	30 June 1999
10.#	In order to minimise environmental impact, all labels will be required to carry the following precautions:	30 June 1999

DO NOT apply under meteorological conditions or from spraying equipment which could be expected to cause spray to drift onto wetlands, natural surface waters, neighbouring properties or other sensitive areas.

DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast within two days of application.

DO NOT apply when irrigating or for at least two days after irrigation, or to waterlogged soil or while water remains in furrows unless tailwater can be captured.

Review Outcome

Key Date

- 11.#** Withholding periods (WHPs) for uses which are currently less than two days will be increased to two days. These uses include:

30 June 1999

Beetroot, Chou Moullier, cole crops, cucurbits, green beans, field and green peas, leaf vegetables, silver beet, stalk vegetables, tomatoes and turnip.

All other current withholding periods (WHPs) for human food, including pulses and leafy vegetables, should remain. Pulses, brassica and leafy vegetables, when treated for human consumption only, shall not be deemed different from other human food commodities in this regard. The establishment of a grazing WHP shall depend on the maintenance of the slaughter interval of 42 days and/or on the feasibility of not feeding crops of concern. The following label statements are required:

30 June 1999

FOR HUMAN FOODS

**SEE THE CROP HARVEST
WITHHOLDING PERIODS (WHPS)
SPECIFIED IN THE INSTRUCTION
TABLE.**

**FOR ANIMAL FEEDS (INCLUDING PULSES,
VEGETABLES, VEGETABLE AND FRUIT
WASTES, FODDER AND FORAGE):
DO NOT RE-APPLY WITHIN 7 DAYS.
DO NOT GRAZE ORCHARDS AFTER
APPLICATION.**

DO NOT FEED TREATED CROPS OR CROP PARTS (EXCEPT COTTONSEED/MEAL) TO LACTATING COWS PRODUCING MILK FOR HUMAN CONSUMPTION.

A grazing WHP of four weeks plus 42 days slaughter interval should be observed for legumes, vegetables and any other crops intended for forage except for maize and sorghum as noted next. A grazing WHP of eight weeks plus 42 days slaughter interval should be observed for maize and sorghum forage.

Where processed commodities such as apple pomace, citrus pulp or fruit peels in a cannery are traditionally traded as animal feeds, exchanges of information on crop and animal produce residues between farmers and processors should be actively promoted and facilitated by grower organisations and government agencies.

The following crop harvest WHPs and withhold from slaughter intervals are to be included in Label Instructions as shown below:

30 June 1999

Crop/Commodity	Crop Harvest WHP	Animal Management
Cottonseed/meal	4 weeks	Nil slaughter interval
Apples & Pomace	4weeks	42 day slaughter interval
Grain legumes & Pulses and Fodder/stubble	4weeks	42 day slaughter interval
Pasture seed legumes	4 weeks	42 day slaughter interval
Tropical and sub-tropical fruits & fruit by-products	4 weeks	42 day slaughter interval
Legume vegetables	4 weeks	42 day slaughter interval
Other vegetables (eg tomato, leafy vegetables)	4 weeks	42 day slaughter interval
Citrus & citrus pulp	4 weeks	42 day slaughter interval

The following crop/commodities are special cases which require different treatment to avoid violations of animal MRLs. The following information is to be included on labels as shown below:

30 June 1999

Crop/Commodity	Crop Harvest WHP	Animal Management
Cotton trash	Not Applicable	Do not feed to animals
Legume vegetables	2 day	Do not feed to animals
Maize grain	8 weeks	Nil slaughter interval
Maize fodder	8 weeks	42 day slaughter interval
Other vegetables (eg tomato, leafy vegetables)	2 day	Do not feed to animals
Sorghum grain	8 weeks	Nil slaughter interval
Sorghum fodder	8 weeks	42 day slaughter interval

Health

	<u>Review Outcome</u>	<u>Key Date</u>
12.#	All product registrants and TGAC approval holders are required to produce Material Safety Data Sheets for their respective TGAC and products by 30/06/1999.	30 June 1999
13.#	The First Aid and Safety Directions as revised will appear on the label as follows:	30 June 1999

EC and ULV all strengths

100	Very dangerous
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
207 162	Will damage eyes
161 164	Will irritate the skin
210 211	Avoid contact with eyes and skin
220 222 223	Do not inhale vapour or spray mist
279 280 281 282 290 291 294 298b 301 (or 297 300)	When opening the container, preparing the spray and using the prepared spray wear protective waterproof clothing, elbow-length PVC gloves, water resistant footwear and full-facepiece respirator (or goggles and half facepiece respirator)
340 341 343	If product or spray in eyes, wash it out immediately with water

- 340 342 If product on skin, immediately wash area with soap and water
- 350 After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
- 360 361 After each day's use, wash gloves, goggles,
363 364 respirator and if rubber wash with detergent
366 and warm water and contaminated clothing

Supply and Use

	<u>Review Outcome</u>	<u>Key Date</u>
14.#	<p>In order to limit supply and use to suitably trained persons, endosulfan will be included in the Agricultural and Veterinary Chemicals Code Regulations as a restricted chemical product, and labels will be altered accordingly by the inclusion of the following wording:</p> <p>RESTRICTED CHEMICAL PRODUCT - ONLY TO BE SUPPLIED TO OR USED BY AN AUTHORISED PERSON</p> <p>It is proposed that 'authorised persons' will be those who have obtained Farmcare Australia accreditation or another accreditation acceptable to the NRA or who are licensed spraying contractors.</p>	30 June 1999
15.	Suppliers must obtain proof from purchasers that they are authorised to possess and use endosulfan before supplying endosulfan.	30 June 1999
16.#	Existing guidance on safe flagging procedures needs to be upgraded by industry by 30/06/1999 . Human flagging in aerial operations is not acceptable unless flaggers are protected by engineering controls such as cabs.	30 June 1999
17.#	The NRA will adopt the FAO compositional standard for this chemical. All TGACs will be required to comply with this standard (Regulation 42 concerning standards) by 30/06/1999 .	30 June 1999

Review Outcome

Key Date

18. In order to better manage spray drift, a spray drift minimisation strategy is to be employed at all times. The strategy envisaged is exemplified by the cotton industry's treatment of buffer zones in their recently published *Australian Cotton Industry Best Management Practices Manual*, December 1997. Adoption of in crop buffer zones or other protective measures which accord with the confirmed findings of current research should be actively promoted by representative grower organisations.

30 June 1999

Compliance

19. The NRA and relevant State departments will monitor the supply and restricted use regime to ensure the restrictions are being complied with.

Ongoing

Advice to Users and Industry

1. All feedlots and/or abattoirs for beef export should monitor residues in animal feed and animal produce. Where it is impractical to have an on-site laboratory, monitoring could be contracted to other laboratories.
2. Packaging and mixing/loading mechanisms should be improved to avoid the use of open pour methods and minimise worker exposure to the concentrate.
3. Industries are encouraged to use ground application whenever possible near sensitive areas to minimise the potential for drift of chemical off target.
4. Industries are encouraged to use ground application during early crop stages when band spraying is feasible to minimise the amount of endosulfan applied per hectare and reduce the amount falling on the soil surface.
5. Continued research into comparing ULV and EC formulations with regard to drift and run-off potential should be pursued to help minimise off-farm movement of endosulfan.
6. Use of endosulfan at high temperatures (above 30° C) should be avoided whenever possible due to increased volatility losses into the atmosphere at higher temperatures.
7. Training requirements for the safe handling of pesticides in aerial spraying applications, especially regarding the potential for spray drift and other unintended off-target deposition, should be strengthened.