Australian Government

Australian Pesticides and Veterinary Medicines Authority

ENDOSULFAN

REVIEW OF NEW INFORMATION SINCE THE 1998 AND 2005 REVIEWS

Prepared for the APVMA by:

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EXECUTIVE SUMMARY

Since the completion of the endosulfan review in 2005, a significant amount of new information has become available in relation to both the toxicity and environmental aspects associated with endosulfan. The Department of Environment, Water, Heritage and the Arts (DEWHA) and the Office of Chemical Safety Environmental Health (OCSEH) have considered this new information and made recommendations for the use of endosulfan in Australia.

There are currently 5 registered endosulfan products:

NCRIS	Product Name	Registrant
32799	NUFARM ENDOSULFAN 350 EC INSECTICIDE	NUFARM AUSTRALIA LIMITED
50004	THIODAN EC INSECTICIDE	BAYER CROPSCIENCE PTY LTD
52163	FARMOZ ENDOSULFAN 350 EC INSECTICIDE	FARMOZ PTY LIMITED
61503	KENSO AGCARE ENDO 350 EC INSECTICIDE	KENSO CORPORATION (M) SDN. BHD.
64421	FARMALINX ENDOSULFAN INSECTICIDE	FARMALINX PTY LTD

There are currently 3 approved endosulfan active constituents:

NCRIS	Approval Holder
44012	EXCEL INDUSTRIES (AUSTRALIA) PTY LTD
44093	FARMOZ PTY LIMITED
57040	IMTRADE AUSTRALIA PTY LTD

Environment

An assessment of new environmental information available since the completion of the 1998 endosulfan review was undertaken by DEWHA. Endosulfan displays the characteristics of persistence, bioaccumulation and toxicity. Substantial evidence demonstrates that endosulfan is highly toxic for most animal groups, showing both acute and chronic effects at relatively low exposure levels. Endosulfan is used in a manner that can result in exposure to organisms at levels known to be toxic. Persistence will prolong the exposure and bioaccumulation will build up levels of the chemical in the environment.

The persistent nature of endosulfan is only clearly realised when endosulfan and all of its metabolites are considered. The Interim Environmental Review report only considered the sulfate.

The volatility of endosulfan was well characterised and understood in 1998. What was not appreciated at the time was the distance this vapour travelled.

Exposure to relatively low levels of endosulfan are likely to have sub-lethal and chronic effects on the organism exposed, but these effects are likely to be passing unnoticed as their expression requires an extended period to develop.

At current approved rates of use, endosulfan has been demonstrated to enter aquatic compartments from spray drift and run-off, having lethal and sub-lethal impacts. An assessment of risk from both spray-drift and run-off was undertaken to determine potential adverse effects from current uses. This did not take into consideration the long range transport of endosulfan vapour.

Based on the inherent properties of endosulfan, and given its widespread occurrence in environmental compartments and biota in remote areas, together with the uncertainty associated with the insufficiently understood role of the metabolites that retain the endosulfan chemical structure, it is concluded that endosulfan is likely, because of its potential for off-site movement, to lead to significant adverse environmental effects.

This assessment found that current product labels do not provide the required safe application distance necessary to protect the aquatic environment from lethal and sub-lethal concentrations of endosulfan. Run-off from treated areas, is likely to have an impact on aquatic organisms. It is not feasible to implement mitigation measures to protect the environment from ongoing exposure. The risk assessment undertaken by DEWHA shows that endosulfan use can have unintended consequences capable of causing harm to aquatic organisms.

Toxicology and occupational health and safety

In their consideration of endosulfan, The Office of Chemical Safety Environmental Health (OCSEH) has examined additional information since the 2005 endosulfan review. This included the US EPA Re-registration Eligibility Decision (RED) on endosulfan as well as other publicly available data. The assessment addressed issues such as the endocrine disruption and neurotoxicity potential of endosulfan.

From the public health point of view, the continued use of endosulfan is not a significant risk to public health under the risk management controls and health standards established by the 2005 review.

The outcomes of the toxicological assessment were then used to determine whether the occupational health and safety assessment would require amendment.

Supplementary studies, which included human in vitro percutaneous absorption data, indicated that a lower dermal absorption factor could be used to assess the occupational risk. When coupled with new Australian occupational exposure data, and the use of PHED, the dermal absorption factor used in the 2005 OHS review has been slightly revised. The need for revisions to PPE are indicated to include the use of elbow length chemical resistant gloves when opening the container and preparing and using the spray.

Findings

The continued registration and approval of endosulfan in Australia is likely to have unintended effects on the environment that cannot be mitigated.

1. ENVIRONMENTAL ASSESSMENT REPORT

1.1 Introduction

Endosulfan is a synthetic organochlorine compound commonly used as an agricultural insecticide. It has been sold worldwide since the mid 1950s and it is still used worldwide. In Australia endosulfan is contained in six registered products and is used on a wide variety of crops[1].

Technical grade endosulfan is a diastereomeric mixture of two biologically active isomers (α- and β-) in approximately 2:1 to 7:3 ratio, along with impurities and degradation products. The technical product must contain at least 94% endosulfan in accordance with specifications of the Food and Agricultural Organization of the United Nations (FAO Specification 89/TC/S) with content of the α-isomer in the range of 64-67% and the β-isomer of 29-32%. The α-isomer is asymmetric and exists in two twist chair forms while the β-form is symmetric. The β-isomer is easily converted to α-endosulfan, but not vice versa (INIA, 1999).

Technical information about (eco) toxicity, environmental fate, residues in food and feedstuff, and environmental concentrations of endosulfan is widely available from different sources around the world. The advent of the Stockholm Convention to take action on Persistent Organic Pollutants (POPs) has focussed more attention on endosulfan and produced a large volume of new information on its environmental fate and effects.

The potential environmental risks of endosulfan associated with its use as a pesticide are well documented and have resulted in withdrawal of product registrations or imposition of severe use restrictions in many countries around the world. These potential risks are not limited to the crop areas or the immediate vicinity of product application. In the case of endosulfan, research has shown that environmental impacts have been observed at significant distances, due to medium and long-range atmospheric movement. Environmental concentrations of endosulfan representing a potential risk to aquatic species have been found associated with medium range off-site movement, e.g. values above the reported NOEC for aquatic organisms have been found in the Sierra Nevada Mountains of California (CDPR, 2000).

Although significant regulatory action has occurred since the 1998 report, and the environmental impact has been considered albeit in limited detail, no 'trigger' has been given that would necessitate the need to comprehensively reconsider information regarding the environmental impacts of endosulfan until now. It is only since the consolidation of the information for POPS and the

[1] canola, linseed, safflower, sunflower, cereals, cotton, chickpeas, cowpeas, pigeon peas, adzuki beans, faba beans, field peas, navy beans, mung beans, lupins, soybeans, cabbages, cauliflower, broccoli, beetroot, capsicums, okra, cape gooseberry, carrots, celery, cucurbits, egg plant, potatoes, sweet potato, taro, tomatoes, avocados, cashews, custard apple, citrus, guavas, persimmons, kiwi fruit, longans, loquats, lychees, macadamia nuts, mammey apples, mangoes, passion fruit, pawpaw, pecan nuts, pistachios, pome fruit, pomegranates, rambutans, sapodillas, tamarillos, native trees, shrubs, nursery crops, ornamentals, wildflowers, proteas and tobacco.

regulatory action by other countries that has called into question the methodologies employed in the original 1998 assessment and the need to revisit these. The APVMA requested DEWHA to new scientific developments that have occurred since the 1998 and 2005 APVMA reviews of endosulfan The findings from this assessment will help determine whether there is a need to take further regulatory action on endosulfan.

1.2 Findings of 1998 Interim Environmental Review and Supplemental 2005 Report

In November 1995, a review of endosulfan was initiated because of possible health and environmental effects, residues in commodities, and possible trade implications from use in Australia. An interim report of this review was released in 1998 which contained recommendations for a number of changes to the way in which endosulfan could be used.

During the period 1998 to 2001, the APVMA implemented a range of additional changes to the registrations and label approvals of endosulfan products including declaring endosulfan products to be restricted chemical products (RCPs) and restricting the number of applications for endosulfan per season. To specifically manage spray drift the APVMA imposed mandatory buffer zones, neighbourhood notification requirements before application to cotton, and ultimately cancelled the registration of ultra-low volume endosulfan products. The ‘triggers’ for this action were residue violations in brassicas and residues in beef resulting from spray drift onto grazing land.

1998 Review Findings

The 1998 Endosulfan Interim Environmental Review, while comprehensive, does not necessarily reflect the standards or methodology of environmental assessments under which reviews are currently undertaken[2].

In reviewing the 1998 report, there was no modelling of spray drift as the capacity to estimate buffer zones through modelling had not been developed at the time. While the need for a buffer zone in excess of 150 m for the aquatic environment was raised in the report, this was estimated in a semi-quantitative manner based on the amount of spray drift expected to occur at this distance based on the available literature [based on expected Q for one 0.1% drift estimated to occur at 150 m].

The 1998 review did not include an assessment of run-off and therefore the lethal and sub-lethal effects to aquatic organisms as a result of spraydrift and runoff were not examined. The significance of this new information on the environmental fate – toxicity is discussed in section 4.4 of the report.

[2] Current risk assessment methodology, endorsed by the Environment Protection and Heritage Council, is detailed in the recently published AgVet Risk Assessment Manual, which can be located at: www.ephc.gov.au/taxonomy/term/75 .

The volatility of endosulfan was well characterised and understood in the 1998 review, with Australian data from field experiments in the cotton growing areas estimating around 70% of applied endosulfan lost mainly to volatilisation in the 7 days after application (p333, 1998 review). What was not appreciated at the time was the distance this vapour travelled. The 1998 report was heavily influenced by the views of Simonich and Hites (1995, Section 5.2.4.5, p312) that endosulfan with its relatively low vapour pressure appeared to move off-site in a regional context, rather than the recently documented global movement of endosulfan. Much of the evidence to demonstrate that endosulfan, despite its relatively low vapour pressure, was moving substantial distances off-site and bioaccumulating, was published after the 1998 report was prepared.

The 1998 report noted that endosulfan largely degrades over the course of a year in soils and aquatic sediments to which it partitions, with low levels being carried over from season to season, providing aquatic and soil organisms no relief from exposure. The report also found that this was a concern for the aquatic environment, given indications that endosulfan was bioaccumulative, although bioaccumulation capacity was thought to be limited by the ready elimination of residues from fish. Recent research has now confirmed that although there is limited bioconcentration potential in water-respiring organisms, two additional concerns are apparent: biomagnification in food chains constituted by air-breathing organisms; and, the long-term consequences of a number of persistent metabolites, which maintain the basic chemical structure of endosulfan. These are discussed in detail in section 4.3 of this report.

The 1998 report did find that *"contamination of the broader environment with persistent and toxic metabolites of a volatile insecticide will be difficult to justify should alternatives with equivalent performance become available that do not suffer from this undesirable side effect"* (p366). The significance of this new information on metabolites is also discussed in section 4.2 of this report.

The APVMA interim review report (1998) concluded that, although well retained once in the soil, endosulfan contaminates the broader environment through spray drift, volatilisation and particle transport. The specific concerns with storm runoff into rivers were due to the high aquatic toxicity of endosulfan. Measures were put in place by the APVMA to amongst other things, minimise the impact of pesticides on riverine environments. These included:

- Targets set for reduction in endosulfan levels in surface waters in cotton growing areas. Agreed to as a 25% reduction in number of measurements in upper quartile of past stream concentration values. Continued use of endosulfan contingent upon meeting those targets by 30 June 2001.
- Maximum of 2 sprays (or equivalent) per season limit, unless growers could contain irrigation water or storm runoff water (up to 25mm of rainfall) on their farms.
- Cotton growers to follow the cotton industry Best Management Practices Manual, which focuses on reducing risks to the environment, workers and neighbours.
- New label statement requiring auditable spray records be kept.

- New label statements prohibiting application during irrigation, rain or during weather conditions likely to increase spray drift.

2005 Review Findings

Environmental input into the 2005 Endosulfan Final Report was comparatively minor and restricted to a few pages examining updated data for water monitoring in cotton growing areas. This was specifically to deal with the 1998 Interim report's requirement that "*Trends in the environmental contamination and total quantity used will be re-evaluated by 30 June 2001 to determine whether endosulfan use should be continued*."

During 2000-2001 and 2001-2002 there was a dramatic reduction in the detections of endosulfan in the Namoi, Gwydir and Macintyre catchments. In 2001-02, for the first time since pesticide monitoring commenced in 1990, no endosulfan residues were detected in the Namoi Valley (118 samples collected). Endosulfan concentrations in the Gwydir River catchment in 2001–2002 were the lowest detected since 1991, Furthermore, in following years endosulfan concentrations fell below the ANZECC guidelines value for 99% ecosystem protection across all three valleys (Namoi, Gwydir, Macintyre).

The monitoring results available to the APVMA adequately demonstrated that measures put in place by the APVMA with the cooperation of the cotton industry, have been effective in reducing endosulfan contamination in surface water. Monitored levels had dropped significantly, influenced by the lower amounts used as a result of APVMA restrictions, adoption of the Cotton Best Management Practices (BMP) Manual, much less cotton grown during drought conditions, and the substitution of much of the conventionally grown cotton with genetically engineered Bt-cotton which did not require application of endosulfan.

On this basis it was concluded, in 2005, that the continued registration of endosulfan would not be likely to have an effect that is harmful to the environment.

1.3 New information on Endosulfan

Since the 1998 review a significant amount of information has become available in the published literature, mainly in regards to the potential for endosulfan to enter the environment. This has arisen primarily as a result of the consideration of endosulfan as a potential POP (under the Stockholm Convention). This new information has given the APVMA the 'trigger' to re-examine the environmental impact of endosulfan which had previously not been available.

1.3.1 Examination of changes in the amount used and in use patterns

According to information provided by the Department of Agriculture, Fisheries and Forestry, the volumes of active ingredient sold in the Australian market per year were:

2004: 125.2 tonnes
2005: 119.4 tonnes
2006: 116.4 tonnes
2007: 74.1 tonnes
2008 (to mid-December): 89.9 tonnes.

These data show that apart from 2007, sales levels appear to have remained relatively stable over the past 5 years. According to the 1998 review findings, up to 70% of applied endosulfan is lost through volatilisation in the first 7 days after application, thus up to 70 tonnes of endosulfan is being released to the atmosphere per annum in off-site movement over medium and long-range distances and through contamination of the aquatic compartment by spraydrift and run-off.

Despite its reduced importance for treatment of pests in cotton, endosulfan is still registered and widely used on a significant number of crops. There are currently six registered products containing endosulfan.

The maximum label application rates range from 150 to 840 g ac/ha. However, recent calculations (see Appendix A) show that the maximum application rate can be as high as 2800 g ac/ha.

Examination of the labels indicates that while applications to cotton and many other crops are limited to 1 or 2 sprays per season, this is not the case for horticulture when in many cases the CRITICAL COMMENTS allow “spray as required” which can involve multiple applications (up to 10 or more) per season.

1.3.2 Environmental fate - Persistence

It is now recognised that the persistence of endosulfan should be assessed in terms of a dual evaluation. First, the persistence of the “active” molecules, with insecticidal activity: the isomers α- endosulfan and β-endosulfan, and the main metabolite endosulfan sulfate. Second, the overall persistence of the number of transformation products that maintain a similar chemical structure with the bicyclic hexachloronorbornene structure: endosulfan diol, endosulfan lactone, endosulfan ether; endosulfan hydroxyether; endosulfan carboxylic acid.

Endosulfan aerobic transformation occurs via biologically mediated oxidation. The main metabolite formed is endosulfan sulfate. This compound is slowly degraded to the more polar metabolites endosulfan diol, endosulfan lactone and endosulfan ether. The persistent nature of endosulfan is only clearly realised when the sum of endosulfan and its metabolites are considered, however, this is consistent with the growing realisation of the importance of considering endosulfan and all of its metabolites, and not just the sulfate as previously considered in the 1998 Interim Environmental Review report.

In the field, volatilisation from soil and plant surfaces is expected to be a main dissipation route following its application. These half-life values are difficult to compare with those in the 1998 Interim Review report for endosulfan (through lack of original references), which does, however, note *“projected half-lives for total residues (in the laboratory) are in the range of 9 months to 2 years,* *extending to 6 years in one soil."* Elsewhere it notes that volatilisation does not appear to contribute significantly to field losses of the sulfate metabolite, which declines according to first order kinetics with a half-life in the order of 6 months.

Recent research in the EU dossier risk profile concluded:

"In the aquatic compartment, endosulfan is stable to photolysis. A rapid hydrolysis is only observed at high pH values, and it is non-readily biodegradable. In water/sediment systems (Jones, 2002; 2003) DT_{50}s for the alpha, beta isomers and endosulfan sulfate ranging between 3.3 and 273 days for the total system, were presented. Accumulation of endosulfan sulfate in sediment was seen in all four systems, but as the concentration plateaued in all cases the dissipation rate in sediment could not be established. However, DT_{50}s of at least > 120 d were demonstrated. Endosulfan carboxylic acid similarly accumulated in the water phase. Endosulfan diol, and under acidic conditions endosulfan lactone, were also observed at relevant levels."

DEWHA is satisfied that data generated since the 1998 Interim Review report show that the endosulfan sulfate primary degradate is persistent in sediment.

These two studies (Jones 2002, 2003) have shown the need to adopt the total residues approach due to the complex degradation pathways of endosulfan in water/sediment system, with the carboxylic acid, diol and lactone, which all retain the basic structure, likely to be persistent as well.

The potential for long-range transport, seems to be mostly related to volatilisation followed by atmospheric transfer. The 1998 report (p312), based on the evidence at the time, concluded that vapour pressure was too low to enable extensive long-range transport. However, there is now enough information on the volatility of α and β endosulfan, and therefore the persistence in the atmosphere to support the potential for atmospheric transport. The atmospheric transport at long distances requires a minimum level of persistence in the atmosphere. Atkinson et al (1999) showed that for complex molecules such as endosulfan, AOPWIN (the model generally used), tends to underestimate the atmospheric half-life according to the OH radical degradation. Therefore, it can be concluded that the combination of a high volatility and sufficient atmospheric persistence may result in a significant potential for long-range off-site movement of endosulfan.

Since 1998, several models have been developed for estimating long range transport (LRT) and overall persistence (POV) potential. Results from the CliMoChem model show that POV and LRTP of the endosulfan substance family are similar to those of acknowledged Persistent Organic Pollutants, such as aldrin, DDT, and heptachlor. The results also show that POV and LRTP of the entire substance family i.e. including the transformation products, are significantly higher than those of the parent compounds alone.

1.3.3 Environmental fate - Bioaccumulation

The 1998 Environment report noted that current evidence suggested that endosulfan was not a persistent pollutant because residues were readily eliminated from fish. The report did not assess bioaccumulation potential in air breathing mammals.

Three complementary information blocks were analysed in the risk profile for endosulfan (POPRC 2009) to assess the bioaccumulation and biomagnification potential of endosulfan and its degradation products: the screening assessment based on physical-chemical properties; the analysis of experimental data, including bioconcentration, bioaccumulation and toxicokinetic studies; and the analysis of field-collected information.

A large number of studies which referenced information on measured levels of endosulfan in biota all over the world are available. Endosulfan and its metabolite endosulfan sulfate are frequently found in crops and in the vicinity of treated sites, as well as in remote areas where the presence of this pesticide must result from medium and long range transport from those areas in which endosulfan has been used.

Endosulfan has been detected in biota in the Arctic (5 terrestrial, 1 freshwater and 13 marine species with maximum levels between 0.39 to 130 pg/g lw) [3] and Antarctic (a seal species and krill with maximum levels of 451 pg/g lw). Monitoring data have detected endosulfan (and endosulfan sulfate) in the air, the freshwater, the marine water and the sediment of the Arctic and/or Antarctic regions. Therefore, there is sufficient evidence that endosulfan is transported at long distances and bioaccumulates in biota in remote areas. α-Endosulfan was found in 40% of samples of Antarctic krill.

The geometric mean level detected was 418 pg/g lw, the maximum was 451 pg/g lw (Bengston et al., 2008).

Also in the Canadian Arctic concentrations of α-, and β-endosulfan and endosulfan sulfate in ice-algae, phytoplankton, zooplankton, marine fish and ringed seal have been presented. Concentrations ranged from 0.1 – 2.5 ng/g lipid. Calculated trophic magnification factors were less than 1, suggesting no biomagnification in the ringed seal food chain (Morris et al. 2008). However a trophic magnification factor >1 was calculated for the Southern Beaufort Sea and Amundsen Gulf food webs if marine mammals are included in the food web (Mackay & Arnold 2005).

Quantitative estimates of biomagnification can be obtained through the use of mathematical models calibrated with field data (Alonso et al., 2008). Several published models indicate the potential biomagnification of endosulfan through the food chain. A model of the lichen-caribou-wolf food chain predicts biomagnification of β-endosulfan. The BMFs for wolf range from 5.3 to 39.8 for 1.5 to 13.1 year old wolves (Kelly & Gobas. 2003).

A particularly relevant piece of information was published in 2007 (Kelly et al., 2007). The model predicts a significant BMF for β-endosulfan in air-breathing species, ranging from 2.5 for terrestrial herbivores to 28 for terrestrial carnivores; and BMF below 1 for water-respiring organisms.

[3] pg/g lw - pictogram/gram liveweight

Recently, the role of the octanol/air partition coefficient K_{oa} for the screening assessment of the biomagnification potential of POPs in terrestrial food chains is receiving significant attention. Kelly & Gobas (2003) and Kelly *et al.* (2007) have proposed that the biomagnification of endosulfan in the terrestrial food chain is particularly relevant, because it has a high log K_{oa}. A high K_{oa} causes slow respiratory elimination. The proposed log K_{oa} for α- and β-endosulfan is 10.29; and for endosulfan sulfate is 5.18. Although there are no specific screening thresholds for the K_{oa} the authors suggests that chemicals with a log K_{ow} higher than 2 and a log K_{oa} higher than 6 have an inherent biomagnification potential in air-breathing organisms of terrestrial, marine mammalian, and human food chains provided that chemical metabolic transformation rates are not extensive. Endosulfan α- and β isomers clearly fall within this category; its primary metabolite endosulfan sulfate is very close.

The risk profile (POPRC 2009) reports an outdoor aquatic microcosms study estimated bioaccumulation factors of about 1000, based on total radioactivity but up to 5000 for endosulfan sulfate. A similar situation is observed in the dietary exposure experiments with aquatic organisms. The initial "standard" assessment indicates a low bioaccumulation from food in cladocerans exposed to contaminated algae and in fish exposed to contaminated food. However, an in-depth analysis of the results in terms of the comparative assessment of the long-term toxicokinetics of endosulfan and its degradation products reveal some concerns, for example, the endosulfan sulfate concentrations in the fish exposed to endosulfan in the diet were low but remained unchanged during the whole depuration phase.

The bioconcentration potential of endosulfan in aquatic organisms is confirmed by experimental data. The validated bioconcentration factor (BCF) values range between 1000 and 3000 for fish, from 12 to 600 for aquatic invertebrates; and up to 3278 in algae.

Thus, reported BCFs are below the criterion of 5,000; and the log Kow is measured at 4.7, which is below the criterion of 5. However, measured BAF and BMF in Arctic organisms show that endosulfan has an inherent high bioaccumulation and biomagnification potential. Additionally, endosulfan was detected in adipose tissue and blood of animals in the Arctic and the Antarctic. Endosulfan has also been detected in the blubber of minke whales and in the liver of northern fulmars. Therefore, there is sufficient evidence that endosulfan enters the food chain and that it bioaccumulates and has the potential to biomagnify in food webs.

1.3.4 Environmental fate – Toxicity

Substantial evidence documented in the scientific literature demonstrates that endosulfan is highly toxic for most animal groups, showing both acute and chronic effects at relatively low exposure levels. Fish are the most susceptible species to the detrimental effects of endosulfan. Table 1 is a compilation of some of the most sensitive end points taken from the 1998 review (APVMA, 1998) and some more recent publications. Many of these end points, including those for aquatics invertebrates, are well below 1 μg/L.

Table 1: Compilation of most sensitive endpoints

	LC50 (96 hr) μg/L	**Chronic NOEC μg/L**	**Reference**
Australian Studies			
Rainbow trout Mosquitofish Eastern rainbow fish Common carp Bony bream Golden perch Silver perch Harlequin fish	0.7 2.3 0.5-5.0 0.1 0.2 0.5 2.3 0.2		Sunderam et al., 1992
Juveniles golden perch	LC50 (34 h) 2.8		Fleur and Hyne, 2009
Mayfly nymphs	LC10 (48 h) 2.8-6.2 LC50 (48 h) 12.3-15.9		Hose et al., 2003a
USA EPA			
Rainbow trout Bluegill sunfish Fathead minnows Spot Eastern oyster Grass shrimp Pink shrimp Stonefly	0.47 1.7 1.5 0.09 0.45 1.3 0.04 2.3		USA EPA 2007
ANZECC WQG			
Freshwater		0.03	ANZECC, 2000

However, toxicity alone is insufficient to demonstrate that endosulfan has adverse effects on the environment when used in the approved manner. Similarly, persistence and bioaccumulation themselves may not necessarily demonstrate adverse effects. Persistence will prolong the exposure and bioaccumulation will build up levels of the chemical in the environment. Endosulfan has all three characteristics and is used in a manner that can result in exposure to organisms at levels known to be toxic.

1.4 RISKS ARISING FROM USE – REVISED ASSESSMENT

An assessment of risk from both spray-drift and run-off was undertaken to determine potential adverse effects from current uses. Neither of these were considered in such detail in the 1998 review due to the lack of appropriate methodology. Therefore the assessment was limited to a qualitative assessment only. Detailed results of the risk assessment outlined in Appendix A - Risks Arising from Use, are discussed below:

1.4.1 Spray drift

Using the current spray-drift methodology implemented by the APVMA (APVMA, 2008), calculations for common applications of endosulfan in Australia indicated that for spray drift considerations, very large buffer zones for protection of the aquatic compartment are required (i.e. to fall below the Predicted No Effect Concentration). The buffer for ground application is >300 m and the minimum aerial buffer is 2000 m (well in excess of the model's validated range of 800 m). These calculations are based only on a single application. These buffer distances would be much greater if the current label recommendations are included in the calculations (i.e. the current label allows up to 10 or more sprays per year in some applications).

1.4.2 Runoff

Using the most recent run-off methodology developed by DEWHA, in all the tested scenarios there were clear indications of unacceptable risk to the aquatic compartment from the effects of endosulfan. Further, adequate mitigation measures could not be implemented because of the large Risk Quotients. The environmental concentrations predicted from modelling (PEC = 9-700 μg/L) are well within the measured concentrations of total endosulfan in river water following storm run-off (0.07-900 μg/L) (Leonard et al., 2000; Leonard et al., 2001; Hose et al., 2002; Hose et al., 2003a; Hose et al., 2003b).

Therefore, using current methodologies, there are clear indications of unacceptable risk to the aquatic compartment from both endosulfan spray-drift and run-off.

1.4.3 Exposure to lethal concentrations

Substantial evidence documented in the scientific literature demonstrates the environmental impacts from exposure to lethal concentrations of endosulfan from run-off. Leonard et al. (2000) reported a negative correlation between endosulfan concentrations (ranging from 13-911 μg/L, which are well within the predicted PEC by the run-off model - Appendix A) in the Namoi River in the 1995/96 and 1997/98 cotton growing seasons and the population densities of six dominant macro invertebrate taxa (mayfly nymphs Jappa kutera, Atalophlebia sp., Tasmanocoenis sp., Baetis sp. and the caddisfly larvae Cheumatopsyche sp. and Ecnomus sp.). They also confirmed that endosulfan entered the riverine environment during storm events in both run-off water and run-off sediment, as suggested by other studies (Leonard et al., 2001; Fleur and Hyne, 2009). Leonard et al. (2001) linked the changes in the population densities of mayfly Jappa kutera to the metabolite endosulfan sulfate in the Namoi River. They also reported an increase in endosulfan (and endosulfan sulfate) toxicity with increases in exposure time (i.e. the toxicity doubled from 24 hours to 96 hours). Hose et al. (2003b) reported that changes observed in riverine macro invertebrate (Atalophlebia spp.) communities were the result of endosulfan contamination, but the changes were associated with chronic rather than acute exposure (i.e. all the detected endosulfan concentrations were below a lethal concentration).

Significantly, other studies have reported the detrimental effects on organisms exposed to high-levels of endosulfan (i.e. concentrations comparable to those detected in the Naomi River and the predicted concentration by the run-off model – Appendix A).

Hose et al. (2002) reported changes in macro invertebrate communities after exposure to endosulfan of 6.14 μg/L. Hose et al. (2003a) reported reduced abundances of the mayfly Jappa kutera and algal blooms after exposure to endosulfan (for 48 hours at 6.87 and 30.70 μg/L treatments). Of particular note, the reported NOECs for endosulfan on macro invertebrate assemblages were 8.69 μg/L at 12 hours and 1.00 μg/L at 48 hours (which suggests exponential increases in toxicity with longer-term exposure). Fleur and Hyne (2009) reported an LC50 value (34 hour) of 2.8 μg/L for golden perch M. ambigua in caged tests from a mesocosm study at the Namoi River. Relyea (2009) reported 84% mortality of leopard frog larvae when exposed to 6.4 μg/L and significant negative and positive changes to the population of zooplankton, phytoplankton, periphyton, and invertebrates at the same concentration.

It is clear from the above literature that the measured concentrations of total endosulfan in river water following storm run-off exceeded lethal concentration values in river water for various species (Leonard et al., 2000; Leonard et al., 2001; Hose et al., 2002; Hose et al., 2003a; Hose et al., 2003b; Fleur and Hyne, 2009). Additionally, these reported effects and the exposure pathway (together with the PEC predicted by the run-off model – Appendix A) cannot be ruled out in the future, as past experience indicates that during wetter seasons the demand for endosulfan use increases, thereby also increasing the amount of run-off (containing endosulfan) from farming areas.

1.4.4 Exposure to sub-lethal concentrations

There is also concern about the exposure to relatively low-level concentrations of endosulfan, which may have sub-lethal and chronic effects on aquatic organisms. These potential exposure mechanisms are relevant because continuous or pulse exposure to low levels may lead to a number of pathological and disturbed biochemical processes, which may compromise future components of fitness, rather than immediate survival of the exposed organisms (Broomhall, 2002; Ribeiro et al., 2001).

There are several published studies demonstrating the effects when organisms are exposed to relatively low-level concentrations of endosulfan (i.e. in many cases concentrations that are just above the lethal and the chronic PNEC used in the DEWHA calculations – Appendix A). Hose et al. (2003) demonstrated that decreased mayfly nymphs Atalophlebia spp. in the Namoi River were mainly the result of chronic exposure to sub-lethal concentrations of endosulfan (in the range of 0.07-0.3 μg/L). The same authors also reported negligible effects on the mayfly Atalophlebia sp. when exposed to endosulfan concentrations below the lethal and the chronic PNEC in several reference site rivers (0.008-0.026 μg/L) (Appendix A). Fleur and Hyne (2009) reported significant effects on juveniles of golden perch at a sub-lethal dose of 0.09 μg/L when exposed to short pulses of endosulfan in natural waters. These workers also reported mortality >40% when juveniles were exposed to 0.09 μg/L for longer periods. Shenoy et al. (2009) observed 100% mortality for R. pipiens exposed to 1 µg/L endosulfan over 28 days. Exposure to 0.2 µg/L also resulted in significant mortality. Further, increasing water temperatures at the time of exposure to endosulfan (0.68 g/L) increased the vulnerability of Litoria citropa tadpoles to predation by odonates over 3 weeks later (this effect was only noted for exposure to endosulfan (Broomhall, 2002). It also reduced their size and feeding behaviour (Broomhall and Shine, 2003).

1.4.5 Discussion

Therefore, using current methodologies, there are clear indications of unacceptable risk to the aquatic compartment from both endosulfan spray-drift and run-off.

The spray-drift and run-off model results indicate that safer exposure levels are below the lethal and chronic PNECs (i.e. 20 and 30 ng/L) and these very low-level concentrations are only achieved using very large buffer zones. The modelling indicates that if used according to current label instructions, it would be likely that low-level concentrations of endosulfan (i.e. above the safe levels predicted by the models) are entering the aquatic compartments and causing sub-lethal and chronic effects on aquatic organisms. Furthermore, in many cases the effects from sub-lethal and chronic exposure may take a relatively long time to be expressed and identified, and would be difficult to link these effects back to the original source (Broomhall, 2002).

The results of the risk assessment, documented at Appendix A, provide sufficient justification to conclude that drift from endosulfan application can have unintended consequences namely harm to aquatic compartments. There is also concern about the exposure to relatively low levels of endosulfan, which are likely to have sub-lethal and chronic effects on the organism exposed, but these effects are likely to be passing unnoticed as their expression requires an extended period to develop. Furthermore, the current label does not provide the required safe application distance necessary to protect the aquatic environment from these types of concentrations and it is not feasible to implement the appropriate mitigation measures to protect the environment from ongoing exposure, especially if multiple applications are considered.

1.5 Discussion on changes since previous reviews

A substantial amount of new information on endosulfan has become available since the comprehensive 1998 Interim Environment Review and the comparatively smaller 2005 Final Report for endosulfan were published. Some of the assumptions and methodologies employed in the earlier assessment are no longer appropriate, specifically:

- The recognition that both persistence and toxicity for the whole family of endosulfan metabolites need to be taken into account, rather than simply the primary metabolite, endosulfan sulfate as was previously considered in the 1998 review.
- Recent studies have shown the need to adopt the total residues approach due to the complex degradation pathways of endosulfan in water/sediment system, with carboxylic acid, diol and lactone, which all

retain the basic structure, likely to be persistent as well. The persistent nature of endosulfan is only clearly realised when the sum of endosulfan and its metabolites is considered and not just the sulfate as previously considered in the 1998 Interim Environmental Review report.

- DEWHA's risk assessment has shown that application drift and run-off from endosulfan use can have unintended consequences capable of causing harm to the aquatic environment. This was determined by undertaking a risk assessment to determine the buffer zones needed to obtain exposure concentrations that are below the Predicted No Effect Concentrations (PNEC). The outcome of this assessment indicates that the Predicted No Effect Concentrations was obtained only under large buffer zones (>300 m for ground and >2000 m for aerial). These large buffer zones are not implemented under the current label instructions. Therefore, it is concluded that it is more probable than not those concentrations higher than the PNEC are entering the aquatic environment now. There is substantial evidence in the published literature demonstrating the effects when organisms are exposed to concentrations that are higher than the PNEC. The concentrations that are higher than the PNEC were classified as those causing lethal effects and those causing sub-lethal or chronic effects. This is documented in section 4.4, based on the risk assessment contained in Appendix A.

- The recent availability of modelling capacity to estimate spray drift buffer zones for the protection of the aquatic environment demonstrates that the current buffer zones aimed at protecting adjoining properties as identified in the 2005 review are not adequate to protect aquatic organisms. Calculations using the APVMA published models indicate for spray drift that these buffers are very large, particularly when applied by air, and increase further with multiple applications.

- Substantial evidence in the scientific literature demonstrates that lethal concentrations of endosulfan are being found in the aquatic environment, as a result of spray drift and run off from current uses. Run-off modelling demonstrates clear indications of unacceptable acute risks to the aquatic environment (very high RQ values). If the RQ was close to acceptable (equal to 1) then refinements to assumptions may mitigate the predicted risk. In the case of endosulfan the RQs, even after several mitigation steps, in all tested scenarios are much greater than 1 (lowest RQ is 65 from runoff at 735 g/ha – Table 6 Appendix A) indicating substantial risks to the environment. As such further mitigation is not possible.

- The modelling indicates that if used according to current label instructions, it would be likely that low-level concentrations of endosulfan (i.e. above the safe levels predicted by the models) are entering the aquatic compartments and causing sub-lethal and chronic effects on aquatic organisms. Furthermore, in many cases the effects from sub-lethal and chronic exposure may take a relatively long time to be expressed and identified, and would be difficult to link these effects back to the original source.

- There is now recognition, based on evidence published in the literature post-1998, that endosulfan is a global pollutant. There is enough information on the volatility of α- and β- endosulfan to support the potential for atmospheric transport. Taking into account the much lower temperatures of the troposphere, the environmental half-life of endosulfan under real situations is likely to be even longer.

- Model estimations, based on measured concentration of key elements from remote Arctic food chains, indicate significant biomagnification of endosulfan in terrestrial ecosystems.

- The advent of the Stockholm Convention to take action on Persistent Organic Pollutants (POPs), has focussed more attention on endosulfan and resulted in a large volume of new information on its environmental fate and effects.

- The adoption of persistent, bioaccumulative and toxic (PBT) criteria for use in regulatory decision making in Australia has provided a quantitative assessment of chemicals that meet this criteria and a framework for policy decision-making in relation to regulating their use, with respect to impacts on the environment. Endosulfan meets this criteria.

Noting the key points above and the recommendations of the 1998 report to reduce environmental loads of endosulfan, at least 70 tonnes per annum are still being released to the environment. At current approved rates of use, endosulfan has been demonstrated to enter aquatic compartments from spray drift and run-off, and resulting in lethal and sub-lethal impacts.

The risk assessment undertaken by DEWHA shows that endosulfan use has the potential to lead to unintended consequences, namely it can cause harm to aquatic compartments. This is supported by the scientific literature that documents measured concentrations of total endosulfan in river water following storm run-off which exceeds lethal concentration values for various species. In addition, exposure to relatively low levels of endosulfan resulted in sub-lethal and chronic effects on aquatic organisms as reported in several published studies.

1.6 Conclusion

Endosulfan displays the characteristics of persistence and bioaccumulation, and is a highly toxic compound for most animal groups. DEWHA is no longer able to recommend that the APVMA can be satisfied that the continued use of endosulfan will not result in unintended effects that are harmful to animals, plants or to things, or to the environment.

Even if the issues with the active constituent could be resolved, the current label does not provide the required safe application distance necessary to protect the aquatic environment and it is not feasible to implement the appropriate mitigation measures to protect the environment from ongoing exposure, especially if multiple applications are considered.

2. TOXICOLOGY AND OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT SUMMARY

2.1 Introduction

The OCSEH has conducted an assessment of existing commercial data holdings and currently available published information on endosulfan to determine whether the continued use of endosulfan would not present an unacceptable human health risk to those using the chemical in an occupational environment or to members of the general public who may be exposed to the chemical. The full toxicology and occupational health and safety assessment reports can be found in Volume 2.

2.2 Toxicology

Endosulfan is a broad spectrum insecticide/acaricide which is registered in Australia for the control of a large variety of insects and mites in ranges of horticultural and agricultural crops. Like other organochlorine pesticides, the toxicity of endosulfan to both insects and humans arises from over-stimulation of the nervous system.

The APVMA (1998, 2005) and US EPA reviews (2002) of endosulfan evaluated comparable databases and adopted similar regulatory approaches on most issues. Recently published studies and conclusions of the US EPA and ERMA New Zealand have now been considered. The specific issue of whether endosulfan should be categorised as an endocrine disruptor remains as one significant difference between the two agencies mainly arising from the US EPA inclusion of data from all endocrine systems as well as potential effects in wildlife.

The APVMA evaluation reported endocrine-related effects seen in test animals, particularly testicular toxicity, but noted that these appear to arise from homeostatic disturbance resulting from systemic toxicity. The APVMA report concludes that endosulfan binding to the oestrogen receptor is insignificant and considers that the regulatory endpoint chosen (see page 10 of this report for the NOEL table) is adequately sensitive and protective against potential endocrine disruption by endosulfan. Furthermore, the recently evaluated developmental neurotoxicity study reported no effects on sperm parameters

The US EPA evaluation noted the effects seen in test animals and argued additionally that the effects seen in amphibians, fish, birds and hormone receptor studies are indicative of potential endocrine disruption. Recently Cal DPR (2008) stated that the uncertainty regarding endosulfan as an endocrine disruptor has been reduced following the submission of the developmental neurotoxicity study in rats where there were no treatment related effects on sexual maturation of offspring at the highest dose tested (29.8 mg/kg bw/day).

A full discussion of the toxicology aspects associated with endosulfan can be found in volume 2 of the endosulfan report

From the public health point of view, there are no compelling reasons to change the conclusions of the 1998 and 2005 APVMA reviews with respect to the endocrine disrupting potential of endosulfan. While the effects seen in wildlife indicate that endosulfan may have endocrine disrupting potential in some species, the overall weight-of-evidence is that endosulfan has limited endocrine disrupting potential in mammals. The endocrine disrupting potential of endosulfan is not a significant risk to public health under the risk management controls and health standards established by the recent review.

2.3 Occupational health and safety

In the 2005 review of endosulfan the OCSEH used both the in vivo rat study by Craine (1988) and an in vitro study by Davies (2002) to estimate a dermal absorption factor for human skin. In accordance with the method proposed in the EC Draft Guidance on Dermal Absorption, the rat in vivo absorption values are adjusted by the ratio of the human and rat in vitro absorption values obtained in the Davies (2002) study to derive dermal absorption factors for humans of 0.5% for concentrates and 1.52 % for spraying and re-entry activities.

In this present consideration of endosulfan, the Davies (2002) study was reassessed and revised dermal absorption factors of 0.8% for concentrates and 2.2% for spraying and re-entry activities were established. In the 2005 report, the calculations of the total absorbed dose of endosulfan on human skin did not include the percent of endosulfan present on tape strips. The endosulfan on the tape strips should be included in the absence of evidence that this material would not be absorbed.

In vivo studies showed that absorption continues for > 7 days and that the majority of endosulfan found in the skin at 24 hours is eventually absorbed. Therefore the dermal absorption factors have been recalculated to include the percentage endosulfan on tape strips together with the percentage remaining on the epidermis plus the percentage in receptor fluid. These revised dermal absorption factors are the same as those used by the European Union.

Amendments to the dermal absorption factors were use to recalculate worker exposures for mixing, loading and applying EC endosulfan products, as well as re-entry activities. The recommendations for PPE remain basically unchanged apart from the recommended inclusion of elbow length chemical resistant gloves when opening the container and preparing and using the spray. The re-entry interval estimations in cotton, melon, peach and grape crops, also remains unchanged.

2.4 Conclusion

Taking into consideration all of the available information since the completion of the 2005 APVMA endosulfan review, OCSEH recommends that the use of endosulfan under current uses and controls, apart from minor amendments to personal protective clothing, will not present a risk to human health or worker safety.

3 Status of Endosulfan under international conventions and restriction on uses since 1998

A consequence of Australia's ratification of the Stockholm Convention in 2004 was the need to agree on a national version of the many international criteria for identifying persistent, bioaccumulative and toxic (PBT) substances based on the inherent properties of the chemical. As noted in Article 3.3 of the Stockholm Convention:

"Each party that has one or more regulatory and assessment schemes for new pesticides or new industrial chemicals shall take measures to regulate with the aim of preventing the production and use of new pesticides or new industrial chemicals which, taking into consideration the criteria in paragraph of Annex D, exhibit the characteristics of persistent organic pollutants."

The widespread acceptance of PBT criteria and characteristics is an important aspect in performing a risk assessment. In the 1998 report, the regulatory risk focussed on the health and environmental consequences of local episodic exposures, considered the expected benefits of the application, and the 'acceptability' criteria differed from that necessary for assessing persistent pollutants.

The Australian PBT criteria are summarised in Appendix B of this report.

As a consequence of endosulfan's nomination as a persistent organic pollutant (POP) under the Stockholm Convention, a risk profile for the chemical was developed by the POPRC through international research and collaboration involving experts from 26 countries and the compilation of over 6000 pages of reference material.

Endosulfan is subject to a number of regulations and action plans:

- In March 2007 the Chemical Review Committee (CRC) of the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade decided to forward to the conference of the parties of the Convention (COP) a recommendation for inclusion of endosulfan in Annex III. Annex III is the list of chemicals that are subject to the PIC procedure. Listing in Annex III is based on two notifications from different regions of regulatory action banning or severely restricting the use for health or environmental reasons that were found to meet the criteria listed in Annex II of the Convention. Meanwhile, the CRC has been evaluating further notifications of endosulfan. With the recent New Zealand ban on endosulfan, this brings to 17 countries (plus the entire European Community) that have notified final regulator actions to ban endosulfan under the Rotterdam Convention on the Prior Informed Consent since the completion of the 1998 Environment Review Report on Endosulfan (www.pic.int/reports/FRA-Parties-ByChem-list.asp)

- Endosulfan is recognised as one of the twenty-one high-priority compounds identified by UNEP-GEF (United Nations Environment Programme – Global Environment Facility) during the Regional Evaluation of Persistent Toxic Substances (STP), 2002. These reports have taken into account the magnitude of usage, environmental levels and effects for human beings and for the environment of this compound.

- The Sahelian Pesticides Committee (CSP) has banned all formulations containing endosulfan. The CSP is the structure for the approval of pesticides for CILSS member States (Burkina Faso, Cap Verde, Chad, Gambia, Guinea Bissau, Mali, Mauritania, Niger and Senegal). The deadline set for termination of the use of existing stocks of endosulfan was 31/12/2008.

- The UN-ECE (United Nations Economic Commission for Europe) has included endosulfan in Annex II of the Draft Protocol on Pollutant Release and Transfer Registers to the AARHUS Convention on access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

- The OSPAR Commission has included endosulfan in the List of Chemicals for Priority Action (update 2002).

- In the Third North Sea Conference (Annex 1A to the Hague Declaration), endosulfan was agreed on the list of hazardous priority substances subject to measures for reducing atmospheric emissions to the aquatic environment.

The use of endosulfan has been banned in at least 60 countries[4].

3.1 United States Environmental Protection Agency (USEPA) regulatory activity

In 2002 the USEPA imposed significant restrictions on the way in which endosulfan could be used. Many uses were cancelled, restriction to the way in which the chemical was applied were made, as were the rates at which endosulfan cold be applied.

In June 2010 the USEPA announced that it was taking action to end all uses of endosulfan. The EPA finds that there are risks above the Agency's level of concern to aquatic and terrestrial wildlife, to birds and mammals that consume

[4] Austria, Bahrain, Belgium, Belize, Benin, Bulgaria, Burkina Faso, Cambodia, Cape Verde, Chad, Colombia, Cote d'Ivoire, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Gambia, Germany, Greece, Guinea Bissau, Hungary, Indonesia, Ireland, Italy, Jordan, Kuwait, Latvia, Lithuania, Liechtenstein, Luxembourg, Malaysia, Mali, Malta, Mauritania, Mauritius, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Poland, Portugal, Qatar, Romanian, Saudi Arabia, Senegal, Singapore, Slovakia, Slovenia, Spain, Sri Lanka, St Lucia, Sweden, Switzerland, Syria, the United Arab Emirates, United Kingdom.

aquatic prey in which endosulfan has bio-accumulated and to workers applying endosulfan and conducting activities in the field after the pesticide is used.

Neither the APVMA nor the EPA has identified any risks to human health through dietary exposure. Similarly, there are no concerns about household exposure as endosulfan is not approved for household use in either country.

Under the federal pesticide law, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA must consider both endosulfan's risks and benefits, not an option available under Australian legislation. The USEPA has evaluated the human health and ecological risks as well as the benefits of endosulfan uses. While a few crop uses have relatively high benefits for growers, the nationwide benefits to society as a whole are low for all uses of endosulfan and do not exceed the risks. EPA has determined that pesticide products containing endosulfan do not meet the standard for registration under FIFRA.

From a scientific standpoint the registrant, Makhteshim Agan North America has stated that they disagree with the EPA's conclusions and believes that key uses are still eligible for re-registration[5]. They note that the EPA has made a number of overly conservative and unrealistic assumptions about how endosulfan is used. However given that the endosulfan market is quite small and the cost of developing and submitting additional data high, they have agreed to negotiate an agreement with the EPA that would provide adequate time for growers to find alternatives.

As at August 2010, the EPA announced a phase-out timetable for the cancellation of endosulfan uses. Under the agreement most currently approved crop uses will cease effective 31 July 2012. The remainder of uses will cease over the following 4 years, the last 4 uses being permitted until 31 July 2016. During the phase out period, additional mitigation measures are required for most uses including extending re-entry intervals, cancelling aerial application, restricting use to wettable powder and emulsifiable concentrate formulations only and limiting maximum rates. Further details are outlined in Appendix D.

The Minister was advised of the US regulatory action by DAFF in June 2010 and the APVMA included a statement on its website.

3.2 Health Canada's Pest Management Regulatory Agency (PMRA) regulatory activity

In August 2010 the PMRA announced its decision to no longer support the registration of endosulfan in Canada. This following re-evaluation of endosulfan in 2002, the introduction of interim risk mitigation measures and consideration of additional comments and information. The PRMA has determined that concerns for human health and for the environment remain.

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[5] Source: Pesticide and Toxic Chemical News August 05 2010

In addition, endosulfan’s persistent and bioaccumulation properties mean that under the Toxic Substances Management Policy it is classifies as a Track 1 substance. Canada is required to take steps to remove such substances from use. Australia does not have such a policy for existing substances.

Canada have yet to announce their phase out timetable for endosulfan products. There are currently 3 endosulfan products registered for use in Canada.

4. RECOMMENDATIONS

The APVMA is not satisfied that the continued approval of endosulfan active constituents and registration of products containing endosulfan:

- would not be an undue hazard to the safety of people exposed to it during its handling;
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA is also not satisfied that the label contains adequate instructions.

From a human health and worker safety perspective, the APVMA could be satisfied regarding continued registration and approval if labels were varied to include the revised safety directions.

However, DEWHA have concluded that the impacts of endosulfan on aquatic ecosystems, could not be effectively managed. Endosulfan is persistent, bioaccumulates and is highly toxic. It also travels significant distances from the site of application. Labels do not contain the necessary instructions to prevent harm to the environment and DEWHA are unable to develop appropriate label instructions to ensure the continued protection of the environment.

On this basis, the APVMA can no longer be satisfied that the continued approval of endosulfan active constituents, registration and use of endosulfan products in accordance with the approved labels would not be likely to have an effect that is harmful to animals, plants or things or to the environment.

Therefore it is recommended that the approval of endosulfan active constituents, registration of endosulfan products and the approvals of associated labels be cancelled. A 2-year period would be allowed for the phase out of supply and use of the product.

Appendix A - Risks to the aquatic environment arising from use (spray drift and run-off)

In scientific terms, the risk assessment "evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors". Undesirable events can include injury, death, or decrease in the mass or productivity of aquatic animals (e.g. fish and invertebrates), terrestrial animals (e.g. birds and wild mammals), plants, or other non-target organisms (e.g. insects), including endangered and threatened species (EPHC 2009).

DEWHA normally assesses the environmental risk from acute or chronic exposure by calculating the Risk Quotient (RQ = PEC/LC50 or NOEC), using the predicted effect concentration (PEC) and the acute toxicity data for the most sensitive species. In aquatic situations, the PEC from application drift reaching lentic water (i.e. 15 cm) is determined as a worst case situation in regard to water depth. Therefore, the most sensitive end-points were selected from Table 1 in section 4.4 of the report, which compiles the most sensitive species from the 1998 Interim Environmental Review. A Risk Quotient equal to 1 is consider acceptable because the estimation of risk is based on the predicted no effect concentration (PNEC) for lethal and the chronic exposure.

Sunderam *et al*. (1992) tested several Australian native and introduced fish over 96 hour periods. The most reliable end-point (LC50) was selected from these data (Endosulfan review, APVMA 1998) in order to estimate the risk from acute exposure. Also, an assessment factor of 10 was used in order to allow protection of larger range of species and sensitivities and for the extrapolation of the laboratory test conditions to the environment.

The ANZECC guidelines for endosulfan recommend the application of the 99% level protection trigger values (TVs), for the freshwater and marine environment, because the 95% level fails to protect some important Australian species from acute toxicity. Therefore, the 99% protection TVs were selected to estimate the risk to the environment. Also, the TV for the freshwater environment is based on the chronic NOEC (considered a high reliability guideline).

Table 1: Summary of most sensitive endpoints

	LC50 (96 h) ug/L	**NOEC μg/L**	**Reference**
Australian Studies			
Harlequin fish	0.2		Sunderam *et al*, 1992
ANZECC WQG			
Freshwater		0.03 (99% protection) 0.2 (95% protection)	ANZECC WQG 2000

The first end-point has been derived by deterministic approach (based on the selection of the most sensitive end-point plus an assessment factor for environmental protection) as commonly derived in risk assessments.

The ANZECC TV is based on the species sensitivity distribution (SSD is based on calculations of a probability distribution of effects and attempts to calculate a pre-determined level of environmental protection, such as 99% or 95%) which is used when sufficient data are available. The risk assessment below uses both approaches.

For all the scenarios (i.e. the most commonly use applications were chosen), only a single application (noting the current label allows up to 10 or more sprays per year in some applications) has been considered in estimating the water concentration in a 15 cm deep × 300 cm wide stream.

Spray Drift

The current spray-drift methodology implemented by the APVMA (APVMA, 2008) is used to estimate the risk from spray drift (where the assumptions in the model are based on standard application techniques).

The current label application range varies from 150 to 840 g ac/ha. However, calculations (below) show that the maximum rate can be as high as 2800 g ac/ha.

Examination of the labels indicates that while applications to cotton and many other crops are limited to 1 or 2 sprays per season, this is not the case for horticulture when in many cases the CRITICAL COMMENTS allows “spray as required” which can involve multiple applications (up to 10 or more) per season.

Scenario 1 – Ground spraying using orchard airblast.

The maximum concentration is 200 mL product/100 L, based on 70 (0.2 × 350) g active constituent/100 L, for crops such as avocados, macadamias, cashews, custard apples and lychees, but distinctly lower maximum concentrations are used in citrus, and intermediate concentrations for crops such as pome fruit (and for other pests on avocados etc).

The following table of spray drift buffers has been prepared using the following parameters:

- Normal Orchard (Stone and Pome Fruit, Vineyards)
    - o an application rate of 1575 – 2100 g active constituent/ha in 3000 L/ha by orchard airblast for a situation with smaller trees and lower rates. At spray application rate of 3000 L spray/ha, 150-200 mL product/100 L equates to 1575 – 2100 (40 × 30-40) g active constituent/ha.
    - o using the “normal orchard” setting, which is composite orchard combines Grapes and Apple orchards. Mean deposition and 99.85% application efficiency (20 rows).
- Dense Trees (Citrus, Tall Trees)
    - o an application rate of 2800 g active constituent/ha in 4000 L/ha by orchard airblast. At a spray application rate of 4000 L/ha, 200 mL product/100 L equates to 2800 (40 × 70) g active constituent/ha.
    - o using the “dense trees” setting, which is composite orchard combines Almonds, Oranges, Grapefruit, Small Grapefruit (mist

blower) and Pecan orchards. Mean deposition and 98.01% application efficiency (20 rows).

- o AgDRIFT results corrected to approximate the 95% percentile.

Table 2: Predicted risk from endosulfan when ground spraying using orchard airblast (RQ = 1 consider an acceptable risk).

Rate rate g/ha	Drift % at 300 m	PEC ng/L	RQ for SSD PNEC 30 ng/L[1]	RQ for Deterministic PNEC 20 ng/L[2]
1575	0.0039	41	1.4	2.1
2100		55	1.8	2.7
2800	0.05	877	29.2	43.9

[1] ANZECC WQG, 2000. [2] Sunderam *et al*, 1992.

The RQ values (Table 2) show an unacceptable risk to the aquatic compartments from the effects of endosulfan when ground spraying using an orchard airblast. Down wind buffer distances greater than 300 m are required in order to protect the aquatic compartments from these effects.

Scenario 2 – Ground spraying using boom spray.

The maximum label rate is 2.1 L/ha (735 g ac/ha), for cotton and a range of vegetable crops. The label indicates that all nozzles must be operated such that a "medium" spray quality is produced as indicated by the BCPC and ASAE nozzle classification systems.

The following table of spray drift buffers has been prepared using the following parameters:

- an application rate of 2.1 L product (735 g active constituent/ha),
- using AgDRIFT with high (1.27 m) and low boom (0.508 m) settings,
- using the "ASAE Fine to Medium/Coarse" setting,
- using the 13.72 m swath width; 341 μm Dv0.5,
- using the 90th percentile to simulate Medium Spray Quality, and
- using the 50th percentile to simulate Coarse Spray Quality.

Table 3: Predicted risk from endosulfan when ground spraying using boom spray (RQ = 1 consider an acceptable risk).

Rate rate 735 g/h	Drift % at 300 m	PEC ng/L	RQ for SSD PNEC 30 ng/L[1]	RQ for Deterministic PNEC 20 ng/L[2]
Low boom 50th	0.03	137	4.6	6.9
Low boom 90th	0.06	303	10.1	15.1
High boom 50th	0.04	182	6.0	9.1
High boom 90th	0.08	382	12.7	19.1

[1] ANZECC WQG, 2000. [2] Sunderam *et al*, 1992.

The RQ values (Table 3) show an unacceptable risk to the aquatic compartments from the effects of endosulfan when ground spraying using a boom spray. Down wind buffer distances much greater than 300 m are required in order to protect the aquatic compartments from these effects.

Scenario 3 – Aerial application to cotton

The following table of spray drift buffers has been prepared using the following parameters:

- an application rate of 2.1 L product (735 g active constituent/ha) in 30 L spray volume/ha
  - o application method: Aerial Agricultural Fixed Wing, 3 m release height, 50 spray lines and 20 swath width,
  - o spray material: water, 30 L/ha spray volume rate, 0.0245 active fraction, and 0.07 nonvolatile fraction,
  - o ASAE Fine to Medium nozzles to address spraying with medium spray quality,
  - o meteorology: -90 wind direction, 30^0C, 40% relative humidity,
  - o atmospheric stability: overcast, and
  - o the model was used well beyond the validated range of 800 m(maximum downwind distance increased to 3000 m).

Table 4: Predicted risk from endosulfan when aerial spraying (RQ = 1 consider an acceptable risk).

Wind speed km/h	Drift % at 3000 m	PEC ng/L	RQ for SSD PNEC 30 ng/L[1]	RQ for Deterministic PNEC 20 ng/L[2]
20	0.00244	121	4.0	6.0
14	0.00082	41	1.4	2.0
8	0.00060	3.2	0.11	0.16

[1] ANZECC WQG, 2000. [2] Sunderam *et al*, 1992.

The RQ values (Table 4) show an unacceptable risk to the aquatic compartment from the effects of endosulfan from aerial spraying. Buffer distances greater than 3000 m and 2000 m (i.e. for wind speed of 14-20 km/h and 8 km/h, respectively) are required in order to protect the aquatic compartments from the effects of endosulfan.

Runoff

The recently developed run-off model has been used by DEWHA to estimate the risk from run-off.

Table 5 - Summary of the characteristics of Endosulfan that are important in runoff.

Parameter	Value	Crop Situation	Application rate
T1/2	187 days (in water)[1]	Several	735-2800 g ac/ha
Koc	4000[1] (technical endosulfan)		
Water solubility	0.05-0.99[1] mg/L Recommended value: 0.5[1] mg/L		

[1] Endosulfan Draft Risk profile (April 2009)

DEWHA conducts a tiered approach to the risk to aquatic species from run-off. Initially the edge of field concentration is calculated considering application specific factors (Tier 1). If risk is shown, pesticide specific factors are taken into account (Tier 2). This is further mitigated by consideration of dilution of the edge of field water in environmental water (Tier 3).

DEWHA considers the following equation for calculating the percentage run-off:

Equation 1

$L\%_{run\text{-}off}$ = (R/P) × Crsoil_surface × f1slope × f2bufferzone × f3foliar_application × heterogeneity_factor × 100 + suspended_pesticide.

The following parameter are defined based on Australian climate and catchments data:

P = a rainfall event of 100 mm

R = 20 mm of run-off water as a worst case scenario

f1slope = 0.5 based on the worst case for applications on slopes ≤ 12.5% (7°).

f2bufferzone = the default value of 1 (no effect) is used, (Probst *et al* 2005).

f3foliar_application = (1-F_{ret}), where F_{ret} = F_{int} × 0.5. For weeds and bare soil F_{ret} = 0 and f3foliar_application is consequently =1. Since endosulfan is not applied to bare soil but is to relatively young cotton, an Foliar interception (F_{int}) factor of 0.5 was used, resulting in retention of 25% of the applied concentration.

heterogeneity_factor = it is assumed to be 0.5 to reflect the heterogeneity of real fields. This is due to not all parts contributing to run-off. DEWHA estimates that < 50% of an area effectively contributes to runoff in most realistic circumstances [based on (Dunne & Black 1970)]. For pesticides applied to crops a portion is retained by the crop and not available for run-off during the event. DEWHA estimates that ½ of the intercepted pesticide is retained based on Linders *et al*., 2000 citing Willis *et al*., 1994.

suspended_pesticide = 0 for pesticides with water solubility ≥ 1 mg/L. Pesticides in solution is the major form of transportation, with only chemicals with a water solubility of < 1 mg/L being transported primarily by eroded sediment in suspension (Grover R. ed., 1989); paraquat and diquat being notable exceptions). This is due to the volume of run-off water greatly outweighing the mass of eroded sediment transported in a run-off event (*ibid* & Afyuni *et al* 1997).

Results for Tier 1 (considering edge of field concentration and application specific factors)

All factors of equation 1 are considered, excepting Crsoil_surface (i.e. considered in the second tier). The solution for the Equation 1 is 3.75% based on the following figures.

$L\%_{run\text{-}off}$ = (20/100) × 1 (Crsoil_surface) × 0.5 × 1 × 0.75 × 0.5 × 100 + 0 = 3.75%

Based on Tier 1 assumptions, a 3.75% run-off was estimated, together with the PECs at the edge of field and PNECs (Tier 1; Table 6). These values shows unacceptable risk to the aquatic species from the runoff water at the edge of field. Therefore further mitigation was required as the model does not account for adsorption to soil or degradation.

Results for Tier 2 (considering pesticide specific factors and adsorption to soil or degradation)

The percentage runoff was calculated using Equation 1 (using the above parameters) including Crsoil_surface.

Equation 2

Crsoil_surface = $e^{(-3 \ln 2 \div DTsoil)}$ × (1 ÷ (1 + Kd) for three days of degradation.

DTsoil = DT50 of 187 days

Koc = 4000

OC = worst case of 1.0% was assumed (Australian Natural Resources Atlas 2001)

Kd = Koc × % o.c. ÷ 100 = 40

Rainfall = assuming that occurs 3 days after application

Crsoil_surface = $e^{(-3 \ln 2 \div 187)}$ × (1 ÷ (1 + 40) = 0.02

$L\%_{run\text{-}off}$ = (20/100) × 1 (0.02) × 0.5 × 1 × 0.75 × 0.5 × 100 + 0 = 0.09%

Based on Tier 2 assumptions, a 0.09% run-off was estimated, together with the PECs at the edge of the field and PNECs (Tier 2; Table 6). These values show unacceptable risk to the aquatic species from the runoff water. Therefore further mitigation was required as the model does not account for adsorption to soil or degradation. Tier 2 results relate only to the water at the edge of field and do not take into account any dilution by environmental receiving waters.

Results for Tier 3 (considering dilution of the edge of field water in environmental water)

The percentage runoff was calculated using Equation 1 including Crsoil_surface (using all the above parameters).

The following is an adaptation of the USEPA model (USEPA 2004). Consideration is given to a 1500 m^3 water body of environmental significance. This could be represented by a 1 ha pond, 15 cm deep or a low flow (~ 0.03 – 0.06 m/sec; ~ 0.1-0.2 km/h) primary stream with 1500 m^3 per day flow having approximate dimensions of ~ 2 m wide and ~ 25 cm deep (based on Vietz et al. 2003). In a worst case scenario this water body is considered to be fed entirely by the largest likely field to be 100% treated with the pesticide of interest at the maximum rate. The considered field size is 10 ha (USEPA 2004). In most realistic circumstances either the amount of runoff from 10 ha will result in a water body larger than 1500 m^3, or to support such a water body a much larger watershed will need to be considered (*ibid*). This could be considered in a refined model if required. The concentration in the water body may be calculated assuming that 200 m^3 from each hectare for a total of 10 ha flows into the 1500 m^3 water body resulting in a total water body of 3500 m^3.

Based on Tier 3 assumptions, a 0.09% run-off was estimated, together with the PECs considering dilution of the edge of the field water in environmental water and PNECs (Tier 3; Table 6). Again, the results show unacceptable risk to the aquatic species from the runoff into water body of 3500 m^3.

Table 6: Predicted risk from endosulfan from run-off (RQ = 1 consider an acceptable risk).

Rate rate g/h	Model	PEC ng/L	RQ for SSD PNEC 30 ng/L[1]	RQ for Deterministic PNEC 20 ng/L[2]
735	Tier 1	138,000	4594	6891
	Tier 2	3,320	111	166
	Tier 3	2,000	93	65
1575	Tier 1	295,000	9844	14766
	Tier 2	17,120	237	356
	Tier 3	4,100	136	204
2100	Tier 1	394,000	13125	19688
	Tier 2	9,500	317	475
	Tier 3	5,430	181	271
2800	Tier 1	525,000	17500	26250
	Tier 2	13,000	422	633
	Tier 3	7,240	241	362

[1] ANZECC WQG, 2000. [2] Sunderam *et al*, 1992.

In conclusion, the Risk Quotients are much greater than 1 (after several mitigation steps) in all tested scenarios, indicating substantial risk to the aquatic environment. Therefore, no further mitigation would be performed.

Appendix B – PBT criteria

The Australian criteria were developed to be used for preventing new pesticides/veterinary medicines or industrial chemicals exhibiting PBT characteristics from entering the market, and for screening of existing chemicals for further regulatory attention.

There is now broad international agreement that chemicals that are persistent, bioaccumulative, and toxic should be prioritised for eventual phase out. This consensus largely rests on the observation that chemicals with these characteristics cannot be effectively managed because of the characteristics of the chemicals themselves. Once such substances enter the wider environment, any cessation of emissions will not necessarily result in a reduction in chemical concentration and hence any effects become difficult to reverse. As well, these chemicals can travel long distances, meaning it is often not possible to control their movement off-site. In addition, because of the long-term exposures and long life cycle of many important marine species, effects may be difficult to detect at an early stage. Correspondingly, a ‘safe’ concentration in the environment is difficult, if not impossible, to establish.

Criteria for PBT Chemicals

Persistence		
For PBT purposes a chemical is considered persistent in a particular media if its half life in the media exceeds the following:		
	Media	Half-Life
	Water	2 months
	Soil	6 months
	Sediment	6 months
	Air	2 days

Bioaccumulation
For PBT purposes a chemical is considered to be Bioaccumulative if it has a BCF/BAF of >2000, or in its absence of any BCF/BAF measurement a logKow $\geq$ 4.2.

<table>
<tr><th colspan="3">Toxicity</th></tr>
<tr><td colspan="3">For PBT purposes, in respect of aquatic toxicity a chemical may be considered toxic under the following circumstances (corresponding to criteria for GHS chronic category 1):</td></tr>
<tr><td rowspan="3">Non-rapidly degradable substances for which there are adequate chronic toxicity data available</td><td>Chronic NOEC or EC_x (for fish)</td><td>≤ 0.1 mg/L and/or</td></tr>
<tr><td>Chronic NOEC or EC_x (for crustacea)</td><td>≤ 0.1 mg/L and/or</td></tr>
<tr><td>Chronic NOEC or EC_x (for algae or other aquatic plants)</td><td>≤ 0.1 mg/L</td></tr>
<tr><td rowspan="3">Rapidly degradable substances for which there are adequate chronic toxicity data available</td><td>Chronic NOEC or EC_x (for fish)</td><td>≤ 0.01 mg/L and/or</td></tr>
<tr><td>Chronic NOEC or EC_x (for crustacea)</td><td>≤ 0.01 mg/L and/or</td></tr>
<tr><td>Chronic NOEC or EC_x (for algae or other aquatic plants)</td><td>≤ 0.01 mg/L</td></tr>
<tr><td rowspan="4">Substances for which adequate chronic toxicity data are not available (providing criteria for P and B are met)</td><td>96 h LC_{50} (for fish)</td><td>≤ 1 mg/L and/or</td></tr>
<tr><td>48 h EC_{50} (for crustacea)</td><td>≤ 1 mg/L and/or</td></tr>
<tr><td>72 or 96 h ErC_{50} (for algae or other aquatic plants)</td><td>≤ 1 mg/L</td></tr>
<tr><td colspan="2">and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K_{ow} ≥ 4).</td></tr>
<tr><td>Toxicity to other (terrestrial) organisms</td><td colspan="2">Should be considered on a case by case basis, compared with the highly toxic classifications DEWHA has developed for agvet chemicals.</td></tr>
<tr><td>Long term toxicity or evidence such as endocrine disruption effects</td><td colspan="2">Should be considered on a case by case basis.</td></tr>
</table>

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APPENDIX D: US EPA ENDOSULFAN PHASE-OUT

http://www.epa.gov/pesticides/reregistration/endosulfan/endosulfan-agreement.html)

Current as of August 2010

EPA is taking action to end the use of the pesticide endosulfan because it can pose unacceptable health risks to farmworkers and wildlife and can persist in the environment. A formal Memorandum of Agreement with manufacturers of the agricultural insecticide will result in voluntary cancellation and phase-out of all existing endosulfan uses in the United States. Terminating uses of endosulfan will address its unacceptable risks to agricultural workers and wildlife.

Endosulfan is an organochlorine insecticide that can be used on a wide variety of vegetables and fruits, cotton, and ornamental plants. It has no residential uses. Endosulfan is used on a very small percentage of the U.S. food supply and does not present a risk to human health from dietary exposure.

1. Endosulfan Memorandum of Agreement, July 2010

EPA has initiated action to end the use of endosulfan because it can pose unacceptable health risks to farmworkers and wildlife and can persist in the environment. In July 2010, EPA signed a Memorandum of Agreement with the registrants of endosulfan that will result in voluntary cancellation and phase-out of all existing endosulfan uses in the United States. Terminating uses of endosulfan will address its unacceptable risks to agricultural workers and wildlife.

Under the agreement, most currently approved endosulfan crop uses will end in two years, including over 30 crop uses plus use on ornamental trees, shrubs, and herbaceous plants. About 12 other crop uses will end over the following four years. Of these 12, the last 4 endosulfan uses will end on July 31, 2016.

A list of endosulfan uses and last lawful use dates is provided below.

Next Steps

By the end of 2010, each endosulfan end-use product label will be amended to include a table showing the exact dates when it will become unlawful to use the product on the crops included on the label.

By September 2010, EPA expects to publish a Federal Register notice announcing receipt of the registrants' requests for voluntary cancellation and amendments of endosulfan product registrations. Public comment will be invited for 30 days. The Agency expects to grant the requested cancellations and amendments shortly after the close of the comment period.

Endosulfan Crop Uses and Last Use Dates

2. Group A: Use ends July 31, 2012

- Almond, Apricot, Broccoli, Brussels sprouts, Carrots, Cauliflower, Celery (non-AZ), Citrus (non-bearing), Collard greens, Dry beans, Dry peas, Eggplant, Filbert, Kale, Kohlrabi, Mustard greens, Nectarine (CA only), Macadamia, Plum and Prune, Poplars grown for pulp and timber, Strawberry (Annual), Sweet potato, Tart cherry, Turnip, Walnut, Ornamental trees, shrubs, and herbaceous plants, Other uses on product labels not listed above or in Group B, C, D, E, or F

3. Group B: Use ends July 31, 2012

- Cabbage, Celery (AZ only), Cotton, Cucumbers, Lettuce, Stone fruits not listed in Group A, including Nectarine (non-CA), Peaches, and Sweet cherry, Summer melons (cantaloupe, honeydew, watermelon), Summer squash, Tobacco

4. Group C: Use ends July 31, 2013

- Pear

5. Group D: Florida – Use ends December 31, 2014

- All Florida uses of: Apple, Blueberry, Peppers, Potatoes, Pumpkins, Sweet corn, Tomato, Winter squash.

6. Group E: Use ends July 31, 2015

- Apple, Blueberry, Peppers, Potatoes, Pumpkins, Sweet corn, Tomato, Winter squash

7. Group F: Use ends July 31, 2016

- Livestock ear tags, Pineapple, Strawberry (perennial/biennial), Vegetable crops for seed (alfalfa, broccoli, Brussels sprouts, cabbage, cauliflower, Chinese cabbage, collard greens, kale, kohlrabi, mustard greens, radish, rutabaga, turnip)

Mitigation Measures during Phase-Out

In addition to mitigation requirements placed on endosulfan labels in previous years, EPA is requiring new mitigation measures for many crops (those in Groups B through F above) during the endosulfan phase-out period. Although these additional mitigation measures are designed to reduce worker risks, restricting and phasing out all uses of endosulfan will also address risks to wildlife and the environment.

Additional mitigation required during the phase-out varies by crop and includes measures such as:

- canceling aerial use and specifying other application methods
- extending Restricted Entry Intervals (REIs)

- extending Pre-harvest Intervals (PHIs)
- reducing maximum single and/or seasonal application rates

Transition to Alternatives

EPA expects growers currently using endosulfan to successfully transition to lower risk pest control strategies. The endosulfan Agreement helps facilitate this transition by providing growers time to research and adopt lower risk alternatives. Recognizing that endosulfan affords benefits in producing certain individual crops, the Agreement allows a longer phase-out period where the benefits of endosulfan use are highest and fewest alternatives are available.

8. Background on EPA's Reevaluation of Endosulfan

Endosulfan Reregistration Eligibility Decision, 2002

Upon completing a comprehensive review of endosulfan and its risks to human health and the environment, EPA issued the Endosulfan Reregistration Eligibility Decision (RED) in 2002. In the RED, EPA concluded that endosulfan posed dietary, occupational, and ecological risks of concern. The Agency determined that these risks could likely be mitigated to levels below those of concern by deleting use of endosulfan on five crops and changing product labeling to include a number of mitigation measures. These measures were fully implemented in 2007.

Endosulfan Assessments, 2007 - 2009

EPA revised its human health and ecological risk assessments for endosulfan in 2007, based in part on new data submitted by the registrants as required in the 2002 RED. The 2007 risk assessments indicated that:

- endosulfan poses risks of concern to workers who handle and apply endosulfan, and to those who work in fields treated with this pesticide;
- dietary risks to the general population are not of concern;
- ecological risks are above levels of concern. Endosulfan and its sulfate degradate may pose greater ecological risks to aquatic and terrestrial organisms than reflected in the 2002 RED. Long-range transport of endosulfan also is of concern.

In late 2007 and early 2008, EPA asked the public to comment on these human health and ecological risk assessments. EPA also requested comment on the Agency's analysis of endosulfan useage information since the 2002 RED, as well as its preliminary determinations regarding endosulfan's importance to growers and availability of alternatives.

In October 2008, EPA consulted with the FIFRA Scientific Advisory Panel (SAP) on the risk assessment approach for persistent, bioaccumulative and toxic (PBT) chemicals.

Because endosulfan has PBT characteristics, the Agency refined its endosulfan ecological risk assessment based on the SAP's recommendations.

EPA issued impact assessments on eight crop uses of endosulfan in May 2009, and solicited public comment on the assessments as well as any additional information stakeholders had on the importance of endosulfan use in agriculture.

Endosulfan Updated Assessments, 2010

In June 2010, based on updated risk assessments and benefits evaluations developed over the previous several years, EPA concluded that endosulfan poses unacceptable risks to agricultural workers and wildlife, and can persist in the environment. (EPA News Release, June 9, 2010) These risk concerns provided the basis for the Agency's July 2010 Memorandum of Agreement with the registrants to voluntarily cancel and phase out all uses of endosulfan.

Human Health Risk Assessment – New data developed in response to the Agency's 2002 Endosulfan RED shed additional light on the risks faced by workers who apply endosulfan and those who harvest crops and conduct activities in fields after the pesticide is used. EPA found that risks faced by workers are greater than previously known, in many instances exceeding the Agency's levels of concern.

Ecological Risk Assessment – EPA's 2010 revised ecological risk assessment reflected a comprehensive review of all new, currently available exposure and ecological effects information for endosulfan, including independent external peer review recommendations made by the FIFRA SAP. EPA found that there are risks above the Agency's level of concern to aquatic and terrestrial wildlife, as well as to birds and mammals that consume aquatic prey in which endosulfan has bio-accumulated.

Benefits Assessment – As appropriate under FIFRA, EPA also evaluated the benefits of endosulfan uses.